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Medico-Legal Research Using Evidence-Based Medicine*

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Ms. Young provides an introduction for legal researchers to locating and evaluating medical information in the context of evidence-based medicine. Topics covered include defining evidence-based medicine, using and selecting bibliographic databases for medical research, and applying the methods of evidence-based medicine to the process of medical research and evaluating information retrieved.

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Introduction

¶1 Evidence-based medicine (EBM) is the use of the current best evidence when making decisions about the care of individual patients. The best evidence comes from a thorough search of the medical literature for articles and other publications that cover medical research and that apply to a patient's medical problem. In the medical community, EBM is considered the best way to practice medicine.[1] In legal cases where medical evidence is utilized, finding the best medical evidence usually leads to the strongest arguments.

¶2 There are many scenarios that could lead a legal researcher to do medical research. Examples include supporting plaintiffs' attorneys or medical malpractice defense attorneys in a medical negligence case, supporting faculty doing cutting-edge research on health law issues, or supporting a legal clinic that fights for children with special needs. From a legal researcher's perspective, medical literature is often needed for medical proof. Because the medical profession uses EBM to weigh the value of medical literature, legal professionals must apply the principles of EBM in order to apply the standards of proof to medical literature. The goal of EBM, to make decisions based on the best available medical evidence,[2] parallels the goal of the legal system to make judicial decisions based upon the best evidence. Thus, EBM and the law correspond to each other. The clinician's job of making the best clinical decision given the best available evidence is clearly aligned with the legal system's job of making a fair decision given the evidence that comes closest to the truth.

¶3 This article provides an introduction to locating and evaluating medical information in the context of EBM. Topics covered include defining EBM and its importance to medico-legal researchers, using bibliographic databases for medical information research, using the EBM method for doing medical research and evaluating information retrieved, and, finally, surveying reliable electronic and hard copy medical resources that lend themselves to the EBM research methodology.

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1. M. Cameron Hay et al., *Harnessing Experience: Exploring the Gap Between Evidence-Based Medicine and Clinical Practice,* 14 J. Evaluation Clinical Prac. 707, 707 (2008). Similarly, some consider evidence-based librarianship to be the best way to practice librarianship. *See* Susan Nissen Lerdal, *Evidence-Based Librarianship: Opportunity for Law Librarians?,* 98 Law Libr. J. 33, 2006 Law Libr. J. 2.

2. *See* Sharon E. Straus et al., Evidence-Based Medicine: How to Practice and Teach EBM 3–4 (3d ed. 2005).

What Is EBM?

Definition of EBM

¶4 EBM has been defined as "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research."[3] EBM proposes that when a clinical problem occurs, physicians should look at the best "external clinical evidence" first. The main benefit of EBM is that it is objective. EBM stresses the checking of evidence from clinical research in preference to random clinical observations when making clinical decisions.[4]

¶5 The process of EBM calls for "the integration of a physician's clinical expertise with the best available medical evidence obtained from systematic research."[5] The first component, individual clinical expertise, consists of the judgment and clinical skills acquired from clinical experience and practice. This component also includes the physician's capacity to assimilate a specific patient's predilections and particular circumstances into the decision-making process.

¶6 The second component of EBM, the best available medical evidence, is what distinguishes EBM from what has been called "eminence-based medicine."[6] The best available medical evidence is that which is dependable and clinically applicable to the current problem.[7] Reliability in the medical evidentiary context consists of validity and an assessment of the applicability of the evidence to the current situation.[8] The practice of EBM necessitates clinical expertise supported by the best available medical evidence. Without the best available medical evidence, clinical decisions quickly become outdated.[9] Conversely, the best available medical evidence without the context of clinical expertise results in its unsuitable application.

¶7 EBM has been separated into distinct clinical study categories, which are used according to whether the clinical question is one of diagnosis, prognosis, therapy, or other categories.[10] A distinct process for the objective critical evaluation of the scientific evidence available for each clinical study category should be followed.[11] The process is usually a checklist of several questions that are asked about a particular clinical study.[12] The objective is to obtain a reliable appraisal of a par-

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3. David L Sackett et al., *Evidence Based Medicine: What It Is and What It Isn't,* 312 Brit. Med. J. 71, 71 (1996).

4. David L. Sackett & William M.C. Rosenberg, *The Need for Evidence-Based Medicine,* 88 J. Royal Soc'y Med. 620, 621–22 (1995).

5. Stephen Chris Pappas, Comment, *Curing the* Daubert *Disappointment: Evidence-Based Medicine and Expert Medical Testimony*, 46 S. Tex. L. Rev. 595, 599 (2005) (footnote omitted).

6. John M. Eisenberg, *What Does Evidence Mean? Can the Law and Medicine Be Reconciled?,* 26 J. Health Pol. Pol'y & L. 369, 370 (2001).

7. 1 Lawyers' Medical Cyclopedia § 3.32a (2009).

8. *See* David L. Sackett et al., Clinical Epidemiology 188 (2d ed. 1991).

9. *See* Straus et al., *supra* note 2, at 2.

10. *See id.* at 3.

11. Straus devotes individual chapters to the clinical studies of diagnosis and screening, prognosis, therapy, and harm. *Id.* at 67–197.

12. *See* Sackett et al., *supra* note 8, at 366–67.

ticular study's significance and dependability as evidence to be used to make a clinical decision for a particular situation.[13] General principles that are universal to all the categories include making certain that the systematic assemblage of available medical evidence is comprehensive,[14] and deciding how to optimally structure the medical question.[15]

¶8 With time, EBM has become standard medical practice and is now specifically taught in many medical programs.[16] If you are doing something connected to health care today, "being 'evidence based' is de rigeur."[17] However, not all health-care practitioners practice EBM in its true sense. Additionally, just because a research article or practice guideline claims to be evidence based does not mean that it is evidence based in the truest sense.

¶9 It is important to note that EBM is now sometimes called evidence-based practice. It is not exclusively practiced by medical doctors; it is being followed more and more by all kinds of health-care professionals. For example, there are numerous evidence-based practice programs for nurses, physical therapists, and virtually any health-care practitioner in any health-care field.

Why EBM Is the Accepted Trend

¶10 The term *evidence-based medicine* was first used in the early 1990s and has since become widely accepted throughout the world.[18] Some of the acceptance of EBM can be attributed to the availability of more sophisticated technology. With the advent of sophisticated databases, access to medical literature and research has improved. As a result, the understanding of the science and medicine that may affect a particular patient's medical condition has improved. Prior to the availability of electronic databases, a physician usually subscribed to a few journals in his field and read through them as time allowed. Now that physicians can easily search through databases to find all articles on a particular topic, they can be held to a standard of care that requires reviewing the literature.

¶11 Furthermore, the rise in health-care costs has led to increased demand for the justification of costly medical treatments. EBM requires using the best available external evidence.[19] EBM has been shown to improve results for patients and make the best use of health resources.[20]

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13. *See id.* at 375–76 (advising doctors on how to decide which studies are worth reading).
14. *See* SACKETT ET AL., *supra* note 8, at 335–57.
15. *See* STRAUS ET AL., *supra* note 2, at 13–30.
16. Madelon L. Finkel et al., *Teaching Evidence Based Medicine to Medical Students,* 25 MEDICAL TEACHER 202, 202 (2003).
17. Earl P. Steinberg & Bryan R. Luce, *Evidence Based? Caveat Emptor!,* 24 HEALTH AFFAIRS 80, 80 (2005).
18. *See* Jeffrey A. Claridge & Timothy C. Fabian, *History and Development of Evidence-Based Medicine*, 29 WORLD J. SURG. 547, 547 (2005).
19. *See* STRAUS ET AL., *supra* note 2, at 1.
20. Pappas, *supra* note 5, at 602 (2005).

The Intersection Between Law and EBM

¶12 As the use of EBM has grown over the past fifteen years, it has become progressively more likely to be incorporated into clinical decision making. As a result, there is an urgent need for legal research professionals to understand modern techniques for critically evaluating and summarizing the immense quantities of medical information. "[M]uch of this information [may] appear[] as scientific evidence in the courtroom"[21] and must be assessed for its validity by judges and possibly jurors. For example, judges are frequently in the position of having to make decisions about medical conduct without the aid of sound medical evidence. They often face the tricky undertaking of considering clinical studies that are offered as medical evidence by experts on both sides. Statistically based studies reveal how populations, and not individual patients, will fare under a certain procedure. Even if a treatment is not usually effective, when life is at stake desperate people may want to go forward with that treatment, hoping they will be an exception. This can be especially complicated for the legal profession when there is a compelling individual case and little basis to judge whether a procedure is appropriate.[22] "Judges have been given the responsibility of determining the credibility of clinical studies submitted as medical evidence and whether to admit them as evidence."[23]

¶13 As a result of these pressures, the judiciary began seriously questioning the science underlying expert medical testimony. Now, however, with the *Daubert* decision,[24] federal judges have more flexible standards for qualifying expert witnesses. In *Daubert*, the court found that Federal Rule of Evidence 702 is satisfied if expert testimony is based on scientific method.[25] This establishes a "gate-keeping" role for a sitting judge.[26] The factors that guide the court on admissibility of scientific evidence include (1) whether the method or premise can or has been tested, (2) whether it has been subjected to peer review, (3) whether the theory has an identified or possible rate of error and is linked to distinct standards, and (4) whether the practice has broad approval by the appropriate scientific community.[27] Thus, the court's task is not to analyze what the experts say, but what basis they have for saying it. The result is more appropriate scrutiny of the admissibility of all expert tes-

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21. Lisa A. Bero, *Evaluating Systematic Reviews and Meta-Analyses*, 14 J.L. & Pol'y 569, 569–70 (2006).

22. Jeffrey C. Lerner & Diane C. Robertson, *When There Are No Randomized Controlled Trials: A Case History of a Controversial Procedure for Metastatic Breast Cancer*, 14 J.L. & Pol'y 595, 604 (2006).

23. *Id.* at 596.

24. Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993).

25. *Id.* at 597.

26. *General Electric Co. v. Joiner* clarified that the abuse of discretion standard of review was to be used by appellate courts reviewing trial court decisions for admissibility of expert testimony. Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997). *Kumho Tire Co. v. Carmichael* further explained that the *Daubert* standards for admissibility were to be applied to all proposed expert testimony, including nonscientific expert testimony. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 151 (1998). Additionally, *Kumho Tire* described a flexible application of the *Daubert* factors in a particular case while preserving *Daubert*'s focus on trustworthiness. *Id.* at 152–53. This trio of Supreme Court cases thus established a gate-keeping role for judges concerning expert medical testimony, requiring a more critical evaluation of testimony by medical experts.

27. *Daubert*, 509 U.S. at 593–94.

timony and a focus on the relevance and reliability of the scientific data underlying expert opinion.

¶14 Before *Daubert*, the standard for determining the admissibility of scientific evidence in court was the *Frye* test, which required that the scientific evidence presented by an expert witness must be generally accepted within the scientific community.[28] However, the U.S. Supreme Court's decision in *Daubert* determined that Federal Rule of Evidence 702 superseded the *Frye* test, requiring the federal courts to apply the *Daubert* principles. Additionally, all of the states and the District of Columbia have considered the *Daubert* standard. The majority of states have either affirmatively adopted *Daubert*, have similarities to *Daubert,* or hold *Daubert* to be instructive.[29] The judiciary has moved toward a more critical and objective, evidence-based appraisal of medical science.

¶15 This focus on the reliability of the scientific data underlying expert opinion is where EBM becomes relevant to law librarians and attorneys. EBM involves the practice of integrating the best medical evidence with clinical experience and expertise to formulate treatment protocols most likely to benefit the patient.[30] This approach is "essentially identical to the guidance provided by *Daubert* and the Supreme Court's application of Federal Rule of Evidence 702 . . . to determine whether a theory or technique [is] scientific knowledge that could assist the trier of fact."[31] Because EBM can only be applied by looking at existing medical literature, this medical literature has become highly relevant to expert medical testimony.

¶16 Medical experts testify as to their medical knowledge. This medical knowledge is made up of what is drawn from the medical literature and the medical professional's education and clinical experience. The medical literature is made up of all of the written information on a particular topic. This may include treatises and textbooks, journals and periodicals, case history reports, research data, government publications, and demographic studies. The best way to support or challenge a medical opinion is through the medical literature. The medical literature must be used and interpreted in order to make it effective for supporting or challenging a witness's opinion. The application of EBM "significantly reduce[s] judicial uncertainty arising from . . . unsettled medical science . . . ."[32]

¶17 Doctors' opinions may vary, but experts who use EBM demonstrate how good (or bad) the science is behind their opinions. This allows for a thorough and objective assessment of the reliability of medical evidence, resulting in better outcomes. Courts have another avenue for excluding false experts who use unreliable scientific methods. Furthermore, judicial understanding of medical study design may help eliminate *Daubert* challenges to experts and their testimony.

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28. Frye v. United States, 293 F. 1013, 1013 (D.C. Cir. 1923).

29. *See* David E. Bernstein & Jeffrey D. Jackson, *The Daubert Trilogy in the States*, 44 JURIMETRICS J. 351, 357–63 (2004).

30. STRAUS ET AL., *supra* note 2, at 1.

31. Pappas, *supra* note 5, at 597.

32. *Id.*

What Legal Researchers Need to Know

¶18 Legal researchers need to understand the basic tenets of EBM in order to apply its principles to a disputed medical intervention. This includes a basic understanding of the medical literature and how best to search for, find, and apply the best available studies to a patient or a population. This will help ensure that experts who are testifying are held to a standard that requires them to substantiate their opinions.

Medical Literature

¶19 There is a huge amount of medical literature. For example, major universities subscribe to as many as 6000 journals and have more than 500,000 volumes on their shelves. The National Library of Medicine (NLM) receives 27,000 journals annually from all over the world. Additionally, medical literature is continually changing because of both new technology and new discoveries. For example, *Gray's Anatomy,* which is standard in the field of anatomy, has gone through forty editions since it first appeared in 1858. It is now available electronically. New editions will continue to be forthcoming. Even in a field that sounds as settled as anatomy, thousands of parts of the body remain unnamed and undescribed.[33]

¶20 As is true of legal literature, medical literature is divided into primary and secondary literature. Both are evolving because of more technologically sophisticated modes of access, including the electronic database. The primary literature includes descriptions of original studies published as articles in peer-reviewed journals. There are also more and more open-access journals challenging the traditional publishing landscape.[34] Furthermore, data sets are now frequently available electronically. In medicine, secondary literature can be thought of in the traditional sense, but also as synthesized or filtered literature. This secondary literature includes electronic and traditional textbooks, narrative reviews, systematic reviews, practice guidelines, and other tools that allow for searching across multiple databases.

¶21 Once you have decided which resources you are going to search, it is important to have a search plan when beginning your search. A search plan will save time and lead to better results. EBM generally consists of a five-step process: (1) craft a clinical question, (2) search the medical literature, (3) select the best studies, (4) appraise these studies, and (5) apply the results to the patient.

Crafting a Clinical Question: PICO

¶22 Crafting a clinical question requires that a real medical question regarding a patient or group of patients be created for searching the available medical literature.[35] An example might be: "Do probiotics decrease the risk of developing an infection after abdominal surgery?"

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33. 1 Lawyers' Guide to Medical Proof § 103.02 (2009).

34. *See* Karen M. Albert, *Open Access: Implications for Scholarly Publishing and Medical Libraries,* 94 J. Med. Libr. Ass'n 253, 255–56 (2006).

35. Dan Mayer, *Evidence-Based Medicine,* 36 New Eng. L. Rev. 601, 603 (2002).

¶23 In a legal research context, this clinical question might be derived from another question, such as: "Was Dr. X negligent when he prescribed probiotics for Patient Y in order to prevent an infection after abdominal surgery, given that Patient Y got an infection anyway?" In order to show that there was no negligence, one required element might be a lack of causation. You would need to show that probiotics do not cause infections. It would be even better to show that probiotics actually help prevent infections and that EBM based on the literature shows that probiotics help prevent infections in patients who have had abdominal surgery. In a real-life scenario, there would likely be many other possible legal arguments as to why negligence may or may not have occurred. The EBM process would have to be applied to all of the medically related questions.

¶24 The best way to construct a clinical question is to use the mnemonic known as PICO, which stands for (P) patient/population/problem, (I) intervention, (C) comparison, and (O) outcome. All of these elements need to be addressed (explicitly or implicitly) in the clinical question. It is best to map out these elements with a chart.[36] The idea behind using a chart is to help plan the strategy to be used to find as many articles on your topic as possible. These articles can later be narrowed down by determining which are the best kinds of studies with the best methodologies. More detailed information on search formulation can be found in the help functions or tutorials of most computerized databases.

¶25 Let us examine our medical question again: "Do probiotics decrease the risk of developing an infection after abdominal surgery?" If we use the PICO method, you can see why this is an appropriate clinical question. (P) (patient or population) is people who have had abdominal surgery. (I) (intervention) is the prescription of probiotics. (C) is the comparison of some other action to the intervention. This can be the most difficult concept because frequently, as is the case here, the comparison is to a lack of intervention. In other words, "Is taking probiotics better than taking nothing?" Alternatively, the comparison might be to another standard intervention, such as prescribing antibiotics. While we won't consider this in our example, in a real situation the plaintiff might also compare an alternative intervention or a standard intervention to the intervention that actually occurred. (O) is the desired outcome—here it would be to prevent infection. Because our clinical question addresses these issues, we can begin to use it to search our database.

¶26 The four PICO elements can be used to break the question down into components for searching. Using a chart, we would have three components: (1) abdominal surgery, (2) probiotics, and (3) preventing infection. Because the comparison (C) here is to no intervention, the fourth component does not need to be included on the chart. For each component, you would develop possible synonyms or appropriate controlled vocabulary terms, depending on the database.

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36. An example of a simple PICO worksheet created by the Dartmouth Biomedical Libraries can be seen in The Well-Built, Patient Oriented Clinical Question, Oct. 12, 2006, http://www.dartmouth.edu/~biomed/services.htmld/EBP_docs/clin_question_worksheet.pdf.

Searching the Medical Literature: MeSH

¶27 There are a vast number of excellent resources available for searching the medical literature. No matter which resource you are searching, it is important to retrieve all studies that may be relevant to the clinical question.[37] MEDLINE[38] will be used here to demonstrate how to search a medical database, since it is generally considered the premier source for bibliographic coverage of biomedical literature. It is a very sophisticated database with many features for retrieving accurate results. Furthermore, it is most likely that other databases will have fewer searching features than MEDLINE and that the ones that they do have will work similarly to how they work in MEDLINE. Finally, the MEDLINE database lends itself very well to searching for multiple concepts, such as those that you are likely to come up with using the PICO method.

¶28 There are multiple interfaces for MEDLINE. For example, the free database PubMed[39] contains MEDLINE. Additionally, there are several proprietary databases that include MEDLINE, including Ovid and Web of Science. I personally prefer the Ovid interface, mainly because I believe it is much easier to use and understand the controlled vocabulary system MeSH (Medical Subject Headings) using the Ovid interface rather than other available interfaces.

¶29 After using the PICO method to break down the clinical question into concepts, it is important to come up with synonyms for each concept and to use the controlled vocabulary. The controlled vocabulary thesaurus in medicine is called MeSH, an acronym for **Me**dical **S**ubject **H**eadings. It was created by NLM and is designed for indexing, cataloging, and searching medical and health information.[40] When a user enters a keyword or phrase, synonyms, near-synonyms, and closely related concepts are generated to help users find the most appropriate MeSH concept. In the NLM's online databases, many search terms automatically map to MeSH descriptors to "facilitate retrieval of relevant information."[41] The articles and studies in MEDLINE are assigned an average of fifteen subject headings each.[42]

¶30 Several online systems offer access to MeSH. These include the MeSH Browser,[43] which has the entire contents of the vocabulary; the MeSH Entrez databases, which are designed to assist those searching MEDLINE/PubMed; and the Unified Medical Language System (UMLS)[44] with links to many other controlled

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37. Mayer, *supra* note 35, at 603.

38. For detailed information on the MEDLINE database, see *infra* ¶¶ 65–69.

39. PubMed.gov, http://www.ncbi.nlm.nih.gov/PubMed (last visited May 14, 2010).

40. Nat'l Libr. of Med., Medical Subject Headings, Preface, http://www.nlm.nih.gov/mesh/intro_preface.html#pref_rem (last updated Sept. 1, 2009).

41. *Id.*

42. 1 Lawyers' Guide to Medical Proof, *supra* note 33, § 103.13.

43. The MeSH Browser is an online vocabulary look-up aid that can be used to look up MeSH terms. The 2010 MeSH browser can be found at http://www.nlm.nih.gov/mesh/2010/mesh_browser/MBrowser.html (last visited Apr. 20, 2010).

44. NLM has also developed the UMLS as an attempt to standardize the medical language. "The purpose of the UMLS is to aid the development of systems that help health professionals and researchers retrieve and integrate electronic biomedical information from a variety of sources and to make it easy for users to link disparate information systems, including computer-based patient records, bibliographic databases, factual databases, and expert systems." Nat'l Network of Libr. of Med., Nat'l

vocabularies. Additional information about MeSH and direct access to MeSH data are provided at http://www.nlm.nih.gov/mesh.

¶31 MeSH descriptors are organized in both an alphabetic and a hierarchical structure. At the broadest level of the hierarchical structure are headings such as "Anatomy" or "Diseases." More exact headings are found at narrower levels of the hierarchy, such as "Ankle" and "African Swine Fever." There are over 25,000 descriptors in 2010 MeSH. There are also over 172,000 entry terms or "see" cross-references that assist in finding the best MeSH heading; for example, "CPR" is an entry term to "Cardiopulmonary Resuscitation." Additionally, there are 190,000 headings called Supplementary Concept Records[45] (drug and chemicals subject headings that are added on a daily basis) within a separate thesaurus.[46]

¶32 The MeSH system works by building hierarchies of terms associated by "broader-than," "narrower-than," and "related" links. These links demonstrate the connection between interrelated terms and provide a structure that allows searching at a range of levels of specificity from narrower to broader.[47] The MeSH vocabulary is updated annually.

Selecting the Best Studies: Meta-Analyses and Systematic Reviews

¶33 Once you have retrieved studies based on your search, you should select the best type of studies available on your topic. There are many reasons that using the best type of study available is important. First, the better the study, the stronger the medical evidence. Second, in a legal context, if you are able to show that your opponent is relying on study types that are not as strong as possible, you can show that their medical evidence is weak, and therefore that their proof of their complaint may be weak. You may even be able to show, by using a strong type of study such as a meta-analysis, that contradictory testimony based on a single weak study is inadmissible.

¶34 Generally, you can determine the type of study by reading the abstract of the article, which is usually written by the author. First you want to make sure that you are selecting studies that are relevant to your clinical question. As powerful as the MeSH controlled vocabulary and the MEDLINE database are, you may still come up with some articles that are irrelevant to your clinical question. Then, for each relevant article, you should get an idea of what type of study it is and how strong the results are, as well as its applicability to the patient.[48] The main focus discussed here will be on determining what type of study it is and whether it is the best type of study available.

Training Ctr. & Clearinghouse, Frequently Asked Questions, http://nnlm.gov/ntcc/question.html (last updated Mar. 23, 2009).

45. For more information on Supplementary Concept Records see *Supplementary Concept Records*, NLM TECH. BULL., Sept.-Oct. 2004, *available at* http://www.nlm.nih.gov/pubs/techbull/so04/so04_scrs_added_to_mesh.html.

46. U.S., Nat'l Libr. of Medicine, Medical Subject Headings (MESH) Fact Sheet, http://www.nlm.nih.gov/pubs/factsheets/mesh.html (last updated Apr. 1, 2010).

47. *See* U.S., Nat'l Libr. of Medicine, Medical Subject Headings, Preface, http://www.nlm.nih.gov/mesh/intro_preface.html.

48. Mayer, *supra* note 35, at 603 (2002).

¶35 In order to identify the best study types, you need a basic understanding of the study types and where they are on the study hierarchy. This hierarchy of studies is usually graphically represented by a pyramid, with the best studies at the top of the pyramid, since there are relatively few of them, and the weakest studies at the bottom of the pyramid, since there are many.[49] A general list of studies in order from strongest to weakest is meta-analyses, systematic reviews of randomized controlled trials, results of individual controlled clinical trials, observational (uncontrolled) studies, and anecdotal reports of clinical observations.[50] You will most likely want to look at the studies in each category in descending order.[51]

¶36 The most respected methods for gathering, critiquing, and summarizing medical and scientific information are meta-analyses and systematic reviews. They are considered to be at the top of the "hierarchy of evidence" for EBM[52] because they are the most methodologically rigorous. Systematic reviews are intended to generalize results across a comprehensive number of valid studies.[53] Meta-analyses are a type of systematic review that uses quantitative methods.[54] The larger the sample size, the more likely that the results will be clustered around the true effect. In smaller studies, there is an increased chance of random error, so the results are less likely to represent the true effect.

¶37 Meta-analyses and systematic reviews frequently provide the basis for commonly used tools of medical practice such as "practice guidelines, clinical decision support systems, drug formulary decisions, and drug payment schemes."[55] Fortunately, the coverage of medical subjects by systematic reviews and meta-analyses is growing quickly.[56] This leads to better evidence to support the practice of clinical medicine, as well as the general increase in the use of EBM principles.

¶38 *Meta-analysis* is generally considered the best type of study if a particular clinical query lends itself to being analyzed using statistical methods. Meta-analysis augments the power of a single study because it merges the results of many small studies into one study, resulting in a larger sample size. Therefore, "meta-analysis increases the precision of an estimate of an effect by decreasing the variability around the estimate as the sample size increases."[57] Systematic reviews also combine the results of earlier studies using a defined protocol; they do not generally result in

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49. *See* Harvey Cushing/John Hay Whitney Med. Libr., Yale Univ., Pyramid—Evidence-Based Clinical Practical Resources (2006), http://guides.med.yale.edu/content.php?pid=9786&sid=73113.

50. *See* Gordon H. Guyatt et al., *Users' Guides to the Medical Literature: XXV. Evidence-Based Medicine: Principles for Applying the Users' Guides to Patient Care,* 284 J. AM. MED. ASS'N 1290, 1291 tbl.1 (2000).

51. Joseph B. Clamon, *Does My Health Insurance Cover It? Using Evidence-Based Medicine and Binding Arbitration Techniques to Determine What Therapies Fall Under Experimental Exclusion Clauses in Health Insurance Contracts*, 54 DRAKE L. REV. 473, 498 (2006).

52. Gordon H. Guyatt et al., *Users' Guides to the Medical Literature: IX. A Method for Grading Health Care Recommendations*, 274 J. AM. MED. ASS'N 1800, 1800, 1804 (1995).

53. *See* STRAUS ET AL., *supra* note 2, at 283.

54. *Id.* at 281.

55. Bero, *supra* note 21, at 570.

56. Patrick Vavken & Ronald Dortoka, *A Systematic Review of Conflicting Meta-Analyses in Orthopaedic Surgery*, 467 CLIN. ORTHOPAEDICS & RELATED RES. 2723, 2723 (2009).

57. Bero, *supra* note 21, at 573.

a statistical analysis, but rather a descriptive combination of the data. The best kind of meta-analysis should start as a systematic review.[58]

¶39 *Systematic reviews* can produce answers that a single study cannot, because they look at all of the available relevant studies. They are designed to manage the huge amount of information that is characteristic of clinical medicine and allow the reader to identify when scientific results are consistent. When studies that are handled somewhat differently arrive at the same answer, we can presume that the results may be broadened to a larger population. Conversely, systematic reviews enable the examination of discrepancies between the results of individual studies. "By presenting the same information on all studies in the systematic reviews, the review allows the reader to determine whether divergent results might be due to differences in the methods of the original studies, differences in the experimental intervention tested, or variability in the characteristics of the populations tested."[59]

¶40 *Randomized controlled clinical trials* "are carefully planned projects that study the effect of a therapy on real patients. They include methodologies that reduce the potential for bias (randomization and blinding) and that allow for comparison between intervention groups and control groups (no intervention)."[60] As a result, the double-blind randomized controlled trial is accepted by medicine as the highest level of objective scientific methodology.[61] Double-blinding occurs when neither the doctor nor the patient knows which treatment is being given. (In a single-blind study only the patient does not know which treatment is being given.)[62] This decreases the likelihood of bias and of any psychological effect of knowing which treatment the patient is receiving. Nonrandomized controlled clinical trials are weaker studies than randomized controlled clinical trials. In nonrandomized trials, researchers assign patients to specific groups. This leads to the possibility of a greater risk of error in the results because the results may be connected to the method of assignment to a specific group.

¶41 *Cohort studies* are observational (uncontrolled) studies. They study a large population and track patients who have a particular condition or are given a specific treatment over time and compare them with a different population that has not been affected by the condition or the treatment being studied. Cohort studies "are observational and not as dependable as randomized controlled studies," because variables may affect the two groups that are different from the variable in the study.[63]

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58. *Id.* at 570.

59. *Id.* at 572–73.

60. Introduction to Evidence-Based Medicine, Types of Questions and Studies, http://www.hsl.unc.edu/Services/Tutorials/ebm/Supplements/QuestionSupplement.htm (last visited May 10, 2010).

61. Ted J. Kaptchuk, *The Double-Blind, Randomized, Placebo-Controlled Trial: Gold Standard or Golden Calf?*, 54 J. Clin. Epidemiology 541, 541 (2001).

62. John N.S. Matthews, Introduction to Randomized Controlled Clinical Trials 65 (2d ed. 2006).

63. Introduction to Evidence-Based Medicine, Types of Questions and Studies, *supra* note 60.

¶42 *Case control studies* are

> studies in which patients who already have a specific condition are compared with people who do not. They often rely on medical records and patient recall for data collection. These types of studies are often less reliable than randomized controlled trials and cohort studies because showing a statistical relationship does not mean than one factor necessarily caused the other.[64]

¶43 *Case series* and *case reports* are reports on the management of individual patients or a report on a single patient. They are believed to have no statistical validity because there is no control group.[65]

¶44 Fortunately, in MEDLINE, you have the option to limit your search by type of study as an option under "Additional Limits." This makes finding the best types of studies much easier for the novice (and saves time for experts and novices alike). It is important to note that the types of studies that are available as options in MEDLINE are not necessarily fully consistent with the descriptions above. They are similar, but you still must read the abstract of the article to double-check that the MEDLINE designation is correct.

Appraising the Best Studies

¶45 The fourth step is to critically appraise the best studies for their validity and to determine how strong the results actually were. The "potential sources of bias . . . in that study" and "how those sources of bias may affect the results" must be identified.[66] Additionally, the strength of the results from a statistical standpoint must be understood and interpreted.[67]

> Two key elements of a high-quality systematic review are transparency about the methods and data used to conduct the analysis in the review and the comprehensiveness of the review. Transparency is important for reproducibility of results. Comprehensiveness is important so that all relevant data and information are considered to arrive at the conclusions.[68]

¶46 There are some general guidelines that should be followed when assessing systematic reviews and meta-analyses. Generally, a high-quality review must contain:

> 1) an objective or research question, 2) criteria for selecting studies for the review, 3) a search strategy for studies, 4) methods for assessing the validity of included studies, 5) a method for selecting studies for the review, 6) methods for collecting data from the studies, and 7) an analysis plan.[69]

¶47 There are numerous areas where bias can occur in a meta-analysis or review: the structure of the research question, the choice of studies to be included, the extracting of data from the included studies, the critical appraisal of the studies,

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64. *Id.*
65. *Id.*
66. Mayer, *supra* note 35, at 604.
67. *Id.*
68. Lerner & Robertson, *supra* note 22, at 606.
69. Bero, *supra* note 21, at 575.

and the analysis of the studies. As a result, it can be complicated to identify bias and what has caused it.

> One way to avoid bias in a review is to develop a protocol for the review before commencement and adhere to the protocol regardless of the results of the review. A reader of the review can then determine whether the authors conducted it according to the systematic methods proposed. When the reviews are completed, the readers can be assured that the authors adhered to the methods of the protocol and did not change the methods after they started the review. Adherence to a strict protocol can sometimes result in reviews where no studies that meet the criteria for the review can be found. However, . . . these reviews are still useful for identifying gaps in the research literature.[70]

¶48 Some systems have been designed to give the quality of a study a rating. One example is a system created by the National Cancer Institute, where each human study is given two scores. The first score measures the study design on a scale of 1 to 4, with 1 being the best rated study.[71] The second score assigns a letter to the strength of the variable that was measured. The letters are from A to D, with A being the strongest.[72] The strongest rating would be a 1A, which would represent a double-blind randomized controlled trial that showed a high overall survival rate for patients after an intervention such as treatment (e.g., chemotherapy). In general, though, there is usually no existing system for rating the quality of a study.

Applying the Results to the Patient

¶49 The fifth and final step is to apply the results to an individual patient. Studies merely indicate what we expect to happen statistically. Practitioners must then integrate the evidence with their own clinical expertise and with the values of the patient in order to decide how to treat the patient.[73] Patient values can be described as their preferences as patients. There is an assumption that if patients accurately recognize the possible risks and benefits, their choices will mirror their preferences and values.[74] The physician must tell the patient about all information that is applicable to making a decision, such as available treatment alternatives, the benefits and risks of each, and the possible psychological and social consequences. The patient should inform the physician about her values, preferences, lifestyle, beliefs, and knowledge about her illness and its treatment options. This way all of

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70. *Id.* The Cochrane Library publishes protocols for systematic reviews. For example, the *Cochrane Handbook for Systematic Reviews of Interventions* is "the official document that describes in detail the process of preparing and maintaining Cochrane systematic reviews on the effects of healthcare interventions." Cochrane Collaboration, Cochran Handbook for Systematic Reviews of Interventions, http://www.cochrane.org/resources/handbook/index.htm (last visited May 13, 2010).

71. The ratings are (1) for randomized controlled clinical trials, especially double-blinded studies; (2) for nonrandomized controlled clinical trials; (3) for case series; and (4) for best-case series (these provide the weakest evidence because they include just the cases that appear to have benefited from the method/treatment). 13 COURTROOM MEDICINE—CANCER § 5H.13 (2009).

72. The ratings are (A) overall survival (percentage of patients that did not die over a specific period of time); (B) cause-specific survival (percentage of patients that did not die from a particular cause); (C) quality of life measurements; and (D) surrogate factors (indirect factors that are not independent of other factors. *Id.*

73. *See* Mayer, *supra* note 35, at 604.

74. Guyatt et al., *supra* note 50, at 1292.

the treatment options are known to the patient, and together the patient and physician can evaluate them in the context of the patient's specific situation.[75]

¶50 From a legal perspective, patient preference comes into play because more and more jurisdictions are requiring doctors to notify patients of all relevant treatment alternatives and their risks.[76] The reasoning behind this is that patients have the right to make treatment decisions based on their personal values. Thus, integrating patient care with patient preferences is important from both an EBM and a legal perspective.

How to Do a MEDLINE Search

¶51 The purpose of this section is to provide some guidelines on how to get started doing a basic "Advanced Search" in MEDLINE (Ovid). Again, I have chosen the Ovid interface for MEDLINE because I believe it is the easiest to use. However, the basic principles are the same no matter which MEDLINE interface you choose to use.

¶52 The "Advanced Search" is the best way to start in MEDLINE, because it automatically allows you to map terms to MeSH subject headings. You can also search by author, title, or journal from the Advanced Search page. To create a search, first select a search type: keyword, author, title, or journal. Enter the search, and your results will be posted to search history.

¶53 If your keyword or phrase matches the MeSH controlled vocabulary, the Mapping Display page will open with a list of relevant MeSH terms. Click the Information icons ("i") to view scope note information about the subject headings, including definition, date of entry into the controlled vocabulary of the database, and used-for terms (a history of prior indexing of the term). To obtain the quickest and broadest results from the Mapping Display, select the check boxes of subject heading terms to include in your search. Then select the "Include All Subheadings" check box. Choose a Boolean operator from the pull-down menu and click the Continue button. Ovid will post the results to the search history back on the Main Search Page.

¶54 It is also possible to select the "Search as Keyword" check box from the Mapping Display if your initial search term does not map to a subject heading of interest to you or if you would like to run the keyword search in addition to the subject heading search. Ovid then runs a standard keyword search and posts results to your search history back on the Main Search Page.

¶55 At the Main Search Page, where your results are posted under Search History, you will probably find it useful to combine the results of two or more sets from your search strategy. Once you have your results from combining all of your

75. Cathy Charles et al., *Decision-Making in the Physician–Patient Encounter: Revisiting the Shared Treatment Decision-Making Model,* 49 Social Science & Medicine 651, 654 (1999).

76. Unanimous decisions issued separately on July 24, 2009, by the Maryland Court of Appeals and the Wisconsin Supreme Court require doctors to notify patients of all relevant treatment options and their risks. *See* McQuitty v. Spangler, 976 A.2d 1020 (Md. 2009); Bubb v. Brusky, 768 N.W.2d 903 (Wis. 2009). The two courts also clarified that proof of medical negligence is not required for plaintiffs to bring an informed-consent claim.

search terms, you should focus your search using Limits. The best way to combine all of the relevant limits is to click on the "Additional Limits" button, which will give you access to the full suite of database limit options on the "Limit a Search" page. Some more basic limits that you are likely to use for medico-legal research are "human," which retrieves only those records that pertain to human subjects; "English language"; and "publication year." There are many other possible limits. Some of the more relevant for our purposes are "age groups," "CheckTags" (indexed research subject categories), "male" and "female," and finally "publication types."

¶56 "Publication types" is the parameter that allows you to choose the type of study you would like to limit your results to. You may want to first limit your search to the best type(s) of studies available. Then, if you do not get adequate results, you can rerun the same search but include weaker study types. Among the "publication type" options are meta-analysis, randomized controlled trial, and review. A review is not necessarily a systematic review, although it would include systematic reviews. A review is any review of the literature, and you must read it to determine whether it is a systematic review.

Selecting Resources for the Law Library

Monographs and Serials

¶57 When selecting medical resources for a law library, it is useful to understand how medical libraries are organized. Similar to law libraries, they are usually organized into two major groups of print publications: books and journals. Books are classified and cataloged much like books in a law library and journals are arranged alphabetically, just like many legal periodicals within most law libraries.[77] Medical libraries generally use either the Library of Congress classification system or the NLM system.[78]

¶58 A law library that has a need for medical resources will have to do a needs assessment to determine the volume and types of resources needed. However, suggestions can be taken from resources used by medical libraries generally, especially small medical libraries. Most small medical libraries develop their collections based on core titles. There are several generally accepted resources for core books and journals for the medical library. They include the *Brandon/Hill Selected List of Print Books and Journals for the Small Medical Library*, *Doody's Core Titles*, and *Medical and Health Care Books and Serials*.

¶59 The Brandon/Hill list was greatly valued and frequently used by librarians and members of the medical profession for nearly forty years. The original authors were Alfred Brandon and Dorothy Hill, who were directly involved in the project. With the retirement of Dorothy Hill, the last list was published in 2003. Unfortunately, the list will no longer be updated.[79] The list was specifically designed

77. 1 Lawyers' Medical Cyclopedia, *supra* note 7, § 3.35.

78. *Id.*

79. Dorothy R. Hill et al, Brandon/Hill Selected List of Print Books and Journals for the Small Medical Library (2003), http://library.mssm.edu/brandon-hill/small_medical/pdf/brandon4.pdf. The *Selected List of Nursing Books and Journals* and the *Selected List of Books and Journals in Allied*

to be a selection guide for medical or health sciences libraries. The books and journals are categorized by subject, and there is an author/editor index for books and an alphabetical title list for journals.

¶60 There are three tiers within the core list, including a "minimal core list," with the total cost included (for 2003). The complete list contains 672 books and 141 journals for a total cost of $144,486 for the year, including journal subscriptions. Additionally, there is a list that contains 251 "initial purchase" books only and the 141 journals with a total cost of $68,873. Finally, there is a "minimal core list" that consists of 104 "initial-purchase" books only and costs approximately $18,236.

¶61 Although in medicine new editions of books come out frequently, the titles themselves tend to stay the same. As a result, the Brandon/Hill list can continue to be used as a good guide to titles as long as you make sure you have the most recent editions of the books themselves. As time goes on, of course, the Brandon/Hill list will become less relevant. For now, it is especially useful if it is used in combination with another respected list, such as Doody's.

¶62 The purpose of *Doody's Core Titles* (*DCT*) is to offer a comprehensive, current, and authoritative list of print books and software titles (many medical books and textbooks are available in electronic format and some are available in electronic format only or the electronic format has additional features) that embody indispensable knowledge for health professionals or students and are recommended for health and medical libraries. It is developed by over 200 medical librarians and covers 121 specialties. It is a subscription service available at http://www.doody.com/dct.[80] Titles are evaluated by having up to three librarians score each title on a scale of 0 to 3 for five fundamental collection development criteria: (1) authoritativeness of author and publisher, (2) scope and coverage of the subject matter, (3) quality of content (including currentness), (4) usefulness and purpose, and (5) value for money. The scores are averaged to give a general score for each title.

¶63 *DCT* is updated annually. This is important because the collection of core titles and the scoring are also updated each year. Because the list of core titles is available in an online database, it is updated as new information, such as changes in price or the availability of new titles, is acquired. Additionally useful to a small medical library or small medical collection is that library selectors indicate which titles in each specialty are "Essential Purchase Titles." Essential Purchase Titles are the titles recommended for a library with an annual book-buying budget of no more than $7500.

¶64 *Medical and Health Care Books and Serials in Print*[81] is another important source for bibliographic information. It is an excellent resource for small medical libraries because it includes a subset of *Books in Print* and *Ulrich's International Periodicals Directory* that are specific to medicine and health care. It is updated annually and also includes publishers and pricing information. It includes listings

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Health Sciences are also available online. Mt. Sinai, Brandon-Hill Selected Lists, http://library.mssm.edu/brandon-hill (last visited May 13, 2010).

80. At the time of writing, Doody's Core Titles 2010 was being offered for $49.50 for DCT Basic and $149.50 for DCT Premium on its web site. Doody's Core Titles, http://www.doody.com/dct (last visited May 10, 2010).

81. Medical & Health Care Books & Serials in Print (2009).

for more than 109,000 books and more than 22,600 U.S. and foreign serials, divided into 6000 medical and health subject areas, which are cross-referenced.

Electronic Databases

MEDLINE and Related Databases

¶65 As previously discussed, MEDLINE is the natural starting point for medical research. The MEDLINE database is widely recognized as the premier source for bibliographic and abstract coverage of biomedical literature. MEDLINE provides information from the fields of medicine, nursing, and dentistry, as well as coverage in the areas of allied health, biological and physical sciences, humanities and information science as they relate to medicine and health care, communication disorders, population biology, and reproductive biology. The database contains more than twelve million citations from 4600 biomedical journals published in the United States and other countries. Some citations go back as far as 1950. Approximately seventy-five percent of records include an abstract. The former print equivalents to MEDLINE are the *Index Medicus*, *Index to Dental Literature*, and the *International Nursing Index*.

¶66 Although MEDLINE has coverage back to 1950, there are additional citations that are not available in MEDLINE and that are instead in a database called OLDMEDLINE. OLDMEDLINE, like MEDLINE, is available in multiple databases and interfaces, including PubMed and Ovid. These citations are in a separate database because they have not had their keywords mapped to the current MeSH. At this point, approximately seventy-five percent of the older citations have had their keywords mapped to current MeSH. Thus, only about twenty-five percent of older citations are in OLDMEDLINE.

¶67 The two major medical databases that offer MEDLINE are PubMed and Ovid. Both of these are often simply referred to as MEDLINE. Both databases contain approximately the same information. They both utilize the controlled vocabulary MeSH. Ovid (Medline) is a paid database and is expensive. In my opinion, it has a superior interface to PubMed. However, PubMed is a free public database and has the advantage of always being accessible, but with limitations unless you access it through a library that pays for additional content. Both of these databases are essentially indexes. They both offer some articles in full text, but the vast majority of articles can be accessed in full-text format only if the library has purchased the full text from a third party, such as the publisher. However, the abstracts for seventy-five percent of the articles are available for free from either Ovid or PubMed. Additionally, there is an excellent free tutorial from PubMed at http://www.nlm.nih.gov/bsd/disted/pubmedtutorial. Ovid also offers excellent web-based training sessions for their product at http://www.ovid.com/site/trial/ovidsp_db_training/medline_sp/index_auto.jsp.

¶68 MEDLINE is also available on both Westlaw and LexisNexis. Westlaw offers access to MEDLINE abstracts in several of its online products: Medical Litigator on Westlaw, which provides litigation resources; Profiler on Westlaw, which provides information on attorneys, judges, and experts; and Medical Litigator Core

(Module), which provides access to a variety of medical materials.[82] LexisNexis has the MEDLNE;MISC library, which also offers access to abstracts as well as limited full text. The problem with using LexisNexis or Westlaw to search MEDLINE is that users do not have the advantage of using the MeSH indexing or the other limiting options that are available if you are searching in PubMed or Ovid. For example, there is no system to limit your search to a meta-analysis or controlled trial or even the ability to limit to studies with males or females only.

¶69 It is also important to keep in mind that MEDLINE is a product that is maintained by NLM.[83] The MEDLINE (index, abstracts, and some full text) data are available through PubMed along with other life science journals. PubMed is one of many searchable resources available from the NLM's National Center for Biotechnology Information (NCBI).[84] Most of these databases are outside the scope of typical medical research, but might be relevant in certain circumstances that call for pure science research.

The Cochrane Collaboration and the Cochrane Library

¶70 There are many electronic databases/indexes other than MEDLINE. Among the most important of these are databases produced by the Cochrane Collaboration:

> The Cochrane Collaboration is an international, non-profit, independent organisation, established to ensure that up-to-date, accurate information about the effects of health-care interventions is readily available worldwide. It produces and disseminates systematic reviews of healthcare interventions, and promotes the search for evidence in the form of clinical trials and other studies of the effects of interventions.[85]

¶71 "The Cochrane Collaboration was established in 1993, and named after the epidemiologist Archie Cochrane, a British medical researcher who contributed significantly to the development of epidemiology as a science."[86] It compiles the work of thousands of independent contributors from around the world.[87]

¶72 One of the most important sets of publications that the Cochrane Collaboration produces is called the Cochrane Reviews. Cochrane Reviews are systematic assessments of evidence of the effects of health-care interventions. These systematic reviews identify an intervention for a particular disease or other health problem, and determine whether the intervention works. The authors find, assess, and combine evidence from as many relevant scientific studies as possible. They

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82. A list of Medline titles available on Westlaw can be found by searching the West web site (http://west.thomson.com) for the term "medline."

83. Other databases lease MEDLINE content from NLM. "MEDLINE citation data comprises approximately 93% of the data distributed to MEDLINE/PubMed licensees." U.S. Nat'l Libr. of Medicine, Leasing Journal Citations, http://www.nlm.nih.gov/databases/journal.html (last updated Oct. 20, 2009).

84. For a full list of resources available from NCBI, go to http://www.ncbi.nlm.nih.gov/guide/all (last visited May 14, 2010). A full list of databases published by the NLM can be found at: http://www.nlm.nih.gov/databases/index.html (last visited May 14, 2010).

85. Cochrane Collaboration, Newcomer's Guide, http://www.cochrane.org/about-us/newcomers-guide (last visited May 4, 2010).

86. *Id.*

87. *Id.*

summarize conclusions about their effectiveness and make available a collation of the known evidence on a certain topic, so that others can easily review the primary studies for a particular intervention and make informed decisions about health care. The full Cochrane Reviews are published in the Cochrane Database of Systematic Reviews, one of several databases in the Cochrane Library.[88] Cochrane Reviews are known internationally to be among the best sources of high-quality and reliable health information.[89]

¶73 Anyone interested in researching medical questions would find it useful to have a Cochrane Systematic Review available. They are so powerful because they are a complete report of research findings on a particular topic. They summarize data from all existing studies on a particular subject and critically appraise it using unbiased techniques. They are easy to obtain and are updated as new information becomes available.[90]

¶74 The Cochrane Database of Systematic Reviews is published electronically by Wiley as part of the Cochrane Library. It is also available through Ovid. The Cochrane Library is a collection of high-quality evidence-based health-care databases containing more than 2000 full-text articles reviewing the effects of health-care interventions. Abstracts of Cochrane Reviews are freely available from the Cochrane Library web site.[91]

¶75 The Cochrane Library provides links to MEDLINE abstracts and the ISI Web of Science, and links from references in Cochrane Reviews to journal articles cited within them. Additional databases available from the Cochrane Library are the Database of Abstracts of Reviews of Effects (DARE),[92] Cochrane Central Register of Controlled Trials (CENTRAL),[93] Cochrane Methodology Register (CMR),[94] Health Technology Assessment database (HTA),[95] and NHS Economic Evaluation Database (NHSEED).[96]

¶76 DARE is the only database that has abstracts of systematic reviews that have been quality assessed. Each abstract contains a summary of the review and critical comments about its overall quality. CENTRAL has details of published articles taken from bibliographic databases (mostly MEDLINE and Embase) and other sources. The CMR is a bibliography of publications that describe methods used in

88. *Id.*

89. The 2008 impact factors published by Thomson ISI give the Cochrane Systematic Reviews an Impact Factor of 5.182 and rank them as 12th out of 107 in the ISI category Medicine, General & Internal.

90. Bero, *supra* note 21, at 570.

91. Cochrane Library, http://www.thecochranelibrary.com/view/0/index.html (last visited May 13, 2010).

92. http://www.mrw.interscience.wiley.com/cochrane/cochrane_cldare_articles_fs.html (last visited May 13, 2010).

93. http://www.mrw.interscience.wiley.com/cochrane/cochrane_clcentral_articles_fs.html (last visited May 13, 2010).

94. http://www.mrw.interscience.wiley.com/cochrane/cochrane_clcmr_articles_fs.html (last visited May 13, 2010).

95. http://www.mrw.interscience.wiley.com/cochrane/cochrane_clhta_articles_fs.html (last visited May 13, 2010).

96. http://www.mrw.interscience.wiley.com/cochrane/cochrane_cleed_articles_fs.html (last visited May 13, 2010).

carrying out controlled trials. The HTA database combines the details of completed and ongoing health technology assessments (studies of the medical, social, ethical, and economic implications of health-care interventions) from around the world. NHSEED helps decision makers by systematically identifying economic evaluations from around the world and appraising their quality. Finally, the About the Cochrane Collaboration database[97] contains information about the many groups that comprise the Cochrane Collaboration.

Embase

¶77 The Embase database contains over twenty million indexed records from the international research literature. It has citations and abstracts from more than 7000 active, peer-reviewed journals worldwide, covering pharmacology, environmental health, and hospital management, in addition to medicine. The database goes back to 1974. Embase has more than 2000 biomedical titles not offered by MEDLINE.[98] Embase is thought of as particularly powerful in the areas of drugs and disease research. It is also indexed by experts using the controlled vocabulary thesaurus Emtree, which its publisher Elsevier states has twice as many drug synonyms as MeSH.[99] It is definitely a powerful database.

¶78 Although there is no free version of Embase, it is available online via many major database vendors: LexisNexis, which is updated weekly; and DataStar, DIALOG, DIMDI, Ovid Online, and STN, which are all updated daily. Additionally, Embase exists on tape for in-house installation. A fully networkable version is produced through Ovid Technologies.[100]

¶79 When choosing how to access Embase, it is preferable to use a database that will allow you to take advantage of the indexing. Just as with MEDLINE, my personal preference is Ovid Online. It has the most flexibility for taking advantage of the indexing. An additional advantage to Ovid is that both MEDLINE and Embase can be searched simultaneously and duplicates can be easily removed. Searching Embase through LexisNexis limits your searching capabilities, because index searching is extremely curtailed.

CINAHL

¶80 CINAHL: The Cumulative Index to Nursing and Allied Health Literature provides indexing of the literature of nursing and allied health.[101] It covers over

97. http://www.mrw.interscience.wiley.com/cochrane/cochrane_clabout_contents_fs.html (last visited May 13, 2010).

98. Embase Biomedical Answers, Comprehensive Coverage, http://info.embase.com/what-is-embase/coverage (last visited May 4, 2010).

99. *See* Embase Biomedical Answers, Benefits, http://info.embase.com/why-use-embase/benefits (last visited May 4, 2010).

100. *See* Elsevier, Embase, http://www.elsevier.com/wps/find/bibliographicdatabasedescription.cws_home/523328/description#description (last visited May 4, 2010).

101. According to the Association of Schools of Allied Health Professionals:

> Allied Health professionals are involved with the delivery of health or related services pertaining to the identification, evaluation and prevention of diseases and disorders; dietary and nutrition services; rehabilitation and health systems management, among others. Allied health professionals, to name a few, include dental hygienists, diagnostic medical sonographers, dietitians, medical technologists, occupational therapists, physical therapists, radiographers, respiratory therapists, and speech language pathologists.

1200 journals in nursing and allied health. Virtually all English-language nursing journals and primary journals in seventeen allied health disciplines are covered (many back to 1983),[102] as well as many other nursing-related publications, such as books, dissertations, standards of professional practice, and selected conference proceedings. CINAHL also indexes selected legal cases related to health care.

¶81 CINAHL is available in a full-text version and is owned and operated by EBSCO Publishing. As a result, the CINAHL databases are available on EBSCOhost.[103] If you are familiar with searching EBSCOhost, you will find searching CINAHL to be similar to other EBSCOhost databases.

¶82 CINAHL has its own subject headings that are used to index the literature. These subject headings were developed to reflect the terminology used by nursing and allied health professionals. CINAHL subject headings follow the structure of MeSH, but they are not the same as MeSH. Limiting is also available in CINAHL, resulting in more precise retrieval of results.[104]

PsycINFO

¶83 PsycINFO is a database of article abstracts produced by the American Psychological Association. It indexes psychological and behavioral science literature, including journals, technical reports, dissertations, and other materials, from the 1800s to the present (and even some records from the seventeenth and eighteenth centuries). It also has robust indexing that is useful for searching and retrieving documents on specific topics. It contains over 2.8 million records.[105]

¶84 PsycINFO is available directly from the American Psychological Association's database, PsycNET, and also through other distribution vendors. These include DataStar, DIALOG, DIMDI, EBSCO, Elsevier ScienceDirect, Hogrefe Publishing Group, OCLC, Ovid Technologies, and ProQuest (Illumina).[106] The former print equivalent is *Psychological Abstracts*.

Web of Knowledge

¶85 Thomson Reuters Institute for Scientific Information's (ISI) Web of Knowledge (frequently referred to as Web of Science, although technically Web of Science is a subset) is considered the leading citation database because of its cited-reference search, impact factor analysis, and other citation tools. It has multidisciplinary coverage of over 10,000 high-impact journals in the areas of science, social science, and arts and humanities. It also covers international proceedings for over 110,000 conferences.[107]

Ass'n of Schools of Allied Health Professionals, Definition of Allied Health, http://www.asahp.org/definition.htm (last visited May 4, 2010).

102. 1 Lawyers' Medical Cyclopedia, *supra* note 7, § 3.35.

103. *See* EBSCO Publishing, CINAHL Databases, http://www.ebscohost.com/cinahl (last visited May 10, 2010).

104. *See* EBSCO Publishing, CINAHL Databases: Subject Headings and Subject Coverage, http://www.ebscohost.com/cinahl/default.php?id=8 (last visited May 10, 2010).

105. Am. Psychological Ass'n, PsycINFO, http://www.apa.org/pubs/databases/psycinfo/index.aspx (last visited May 10, 2010).

106. *Id.*

107. Thomson Reuters, Web of Knowledge, http://wokinfo.com (last visited May 10, 2010).

¶86 Its most popular group of databases are those included in Web of Science. Web of Science consists of seven databases with information collected from thousands of scholarly journals, books, book series, reports, and conferences. Its content covers over 10,000 of the highest impact journals worldwide and includes the ability to simultaneously search MEDLINE (although without MeSH).

¶87 There are three journal citation databases: Science Citation Index Expanded (SCI-Expanded), Social Sciences Citation Index (SSCI), and Arts & Humanities Citation Index (A&HCI). There are two conference proceedings citation indexes (for science and for social sciences and humanities) that contain the published literature of important conferences, symposia, seminars, colloquia, workshops, and conventions in a broad array of disciplines. Finally, there are two chemistry databases that enable the searcher to use structure drawings to find chemical compounds and reactions. The most directly relevant database to medical research is SCI-Expanded, which covers over 6000 scientific journals.[108]

¶88 In addition to Web of Science, there are many additional powerful resources available through Web of Knowledge. Among the most popular is Journal Citation Reports. This is what is used to determine a journal's "impact factor." This is extremely important in the medical world, and journals with higher impact factors are given more credence throughout the research community. Impact factor is determined using journal performance metrics, which is a systematic, objective means to evaluate journals. It uses a complicated formula that statistically measures how many times the articles in a journal are cited, as well as other factors.[109]

Reference Tools

Dictionaries

¶89 Medical dictionaries are invaluable, and it is important to have at least one current medical dictionary if you are doing any type of medical research. The standard hard copy choices are *Stedman's Medical Dictionary*[110] and *Dorland's Illustrated Medical Dictionary.*[111] *Stedman's* is available in an abbreviated format for free at http://www.medical-dictionary.thefreedictionary.com, along with *Dorland's Medical Dictionary for Health Care Consumers.* It is also available in CD-ROM, which includes audio for pronunciation and approximately 1800 illustrations. *Dorland's* is available for free in an abbreviated format at: http://www.mercksource.com/pp/us/cns/cns_hl_dorlands_split.jsp?pg=/ppdocs/us/common/dorlands/dorland/misc/dmd-a-b-000.htm. It is useful for a library to have both *Stedman's* and *Dorland's*, since each has unique features. A third complementary dictionary is the *Concise Dictionary of Modern Medicine.*[112] This dictionary focuses on more

108. Thomson Reuters, Science Citation Index Expanded, http://thomsonreuters.com/products_services/science/science_products/a-z/science_citation_index_expanded (last visited May 13, 2010).

109. *See* Marie E. McVeigh & Stephen J. Mann, *The Journal Impact Factor Denominator*, 302 J. Am. Med. Ass'n 1107 (2009).

110. Thomas Lathrop Stedman, Stedman's Medical Dictionary (28th ed. 2006).

111. Douglas M. Anderson & William A. Newman Dorland, Dorland's Illustrated Medical Dictionary (3d ed. 2007).

112. Joseph C. Segan, Concise Dictionary of Modern Medicine (2006).

recent terminology and includes references to scientific literature. A more specialized dictionary that is nice to have is a dictionary that focuses on specific syndromes or diseases, such as Magalini's *Dictionary of Medical Syndromes*[113] or *Jablonski's Dictionary of Syndromes & Eponymic Diseases.*[114] Both cite the medical literature. Although the *Diagnostic and Statistical Manual of Mental Disorders* (DSM)[115] is not a dictionary, it is an essential mental health resource. It is best to update these items when new editions become available.

Textbooks

¶90 It makes sense to have at least one basic textbook in any area of medicine that you are researching. There is almost always one textbook that is considered standard in a particular field of medicine. In choosing a textbook, you should be able to determine which one is the standard by looking at *Brandon/Hill Selected List of Print Books and Journals for the Small Medical Library*, *Doody's Core Titles*, or *Medical and Health Care Books and Serials*.

Drug and Toxicology Tools

¶91 If you are doing any kind of medical research it is a good idea to have at least one resource that covers drug information. Most librarians have heard of the *Physicians' Desk Reference* (PDR),[116] which is popular because it contains the same FDA-required information that is found on the package inserts supplied by the drug manufacturers. In addition to hard copy, the PDR is available online at http://www.pdr.net/login/Login.aspx.[117] Generally, electronic versions of drug and toxicology tools are useful because they often have features that are not available in the hard copy or are much more cumbersome to use in the hard copy.

¶92 There are other drug resources that are much more comprehensive than the PDR. One example is *AHFS* [American Hospital Formulary Service] *Drug Information*. This is available both in hard copy and as a database. Some of its benefits are that the drug references are evidence based and peer reviewed and are not based solely on the information provided by the drug manufacturers.[118]

¶93 Another excellent resource is *Drug Facts and Comparisons*, which is available in print or online as Facts & Comparisons 4.0.[119] Both provide unbiased drug descriptions and are arranged by related therapeutic or pharmacological groups, which is preferred by some medical professionals. The online version contains

113. Sergio I. Magalini & Sabina Magalini, Dictionary of Medical Syndromes (4th ed. 1997).

114. Stanley Jablonski, Jablonski's Dictionary of Syndromes & Eponymic Diseases (2d ed. 1991).

115. Am. Psychol. Ass'n, Diagnostic and Statistical Manual of Mental Disorders: DSM-IV (4th ed. 1994).

116. Physicians' Desk Reference: PDR (64th ed. 2010).

117. Free access requires registration and that the registrant be a practicing health professional or student. PDR.net, http://www.pdr.net/login/Login.aspx (last visited May 13, 2010).

118. *See* Am. Soc'y of Health-System Pharmacists, AHFS Drug Information, http://www.ahfsdruginformation.com/products_services/di_ahfs.aspx (last visited May 10, 2010).

119. Wolters Kluwer Health, Facts & Comparisons, http://www.factsandcomparisons.com/Products/Product.aspx?id=116 (last visited May 10, 2010).

additional useful information that lends itself to the online format in particular. There is information on drug interactions, including herbal supplements and food, as well as off-label information.

¶94 *The Merck Index* is another popular drug tool that is available both in print and online.[120] Although it is not particularly comprehensive, it is very helpful for identifying generic and brand names of drugs. It also includes descriptions of chemicals.

¶95 When looking for drug information, it is important to search the drug literature. The NLM has created a bibliographic database for toxicology called TOXNET, available at http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?TOXLINE. It covers biochemical, pharmacological, physiological, and toxicological effects of drugs and other chemicals. Other important databases to search for drug literature include Embase and MEDLINE.

Web Sites

Evaluating Web Sites

¶96 The availability of medical and health information on the web is a major advance in increasing the public's access to health information and self-empowerment when making medical decisions. However, librarians know that web sites cannot be taken at face value and must be evaluated. This is especially true when doing medical research, as the consequences of poor information can be devastating. In addition to quality of information concerns, information on web sites frequently has the potential for being biased, especially if the web site is maintained by a commercial enterprise (e.g., a drug manufacturer). Furthermore, in the medical context, there is the potential for patient privacy issues.[121]

¶97 Generally speaking, there are seven criteria for evaluating health information on the web. These are (1) credibility (source, currency, relevance, and editorial review process); (2) content (accuracy and comprehensiveness); (3) disclosure (purpose of the web site and whether user information is collected); (4) links (evaluative process); (5) design (accessibility, organization, and internal searchability); (6) interactivity (feedback mechanisms and information exchange among users); and (7) caveats (explaining primary purpose of site: e.g., marketing products or providing information).[122] All seven of these criteria should be considered when accessing health information on the web, with particular weight being given to what steps have been taken to ensure that the content of the web site is current and accurate.

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120. Merck, The Merck Index, http://www.merckbooks.com/mindex/index.html (last visited May 10, 2010).

121. Margaret A. Winker et al., *Guidelines for Medical and Health Information Sites on the Internet: Principles Governing AMA Web Sites,* 283 J. AM. MED. ASS'N 1600, 1600 (2000).

122. U.S. Dep't of Health & Human Servs., Agency for Health Care Research & Quality, *Assessing the Quality of Internet Health Information*, http://www.ahrq.gov/data/infoqual.htm (current as of June 1999).

Recommended Web Sites

¶98 By and large, government web sites are excellent resources for health information. The primary examples are MEDLINE and PubMed. One of the best web sites for finding basic health-related information is MedlinePlus (medlineplus.gov), which is designed for health consumers. I recommend starting any new health-related search with a search in MedlinePlus. It is produced by NLM and the National Institutes of Health (NIH). It pulls information from NLM and NIH, as well as other extremely well-vetted government agencies and health-related organizations. It will also simultaneously search MEDLINE using a pre-formulated MEDLINE search. (It is still better to search MEDLINE using MeSH subject headings, but this is a nice way to get your feet wet when you are first starting.) It also has drug information, a medical encyclopedia, a medical dictionary, a directory, interactive tutorials, and health news.[123]

¶99 There are many other excellent web sites. In addition to the NIH (www.nih.gov) and NLM (www.nlm.nih.gov), I recommend the following web sites:

- Agency for Healthcare Research and Quality (www.ahrq.gov): Provides research, data, clinical improvement tools, and quality measurement and improvement tools.
- American Cancer Society (www.cancer.org): Provides accurate, up-to-date information on cancer.
- American Dental Association (www.ada.org): Provides accurate information on oral health topics.
- American Diabetes Association (www.diabetes.org): Provides objective and credible information on diabetes.
- American Heart Association (www.amhrt.org): Provides clinical practice guidelines that suggest appropriate use of diagnostic procedures, therapeutic interventions, and therapies for managing cardiovascular diseases.
- Centers for Disease Control (www.cdc.gov): Provides accurate information on health and safety topics.
- FDA Medical Product Safety Information (www.fda.gov/medwatch/safety.htm): Provides safety alerts for human medical products such as drugs, biologics, medical devices, special nutritionals, and cosmetics.
- Food & Drug Adminstration (www.fda.gov): Provides information on drugs, medical devices, biologics, and radiological health.
- Mayo Clinic (www.mayohealth.org): Provides guides on diseases and conditions, symptoms, drugs and supplements, tests and procedures, healthy lifestyle, and first aid.
- National Center for Complementary and Alternative Medicine (www.nccam.nih.gov): Provides research-based information on complementary and alternative medicine treatments.
- National Center for Health Statistics (www.cdc.gov/nchs): Provides compiled statistical information on America's population and health.

123. *See* U.S. Nat'l Libr. of Med. & Nat'l Insts. of Health, Medline Plus: About Medline Plus, http://www.nlm.nih.gov/medlineplus/aboutmedlineplus.html (last updated July 29, 2009).

- Occupational Safety & Health Administration (www.osha.gov): Provides access to selected occupational safety and health information.

Additionally, most academic medical libraries will have excellent links to web sites.

Clinical Practice Guidelines

¶100 Clinical practice guidelines describe the generally accepted methods for the diagnosis, management, and prevention of particular diseases or conditions. They are designed to meet the needs of most patients in most situations. They should be evidence based and synthesize the published medical literature.[124]

¶101 They are important because they help medical personnel and patients make decisions. They are meant to be guidelines and not a protocol that must be followed. Even though they are generally not designed for laypeople, they are useful in understanding what the whole course of treatment for a particular patient might look like.[125]

¶102 Here are some well-regarded web sites that offer evidence-based practice guidelines:

- American Association of Clinical Endocrinologists (www.aace.com/pub/guidelines)
- American College of Rheumatology (http://www.rheumatology.org/practice/clinical/clinicianresearchers/evidence_based_practice/guidelinesresources.asp)
- American College of Physicians (www.acponline.org/clinical_information/guidelines/?hp)
- American Society of Hematology (www.hematology.org/Practice/Guidelines/2934.aspx)
- American Thoracic Society (http://www.thoracic.org/statements)
- National Comprehensive Cancer Network (www.nccn.org/professionals/physician_gls/f_guidelines.asp)
- National Kidney Foundation (www.kidney.org/professionals/KDOQI/guidelines.cfm)

Other EBM Electronic Tools

¶103 Many online tools exist to assist health professionals in keeping up with evidence-based literature and in practicing medicine using evidence-based guidelines. For the most part, they claim to be based on EBM principles. However, a note of caution—you still need to verify the research behind the content. The following resources are highly regarded by the medical profession:

- Access Medicine (www.accessmedicine.com): Provides access to more than sixty medical titles as well as the information needed to complete evaluations and diagnoses and make case management decisions.

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124. Nat'l Heart Lung & Blood Institute, Nat'l Institutes of Health, About NHLBI Clinical Guidelines, http://www.nhlbi.nih.gov/guidelines (last visited May 25, 2010).

125. *See id.*

- ACP Journal Club (www.acpjc.org): Selects articles from the biomedical literature that report original studies and systematic reviews that merit urgent notice by physicians to keep up with significant advances in internal medicine. The web site has a ten-year archive (from 2000 to the present) of the contents of ACP Journal Club, with regular weeding of out-of-date articles.
- ACP PIER: Physicians' Information and Education Resource (pier.acponline.org): Contains over four hundred evidence summaries published by the American College of Physicians with the intention of defining the standard of care.
- Clin-eguide (www.clineguide.com): Provides an online clinical decision support system. The following databases can be searched simultaneously: 5-Minute Consult Database, A to Z Drug Facts, Cancer Chemotherapy Manual, Drug Facts and Comparisons, Drug Identifier, Drug Interaction Facts, Drug Interaction Facts: Herbal Supplements and Food, Evidence Based Guidelines, Healthwise Disease Oriented Patient Handouts, HL7 Infobutton API, Isabel Diagnosis Reminder System (IDRS), McKesson Patient Handouts, MedCalc3000 Clinical Calculators, MedFacts, National Guideline Clearinghouse, Nonprescription Drug Therapy, Nursing Advisor, Nursing considerations for more than 2000 diseases, Off-Label Drug Facts, Ovid MEDLINE 1996–present, The Formulary Monograph Service, The Review of Natural Products, ToxFacts Treatment Guidelines, Trissel's IV-CHEK, and VisualDx.
- DynaMed (www.ebscohost.com/dynamed/default.php): Provides access to point-of-care resources to support clinical decision-making. This includes clinically organized summaries for more than 3000 topics.
- Essential Evidence Plus (formerly called InfoPOEMs—Patient Oriented Evidence that Matters) (www.essentialevidenceplus.com): Contains content, tools, calculators, and alerts for clinicians. Provides the ability to search the following databases simultaneously: Essential Evidence, Cochrane Systematic Reviews, EBMG Clinical Topic, NGC Practice Guidelines, Daily POEMs, Decision Support Tools and Calculators, Derm Expert, E/M Coding, and ICD-9 Codes.
- Health Services/Technology Assessment Text (HSTAT) (www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat): Provides free access to full-text guidelines that provide health information and support health-care decision making.
- JAMAevidence (www.jamaevidence.com): Provides tools for understanding and applying the medical literature and making clinical diagnoses. Includes guides to systematically appraising the validity, significance, and applicability of claims about the evaluation of health problems and the results of health care.
- MDConsult (www.mdconsult.com): Provides access to evaluation, diagnosis, clinical management, prognosis, and prevention information. Includes full-text articles from over eighty medical journals and clinics, fifty leading medical reference resources, drug information, and patient handouts.
- Micromedex (Thomson Healthcare Evidence) (www.thomsonhc.com/hcs/librarian): Provides clinical information on drugs, diseases, acute care, toxicology, alternative medicines, and patient education tools.

- National Guideline Clearinghouse (www.guideline.gov): Contains a free database index of best practices clinical guidelines, including a guideline comparison tool that gives users the ability to generate side-by-side comparisons of guidelines.
- TRIP (www.tripdatabase.com): Provides a clinical search engine to simultaneously search guidelines, peer-reviewed journals, query-answering services, e-textbooks, medical images, and patient information leaflets. Examples of databases searched include: Agency for Healthcare Research and Quality, Clinical Evidence, Cochrane Database of Systematic Reviews, and Database of Abstracts of Reviews of Effectiveness.
- UpToDate (www.uptodate.com): Contains topic reviews that include a synthesis of the literature, the latest evidence, and specific recommendations for patient care written by leading physicians. It covers more than 7700 topics in fifteen medical specialties. This resource is extremely well respected by medical students and practicing physicians.

Conclusion

¶104 There does not appear to be any true downside to EBM. In the medical world, EBM has been repeatedly demonstrated to improve patient care. In the legal world, it makes sense that sound medical research should support health-related actions and decisions.

¶105 Looking outside the legal profession into other professions reminds us of how important thorough research is. Given how complicated medical research can appear to someone who normally does legal research, it is easy to see how complicated legal research is to those outside of our profession. The question is often raised in law as to what the liability is for lawyers who do not do adequate research. When you look at EBM, it is clear that inadequate research can lead to poor decisions with dire consequences. It is an excellent reminder of the importance of research.