

CHAPTER 10

EVIDENCE-BASED MEDICINE

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Evidence-based medicine (EBM) has been defined as the “conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients”.¹ In recent history, the EBM movement has been credited to a group of clinicians working on new approaches to teaching medical professionals over 25 years ago.² While medical professionals have always relied on clinical experience when making decisions, the original impetus of EBM was to intentionally incorporate appraisal of the best available evidence to resolve practice issues. However, clinical expertise should not be ignored as it is integral to balancing the patient’s clinical circumstances, relevant research evidence, and the patient’s preferences or values when making decisions.³⁻⁴ Clinicians are now expected to not only consult the best available evidence, but also be able to make their own independent appraisal and application of the evidence.⁵ A process or step-wise EBM approach commonly cited in literature is described below and depicted in **Figure 10-1**, which can be used for resolving patient issues or practice challenges.

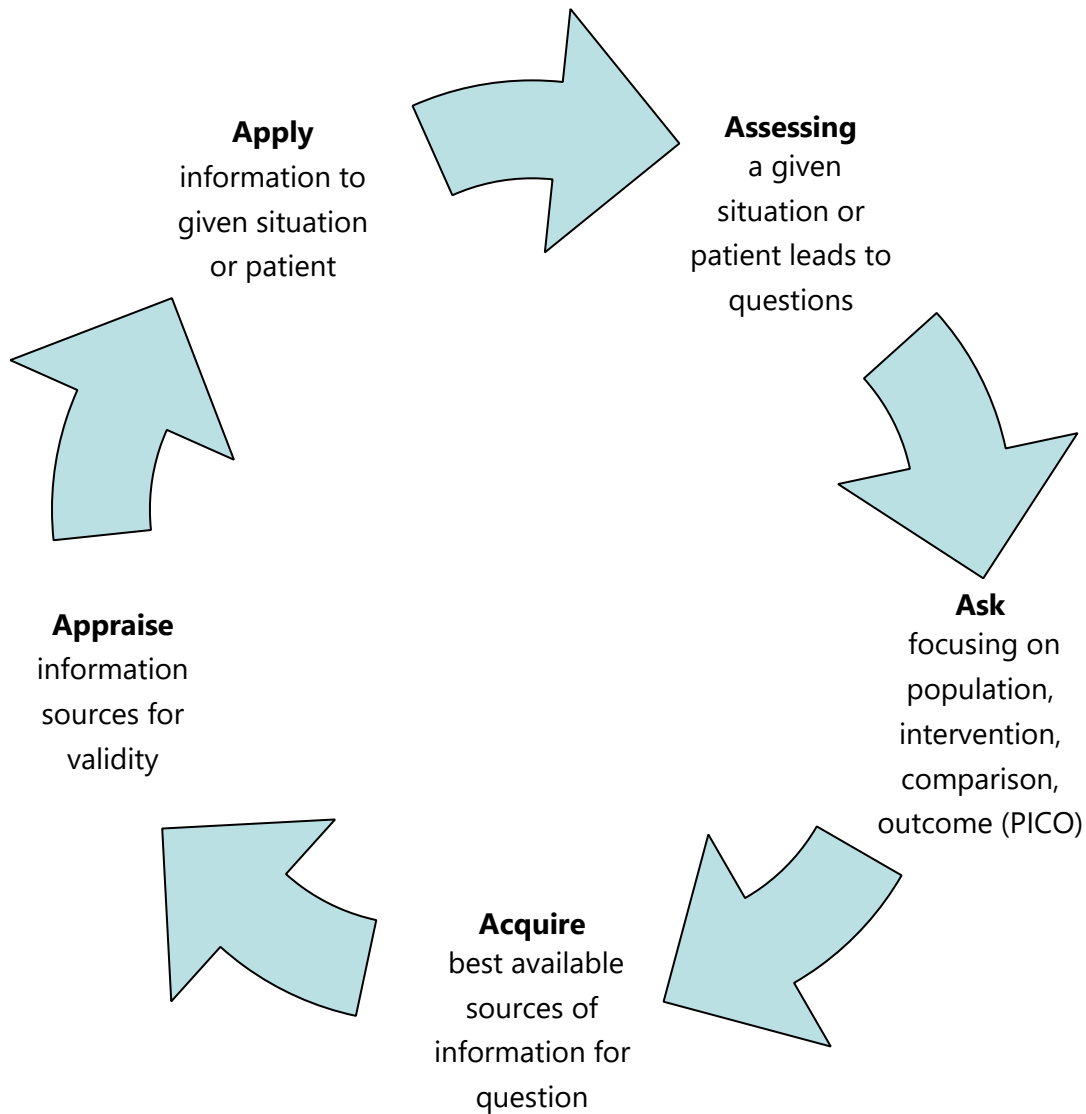


Figure 10-1. Evidence-based medicine cycle

ASSESS

The EBM process starts with an assessment of a patient or practice situation. Assessment is a skill that many first acquire in the classroom or in training programs, and then further develop with experience. Assessing an individual patient or practice situation will likely lead to issues that need to be resolved and resultant questions that need to be answered. These questions that arise are often referred to as knowledge gaps. It is possible that many

knowledge gaps may arise in a single encounter or situation necessitating a prioritization approach to addressing and resolving them. Knowledge gaps will vary among practitioners based on their level of clinical experience and familiarity with the current best available evidence.⁵ Before proceeding, it is important to have a good idea of the clinical status and circumstances of the patient and their preferences or values with respect to their health goals.⁶⁻⁸ Without this crucial step, clinicians may not achieve optimal outcomes for their patients. During this phase, clinicians may need to research background questions, to answer any resounding knowledge gaps, before they pursue specific questions. If a practitioner is unfamiliar with a given disease, intervention, or outcome, it is important to understand these elements before pursuing specific patient questions involving these variables. For example, before answering the question, “does tranexamic acid increase the risk of venous thromboembolism (VTE) in patients with atrial fibrillation who are undergoing knee replacement?” one may need to review background information on how tranexamic acid works, common risk factors for VTE in general, and VTE complication rates in the orthopedic setting. Common sources of information clinicians use to answer background questions are tertiary sources such as review articles or textbooks.

ASK

The next step is to frame the knowledge gap into a structured question. Structured questions are one way of finding answers using keywords that will hopefully best address the situation.⁵ Many databases used to search for literature utilize structured search terms that can accommodate this strategy.

Patient specific questions usually require the practitioner to refer back to original studies or primary literature. On occasion, pre-appraised sources of information such as guidelines or systematic reviews may have addressed the specific question, but more commonly clinicians have to extrapolate information from studies with similar but not identical characteristics of their clinical situation.^{3,5,9} While different types of specific questions may arise in the course of clinical work (e.g. diagnosis, prognosis, therapy, prevention), a suggested general acronym practitioners can remember when structuring questions is PICO. PICO stands for population, intervention, comparator, and outcome.³ In order to be efficient at evaluating a body of literature that is expanding at exponential rates, asking a focused question using a structured template such as PICO, can assist in yielding relevant studies. In the example used previously, the population would be patients with atrial fibrillation who are undergoing knee replacement, the intervention would be tranexamic acid, the comparison is inferred to be not using tranexamic acid, and the outcome is venous thromboembolism. Occasionally, our questions may not yield any literature hits and then we need to expand some element of our

PICO framework. In this case, one might expand the population to patients undergoing joint replacement and leave out atrial fibrillation under the auspices that this still may help answer whether tranexamic acid increases risk of VTE, irrespective of atrial fibrillation.

ACQUIRE

While possessing the requisite skills to assess patients and discern what questions need to be addressed, the process of acquiring information takes time that many practitioners do not have.^{3,5,8,10} One popular approach is to consider the usefulness of information as an equation, with relevance and validity in the numerator and work in the denominator.¹¹⁻¹² The relevance of an information source refers to whether the outcome described is of value to your patient, whether the interventions or practices described are feasible, and if the interventions would lead to a change in practice. The validity refers to the trustworthiness of a given article, and the work refers to the time, money, and effort it takes to obtain an answer to a clinical question. While relying on authority or experience may require little work on the clinician's part, this equation reminds the clinician that information which is not relevant or valid is useless, no matter how much effort is required. This approach also encourages clinicians to focus on finding relevant evidence first and then apply principles for assessing validity rather than vice versa.

Acquiring evidence can be an intimidating task because information appears to be increasing at exponential rates.¹⁰ It is difficult to stay up to date with medical information so one must find ways to efficiently make use of the available evidence. While many types of information are available to practitioners today, this doesn't mean all resources are useful. Knowing types of resources and how they differ from each other, their strengths and weaknesses, and how to use them is an important attribute for efficient practice.¹² Studies on information seeking behavior in literature note that this step is often not pursued when questions arise in practice and when it is pursued, clinicians spend little time on this before either quitting the search or going with what they were able to find.⁵

Strategies to ensure one is getting the best available evidence commonly vary from asking colleagues for their expert opinion, reviewing clinical practice guidelines, searching for systematic reviews and/or meta-analyses on existing literature, to searching databases such as PubMed for original research studies.¹³ While practice guidelines or systematic reviews may appear useful since they have already appraised the validity of information sources, the clinician needs to be aware these can rapidly be out of date, based on the number of trials that get published every day. Likewise, relying on experts or clinical experience to answer questions may be perceived as an efficient way to acquire evidence, but a danger with this

approach is that it assumes that practitioners are up to date with current literature and that he or she is not biased by their own personal experiences. Similar to this, using general search engines on the web can be misleading in that they provide 'hits' but they may not provide information specific to your inquiry.

A traditional model in EBM is the hierarchical approach of categorizing types of resources as seen in **Figure 10-2**.³ This approach implies there are some resources with more validity and relevance than others. Study designs are ranked based upon the likelihood of providing causality estimates. Randomized controlled trials are commonly listed at the top of these models since the design allows the researcher control over various factors. Opinions are commonly listed at the bottom of the pyramid because there is not a readily available way of testing this information for validity.

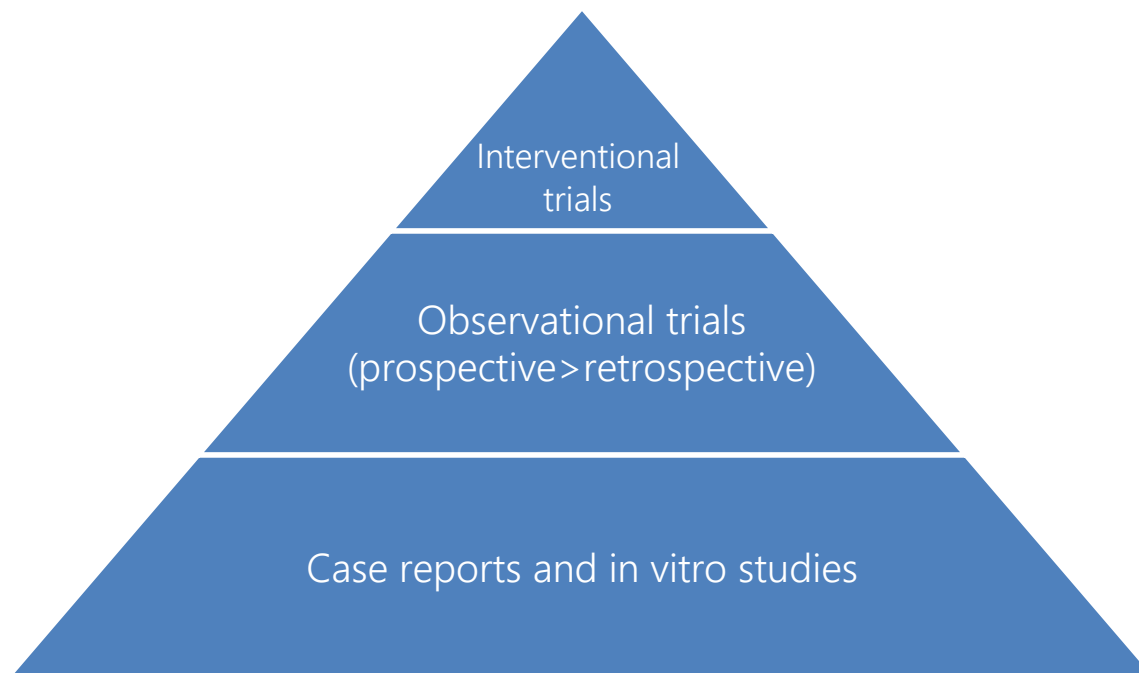


Figure 10-2. Hierarchy of study designs

Another way sources of evidence are described is based on efficiency (i.e. time required for practitioner to find answer) as seen in **Figure 10-3**.^{2,5} In this case, resources that are pre-appraised for validity (e.g. practice guidelines, systematic reviews) are noted on the EBM

pyramid as being more useful while original studies that are not pre-appraised (i.e. reader has to do this) as less useful. However, these models do not adequately address every type of question or resource that could arise so practitioners ultimately need to be familiar with multiple types of resources and how to appraise them.



Figure 10-3. Hierarchy of resources based on efficiency

APPRAISE

After acquisition of evidence, the clinician must be able to appraise the information for validity, or trustworthiness. Depending on the type of original question asked (e.g. diagnostic, prognostic, therapy, etiology), some primary sources of literature are better suited than others. While some sources of information have been pre-appraised (e.g. guidelines, systematic reviews), it is important to determine the process of validation and be able to confirm or agree with the information independently.¹⁴⁻¹⁷ Otherwise this is analogous to

relying on authority or experts again. While prospective controlled studies by design are more suited to answering questions of causality, this does not automatically mean observational study designs are weaker as all studies can have methodologic flaws impacting their validity.¹⁷ Several tools are available for evaluating research evidence for validity. The EQUATOR network (www.equator-network.org) provides reporting guidelines for a variety of study designs in order to enhance the quality and transparency of the published article. The Centre for Evidence Based Medicine (www.cebm.net/critical-appraisal) at the University of Oxford provides appraisal tools to help clinicians determine reliability, importance, and applicability of articles. While these tools can offer a checklist approach to evaluating studies, it is important to remember that the appraisal process is just to determine whether given results are plausible, not whether they should be used in your patient or practice setting. A common criticism of EBM is that it implies there is a stepwise appraisal approach (i.e. cookbook approach) to treating every practice issue. This objection is related to the loss of perception of autonomy in decision making and is an untoward application of EBM with respect to standardizing care and insisting on one way of doing things. However, this is not the intent of EBM and it actually acknowledges the role of experience and intuition and the fact there are differences in skill, is what explains variations in results at times.¹⁻⁴

APPLY

After the evidence has been acquired and appraised, it must be applied back to the individual issue, be it a patient or practice situation. This process of application should not be based solely on the conclusions of studies written by study investigators or the opinions of experts. A danger with relying on those with vested interest in a given intervention, could be misappropriating what is of value both to patients and clinicians. For example, drug and medical device companies could set research agendas to define what are relevant disease characteristics, what test and treatments to compare (thus of value) and what outcomes will be valuable.³ Additionally, with a lot of drug therapies available that have marginal, if any, differences in outcome, it is important to be able to answer what is the best course of action for this patient, in these circumstances, and at this time in their illness or condition?^{8,18} External evidence can inform but not replace individual expertise. This is what ultimately is drawn upon to balance research evidence plus clinical status, and decides what applies to whom and if it should be used in a decision. There may be tradeoffs that affect a given decision and some recommendations may be stronger or weaker based upon these factors such as cost, risks, and benefits. An online resource that can be used to develop recommendations based on these factors is <http://www.gradeworkinggroup.org>.¹⁶ While costs are often not necessarily the focus of EBM, certainly effective care is important, and ineffective care would

be seen as waste from a cost standpoint. Effectiveness depends on not only whether something can work but also on the accuracy of diagnosing a condition, compliance with protocols, patient adherence, and coverage. Just because something can work doesn't mean it will be used in the right people, at the right time, if patients will take it right, or whether people can afford it.¹⁸ Often, an overlooked area in the EBM process is an ideal way to present information to patients so that they can make an informed decision. Keeping in mind that the original reason to apply EBM is resolve patient issues or questions, the way this information is communicated to patients plays a large role in achieving optimal outcomes.

ASSESS

We end where we started. That is, after applying the research evidence to the clinical situation and taking into account the patient preferences and values, we should seek out whether issues have resolved or whether new issues have presented. This is why this process is sometimes referred to as a cycle.

SUMMARY

Evidence is essential, but not sufficient, for practitioners wanting to use EBM. The best available evidence, clinical context, and patient preferences integrated with clinical experience are what make up the hallmark of decision making.⁷ Without clinical experience, practice is at risk of becoming dictated by checklists on appraisal of evidence, which may be inapplicable to or inappropriate for an individual patient. Without the best evidence, practice is at risk of becoming rapidly out of date, to the detriment of patients.¹ It is this individual expertise that can effectively integrate experience and evidence within context, decides whether external evidence should be applied at all, and if so, how it should be integrated.¹

Efficient EBM practice requires formulating focused questions (PICO), matching questions to most appropriate resources, assessing confidence in estimates, and understanding how to apply results to clinical decision making. In addition, given the acknowledgment of time constraints, we need to ensure that management strategies are consistent with patient values and preferences.

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