ABBREVIATED WORKSHOP MANUAL
Duke Teaching and Leading EBP:
A Workshop for Educators and Champions of Evidence-Based Practice

Contributing authors: Sheri Keitz, Connie Schardt, Megan von Isenburg, Sarah Cantrell, Grace Thrall, Tom Owens, Larry Young, Jamie Fox.

The workshop concluded in April 2024.

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Intro to Evidence-Based Practice

Core Concepts on Teaching EBP

Notes on learning and teaching about **EBP Framework:**

1. **Background**: There are many concepts and key terms that have relevance across many of the specific content areas such as therapy, diagnosis, harm, and prognosis.

2. Key concepts and terms
   - Principles of EBP: **hierarchy of evidence** and role of patient **values and preferences**
   - The 5 A's of the evidence cycle

3. Clinical questions and searching
   - Clinical question formation: PICOTT (**p**atient, **i**ntervention, **c**omparison, **o**utcome, **t**ype of question and **t**ype of study you seek to find)
   - Sources of best evidence including pre-appraised resources, and searching the biomedical literature (including PubMed)

4. General principles pertaining to understanding data and assessing bias
   - Critical appraisal process including evaluating studies for risk of bias, understanding results and applying evidence to particular patients and populations
   - Random Error (chance) versus Systematic Error (bias)
   - Clinical versus statistical significance
   - Relationship between sample size and number of outcomes and confidence in estimates

Evidence Cycle

The five A's of the Evidence Cycle

Incorporating the best evidence into clinical care requires a systematic approach in order to be manageable. A clear series of steps known as the Evidence Cycle can provide an excellent paradigm to guide you through this process. The foundation of evidence-based care remains an excellent clinical evaluation. The clinician must **ASSESS** the patient and the problem to determine the pertinent issues, which may include a differential diagnosis, treatment decisions, or prognosis. The clinician must draw from this evaluation and **ASK** a clear, answerable question to be pursued. The next step is to efficiently **ACQUIRE** the evidence from an appropriate source. Potential sources include original research studies, systematic reviews, evidence-based journal abstracts, textbooks, and computerized decision support systems. With a potential source in hand, the clinician must **APPRAISE** the evidence to further examine its worth and reliability. Finally, the process must conclude by returning to the individual patient, as the clinician has to decide whether it is appropriate to **APPLY** the evidence to the particular patient and their unique values and circumstances. Evidence alone is never sufficient to direct decision making. Rather, it must be put into context with a patient's values.

ASSESS: Clinical Evaluation

The method of evidence-based clinical practice (EBCP) begins with a thoughtful assessment by a clinician who incorporates all the pertinent data. A common fallacy is that EBCP somehow devalues the fundamental tenets of the practice of medicine, specifically clinical expertise. A comprehensive understanding of pathophysiology and the thorough history and physical remain a critical starting point for the process.

ASK: Clinical Question Development

The first critical step is to clarify one or two key issues that come up in the course of caring for your patient and to develop a focused clinical question. Despite its critical place at the start of the evidence cycle, question development is often not a focus of training. In a survey of 417 internal medicine program directors, only 44% of programs with evidence-based medicine curricula included posing a focused question as an objective.[i] However, without this critical first step, the rest of the steps are immaterial.

The Anatomy of the Clinical Question (PICOTT)

One useful approach to framing a clinical question involves distilling the question into several key elements. In this framework, there are 4 components to every clinical question, the Patient population, Intervention, Comparison and Outcome (PICO).[ii] In addition, we add two "T"s to capture the type of question being asked (e.g. Therapy) and the type of study you would want to find (e.g. RCT). We can use this framework to clarify the steps that we must take to find the evidence we seek.

ACQUIRE: Searching for the Evidence

Armed with our well-built clinical questions, our attention next turns to finding the evidence in the medical literature. Many resources are currently available; therefore, we must learn to appreciate the pros and cons of each type to determine when each one can best be applied. We also have to learn how to access resources that can maximize our efficiency, such as a systematic review, clinical practice guideline or an evidence-based journal abstract.

APPRAISE: Critical Appraisal of the Evidence

Much of the initial attention in the realm of evidence-based medicine focused on the critical appraisal portion of the evidence cycle. A growing body of resources exists in various print and electronic formats to aid readers of the medical literature in the critical appraisal process. The following tables were abstracted from the *Users' Guides to the Medical Literature* from the evidence-based medicine working group. (See Table)

APPLY: Applying Evidence to the Patient

Every management decision requires value-laden deliberation and judgment. Each piece of evidence that we review adds something to our understanding of our patient's situation. However, we need to consider how to generalize the results from clinical trials to our individual patient. We must consider whether the patient populations and treatments or interventions are comparable to our setting. The final challenge is to combine the evidence and clinical expertise with compassion and patient values. Clinicians trying to engage the medical literature for best care must take the information from these studies to try to help individuals within the context of their own values and preferences.

How serious is the risk of bias?

Table extracted from *User's Guide to the Medical Literature, Evidence-Based Medicine Working Group*
(Note: Bold Text indicates the questions that can serve as your first screen for validity)

Therapy or prevention	**• Was the assignment of patients to treatments randomized?**
	• Were all of the patients who entered the trial properly accounted for and attributed at its conclusion?
	• Were patients, clinicians and study personnel kept "blind" to treatment received?
	• Were the groups similar at the start of the trial?
	• Was the trial stopped early?
Diagnosis	**• Was there an independent, blind comparison with a reference standard?**
	• Did the patient sample include an appropriate spectrum of the sort of patients to whom the diagnostic test will be applied in clinical practice?
	• Did the results of the test being evaluated influence the decision to perform the reference standard?
	• Were the tests methods described clearly enough to permit replication?
Harm	**• Were there clearly identified comparison groups that were similar with respect to important determinant of outcome, other than the one of interest?**
	• Were outcomes and exposures measured in the same way in the groups being compared?
	• Was follow-up of patients sufficiently long and complete?
	• Is the temporal relationship correct?
	• Is there a dose-response gradient?
Prognosis	**• Was there a representative and well defined sample of patients at a similar point in the course of disease?**
	• Was follow-up sufficiently long and complete?
	• Were objective and unbiased outcomes criteria used?
	• Was there an adjustment for important prognostic factors?
Systematic Review	**• Did this review address a focused clinical question?**
	• Were the criteria for article inclusion appropriate? (taking into account the type of question being asked)
	• Was the search for relevant studies exhaustive?
	• Was the validity of the included studies appraised?
	• Were the assessments of studies reproducible?
	• Were the results similar from study to study?
Practice Guidelines	**• Were all important options and outcomes clearly specified?**
	• Was an explicit and sensible process used to identify, select and combine evidence?
	• Was an explicit and sensible process used to consider the relative value of different outcomes?
	• Were the important recent developments included?
	• Has the guideline had peer review and testing?

What are the results?

Can you apply the results to your individual clinical question?

Table extracted from *User's Guide to the Medical Literature, Evidence-Based Medicine Working Group*

For All Types of Questions		• What are the overall results and the precision of the estimates? • Are the results are applicable to your own individual population or patient? (Were the study patients similar to my own? Was the setting of the study applicable to my practice?)
Type of Question		• Considerations Specific to Particular Types of Questions
Therapy or Prevention	*results*	• To estimate the size of the Treatment effect, you want to look at Relative Risk, Odds Ratios or Numbers Needed to Treat to prevent adverse outcomes (See Survival Statistics Cheat Sheet)
	applicability	• Were all clinically relevant outcomes considered?
		• Are the benefits worth the harms and costs?
Diagnosis	*results*	• To estimate the ability of a test to change your pretest probability of disease, you want to look at Likelihood ratios (See Survival Statistics Cheat Sheet)
	applicability	• Will the test be reproducible and well interpreted in my practice setting?
		• Will the test results change my management?
		• Will my patients be better off because of the test?
Harm	*results*	• To estimate the strength of the association between the exposure and the outcome, you want to look at Relative Risk, Odds Ratios or Numbers Needed to Cause adverse outcomes (See Survival Statistics Cheat Sheet)
	applicability	• What is the magnitude of the risk?
		• Should I attempt to stop the exposure?
Prognosis	*results*	• To estimate the prognostic risk, you want to look at absolute risk (e.g. 5 yr. survival rate), relative risk (e.g. risk from a prognostic factor) or cumulative events over time (e.g. survival curves).
		• What are the possible outcomes and how likely are they to occur over time?
	applicability	• Will the results lead directly to selecting therapy?
		• Are the results useful for counseling patients?
Systematic Review	*results*	• What are the overall results when considering all of the studies reviewed and what is the precision of these results?
	applicability	• Specific Questions to determine whether you can apply these results to your population or patient should be determined by the type of question you are asking (e.g. Therapy vs. Diagnostic Testing, vs. Prognosis)
Practice Guidelines	*results*	• Are practical, important recommendations made?
		• How strong are the recommendations?
		• Could the uncertainty in the evidence or values change the guideline's recommendations
	applicability	• Is the objective of the guideline consistent with mine?
		• Are the recommendations applicable to my patients?

[i] Green ML. Evidence-based medicine training in internal medicine residency training programs. J Gen Intern Med 2000; 15: 129-133.

[ii] Richardson WS, Wilson MC, Nishikawa J, Hayward RSA. The well-built clinical question: a key to evidence based decisions. ACP Journal Club. Nov-Dec 1995; 123: A-12.

Article with an Example of Applying Evidence

Muir, AJ, Keitz, SA, and Schardt, CM. Applying evidence to the care of a patient with hepatitis C: How to develop a focused clinical question. Seminars in Medical Practice Sept 2002 5(3):6-16.

Clinical Question

The Clinical Question and Information Resources

Answering the Clinical Question: Critical Appraisal- Survival Skills

Define the Clinical Question.
1. Patient, Population or Problem
2. Intervention, Prognostic Factor, Exposure
3. Comparison (if appropriate)
4. Outcome you would like to measure or achieve
5. Type of Question you are asking
6. Type of Study you would want to find

As a fundamental part of your thinking about the elements of the clinical question, you need to decide what 'type' of question you are asking, as well as what kind of study you would love to find. This is because you will need to consider those questions when you are moving on to the next step of selecting and finding your resources.

What types of questions may we come up with?

Question Type	Possible Study Designs
1. Clinical Examination	Prospective cohort, blind comparison to Reference Standard
2. Diagnostic Testing	Prospective cohort, blind comparison to Reference Standard
3. Prognosis Series	Cohort Study (can be in the context of an RCT) > Case Control > Case
4. Therapy	RCT is really the only way we want to answer this question
5. Etiology / Harm	RCT (if possible and ethical) > Cohort Study >Case Control > Case Series
6. Prevention	RCT > Cohort Study >Case Control >Case Series
7. Cost	Economic Analysis
8. Self-Improvement/Education	
9. Quality Improvement	
10. Health Services Research	
11. Differential Diagnosis	

Question to Consider: **Was the type of study the strongest that could have been performed under the circumstances?**

Remember that it may not be either practical or ethical to use certain methodologies depending on the question. For example, it would not be ethical to randomize someone to a harmful treatment. Likewise, it may not be possible to do a prospective trial for an outcome that either takes years to develop or is very rare.

Types of Studies:

Experimental Design:
Randomized Control Trial (RCT) Randomization should ensure that comparison groups are equal. This is an experimental method.
Non- Experimental Design:
Cohort Study: follow one or more groups of individuals who have not yet suffered the adverse event and monitor the number of outcomes that occur over time. These need to be done when it is either not ethical or not practical to randomly assign patients to be "exposed" to something. Observational Design can be prospective or retrospective.
Case-Control Study: Collection of "cases" who have suffered the outcome and "controls" who have not. Investigators count the number of patients with a prognostic factor in the cases and the controls. These need to be done when the outcome of interest is rare or takes a long time to develop.
Case Series and Case Reports: Reports of patient scenarios that do not provide any comparison group.

PICO Table Handout

Patient, Population or Problem	How would I describe a group of patients similar to mine	
Intervention, Prognostic Factor, Exposure	Which main intervention, exposure, or prognostic factor am I considering?	
Comparison (if appropriate)	What is the main alternative to compare?	
Outcome you would like to measure or achieve	What can I hope to accomplish, measure, improve, affect?	
Type of Question you are asking	How would I categorize this question?	
Type of Study you would want to find	What would be the best study design in order to answer this question?	

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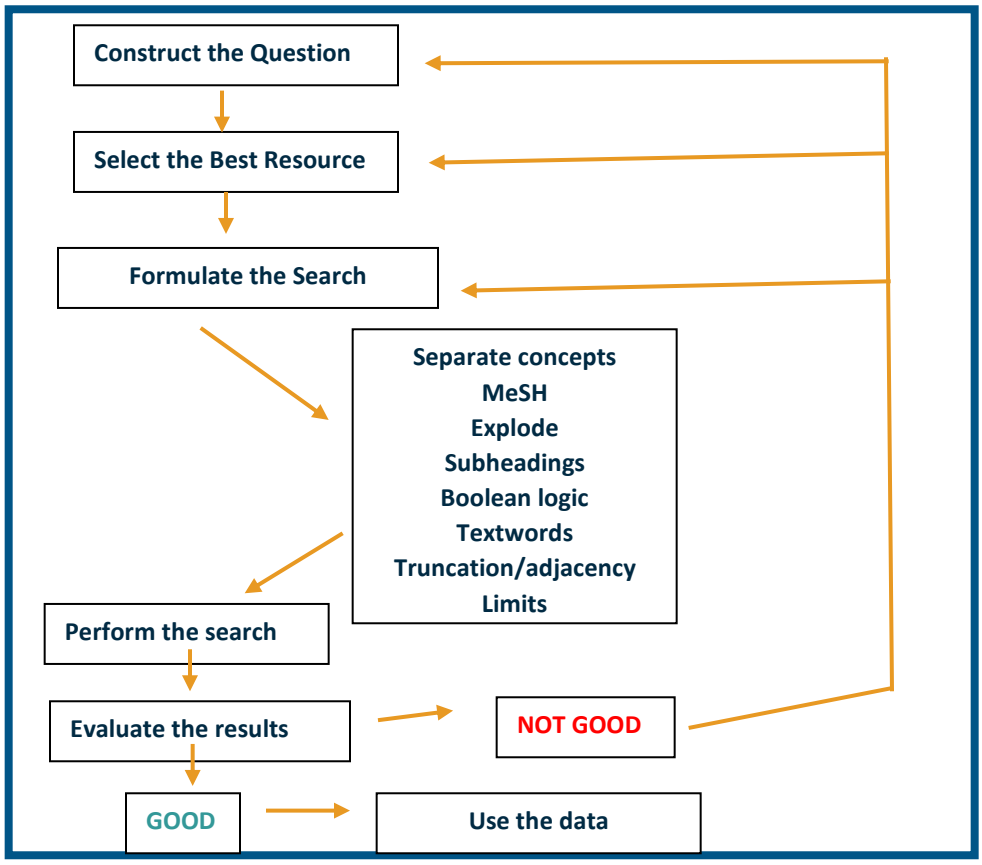
Searching for Evidence

Formulating Search Strategy



Parts of the Question:	Your question:	Your search strategy:
Patient Problem		
Intervention		
Comparison		
Outcome		
Type of Question		
Type of Study		

EBM Resources Comparison Chart

EBM Database/Resource	Access options	Content summary	Value/significance	More info/Bottom Line
ACP Journal Club American College of Physicians American Society of Internal Medicine (ACP-ASIM) acpjc.acponline.org/index.html	- Abstracts included in PubMed (free) - Web access at acjc.acponline.org/ ($) - In print or online in *Annals of Internal Medicine* ($)	Includes value-added abstracts and commentary on selected original studies and systematic reviews. Focus is internal medicine.	Filtering of 100+ top journals for clinically relevant, methodologically sound studies. Expert commentaries on clinical usefulness supplement enhanced abstracts.	Excellent source to find important studies in medicine that are pre-appraised. JAMA. 2000; 283(14): 1875-1879
ACCESSSS From McMaster University https://www.accessss.org/	-Free to search -Registration required -Articles that are not open access must either be purchased or accessed through one's institution (option to link to your institution)	Pre-appraised evidence to address this key question: what is the current best available evidence to support clinical decisions.	Sorts results based on the EBHC Evidence Pyramid 5.0 (systems, summary clinical texts, guidelines, systematic reviews, studies).	Sorting by evidence level and study design is helpful.
Cochrane Library www.cochrane.org	- In the Cochrane Library ($) - Abstracts only at www.cochrane.org/ (free) - Abstracts in PubMed	Regularly updated collection of EBM databases, including: - Cochrane Database of Systematic Reviews - Cochrane Central Register of Controlled Trials - CDSR protocols	The Cochrane Library aims to "prepare, maintain & promote the accessibility of systematic reviews of the effects of healthcare interventions."	Within the Cochrane Library, it's the Cochrane Database of Systematic Reviews that is of primary interest to clinicians. It sets the gold standard for quality reviews on clinically-relevant topics. J Med Libr Assoc. 2005 July; 93(3): 409–410
Cochrane Central Register of Controlled Trials (CENTRAL)	- In the Cochrane Library ($)	An international collection of controlled trials from a variety of sources.	Includes reports published in other sources not currently listed in MEDLINE or related databases.	Use the Cochrane Trials register when preparing a new systematic review or searching for clinical trials from the international literature.

Cochrane Database of Systematic Reviews	- In the Cochrane Library ($) - Abstracts only at www.cochrane.org/ - Abstracts in PubMed	Systematic reviews, most using meta-analysis, from the 50 Collaborative Review Groups. Focused topic summaries.	The gold standard for systematic reviews.	Use the Cochrane Database of Systematic Reviews to locate high quality, well-documented Systematic reviews.
DynaMed EBSCO www.dynamed.com	- Online ($) - App available ($)	Focuses on diagnosis and treatment options. Systematic literature surveillance process monitors over 500 journals and integrates new evidence as it is published.	Extensive; updated daily. The bulleted format provides highlights from primary literature; users are encouraged to access original studies. Adheres to EBM principles – doesn't answer questions for you.	Use for finding the evidence at the point of care. Useful for tracking back to the original studies. J Med Libr Assoc. 2005 July; 93(3): 412–414
Essential Evidence Wiley www.essentialevidenceplus.com	- Online ($)	Filtered, synopsized, evidence-based information, allowing you to search across multiple databases, including EBM Guidelines, Daily POEMs, Cochrane Abstracts, Practice Guidelines, Calculators, Diagnostic Tests, and Calculators	Integrated system for quick searching of key resources; primarily of interest to family medicine practitioners.	Use Essential Evidence for "just-in-time" evidence-based answers to primary care clinical questions. Med Ref Serv Q. 2009 Spring; 28(1):105-6. DOI: 10.1080/02763860802616144
Google Scholar www.scholar.google.com	- Online (free)	Searches broadly across a variety of web-based resources	Easy to use; familiar tool; does not disclose exactly what sites and resources it searches. Lacks good EBM filters.	When you can't find information in other databases N Engl J Med. 2006 Jan 5;354(1):4-7 J Med Libr Assoc. 2006 January; 94(1): 97–99
PubMed Clinical Queries National Library of Medicine https://www.ncbi.nlm.nih.gov/pubmed/clinical/	- Online (free) via PubMed – www.pubmed.gov	Filters for retrieving methodologically sound studies in four categories (therapy, diagnosis, etiology, and prognosis) plus systematic reviews.	Quick access for retrieving evidence-based original studies and systematic reviews from MEDLINE (based on the work of RB Haynes from McMaster).	Use PubMed's clinical queries to select evidence-based studies from the MEDLINE database.

TRIP Database Centre for Research Support www.tripdatabase.com	- Online (free)	Meta-search engine for sources of high-quality internet information, including PubMed's clinical queries, government guidelines, e-journals, and e-textbooks.	EBM-specific features such as a PICO search, evidence filters, and rapid review make this a relevant and interesting way to search for the best evidence.	Use TRIP when seeking pre-appraised evidence, reviews, and guidelines. Strong UK/Canada/Australia focus.
UpToDate www.uptodate.com	- Online ($)	Concise, peer-reviewed topical summaries, chiefly in internal medicine and its subspecialties, focusing on diagnosis and treatment.	An easy-to-use database that provides quick answers to clinical questions. Summaries are a combination of synthesized literature reviews and expert knowledge.	Use UpToDate for peer-reviewed answers to specific clinical questions J Med Libr Assoc. 2003 January; 91(1): 97

PubMed Basics

PubMed® is the U.S. National Library of Medicine's (NLM) premier search system for health information. It is available **free** on the Internet at **http://mclibrary.duke.edu/pubmed**

PubMed Content
Content includes:
• **Publisher-supplied citations** that will be analyzed to receive full indexing for MEDLINE if they are biomedical in nature
• **In-process citations** that have not yet been analyzed and indexed for MEDLINE®
• **Indexed for MEDLINE** citations of articles from about 5600+ regularly indexed journals; MEDLINE makes up nearly 90% of PubMed.

PubMed Features
• Sophisticated search capabilities, including spell checker, Advanced Search Builder, and special tools for searching for clinical topics
• Assistance in finding search terms using the MeSH (Medical Subject Heading) database of MEDLINE's controlled vocabulary
• Ability to store citation collections and to receive email updates from saved searches using PubMed's My NCBI
• Links to full-text articles, to information about library holdings, and to other NLM databases and search interfaces

PubMed Searching

To search PubMed, type a word or phrase into the query box, including subject, author and/or journal. Then click on the **Search** button or press the Enter key. Combine search terms with connector words: "AND", "OR" or "NOT" using upper case letters.

PubMed offers alternative searching options; for example, the Auto Suggest drop down menu appears when entering words and often a **Titles with your search terms** box is available after a search.

Limit searches by using the **Filters** list in the left navigation bar. Click on a term to activate or deactivate the filter. Use **Choose additional filters** for the full list of filters including Text availability, Publication dates, Species (Humans or Animals), Article types, Languages, Subjects, Ages, Sex, and Journal categories. Multiple choices may be made within sections. Make selections then click the **Search** button.

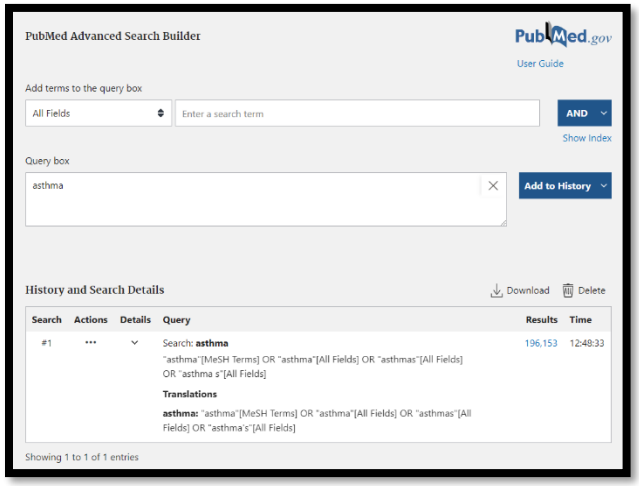
The **Filters activated** message appears above the search results list and limits remain in effect until removed or cleared.

Advanced Search

The Advanced search link provides two options to refine and focus a search: a Search Builder and Search History.

PubMed Advanced Search Builder offers the creation of a search using Boolean operators. Using the All Fields selection will run search terms through the Automatic Term Mapping process. A specific field may be selected from the drop-down menu to apply to the term. **Show index list** is available to display the search field index and the number of citations for each term in the search field. The Index display allows selection of multiple terms to "OR" together.

History and Search Details tracks search statements and numbers them, and also provides information on how PubMed interpreted the search (**Search Details, under >**).

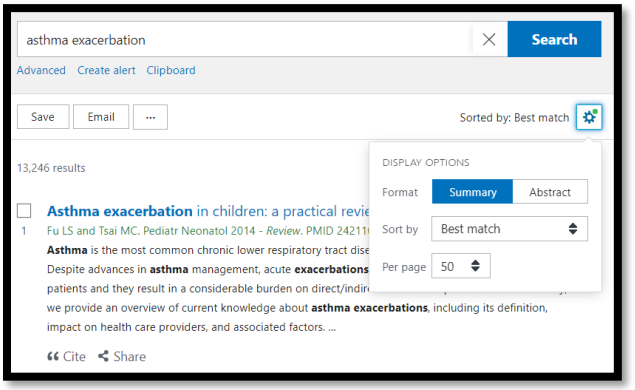


As mentioned, **Search details** provides information on how PubMed ran a search. PubMed looks first for the word or phrase as a MeSH term, then for journal titles, then authors. PubMed also searches "All Fields" for the word(s). **Search details** show how PubMed maps terms to MeSH headings (a process called Automatic Term Mapping).

Clipboard

This feature allows collection of selected citations from one or more searches for saving, printing, e-mailing, ordering, or storing in My NCBI Collections. The link is visible only when items are stored on the Clipboard. Click the check box next to citations to select them. Then click on the three ellipses next to Save and Email; select Clipboard from the dropdown list. To see the selected citations, click on the **Clipboard** link under the search box.

PubMed Search Results



After clicking on the **Search** button, PubMed displays a list of results in Summary format. To retrieve more information about the search results, use the **Sorted By** menu to change the view to the **Abstract** format.

PubMed defaults to showing the search results by **Best Match**, a relevancy ranking option. You can change the sort order to **Most Recent** or **Publication Date** here.

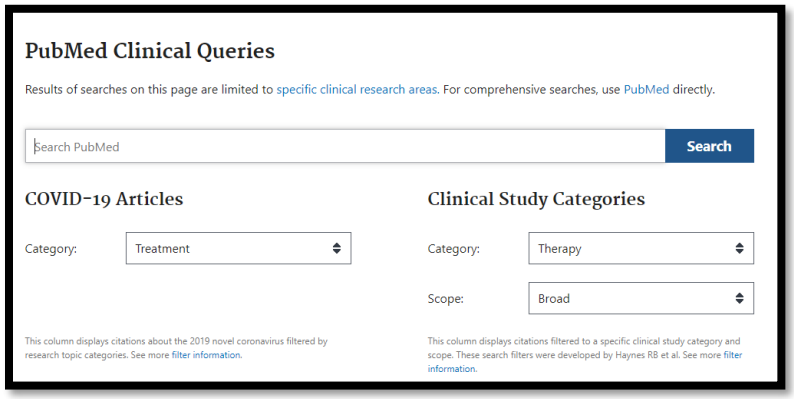
Similar Articles

A helpful PubMed feature is the ability to find citations that are similar to those of interest. To review Related Articles, click on a citation and scroll or click on the **Related Articles** link in the right-hand menu on the Abstract view.

MeSH Database

Articles are indexed using a powerful vocabulary, called Medical Subject Headings (MeSH). The MeSH Database provides the option of identifying appropriate MeSH terms for searches.

The **MeSH Database** is available from the PubMed homepage. Use the MeSH database to search for a particular term or concept. If multiple items are retrieved, click on the desired term to view and select subheadings and other options. Then click on the **Add to Search Builder** button on the right side of the screen. When finished adding terms, click **Search PubMed** to complete the search.



Clinical Queries

PubMed's **Clinical Queries** section, accessed from the homepage or the Advanced Search page, makes it easier to find articles that report applied clinical research.

To search by **clinical study category**, enter search terms in the box provided. Then select a category: etiology, diagnosis, therapy, prognosis, or clinical prediction guides and then choose either "broad" or "narrow" scope.

You can also access the Clinical Queries on the Duke PubMed results page, where the filters appear on the right of search results.

Saving, Emailing, and Downloading Results

After selecting your citations (i.e. from checked boxes or Clipboard), select **Save** or **Email**. The Save option allows you to send the citations via .RIS to citation management tools; you can also download a list of the PMIDs, or save the citations in a .CSV file.

Saving Searches in PubMed: My NCBI

Sign in or Register

Connect to http://www.mclibrary.duke.edu/pubmed. In the upper right corner of the screen click on **Log in**. If you have an account, you can sign in using your username and password. New users may register by clicking on **Register for an account**.

Save a Search | Get Updates via Email

My NCBI allows you to save search strategies. It can also deliver updates of search results to your email on a schedule that you determine.

Creating a Search Strategy

There are two ways to create a search strategy in PubMed.

1. Enter all terms into the search box, e.g. osteoarthritis AND (exercise OR exercise therapy).
2. On the **Advanced Search** page, build a strategy from the *History* using search numbers, e.g., #1, or click the *Add to builder* link corresponding with the relevant search sets.

   #4 Search **#1 AND (#2 OR #3)**
   #3 Search **exercise therapy**
   #2 Search **exercise**
   #1 Search **osteoarthritis**

Saving a Search Strategy

1. From the Results screen, click on **Create alert** below the search box. **NOTE**: The entire session history will not be saved, only the search statement that you are currently viewing. This search statement should include all relevant concepts.
2. Sign into **My NCBI**, if you are not already.
3. Review the search strategy for accuracy. Note that set numbers have been replaced by the terms searched.
4. Enter a new name for the search and click **Save**. **SUGGESTION**: Choose a name that is short and meaningful.
5. Select **No** or **Yes** to receive email updates.
6. If **Yes**, fill in the form indicating how often to get updates, the result format, and the number of items to send.
7. To access, delete, or edit settings of a search, sign into **My NCBI** and click on **Manage Saved Searches**.

Save Citations into My NCBI Collections

My NCBI also allows you to save individual citations indefinitely. You may create multiple collections within My NCBI for specific research projects that may be viewed privately or publicly shared with others.

Saving Selected Citations

1. After running a search, select the citations that you would like to save from the Results list by placing a checkmark in the box next to the citation.
2. Using the three ellipses next to Save and Email, select **Collections** from the dropdown. ***Note: Don't choose My Bibliography***, as this is a separate function tied to the NIH open access policy, not a way to build a bibliography for a research topic.
3. Select whether you would like to create a new collection for the citations, which is the default option, or append (add) them to an existing collection.
4. Enter a name for your new collection or choose an existing collection from the drop-down menu. Click **Save**. **SUGGESTION**: If you choose to create a new collection, choose a name that is short and meaningful.
5. To access, delete, or share collections, sign into **My NCBI** and click on **Manage Collections.**

Setting Up Filters in PubMed: My NCBI

Sign in or Register

Connect to http://www.mclibrary.duke.edu/pubmed. In the upper right corner of the screen, click on **Log in**. If you have a My NCBI account, you can sign in using your username and password. New users may register by clicking on **Register for an account**.

Filters

Filters allow you to group your search results by specific criteria, such as publication type or age groups. They appear at the top of the column to the right of your results. Clicking on a filter will display results limited by the selected filter.

Note: When you sign in, your preferences will override these defaults.

To Add a Filter from the Results Page

1. Click on **Manage Filters** at the bottom of the **Filter your results** box to the right of your results and sign in.
2. You can select from the lists of **Popular**, **LinkOut**, **Properties**, **Links**, or **Search** to find filters.
3. Check the filter you would like to add.
4. To go back to your results, click on **PubMed** under **Popular** at the bottom of the page, then choose **Advanced Search** to access your search history.

Examples of Useful Filters:

These filters can make your PubMed searches faster and more efficient. To apply a filter, simply search for the filter name and then place a checkmark next to it.

- **Duke Medical Center Library** limits searches to articles that the Duke Medical Library has access to in electronic or print format. We have access to additional articles than what appear with this filter, so be sure to check the "All" list in your results and follow Get it @ Duke links to see if we have a particular citation.
- **Clinical Queries** limits searches using the Clinical Query filter for selected question types, such as **Therapy/Narrow**. Learn more about clinical queries at http://www.ncbi.nlm.nih.gov/books/NBK3827/#pubmedhelp.Clinical_Queries_Filters.
- **NOTE**: Clinical queries are listed under **Properties.** Therapy/Narrow is recommended, as it filters your search results to look for randomized controlled trials. Other queries are also available.
- **Age Groups** limits searches to articles indexed to specific age groups, such as children or the aged.
- **Nursing Journals** limits searches to articles in nursing journals.

Create Your Own Custom Filters:

Want to filter results to a group of journals or a specific search strategy? Custom filters allow you to create and save filters based on search strategies, such as a set of journals or a group of drugs.

- Tips: First run a search that captures your custom filter strategy in PubMed, then copy the strategy from the Search. Details box on your search results and paste it into the custom filter area in My NCBI.

Therapy

Therapy Core Concepts

Notes on learning and teaching about **Therapy:**

1. **Background**: Many teachers and users of the medical literature will spend most of their time reading and teaching about randomized trials. Randomized methodology is intended to set up groups with equal prognosis that allow interventions to be compared on a level playing field. Many different types of questions are addressed using this study design including therapeutic interventions, screening, disease management strategies (e.g. intensive versus standard blood pressure control), or systems interventions (e.g. strategies to decrease readmissions).
2. Key concepts and terms
    - Concept of equal prognosis between groups
    - Randomization including intent of randomization and generation of random sequence (stratification and blocking)
    - Allocation Concealment
    - Blinding (masking)
    - Measures of treatment effect
        - Risk Ratio (also called Relative Risk)
        - Relative risk reduction or relative benefit increase
        - Risk Difference (also called Absolute Risk Reduction or Absolute Benefit Increase)
        - Number Needed to Treat (NNT)
    - Understanding precision: confidence intervals
    - Patients analyzed in the groups to which they were randomized (Intention to treat)
    - Follow-up
    - Applicability and generalizing results
        - Surrogate versus patient-important outcomes
        - Risk versus benefit considerations
        - Values and preferences in decision-making
3. Additional topics pertaining to therapy
    - Trials stopped early for benefit
    - Composite end points
    - Non-inferiority trials
        - Non-inferiority margin (incorporation of risk / benefit considerations)
        - Per-protocol analysis vs. Intention to treat analysis
        - Beware of faulty comparators (e.g. wrong dose or monitoring of the standard treatment) that make standard treatment look less effective

Therapy Critical Appraisal Form

Citation:

How serious is the risk of bias?	
Did intervention and control groups start with the same prognosis?	
Were patients randomized?	
Was randomization concealed?	
Were patients in the study groups similar at baseline with respect to prognostic factors?	
Was prognostic balance maintained as the study progressed?	
To what extent was the study blinded?	
Were groups prognostically balanced at the study's conclusion?	
Was follow-up complete?	
Were patients analyzed in the groups to which they were randomized?	
Was the trial stopped early?	
What are the results?	
How large was the treatment effect?	
How precise was the treatment effect?	
How can I apply the results to my patient care?	
Were the study patients similar to my patient?	
Were all patient-important outcomes considered?	
Are the likely benefits worth the potential harms and costs?	

Adapted from McMaster Evidence-based Clinical Practice Workshops and the Users' Guide to the Medical Literature 3rd Ed.

Citation:

How serious is the risk of bias?	
Did intervention and control groups begin the study with a similar prognosis?	
Were patients randomized?	
Was randomization concealed?	
Were patients similar at baseline with respect to known prognostic factors?	
Was prognostic balance maintained as the study progressed?	
Were patients, caregivers, collectors of outcome data, adjudicators of outcome, and data analysts aware of group allocation?	
Were groups prognostically balanced at the study's conclusion?	
Was follow-up complete?	
Was the trial stopped early for benefit?	
Were patients analyzed in the groups to which they were randomized?	
Did the investigators guard against an unwarranted conclusion of non-inferiority?	
Was the effect of the standard treatment preserved?	
Did the investigators analyze patients according to the treatment they received, as well as to the groups to which they were assigned?	

What are the results?	
How large was the treatment effect?	
How precise was the estimate of the treatment effect?	
How can I apply the results to my patient care?	
Were the study patients similar to my patient?	
Were all patient-important outcomes considered?	
Are the likely advantages of the novel treatment worth the potential harms and costs?	

Adapted from McMaster Evidence-based Clinical Practice Workshops and the Users' Guide to the Medical Literature 3rd Ed.

FRISBE Therapy Critical Appraisal Worksheet with Key Learning Points

THERAPY STUDY	Article author/year: _____	Key Learning Points
A. ARE THE RESULTS VALID? ("FRISBE") **F = Patient Follow-Up** Were all patients who entered the trial properly accounted for and attributed at its conclusion? Was follow-up complete?		*How do dropouts threaten validity?* Study participants are lost to follow-up (LTF) when their status/outcomes are not known at the end of the trial. Often the reason that they are lost to follow-up relates to a systematic difference in their prognosis from those who continue with a study until the end (e.g. patients LTF do worse/are dead or may be greatly improved/ don't feel the need to continue in the study). Thus, the loss of many participants may threaten validity. Furthermore, if the loss to follow-up is different between the two groups, dropouts or those lost to follow-up may create missing data that can disrupt the balance in groups created by randomization.
AR = Randomization Was the allocation (assignment) of patients to treatment randomized? Was the allocation concealed?		*Why is randomization important?* Effective randomization guarantees that each subject has an independent and fixed chance of being allocated to each group. The chance is usually equal (e.g. in parallel group design where a participant is randomized to one of two or more interventions). Randomization aims to balance groups for known and unknown prognostic factors by allocating subjects to groups by chance alone. If randomization is correctly done, any group differences should be attributable to chance alone. The intent is to minimize chance differences so that any observed group differences can be attributed to the effect of treatment. Allocation concealment assures that those assessing eligibility and assigning subjects groups don't have knowledge of the allocation sequence.

I = Intention-to-Treat Analysis Were patients analyzed in the groups to which they were randomized? Were all randomized patient data analyzed?		*Why is intention-to-treat analysis important?* ITT preserves the balance of prognostic factors in groups created by the original random group allocation. It provides the truest estimate of the effects of treatment allocation in real-world practice by including data from crossovers, non-adherents, dropouts and those lost to follow-up, plus estimates of missing data points. ITT thereby avoids overly optimistic estimates of treatment efficacy resulting from excluding non-compliers.
S = Similar Baseline Characteristics of Patients Were groups similar at the start of the trial?		*Why should groups be similar at baseline?* It is important to verify that those factors known to influence outcome are equally distributed. And to assess the potential effect on the study outcome of an imbalance that occurs by chance.
B = Blinding Were patients, health workers, and study personnel "blind" to treatment?	Blinded groups included (Y=yes, N=no, U=uncertain): _____ patients _____ providers _____ raters or assessors _____ data analysts _____ adjudicators	*Why is blinding important?* Blinding equalizes the effect of patient and provider expectations on outcome across groups. For raters, blinding minimizes subjectivity in outcome measurement. For providers, blinding eliminates the possibility of either conscious/unconscious differential administration of effective intervention to either group: i.e. co-interventions (unintended additional care to either group) or contamination (provision of intervention to control group).
E = Equal Treatment Aside from the experimental intervention, were the groups treated equally?		*Why should groups be treated equally?* Equal treatment helps guarantee that the groups will remain prognostically balanced by avoiding systematic differences in the care provided other than the intervention.
Summary of article's validity	Notable strengths / weaknesses: Overall, this trial method is (strong/adequate/weak) Potential threats are (minimal/modest/serious/fatal) and would likely bias the results of the study towards (overestimate/underestimate) of treatment effect.	How serious are the threats to validity and in what *direction* could they bias the study outcomes? Include notable strengths/weaknesses as well as the direction of the biases and how that may impact interpretation of results.

<table>
<tr>
<td>B. WHAT ARE THE RESULTS?

How large was the treatment effect?

How precise was the treatment effect?</td>
<td>1) Response rates on dichotomous outcome measure:

<table>
<tr><th>Outcome</th><th>EER[1] (n=)</th><th>CER or EER[2] (n=)</th><th>Risk Difference</th><th>NNT (95%CI)</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
</table>
Risk Ratio

Risk Difference

NNT or NNH</td>
<td>Calculate and state the plain English meaning of summary statistics for dichotomous outcomes:

Risk Ratio

Risk Difference

NNT or NNH</td>
</tr>
<tr>
<td>C. WILL THE RESULTS HELP ME IN CARING FOR MY PATIENTS?

Can the results be applied to my patient?

Were all clinically important outcomes considered?

Are the likely treatment benefits worth the potential harms and costs?</td>
<td></td>
<td></td>
</tr>
</table>

Therapy Formulas

	Outcome		
	Outcome Present	Outcome Absent	
Treated/ Exposed (Y)	**a** Outcome present in treated patient	**b** Outcome absent in treated patient	**Y= Risk of Outcome in Treated Group** =a/(a+b)
Control/ Not exposed (X)	**c** Outcome present in control patient	**d** Outcome absent in control patient	**X= Risk of Outcome in Control Group** =c/(c+d)

I. Relative Risk

The ratio of risk of outcome in treated group (Y) as compared with control group (X)

RR=Y/X = a/(a+b) / c (c+ d)

This always tells us whether the observed outcome (effect) occurs more or less often in the exposed group than in the unexposed group. Calculations for RR are identical whether you are asking a question about therapy or a question about Harm. Relative Risk can only be calculated from RCTs or cohort studies where we can determine outcomes of interest in exposed / treated groups and unexposed / control groups. (Note: for case-control studies, the numbers of cases and controls and, therefore, the proportion of individuals with the outcome is chosen by the investigator- for case-control studies we use odds ratios: Odds Ratio = (a/c) / (b/d)

II. Relative Risk Reduction

The percent reduction is percent decrease in risk in the treated group (Y) as compared with control group (X)

RRR= [X – Y] / X or 1- RR

For Questions of Harm: You calculate the Relative Risk Increase: The calculation is exactly the same as for Treatment, however, you will have an increase in relative risk.

III. Absolute Risk Reduction

The difference in risk between the control group (X) and the treated group (Y). The risk is higher in the control group, therefore, the you subtract

ARR = X (Control) -Y (Treated)

For Questions of Harm: You calculate the Absolute Risk Increase. Because the risk is higher in the treated group, the ARI= Y(Treated)- X (Control)

IV. Number Needed to Treat

NNT is the reciprocal of the ARR **NNT = 1/ARR = 1/(X-Y)**
(an NNT of 20 means that 20 patients must be treated to prevent one adverse outcome)

For Questions of Harm: You calculate the Number Needed to Harm: The calculation is exactly the same as for Treatment, however, you will take the reciprocal of Absolute Risk Increase: **NNH=1/ARI = 1/(X-Y)**
(a NNH of 20 means that for every 20 patients treated, we will cause one adverse outcome)

Harm

Harm Core Concepts

Notes on learning and teaching about **Harm:**

1. **Background:** Questions of Harm are answered by a diverse set of study designs. For some questions of harm (e.g., harms associated with a particular therapy), harm can be studied in the context of RCTs simply by measuring harms in addition to benefits in your trial (e.g. an RCT studying thrombolytics would measure improvement in mortality as well as an increase in bleeding). However, when outcomes are rare, or studying them would be unethical, other study designs are frequently required. The context of harm can allow learners and teachers of the medical literature to gain an appreciation of the hierarchy of evidence (understanding the strengths and potential biases associated with different study designs to provide a gradation of more to less bias).
2. Key concepts and terms
    - Hierarchy of evidence
    - Study design ranging from experimental (RCT) to observational (cohort, case-control, case series)
    - Direction of inquiry
    - Odds vs. Risk and when each can be used
    - Association versus causality

Harm Critical Appraisal Form, Cohort Study

Citation:

How serious is the risk of bias?	
Aside from the exposure of interest, did the exposed and control groups start and finish with the same risk for the outcome?	
Were the patients similar for prognostic factors that are known to be associated with the outcome (or did statistical adjustment level the playing field)?	
Were the circumstances and methods for detecting the outcome similar?	
Was the follow-up sufficiently complete?	
What are the Results?	
How strong is the association between exposure and outcome?	
How precise is the estimate of risk?	
How can I apply the results to my patient care?	
Were the study patients similar to patients in my practice?	
Was follow-up sufficiently long?	
Is the exposure similar to what might occur in my patient?	
What is the magnitude of the risk?	
Are there any benefits that are known to be associated with the exposure?	

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Harm Critical Appraisal Form, Case-Control Study

Citation:

How serious is the risk of bias?	
Did the cases and control group have the same risk (chance) for being exposed in the past?	
Were cases and controls similar with respect to the indication or circumstances that would lead to exposure?	
Were the circumstances and methods for determining exposure similar for cases and controls?	
What are the Results?	
How strong is the association between exposure and outcome?	
How precise is the estimate of risk?	
How can I apply the results to my patient care?	
Were the study patients similar to patients in my practice?	
Was follow-up sufficiently long?	
Is the exposure similar to what might occur in my patient?	
What is the magnitude of the risk?	
Are there benefits that offset the risks of the exposure?	

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Prognosis

Prognosis Core Concepts

Notes on learning and teaching about **Prognosis:**

1. **Background**: The concept of prognosis (the estimated probability of outcomes of disease processes over time) is at the core of what clinicians do. Cohort studies typically follow one or more groups of people with similar characteristics over time and provide information on the occurrence of outcomes. Cohorts can be prospective or retrospective; the subjects can be population or community-based or tertiary care patient populations. Understanding how and when the cohort is defined and how and when the outcomes are measured is core to understanding the literature pertaining to prognosis.
2. Key concepts and terms
    - Cohort Study
    - Appropriate or inappropriate measurement of exposure
    - Statistical adjustment for prognostic imbalance
    - Lost to follow up
    - Risk factor vs. Prognostic factor
    - Bias
    - Incidence vs. Prevalence
    - Odds Ratio vs. Risk Ratio
    - Survival analysis (sometimes called Kaplan-Meier Analysis) and hazard ratio

Prognosis Critical Appraisal Form

Citation:

How serious is the risk of bias?	
Was the sample of patients' representative?	
Were patients classified into prognostically homogeneous groups?	
Was follow-up sufficiently complete?	
Were outcome criteria objective and unbiased?	
What are the results?	
How likely are the outcomes over time?	
How precise are the estimates of likelihood?	
How can I apply the results to patient care?	
Were the study patients and their management similar to those in my practice?	
Was the follow-up sufficiently long?	
Can I use the results in the management patients in my practice?	

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Diagnosis

Diagnosis Core Concepts

Notes on learning and teaching about **Diagnosis:**

1. **Background:** The importance of diagnostic reasoning cannot be overstated for teachers and users of the medical literature, yet this is an area in which many feel uncomfortable. The key concepts here can be separated into categories of 1) study design (prospective comparison to reference standard) for those wishing to review the original literature about diagnostic tests and 2) diagnostic reasoning and using likelihood ratios.

2. Assessing the validity of a study regarding a diagnostic test (risk of bias)
   - Optimal study design: prospective comparison to reference standard
   - Representative study group
   - Uniform comparison to a reference standard
   - Blinding of those interpreting the new test and reference standard (stumbling block: learners may confuse this concept with blinding in an RCT)

3. Understanding diagnostic test results
   - Sensitivity / Specificity
   - Likelihood Ratios

4. Diagnostic thinking (how do we use diagnostic test results)
   - Pretest probability and/or prevalence
   - Using a likelihood ratio (including use of the nomogram)
   - Posttest probability
   - Action threshold
   - Role of patient values and preferences as well as clinical circumstance in decision-making

5. Additional topics
   - Interobserver agreement / agreement beyond chance (Kappa)
   - Positive and negative predictive values and the downsides of using these test characteristics
   - Clinical Decision Rules
   - Understanding the role of randomized trials for studying implementation of a diagnostic test strategy (e.g. an intervention to use Ottawa ankle rule to decrease ankle x-rays in an emergency department)

Diagnostic Test Critical Appraisal Form

Citation:

How serious is the risk of bias?	
Did participating patients constitute a representative sample of those presenting with a diagnostic dilemma?	
Did investigators compare the test to an appropriate, independent reference standard?	
Were those interpreting the test and reference standard blind to the result of the other test ?	
Did all patients receive the same reference standard irrespective of the results of the test?	
What are the results?	
What are the likelihood ratios for the various possible test results?	
How can I apply the results to patient care?	
Will the reproducibility of the test results and its interpretation be satisfactory in my clinical setting?	
Are the study results applicable to patients in my practice?	
Will the test results change my management strategy?	
Will patients be better off as a result of the test?	

Adapted from McMaster Evidence-based Clinical Practice Workshops and Users' Guide to the Medical Literature 3rd Ed.

Differential Diagnosis Critical Appraisal Form

Citation:

How serious is the risk of bias?	
Did the study patients represent the full spectrum of those with this clinical problem?	
Was the diagnostic evaluation definitive?	
What are the Results?	
What were the diagnoses and their probabilities?	
How precise are the estimates of disease probability?	
How can I apply the results to patient care?	
Are the study patients and clinical setting similar to mine?	
Is it unlikely that the disease possibilities or probabilities have changed since this evidence was gathered?	

Adapted from McMaster Evidence-based Clinical Practice Workshops and Users' Guide to the Medical Literature 3rd Ed.

Screening Critical Appraisal Form

Citation:

How serious is the risk of bias?	
Is there randomized controlled trial evidence that the intervention benefits people with asymptomatic disease?	
What are the recommendations, and will they help you in caring for patients?	
Were the data identified, selected, and combined in an unbiased fashion?	
What are the benefits?	
What are the harms?	
How do benefits and harms compare in different people and with different screening strategies?	
What is the effect of individuals' values and preferences?	
What is the effect of uncertainty associated with the evidence?	
What is the cost-effectiveness?	

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Diagnostic Test Worksheets

Definitions and the 2x2 table

	"Reference Standard" Result			
	Condition Present	Condition Absent		
Positive Test	True Positive (a)	False Positive (b)	TP + FP a+b	**PPV*** = a/(a+b) Of patients who test positive, the proportion who have disease
Negative Test	False Negative (c)	True Negative (d)	TN + FN c+d	**NPV*** = d/(c+d) Of patients who test negative, the proportion without disease
	TP + FN a+c	TN + FP b+d	a+b+c+d	**Prevalence** = (a+c)/(a+b+c+d)
	Sensitivity = a/(a+c) Of patients with disease, the proportion who test positive	**Specificity** = d/(b+d) Of patient without disease, the proportion who test negative	**Accuracy** = (a+d)/(a+b+c+d) Of all patients in the study population, the proportion with true test results	Of all patients in the study population, the proportion with disease

(*test is affected by disease prevalence)

PPV = Positive Predictive Value. NPV = Negative Predictive Value

Sensitivity

PID = Positive In Disease

In a test with high sensitivity, this test will find most patients who have the disease.

In a test low sensitivity, many patients will disease will be missed (many false negative results)

SnNOUT = a Sensitive test with a Negative test result, rules OUT disease

Specificity

NIH = Negative In Health

In a test with high specificity, this test will correctly label patients with the disease

In a test with low specificity, this test will incorrectly label patients as having the disease (many false positives)

SpPIN- a Specific test with a Positive test result rules IN disease

Mathematical demonstration of how prevalence affects Positive Predictive Value:

Population size = 100,000, Sensitivity =90%, Specificity =90%

disease prevalence = 1%	disease prevalence = 0.1%

	(+) disease	(-) disease	
(+) test	900	9,990	PPV= 8.3%
(-) test	100	89,100	
	1,000	99,000	100,000
11 false (+) for every true (+)			

	(+) disease	(-) disease	
(+) test	90	9,990	PPV= 0.9%
(-) test	10	89,910	
	100	99,900	100,000
111 false (+) for every true (+)			

Likelihood Ratios:

Combine sensitivity and specificity into one measure

Conceptual Framework: How good is a diagnostic test in discriminating between patients with disease and those without disease?

Definitions:

- a likelihood ratio is a ratio of likelihoods
- likelihood of a disease based on a specific test result
  - (e.g. negative rapid strep test, intermediate VQ scan, WBC > 20,000 for appendicitis)
- a likelihood ratio compares the likelihood of a particular test result in patients with disease to the likelihood of that same result in patients without that same disease
- a likelihood ratio of 10 means that this specific test result is ten times more likely to occur in patients with disease than patients without disease
- a likelihood ratio modifies your pretest probability to generate a new, posttest probability

Math:

- By convention, a likelihood ratio compares the frequency that a specific test result (e.g. rapid flu negative) in patients **WITH** disease divided by patients **WITHOUT** disease

- Likelihood ratio for a **positive** test

$$\frac{\text{Proportion of patients who test positive who have disease}}{\text{Proportion of patients who test positive who do not have disease}}$$

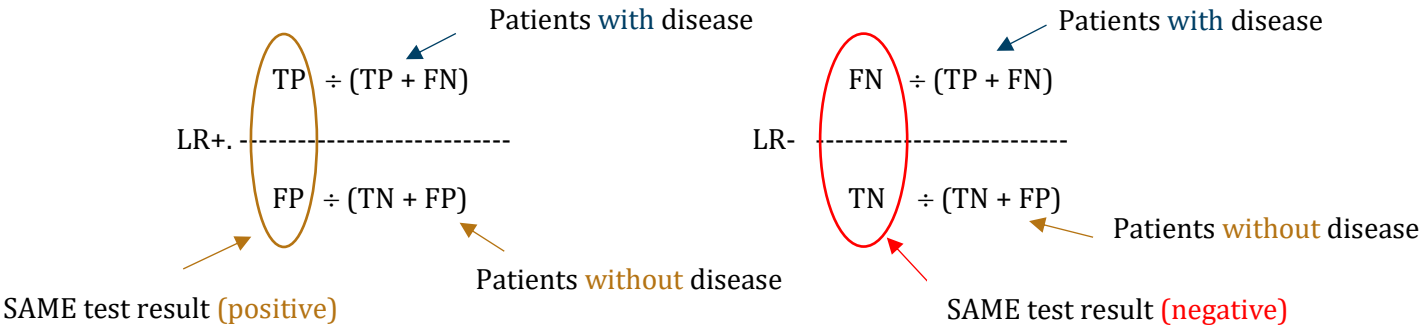
$$\frac{\text{Proportion of patients with positive rapid flu test who have influenza}}{\text{Proportion of patients with positive rapid flu test who do not have influenza}}$$

- Likelihood ratio for a **negative** test

$$\frac{\text{Proportion of patients who test negative who have disease}}{\text{Proportion of patients who test negative who do not have disease}}$$

$$\frac{\text{Proportion of patients with negative rapid flu test who have influenza}}{\text{Proportion of patients with negative rapid flue test who do not have influenza}}$$

- Going back to the 2x2 table



- Relating LR to Sensitivity and Specificity: sometimes you will want to convert sensitivity and specificity directly into LR (+) or LR (-) – this can be done with commonly used smartphone apps.

positive likelihood ratio = sensitivity/(1-specificity)
negative likelihood ratio = (1-sensitivity)/ specificity

Summary Methods SR MA Guidelines

Systematic Review Core Concepts

Notes on learning and teaching about **Systematic Review and Meta-analysis**:

1. **Background:** Systematic Reviews / Meta-analyses are examples of a summary methodology that summarizes original, individual trials. The subjects of a systematic review can be thought of as the papers that are brought together to answer a particularly focused question. Thus, the methods for a systematic review or meta-analysis will talk a lot about the papers that were collected for the study including how they were identified, selected, graded for quality, and possibly (in the case of meta-analysis) combined. These summaries can be on many different kinds of clinical questions (e.g. therapy, diagnosis, or prognosis).

2. Key concepts and terms:
    a. Narrative Review vs. Systematic Review vs. Meta-analysis
    b. Summary estimate or pooled estimate of effect
    c. Forest Plots including point estimates, confidence intervals, and line of no difference
    d. Heterogeneity including I^2 and yes/no tests for heterogeneity with p-values
    e. Reporting bias including publication bias and funnel plots
    f. GRADE (Grading of Recommendations, Assessment, Development, and Evaluation)

3. Additional Topics
    a. Network Meta-analysis

Citation:

Assessing the Credibility of the Systematic Review Process	
Did the review address a focused clinical question (i.e. can be framed in PICO format)?	
Was the search for relevant studies detailed and exhaustive?	
Were selection and assessment of studies reproducible?	
Was the risk of bias of the primary studies assessed?	
Did the review address possible explanations of between-study differences in results using prespecified hypotheses?	
Did the review describe a process to assess confidence in effect estimates? (e.g. GRADE tool to assess quality of the body of evidence)	
Understanding the Summary Estimate of a Meta-analysis	
What is the magnitude of treatment effect? (what is the pooled estimate?)	
How precise are the results? (i.e. confidence interval around the pooled estimate)	
Rating Confidence in the Estimates (the Quality of a Body of Evidence)	
How serious is the risk of bias in the body of evidence?	
Are the results consistent across studies? (i.e. heterogeneity or inconsistency)	
Do the results directly apply to my patient? (i.e. PICO, generalizability, indirectness)	
Is there a concern about reporting or publication bias?	
Are there reasons to increase or decrease the confidence of the rating? (*Randomized trials start high and observational studies start low)*	
Overall, what is the quality of the body of evidence by outcome? (High, moderate, low, very low)	
How can I apply the results to my patient care?	
Did the review present results that are ready for clinical application? (e.g. patient important outcomes, absolute benefit /risk)	
Are the study patients similar to my patient and are likely benefits worth potential harms/costs?	

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Comparing different types of reviews

Teaching Table for Comparing Several Common Kinds of Summary Articles:

Background: Efficient application of the medical literature requires that we make optimal use of articles in which the authors have combined information from multiple individual original studies. Systematic Review and Meta-analyses are increasingly available to pull together a comprehensive set of available original articles on a particular focused clinical question. Clinical Practice Guidelines also pull together multiple original sources; however, the starting point is a clinical problem made up of many individual, focused clinical questions. Clinical Practice Guidelines are frequently based upon the work of systematic reviews and meta-analyses.

Systematic Review, Meta-analysis and Clinical Practice Guidelines: The following table can be used in a teaching setting to help your learners understand the differences between these summary methodologies. One way to use the table is to begin with the headings on top and create the table interactively with the learners answering questions about the different types of studies.

	Unsystematic Review	Systematic Review	Meta-analysis	Clinical Practice Guideline
(also known as)	Narrative Review	Qualitative Review	Quantitative Review	
Evidence Summary?	Maybe (at the discretion of the author)	Yes	Yes	Yes
Is this review based on a focused clinical question?	No A narrative review is usually based on a clinical problem (e.g. Review of GI Bleeding)	Yes	Yes	No A family of questions related to a complex clinical problem (e.g. diabetes care)
Does this kind of review have a methods section?	No. Narrative reviews are written in the style suggested by the journal and the author without an explicit methodology.	Yes. Systematic Reviews have methods sections that include comment on the following core elements of article selection: How they found the evidence (comprehensive search strategy) How they determined the quality of the evidence (validity check)	Yes. Meta-analyses Have methods sections that include everything in a Systematic Review (comprehensive search strategy and validity check) AS WELL AS a Summary Statistic (combining the data from individual studies based on precision including sample size and variability)	Yes. A Clinical Practice Guideline allows an integration of how to approach a clinical problem. Methods include a description of comprehensiveness, quality, validity and also the process for making recommendations when there is no evidence
Who's viewpoint is represented?	The authors (Expert Model / Authority)	Evidence Model: this is simply a systematic collection and 'grading' of scientific data	Evidence Model: based on a systematic review with a combining of data from individual studies into a summary statistic	Evidence Model and Expert Model combined: This includes both evidence and expert opinion when evidence is not available.

A Shorter Version of the Teaching Table for Systematic Review and Meta-analysis:

	Narrative Review	Systematic Review	Meta-analysis
Kind of question	Topic (e.g. GI bleed)	Focused Question	→ (same as SR)
Methods	None	Comprehensive Search	→ (same as SR)
		Screen articles for validity	
Results	None	Summary of Evidence	Summary Stat
		(can be qualitative)	
Who's perspective	Authority Model	Evidence Model	→ (same as SR)

Meta-analysis, Decision Analysis, and Economic Analysis: Another set of summary methodologies includes decision and economic analysis. You can use a similar strategy for teaching about these kinds of papers. First, you point out that there are three different types of measures that researchers might make (outcomes, values, and costs). Then you can elicit examples from

Outcomes	Values	Costs
Examples:	Examples of different viewpoints	Examples:
	(i.e. who's values?)	
# admits	Patients	Drug costs
time to symptoms	Hospital / administrators	personnel
time to C/C	parents	admission $$
side effects	physicians	lost work /wages
mortality	insurance	lost school/ work
	society	equipment

How these come together in summary articles:

Meta-analysis / Overview: summary of the outcomes literature
Decision Analysis: takes all the outcomes and considers the weight of values (outcomes x values)
Economic Analysis: takes outcomes, values, and costs
(at times, does not include values as below)

Types of cost studies:

Cost-benefit analysis: all outcomes are in monetary units and no value assigned
Cost-effectiveness: monetary cost compared with a clinical unit of efficacy
Cost-utility analysis: monetary costs compared with outcomes measured in terms of social value
(e.g. Cost per QALY)

Qualitative and Other Methods

Other Topics Core Concepts

Notes about learning and teaching about **Other Topics**:

1. In addition to the CORE areas, there are many iterations of critical appraisal exercises. In this section, we have given you some examples of commonly related topics that come up. Specifically, we have given you several examples of the following kinds of topics: Qualitative Research, Prevention, and Screening. These might be appropriate topics for more advanced learners or for taking home to try sometime in the future. These topics build on the knowledge and skills that are developed in the CORE areas but are slight deviations from the CORE.

2. Prevention. Prevention is frequently studied in a manner similar to therapy (i.e. with RCT methodology) because it is an intervention (e.g. aspirin to prevent MI). However, one of the main differences pertains to the relative balance of potential benefit to potential harms because prevention deals with individuals who are without the target disorder (primary prevention) or who are trying to prevent recurrence (secondary prevention) whereas a therapy is required to treat a present disorder to prevent related adverse outcomes.

3. Screening. Screening is also frequently studied by RCT because it too is an intervention. In this case, a diagnostic test is used as an intervention to screen for and identify early disease and ultimately to prevent adverse outcomes once the disorder is identified. However, screening can also be studied in terms similar to the study of a diagnostic test, if the question pertains to the ability of the diagnostic test to pick up the target disorder. In this case, then the methodology would more parallel a prospective comparison to a reference standard as in a classic diagnostic test study.

4. Qualitative methods. Qualitative research uses open-ended methodology (e.g. focus groups or in-depth interviews) to generate hypotheses and expand our thinking in the area of inquiry. Because we are more familiar with quantitative methods, teaching can be both challenging and fun. This section includes an example of several types of teaching exercises to offer some thoughts about how one might teach qualitative methodology.

Quantitative vs. Qualitative Methods Comparison

	Quantitative Methods	Qualitative Methods
Goal	Tests hypotheses Determines: **whether** (benefits, risks harm) & **how much**	Generates hypotheses Determines: **what, how, why**
Type of Reasoning	Deductive	Inductive
Study Designs	Randomized clinical trials Epidemiologic data Close-ended surveys	In-depth interview Focus groups Field observation Document content analysis
Outcomes	Frequency distributions P-values Effect sizes	Thick descriptions and/or theoretical structure Domains and attributes of phenomena
Question Structure	Close-ended: Continuous (e.g. age) Ordinal (pain scale 1- 10) Dichotomous (yes/no) Categorical (strongly agree, agree, etc.)	Open-ended Semi-structured interview Focus Groups with trigger questions In-depth interviews
Analyses	Univariate statistics Measures of association Multivariate statistical modeling (e.g. regression)	Grounded theory – open and axial coding Template coding Inter-rater reliability - kappa statistic
Sampling	Probability based -- designed to permit clinical and statistical significance based on frequency of observed outcomes	Theoretically based – designed to include observations from relevant and comprehensive pool of informants
Sources of Bias	Measurement selection Measurement error Reported via confidence intervals and statistical significance Most strongly associated with item *validity*	Investigator coding and interpretation Reported via kappa statistic of agreement beyond chance Checked by informant review of investigator interpretations Most strongly associated with item *reliability*

Qualitative Methods Appraisal Form

Citation:

Is the qualitative research relevant?	
Are the results credible?	
Is there a specific qualitative research method cited?	
Was the choice of participants or observations explicit and comprehensive?	
Were research ethics approval obtained?	
Was data collection sufficiently comprehensive and detailed?	
Were the data analyzed appropriately and the findings corroborated adequately?	
What are the results?	
What are the results?	
How can I apply the results to patient care?	
How does the study offer helpful theory?	
Does the study help me to understand the context of my practice?	
Does the study help me to understand social phenomena in my practice?	

Adapted from McMaster Evidence-based Clinical Practice Workshops and Users' Guide to the Medical Literature 3rd Ed.

Clinical Decision Analysis Appraisal Form

Citation:

Is this a newly derived instrument? (Level IV)	
Was validation restricted to the retrospective use of statistical techniques on the original database? (If so this is a Level IV rule). If so, consider the following standards for initial development of a decision rule.	
Were all important predictors included in the derivation process?	
Were all important predictors present in significant proportion of the study population?	
Does the rule make clinical sense?	
Has the instrument been validated? (Level II or III) If so, consider the following:	
Did validation include prospective studies on several different populations from that used to derive it (II), or was it restricted to a single population (III)?	
How well did the validation exercise meet the following criteria? Were the patients chosen in an unbiased fashion and do they represent a wide spectrum of severity of disease?	
Was there a blinded assessment of the criterion standard or outcome event (or was the outcome all-cause mortality) for all patients?	
Was there an explicit and accurate interpretation of the predictor variables and the actual rule without knowledge of the outcome?	
Was there 100% follow-up of those enrolled?	
How powerful is the rule (in terms of sensitivity and specificity; likelihood ratios; proportions with alternative outcomes; or relative risks or absolute outcome rates)?	
Has an impact analysis demonstrated change in clinical behavior or patient outcomes as a result of using the instrument? (Level I)	
How well did the study guard against bias in terms of differences at the start (concealed randomization, adjustment in analysis) or as the study proceeded (blinding, cointervention, loss to follow-up)	
What was the impact on clinician behaviour and patient-important outcomes?	

Adapted from McMaster Evidence-based Clinical Practice Workshops and Users' Guide to the Medical Literature 3rd Ed.

Clinical Practice Guidelines Appraisal Form

Citation:

Is the clinical question clear and comprehensive?	
Is the recommended intervention clear and actionable?	
Is the alternative clear?	
Were all of the relevant outcomes important to patients explicitly considered?	
Was the recommendation based on the best current evidence?	
Are values and preferences associated with the outcomes appropriately specified?	
Do the authors indicate the strength of their recommendations?	
Is the evidence supporting the recommendation easily understood?	
For strong recommendations, is the strength appropriate?	
For weak recommendations, does the information provided facilitate shared decision making?	
Was the influence of the conflict of interests minimized?	

Adapted from McMaster Evidence-based Clinical Practice Workshops and Users' Guide to the Medical Literature 3rd Ed.

Economic Analysis Appraisal Form

Citation:

Are the results valid?	
Did the recommendations consider all relevant patient groups, management options, and possible outcomes?	
Did the investigators adopt a sufficiently broad viewpoint?	
Are results reported separately for relevant patient subgroups?	
Is there a systematic review and summary of evidence linking options to outcomes for each relevant question?	
Were costs measured accurately?	
Did investigators consider the timing of costs and outcomes?	
What are the results?	
What were the incremental costs and effects of each strategy?	
Do incremental costs and effects differ between subgroups?	
How much does allowance for uncertainty change the results?	
How can I apply the results to patient care?	
Are the treatment benefits worth the harms and the costs?	
Can I expect similar costs in my setting?	

Adapted from McMaster Evidence-based Clinical Practice Workshops and the Users' Guide to the Medical Literature 3rd Ed.

Strategies for teaching About Qualitative Research

The Teaching Opportunity:

Background:

Once you have identified a teachable topic for your team- you need to assess how much time you would like to spend on qualitative research methods and on the review of this paper. Each of the following 4 tips would lead up to a critical analysis of the qualitative study you have selected.

1. **15-minute tip:**
   You might begin by asking your group whether they can define and compare the characteristics of Quantitative vs. Qualitative Research with respect to the following categories. You can use the information in the User's Guides to help clarify the issues.

Table 1: Compare and Contrast Quantitative and Qualitative Research

What kind of information is being gained?	Quantitative Research	Qualitative Research
Type of Reasoning?		
Methods (Types of study designs used)		
Product of the work (i.e. what will be reported in your results section?)		
Measurements and Questions (Open vs Close ended)		
Statistical Considerations		
Sample Size Issues		
Sources of Bias		

2. **30-minute tip:**

   You might follow the exercise using table I (above) with a discussion surrounding Mr. W. Specifically ask, what are the things that we can do to improve the quality of Mr. W's time prior to his death? Have half of the group come up with Quantitative Outcomes and the other half come up with Qualitative Outcomes.

Quantitative Outcomes	How you would measure them	Qualitative Outcomes	How you would measure them

3. 60-90 minute workshop: Experiential learning about Qualitative Research

If you want to try something a little bit different, you could try an exercise that would really drive home the differences between the two research methodologies. Have your groups actually design and perform an experiment trying to clarify the following research question.

Research Objective: In search of a Good Breakfast: Observations of hungry medical residents—the Donut Trial.

Directions: Groups separated into qualitative and quantitative teams. You can use a coin toss to randomly assign people to their groups.

Materials: Two boxes of donuts, identical in content- one box per each team. (cookies or other food items would work as well as long as you have two identical sets)

Goal: Each team has 20 minutes to use their methodology to describe the donut breakfast in their group. The winning team will be that one which comes closest to "truth" about the breakfast provided as determined by an unbiased judge (to be picked by you!). Validity will be judged as the ***truthful correspondence of results with an objective reality.***

The qualitative team must use open-ended evaluations, inductive reasoning and describe the important characteristics of the breakfast. They should use their data to generate hypotheses and may be experiential.

The quantitative team must use close-ended evaluations, deductive reasoning with hypothesis testing. Their hypotheses should be based on their prior experiences concerning what characteristics would be important. Attempts must be made to avoid bias. They must be able to apply quantitative statistics to their measurements (not actually do the statistics, just be able to!)

Assessing Validity: Is there a truthful correspondence of results to a presumed "objective reality."

Methodologic rigor:

1. Is the study designed to address its research question and objectives appropriately?
2. Methods section: should include, participant selection, methods of data collection, comprehensiveness of data collection, procedures for analyzing data and corroborating findings.

User's Guide to the Medical Literature: Critical Appraisal Worksheet for Qualitative Research:
Citation: Steinhauser, KE. et. al. In search of a good death: observations of patients, families, and providers. Ann Int Med. 2000;132:825-832

Validity Criteria	
What is the Research Question?	
Were participants relevant to the research question? Was participant selection well-reasoned?	
Were the data collection methods appropriate for the research objectives and setting? (Field observation, interviews, document analysis)	
Was the data collection comprehensive enough to support rich and robust descriptions of the observed events?	
Were the data appropriately analyzed and the findings adequately corroborated?	
Study Results	
What are the results of the study? How evocative and thorough is the description?	
Applicability to patient care	
How do the results of this study help me care for the patients? Does this study help me understand the context of my practice?	
Does this study help me understand my relationships with my patients and their families?	

Adapted from McMaster Evidence-based Clinical Practice Workshops

Teaching Strategies

Teaching Strategies Introduction: Teaching Tips and Materials

Notes about learning and teaching this section's **Teaching Tips and Materials:**

1. **Filling the Tool Bag:**

   This is a series of teaching tips and strategies for teaching EBM that have been compiled from our collective teaching experiences, i.e., from the successes and failures of experienced EBM educators in Canada and the U.S. In addition to the actual tool-bag table is an article entitled "EBM Package Writer Suggestions" which outlines helpful hints on how to select articles and craft EBM sessions aimed at educators who wish to write and teach EBM sessions or workshops.

2. **Ridicularium Exemplario:**

   This is a teaching strategy that can help learners when you or they get 'stuck' in the details.

3. **Critical Appraisal Sheets:**

   This "teaching tips" section also includes an extra, blank set of critical appraisal sheets for all of the topics covered (for use in the future and for copying, etc.). In addition, you will also find critical appraisal sheets for future use with topics not covered at this year's conference.

4. **Curriculum Planner Workbook for Residency Training:**

   This workbook addresses the particular needs and objectives of residency education although most of the principles, guidelines, and strategies presented here are applicable to almost any teaching situation.

Tips for Creating Examples: Writer Suggestions to Consider

Background:

Writing effective teaching packages for evidence-based medicine is challenging. Teaching settings, venues, audiences, and experience levels of teachers and students vary widely. Nonetheless, there may be elements of a teaching package and approaches that increase the likelihood of a successful package. In order to explore methods for writing successful packages, we surveyed experienced teachers of evidence-based medicine who have had several years of experience with package writing. Specifically, we asked them to identify features of past packages that have produced success as well as features of past packages that have created stumbling blocks for learners. The following summary of suggestions may help guide you in writing your own teaching packages.

General Summary of findings:

Respondents agreed that the key to a successful package is a *methodologically strong paper as it is applied to a clinically interesting case*. In addition, it was felt that there should be adherence to certain 'rules' in terms of which methodology is highlighted in each package as well as the spectrum of material covered in each. Those package writers who responded felt overall that we need to *simplify* the packages and perhaps stick more closely to simply providing the clinical case, possibly teaching settings and the critical appraisal materials (including, of course, application).

Summary of particular points:

1. Format and material covered should be consistent. Suggestion: Package writers might consider the following *outline* for the flow of each teaching package.
    - Clinical Case / Teaching setting(s)
    - Clinical Question Formation
    - Brief comment on acquiring the evidence
    - Summary of material in package, section(s) of Users' Guides book where relevant methodological discussion is to be found
    - Critical Appraisal sheet filled in with application addressed in this context
2. Certain teaching packages should be consistent in study design used. Suggestions:
    - Therapy: RCT
    - Harm: Cohort or Case Control Study to allow the participants the opportunity to learn about and practice these study types
    - Meta-analysis: summary of therapy trials, as opposed to other types of questions
    - Prognosis: Case Control or (much more frequently) Cohort methodology (can be in the context of an RCT)
    - Diagnosis: Prospective cohort with comparison to a reference standard
3. General Strategies that have produced *successful* teaching packages in the past:
    - Papers with clear, transparent, excellent methods sections
    - Clinical cases that are engaging, that may provide a new perspective that clinicians were not aware of or that provide points for interesting consideration regarding application of evidence

4. General Strategies that have produced *difficult* teaching packages in the past:

    - Poor methodology of the paper
    - Unclear or incomplete methods sections
    - Beware of papers that have their methods described in another paper
    - Cases or papers that are too complex
    - Uninteresting or irrelevant clinical problems

5. *Fun* suggestions that might be tried in the future:

    - Inclusion of expected stumbling blocks and troubleshooting strategies particular to the specific package
    - Cases that use multiple versions of the same evidence (e.g. ACP journal club summaries as well as the entire article)

6. Feedback on *Diagnosis* Teaching Packages:

    - The paper should provide enough data to calculate or extract multiple levels of Likelihood Ratios (LRs).
    - Papers with dichotomous outcomes may not illustrate the power of LRs.
    - It is important to highlight the great impact of patient values on the application of test results.
    - It is valuable to include discussion of test threshold and action threshold.

7. Feedback on *Systematic Review / Meta-analysis* Teaching Packages:

    - The paper should focus on therapy and summaries of RCTs.
    - Forest plots are very useful for teaching concepts including heterogeneity.

8. Feedback on *Therapy* Teaching Packages:

    - It is generally necessary to choose a positive trial with at least one dichotomous variable. Otherwise, there isn't an opportunity to practice RRR, RD, NNT.
    - As one of the fundamental packages and as therapy is the most prevalent kind of paper in the literature, it makes sense to keep this one 'timely' and on the forefront of emerging therapies.
    - Applicability and generalisability should always be addressed.
    - Ideally, it will be easy to identify sub-groups at different baseline risk to get an accurate notion of the baseline risk and to facilitate using baseline risk and RRR to calculate NNT.
    - It might be fun to have a low-risk group that would lead one to question the treatment (moving the threshold NNT) in the setting of an appreciable harm/cost to balance the benefit.

9. Feedback on *Guideline* Teaching Packages:

    - Repeated difficulty has been linked to the very lengthy nature of many good guidelines (most are 20-50 pages or more!).
    - To get around lots of reading one might:
        a) Direct learners to key parts of the methods and results instead of the entire guideline.
        b) Select one recommendation in the guideline and focus on that one.
        c) Use resources and summaries available on the web (e.g. www.guidelines.gov).

Ridicularum Exemplario

The Challenge: To keep learners focused on the knowledge or skill set that you want to address and to avoid digressions over clinical passion…

Example: ***Has this ever happened to you?***

Scenario: You were asked to come to a meeting of nurses at your hospital to help them generate some excitement for EBM. Specifically, you want to help them get excited about clinical question formation. They have little to no background in EBM. You present a case of a hospitalized patient with delirium because most of them are inpatient nurses and you wanted the case to 'hit home' and be relevant to them. As you begin trying to draw clinical questions out of them, they begin arguing about the clinical scenario. They ask you endless questions about the clinical case, the providers involved, the color of the room that the patient was in, the size of the hospital gown…When it is clear that they cannot move past the 'facts' of the case, you sigh and try a different approach.

Teaching goal: to practice skills in clinical question formation
Stumbling block: the details of the case generated excitement but got in the way of your message
Possible alternative strategy: Ridicularum Exemplario

Core components of Ridicularum

- Derive an example that is completely ridiculous, but sets the stage for a discussion of the curricular points you want to make.
- The example can be non-medical or medical but it must avoid any link to reality to be effective.
- Can be used for any teaching quest
- Can be incredibly engaging and lots of fun!!

Ridicularia from Durham:

- The DONuT: (The **D**uke **O**bservational **N**utrition **T**rial)-

  Goal: to teach about qualitative methods. Residents are randomized to a qualitative methods arm or a quantitative methods arm. Once in randomly assigned groups, they are given a 'grant' from Dunkin' Donuts to design a trial to identify the qualities of a good donut breakfast. They MUST design the trial using the methodologies associated with their randomized groups.

- The Parking Ticket:

  Goal: to teach the principles of decision analysis. A scenario about a parking decision regarding parking in a nearby illegal spot vs. the farther away pay parking lot.

- The Dancing Ballerinas:

  Goal: to teach principles of risk. A scenario about risks involved with wearing different colors of ballet shoes and an intervention that can change the color of the shoe in a proportion of ballerinas.

- The Drive Home:

  Goal: to teach principles regarding prognosis. A scenario regarding a 'spirited discussion' between a husband and wife on the way home from a dinner party.
  Discussion surrounds risks involved with the driving behaviors of one of the spouses. (This scenario is based on a real interaction but the names have been changed to protect the innocent.)

- Messages from Mom:

  A series of trigger audio clips of a rather overprotective mom regarding the health and safety of her daughter. The goal is to practice clinical question formation in the context of these examples.

Filling the Tool Bag Strategies for making it fun and effective

Teaching Objectives	Setting	Strategy
Overall Objectives		• Always define your goals in advance and discuss them at the beginning of the session. • Limit yourself to three major goals per session (more will be lost, and you may risk losing all of them).
Clinical Relevance		• Begin and end with a patient case / clinical question.
	Keep the learners involved.	• Ask open-ended questions. • When someone asks a question, turn it back to the group, i.e., "what does the group think?" or "can anyone help out here?" (This also buys the tutor some time, in case the answer isn't immediately apparent to the tutor!)
Incorporation of Values into Decision-Making		• Openly discuss the portion of decision-making that remains intuitive, emotional, sensitive to the needs of the patient and the community in which they live.
Physical Needs	Recognize the limits of your learners' tolerance.	• Take time for a stretch. • Attend to food needs at all times. • Cookies are therapeutic.
Emotional Needs	Effective learning requires an emotionally-safe environment.	• Make sure everyone knows it is okay not to know! • Make sure everyone knows it is okay to disagree (agreeably)! • Be open about your own limitations! • Look for opportunities to compliment and praise. • Call "time-outs" when the group dynamic becomes tense. Ask the group what is happening with the process, and then try to return the focus to the problem/case.
	Capitalize on disagreement.	• Try to incorporate the rest of the group into the discussion. • Seize the right opportunity for wrap-up or closure.
Using Examples / Case Scenarios	Pre-test probability	• Use cases in order to capture very low-risk patient, very high-risk patient and very 'toss of a coin' risk patient.
	Diagnostic Tests	• Use extreme examples of cases to make people commit to a pre-test probability. • Use the examples to define cases that • are extremely low pre-test probability, extremely high pre-test probability, and the middle cases.
Language Pitfalls		• Don't use jargon / use simple plain language. • Ask those learners who use jargon to explain the term(s) to the rest of the group.
	General Strategies	• Vary the pace of your session by taking time out to give specific tasks or skills-practice to the group members. • Break your group into smaller working groups of 2-5 people.

		• Be very clear about what you want them to do (e.g., "assess the therapy validity criteria for this paper" or "take 5 minutes to review the methods and describe the patient population").
User-Friendly Statistics		• Emphasize the difference between "statistical significance" and "clinical importance."
User-Friendly Statistics	Calculations: NNT, LR	• Set the exercise up properly: 1. Set up the importance in the big picture. 2. Model the calculation (show them one). 3. Ask them to do another permutation. 4. Return to the original importance of the calculation. • Give defined small tasks and break into groups of 2 or 3 to do specific calculations.
Teaching Definitions	Confidence intervals, likelihood ratios, sensitivity, specificity etc.	• Try several different ways of defining the same thing - coming from different viewpoints • Relate it to a scenario or example so we can put the definition into a framework.
User-Friendly Statistics	Learning to Love a Likelihood Ratio	• Take home points: 1. You can utilize likelihood ratios for a range of values for a given diagnostic test – i.e. it is not a (+ or -) dichotomous measure. 2. Sensitivity / Specificity are properties of the test, Positive, and Negative. Predictive value is properties of a test in a population, LR allows you to apply the test directly to an individual patient. 3. The likelihood moves you from a pretest to a post-test probability. You must estimate pre-test probabilities first and acknowledge the uncertainty that goes along with that. • You don't have to draw the 2x2 table if you don't want to do calculations and just want to talk about LR. If you want to calculate, it is hard to do without the 2x2.
Directed Engagement of Learners		• Assign your learners to a point of view, a role or a specific task. • Clinical Practice Guideline – Randomize one-half of the room to 'love them' and one-half of the room to 'hate them.'
Silence	Groups or individuals who will not participate	• 16-second rule: Refrain from jumping in to fill the silence yourself! (May require longer for cultures in which participation is less accepted; may require shorter for people from New York!)
Discussion dominators		• Use "time-outs" when someone is dominating the discussion or 'knows it all.' Ask the group members to talk about individual responsibilities (for loud ones to lighten up and quiet ones to contribute more).

Using the Blackboard		• Plan in advance what you will do. • Put up one thing at a time and orient the group to what you are writing up there. • Have someone else write on the board so that you can focus on teaching and to optimize engagement. • Have the other learners direct their peer at the board in what to do.
Using Handouts	Using Tables and Figures	• Hand out only what you need. • Give brief orientation to the table. • Be specific in your direction of what you want people to see from the table.
	Reinforcing and providing resources for home	• If you hand something out, people will read it instead of listening to you; hand out take home papers at the end. • Do write down formulas and calculations if you believe in their importance. • Tell learners at the beginning that you will provide a handout so that they can focus on participating rather than taking notes.
Issues of Time Management	How to deal with questions that come up that you don't have time to answer?	• Answer quickly. • Canvas the Group, diagnose your learners. • Return to the "Parking Lot."
	Be Realistic	• You always have less time than you think you do. • Juicy issues are fun, but also juicy—they take time! Budget for it. • Stop from time to time to synthesize/summarize – for emphasis and to check in with learners.
	Trim the Fat	• Clearly define your teaching goals so that you can differentiate what you must have from what you may have from what should be cut.
	Save time for closure.	• Come to closure about the article and the clinical scenario. • Closure does not mean "unanimous agreement."
	Clinical Practice Guidelines, Decision and Economic Analysis	• Perspective is a key teaching point for each of these methodologies. • Divide into groups and assign perspectives (the managed care plan, the patient/family, the doctor's office, the hospital, society).
		• HAVE FUN! If you enjoy what you do, your learners will too.

Feedback: 6T's Teaching Tips

(Figurski, Patel, Keitz, Cook, EBM Workshop 2005)

Objective: To provide a touchstone to plan and evaluate each teaching session

Teaching Utility:

1) Provides tips to help plan teaching sessions (but is not exhaustive)
2) Provides framework for session evaluation (if they get too detailed)
3) Symbolizes group culture (can add logos for fun)
4) Can be modified (this used to be 4Ts in June 2005)

The 6 **T**'s	**Observations and Suggestions**
Time management (before & during)	
Teamwork (ensure engagement)	
Tools (use them)	
Triage (decide what you can't cover)	
Tone (respectful, safe)	
Take home message(s) (obligatory!)	
Other **T**hings…	

Background: What is a curriculum?

The ***definition of a curriculum*** is simply a ***planned educational experience***. It is a systematic planning approach that some educators use to help them articulate, achieve and evaluate educational goals.

Most medical education curriculums are based on a behaviorist model of education. In this model, there is the identification of specific learning objectives and an emphasis on the acquisition of competency of various knowledge and performance tasks. Increasingly EBM enthusiasts are aware that this approach is necessary but not sufficient to help our learners emerge as Evidence- Based practitioners. There are lessons from other educational models that educators interested in the area of EBM should explore, such as the social learning theory or cognitive theory. For example, social learning theory emphasizes the importance of a collaborative learning environment in which new learners are mentored through interactions with role models.

A successful curriculum is one that addresses the unique needs and goals of your learners and educators in your own setting. The information that follows is meant as a resource to help stimulate thought and planning in your home environment.

Steps to building your own Curriculum

There are several models for the creation of an academic curriculum. The following is an example of some of the steps to take to start you on your way.

1. Problem ID and General Needs Assessment e.g. “The world needs Evidence-Based Medicine”
2. Needs Assessment of Targeted Learners
    - Identify your targeted learners e.g. the interns, the residents, the urology dept. etc.
    - Determine specific needs of your targeted learners e.g. to question build, to search, to critically appraise a therapy article, to incorporate patient values into decision-making
3. Formulation of Curricular Goals and Specific Measurable Objectives
    - Who will do how much of what by when?
        1. Who? e.g. my interns
        2. Will do? e.g. will search the medical literature
        3. How much? e.g. for seven clinical questions
        4. Of what? e.g. pertaining to therapy questions
        5. By when? e.g. by next Wednesday
4. Educational Strategies Lecture, workshop, skills practice, self-directed learning, role modeling
5. Implementation of the Curriculum which room, what time, which kind of cookies will you serve
6. Evaluation and Feedback If you evaluate, it implies importance and allows improvement

Putting together a curriculum specific for teaching evidence-based clinical practice at home

The following pages go through some steps and guideposts that may help you to design a curriculum for evidence-based clinical practice at your home institutions. The information is divided into the following sections:

I. REMEMBERING THE BASICS
II. THE EVIDENCE BASED PRACTICE COMPETENCY GRID
III. QUESTION BUILDING
IV. SEARCHING THE MEDICAL LITERATURE
V. CRITICAL APPRAISAL STEPPING STONES
VI. APPLICATION TO PATIENT CARE
VII. TARGETED NEEDS ASSESSMENT

I. Remembering the Basics

In setting up your curriculum it is essential that you remember one of the golden rules of evidence-based clinical practice: evidence-based practice begins and ends with the patient. No matter how you put things together, the inclusion of clinical scenarios that are meaningful to the teachers and learners is essential to a successful curriculum. In planning your strategies, you should keep in mind the five steps that are linked together to promote the incorporation of best evidence into clinical practice. These steps are summarized as follows:

1. Question formulation derived from patient care
2. The selection of appropriate information resources and the identification of evidence from the medical literature
3. Critical appraisal (determining validity, evaluating the magnitude of results and determining applicability)
4. Returning to the clinical situation at hand to decide how to implement the evidence

II. The Evidence-Based Practice Competency Grid

The attached grid describes many of the specific knowledge, attitudes and skills that are necessary for the various steps in the evidence-based exercise. The grid can be used to identify jumping points for your curricular planning.

The grid is part of a work in progress by W. Scott Richardson, Mark Wilson, and Sheri Keitz. We encourage your feedback as you reflect on your learners' needs. Please pass along thoughts and comments on how we can improve the grid to Sheri Keitz (sheri.a.keitz@lahey.org)

III. Question Building

How to ask questions

Asking a clinical question that can be answered is one of the most important skills that you will teach your learners. A well-built clinical question derived from patient care is necessary to drive the subsequent steps in the process. The nature of the clinical question will drive the choice of information resources and focus an effective MEDLINE/PubMed search strategy. The kind of question that you ask (e.g. therapy vs prognosis) will determine the kind of research study that you will want to find (e.g. randomized controlled trial vs cohort study) as well as the critical appraisal skills that you will need to determine validity. Finally, the clinical questions will ultimately guide your use of the information retrieved when you decide whether that information is applicable to your individual case at hand. Given the central and essential role of the clinical question, the skills, attitudes and knowledge that relate to question building must be central and essential to any curriculum planning.

As with any skill, it needs to be modeled, taught, reinforced, and practiced. Learners must have feedback to help them understand why certain questions lead to fruitful searches and why some questions don't. Of equal importance, they must learn to prioritize which questions they should pursue with rigor and which questions should occupy less of their time. Without practice, feedback and prioritization skill our learners may become frustrated and disillusioned.

You may wish to dedicate some formal, academic time to a workshop dedicated to question building. In addition, many of us use question cards, such as the one enclosed in this Workbook to facilitate ongoing questioning. No matter how you choose to reinforce the importance of the clinical question, you will likely need to combine several teaching strategies to get your learners tuned into this critical skill.

IV. Searching the Medical Literature

MEDLINE (via PubMed or Ovid) Strategy Assessment Tool

The purpose of this instrument is to break down the searching process into the fundamental parts and concepts. A teacher can use it to define elements of the curriculum that are necessary for teaching effective searching skills. A learner can use it to evaluate their own searches to determine whether or not they have used the appropriate concepts to search the Medline database. This tool was created at Duke University by Connie Schardt, MLS, Chris Cabel, MD and Sheri Keitz, MD, Ph.D. We are testing the utility of this tools and are eager for feedback. Please send comments to Sheri Keitz (sheri.a.keitz@lahey.org) and Sarah Cantrell (sarah.cantrell@duke.edu).

I. Getting Started-- Fundamental Information to get you started	
What is the Clinical Question?	
What are the key elements of the question?	
II. Primary Guides to Effective Searching:	
Did the Search Strategy address all of the key elements of the Search Question?	
Was the question divided into concepts and each concept searched separately?	
Were sets combined correctly (i.e. appropriate use of Boolean logic: AND, OR)	
III. Secondary Guides to Effective Searching:	
Were MeSH terms used whenever possible?	
Were text words used when MeSH headings were not available or appropriate?	
IV. Additional Strategies for fine tuning a search:	
Was methodologic filtering used? (Including clinical query filters, publication types, or MeSH that address research methods)	
Were subheadings used?	
Was text word truncation and adjacency used?	
Were appropriate limits applied?	

V. Critical Appraisal Stepping Stones

All Critical Appraisal exercises are not creating equally: Part I

When selecting which type of articles to teach and discuss, learners' levels of sophistication, background and experience must be taken into account. For all learners, the questions most commonly asked related to therapy, followed by diagnostic testing, etiology/harm, and prognosis. Therefore, it will be our goal to sure that the learners are comfortable with the following topics. (Note: a more detailed listing of competencies is presented in the competency grid.)

Essential Tools	Critical points of knowledge
1. Question Building	4 parts of a clinical question and question 'map'
2. Acquiring the evidence	Accessing the literature, MEDLINE (via PubMed or Ovid) searching, electronic resources
3. Therapy	Number needed to treat; Risk/ Benefit Ratio
4. Diagnostic Testing	Likelihood ratios
5. Etiology/ Harm	Number needed to harm; Case-Control/ Cohort study methods
6. Prognosis	Bias; inception cohort; cohort study methods
7. Overview articles	Focused question, assessment of comprehensive search and study rigor
8. Clinical Practice Guidelines	Comprehensive look at options/ outcomes/ literature

Once learners are up to speed on those skills that relate to these topics, consideration can be made to moving on to other topics such as economic analysis and clinical decision analysis.

All Critical Appraisal exercises are not creating equally: Part II

When selecting specific articles for teaching and discussion, once again consideration must be made to the sophistication of the learners. For all learners, it is of critical importance that the articles be of clinical interest to them. For early learners, a more directed approach may be taken in ensuring that they select methodologically strong articles to optimize success for the critical appraisal exercise. When early learners select their own articles, there is the risk that many of the articles selected may be 'fatally' flawed and learners will not feel successful. It is important to avoid nihilism ("all articles are flawed; therefore, why should we do this?) In this setting, appropriate feedback and redirection are often necessary for naïve learners.

VI. Application to Clinical Care

Evidence-based medicine begins and ends with the patient or clinical situation. It is essential that issues of applicability be addressed for each paper reviewed. This allows discussion of the psychosocial context for care, issues of financial and / or social constraints, patient and societal values. Key concepts include 'generalizability', comfort with value-laden decision-making and strength of inference.

VII. Targeted Needs Assessment

Identification of resources and barriers

I. Who are my learners and when and where can I teach them? Identify each set of learners (e.g. interns, residents, fellows, etc.) you are targeting and the various settings you want to impact in your curriculum (e.g. ambulatory block rotation, ward service, morning report, journal club etc.) Be sure to identify the settings that are appropriate for each set of learners.

Learners:	Setting:

II. Who are my colleagues and what can I convince them to do?

Colleagues:	Tasks that they can help with:

III. What materials and resources do I require? Of those, what do I have and what do I need to get? Specifically consider faculty time, computer resources, space

Resource	Have it (Name it)	Need it (How can I get it)

IV. What are the barriers to your success and how are you going to solve them?

Barrier:	Solution:

Evidence Based Clinical Practice Competency Grid

	Knowledge	Attitudes	Skills
Assess: Assess the patient and the clinical scenario	- Basic clinical skills (H&P) and disease-specific knowledge	- Acceptance of knowledge deficits - Interest in self-improvement and in increasing fund of knowledge	- Formulation of clinical assessment of the individual patient - Assessment of learning needs as a health professional
Ask: Clinical Question Formation	- The anatomy of a question - The Map for Clinical Questions (e.g. therapy vs diagnostics vs prognosis)	- Curiosity - Comfort with Uncertainty - Value active learning - Learn to sort through which questions are of greatest importance to you or your patients.	- Formulate a question - Identify it's "location" on the Map for clinical questions - Identify the research method that will best answer the question (e.g. RCT vs cohort) - Create a hierarchy of importance for which questions you will invest time and energy in
Acquire: Selecting and getting the evidence			
A) Searching the Medical Literature	- MEDLINE as a database - MeSH vs. Textword / Keyword Searching - Methodologic filtering	- Fear of the volume of available medical literature - Deal with aversion to technologies	- Tie key elements of the question to specific search strategies - Timely and efficient searching - Boolean Logic: (And / Or / Not) - Explode, Focus, Truncation, Limits and Subheadings
B) EBM Resources	- Awareness of alternative resources Assessment of evidence-based nature of resources	- Willingness to explore numerous apps and resources - Value efficiency	- Computer literacy - Informatics
Appraise: Critical Appraisal	- Practical clinical epidemiology (User's Guide to the Medical Literature) - Primary Guides vs secondary guides for validity - Fatal Flaws - Survival Statistics - Creating a hierarchy of evidence	- Address innumeracy - Promote readiness to challenge authority (Challenge them to be critical, don't accept it as it must be so) - Promote enthusiasm and avoid Nihilism	- Identify which article will answer your question - Apply these skills real time settings
Apply: Application of Evidence to Clinical Care	- Getting the individual patient Number needed to treat (NNT) or Number needed to Harm (NNH) - Going from pre-test to post-test probabilities (likelihood ratios) - Strength of inference	- The recognition that value judgments are implicit in every clinical decision and are being made all the time by physicians based on the MDs and patient's value systems - Comfort with making value-based recommendations	- Solicit patient preferences - Assess co-morbidity - Consider social support of patient - Assess where the patient's value system lies on the paternalism to technical continuum
Evaluation of Performance	- Understanding the elements of quality measurement and self-assessment	- Addressing reluctance to assess one's own behavior to identify areas for improvement - Readiness and willingness to change one's own behavior	- Measure / Assess - Intervene - Re-measure /Reassess

Sample Evidence-Based Medicine Curriculum

Building a Curriculum in Evidence Based Medicine
Example of a Curriculum Document

Example:
A plan for an Evidence-Based Medicine Curriculum at Duke University /Durham VA Medical Center

Background: The following example is a curriculum-planning document from Duke University, NC, and the Durham VA PRIME Program. At Duke and the VA, we have been running EBM workshops for the past 6 years. In planning for the next academic year, we wanted to increase the use small groups of residents working closely to create mentorship opportunities between senior residents and interns. Please direct questions, thoughts or comments about this curriculum to Sheri Keitz (sheri.a.keitz@lahey.org)

1. General Needs Assessment:
   - General Goals of an EBM Curriculum: To implement a structured series of workshops to provide the fund of knowledge and skills necessary to incorporate the best evidence in the care of individual patients
   - Current Workshop series is well received but not uniformly delivered to all Medicine House officers
   - We have limited faculty to teach the house officers- if we want to do more teaching, we will need the house officers to do it
   - Task: To Disseminate the Curriculum to all house officers over the course of the three-year residency program using the residents to teach and mentor each other
2. Needs Assessment of Targeted Learners
   - INTERN Goals:
     - To Instruct them in Question Building and Basic Searching Skills
     - To provide role models and examples of EBM in practice
   - SECOND YEAR RESIDENT Goals:
     - To provide them with the teaching and leadership skills
     - To provide them with content and skills base to practice and teach EBM
     - To pair them with faculty mentors to co-teach sessions on EBM
   - THIRD YEAR RESIDENT Goals:
     - To allow them to teach and lead sessions on EBM independently
     - To give them the opportunity to be role models and mentors for interns
3. Formulation of Broad Curricular Goals
   - Interns will be exposed to question building and searching skills in two large group sessions (60 minutes each) lead by faculty
   - Interns will practice the EBM exercise in workshops lead by SECOND YEAR RESIDENTS and THIRD YEAR RESIDENTS (60 to 90-minute sessions)
   - SECOND YEAR RESIDENTS will be paired with faculty mentors on their Ambulatory Block Time and each will co-lead one EBM session and participate in the sessions lead by their peers.
   - THIRD YEAR RESIDENTS will participate in learning teams with interns and each will lead one EBM session and participate in the sessions lead by their peers.
4. Specific Measurable Objectives
   - All workshops will focus on the Competencies needed for the Practice of Evidence-Based Medicine (See Table)
   - Objectives of all Workshops:

After completing this workshop, you should be able to:

1. Create a pertinent answerable question from a clinical case scenario
2. Plan and carry out a directed Medline search that produces the articles to be discussed concerning the topic being discussed
3. Determine whether the article(s) give us valid information concerning the question at hand.
4. Determine whether the results are applicable to the patient in "your practice" case

5. Educational Strategies
   - Case Based Learning
   - Interactive Workshops
   - The Creation of Learning Teams (groups of SENIOR RESIDENTS and INTERNS)
   - Train the trainer (Faculty training the senior house officers to teach the interns)

6. Implementation of the Curriculum
   - Part I: Two didactic Sessions for interns: Question Building and Medline Searching
   - Part II: The Creation of Learning Teams:
     - 8 Teams (7 THIRD YEAR RESIDENTS, 7 Interns) who will work together for the entire year
     - 7 Workshop Sessions over the course of the year:
       - Each Workshop Topic has a faculty member as "Content Leader"
         - Therapy
         - Diagnosis
         - Evidence-Based Physical Exam
         - Prognosis
         - Harm
         - Systematic Review
         - Cost-Effectiveness Analysis
       - Content Leader's Job: To meet with the 7 THIRD YEAR RESIDENTS who are scheduled to lead the Learning Teams and prepare them to teach that topic
       - Session Facilitators: 1 Faculty Facilitator for 2 Learning Teams. The job of the session facilitator is to problem solve during the sessions, to keep people running on time and to gather the two groups together for a 10-minute wrap up at the end of each session.
   - Part III: Modification of Current EBM Workshops during Ambulatory Block time to create co-teachers (faculty + SECOND YEAR RESIDENT). These sessions will continue to be very structured sessions with significant faculty input and direction.

7. Evaluation and Feedback
   - Quality Improvement
   - Objective Measures of Learners skills, knowledge and attitudes
   - We will consider the development of case-based evaluations

How to choose critical appraisal worksheet

How do I know which critical appraisal sheet to use?

Answering the Clinical Question: Critical Appraisal- Survival Skills

A. Define the Clinical Question.

1. Patient, Population or Problem
2. Intervention, Prognostic Factor Exposure
3. Comparison Intervention (if appropriate)
4. Outcome you would like to measure or achieve
5. ***Type of Question you are asking***
6. ***Type of Study you would want to find***

What types of questions may we come up with?
(What Type of study would you want to find to answer that question?)

1. Clinical Examination	(Prospective cohort blind comparison to Gold Standard)
2. Diagnostic	Testing (Prospective cohort blind comparison to Gold Standard)
3. Prognosis	(Cohort Study>Case Control > Case Series)
4. Therapy	(RCT is really the only way we want to answer this question)
5. Etiology / Harm	(RCT> Cohort Study>Case Control>Case Series)
6. Prevention	(RCT> Cohort Study>Case Control>Case Series)
7. Cost	(Economic Analysis)
8. Self-Improve / Education	(RCT> Cohort Study)
9. Quality Improvement	(RCT> Cohort Study)
10. Health Services Research	(RCT> Cohort Study)
11. Differential Diagnosis	(Cohort Study)

Question to Consider:
Was the type of study the strongest that could have been performed under the circumstances?
If not… Could you have designed the study better?

Types of Studies:
Experimental Design:

Randomized Control Trial (RCT)
Guarantee Random distribution of factors known and unknown between groups aiming for equal distribution of factors between groups (remember that small studies may be random but not equal…)
This is an experimental method

Non- Experimental Design:

Cohort Study: follow one or more groups of individuals who have not yet suffered the adverse event and monitor the number of outcomes that occur over time. These need to be done when it is either not ethical or not practical to randomly assign patients to be "exposed" to something. Observational Design can be prospective or retrospective.
Case-Control Study: Collection of "cases" who have suffered the outcome and "controls" who have not. Investigators count the number of patients with a prognostic factor in the cases and the controls. These need to be done when the outcome of interest is rare or takes a long time to develop.
Case Series and Case Reports: Reports of patient scenarios that do not provide any comparison group.

B. Which critical appraisal sheet should you use for which study design?

Type of Sheet	Type of studies you would want to appraise with the sheet
Therapy	• Randomized Controlled Trial • Note this should be used for any "intervention" that has been tested by RCT including prevention, an RCT of a diagnostic test strategy, an RCT of a health services research intervention (e.g. change in clinic procedure), an RCT of an education intervention.
Diagnosis	• Prospective cohort, comparison to gold standard
Harm	• Case Control
Prognosis	• Cohort Study
Overview	• Systematic Review / Meta-analysis • Note: this is a summary methodology so you might have several different kinds of articles (Therapy RCT, Diagnosis cohort) BUT the critical appraisal is based on the way that the systematic review / meta-analysis was done.
Practice Guidelines	• Summary methodology based on a broad clinical topic instead of a focused clinical question • Note: Many different individual pieces of evidence will have contributed to the development of a practice guideline (often a Systematic Review of one or more of the key individual questions is associated) BUT the critical appraisal is based on the way the practice guideline was done.

C. Type of Cohort Study and "who" determines which group a participant is in?

Type of Sheet	Questions that will help you determine Validity of the Results
Observational Prospective Cohort to determine prognosis	• Impact of a Prognostic factor • Example: Individuals with ulcerative colitis and the development of colon cancer • Who decides? Fate.
Observational Prospective Cohort to determine prognosis	• Impact of an exposure • Example: Smokers and risk of lung cancer • Who decides? The patient/ person him or herself
Interventional Prospective Cohort to determine effect of an intervention on prognosis	• Impact of an intervention • Example: Steroid inhaler for asthma • Who decides? Random process (if Randomization is done correctly)

How to use the rational clinical examination education guides

It would be better if you began to teach others only after you yourself have learned something.

—Albert Einstein to Arthur Cohen, age 12, who submitted a paper to Einstein[i]

Teachers as learners; learners as teachers

Take a moment to recall teachers who truly influenced your understanding. What about those individuals made them great teachers? Did they simplify key concepts? Did they help you understand why you needed to know or connect ideas to show a common thread? Did they make it fun and interactive? Likely, it was a combination of these factors.

Successful teaching is not a purely spontaneous event, although great teachers will make it seem that way. Rather, effective teaching is deliberate: it follows from practice, patience, and planning. Thus, we created the Education Guides for the Rational Clinical Examination with a systematic approach that provides teachers with tools, tips, and ideas for making the contents of the book real, meaningful, and exciting to their learners.

We intentionally sought learners as collaborators for producing the Education Guides; approximately 90% of the chapters involved Duke University Department of Medicine residents or fellows, often as the lead author of the teaching materials. Learners' active involvement kept the Education Guides relevant to clinical trainees and generalist physicians. It also served to blur the lines between teachers and learners. To teach the material, the Education Guides authors first needed to learn the material! After the authors created the Education Guides, the Editors reviewed the slides for education content, flow and relevance. Finally, authors of the original Rational Clinical Examination article or its Update reviewed the Guide to assure that the content and emphasis were consistent with their prior work.

Both teachers and learners who are in a hurry may access the chapter content through the Education Guides. However, the Guides only complement, not replace the chapters of the Rational Clinical Examination. Readers or educators who choose to use the slides independently from the book will not be well-prepared, as they will miss some of the salient features.

Teaching Tip #1

Be familiar with core content. Preparing to teach is first a learning exercise. The teaching materials provide a summary of the key content to complement each chapter of the book.

Educators and learners are encouraged to spend time understanding the chapters that are particularly relevant to their everyday practice and teaching. Most educators can easily identify clinical conditions or findings that they repeatedly encounter. For example, an attending covering the inpatient hospital service may first become familiar with the chapter on deep vein thrombosis while a resident or medical student preparing for a clinical rotation in their emergency room might study in advance the chapter on acute dyspnea.

Teaching Tip #2

Prioritize your reading and learning to focus on clinical syndromes and settings you most frequently encounter. Identify topics that are predictably present in your clinical education environment and become familiar with the prior probabilities and likelihood ratios that apply.

What's in the education guides?

All the information summarized in the Education Guides comes directly from the original Rational Clinical Examination article or its Update. Each set of teaching materials begins with one or more clinical case scenarios and a series of questions to pose to learners. We always ask that learners explicitly state their impression of likelihoods or probabilities of the target conditions. This immediately forces teachers

into an environment of active engagement. Our interactive approach at the beginning of each Education Guide produces a skill building exercise whereby 1) learners think in terms of probability, 2) we promote retention and understanding by getting learners to name their educated guess and check this estimate against the evidence, and 3) we ultimately either reinforce or redirect their prior assumptions. Each set of teaching materials ends with the resolution of the clinical scenarios followed by "take home messages" and a "bottom line" for the chapter.

In addition to the clinical content and data in the Education Guides, we added teachers' notes and tips. Microsoft® Office PowerPoint® has a feature that allows each slide to be viewed with a Notes page. We used the Notes pages to identify basic principles, potential obstacles, and strategies for interactive teaching such as the use of slide animation. The Notes pages also provide teachers with an additional layer of information to enhance or further explain the bullet points or tables on the slides to assist in preparation for a teaching session.

Field testing of the Education Guides

The teaching strategies and stumbling blocks described as part of the Education Guides have been field tested for clarity and relevance among Duke Internal Medicine residents at the Durham Veterans Affairs Medical Center. The general interactive teaching strategies were developed and tested over the past 5-10 years by experts participating in McMaster University and Duke University workshops on teaching evidence-based practice. Although some of the teaching strategies have been published as a part of the evidence-based teaching tips project[ii] the strategies have not undergone formal testing and thus reflect expert opinion.

Planning for delivery: Maximizing interactivity in classroom settings

The Education Guides use the primary format of PowerPoint® slides. However, educators are encouraged to avoid a purely didactic lecture style for this content (or any content, for that matter!) In fact, if the guides are only used for didactic presentations, we will have failed in our attempt to encourage strategies to address learner engagement. The teaching tips focus on two key elements of engagement: relevance and interactivity.

We systematically designed the case scenarios by including clinical elements that highlight key points in each chapter. When more than one case is used, the cases compare and contrast different aspects of clinical decision making. For example, a chapter may include cases that reflect examples of low, intermediate and high prior probability of disease. This allows the educator to illustrate the impact of differing prior probability on posttest probability. Similarly, the cases might reflect differing patient characteristics that require consideration of action thresholds for pursuing additional tests or implementing a treatment strategy.

Teaching Tip #3

Focus on relevance using a case-based format. Clinical examination is a skill that should be taught in context. In classroom settings, anchor your teaching with the clinical cases provided in the materials, or cases of relevance to you and your learners.

Educators are encouraged to view the PowerPoint® slides as part of a preparatory toolkit, rather than 'readymade' slides set for presentation. In fact, educators may most effectively use the materials for teaching without actually projecting a single slide. For example, a very effective classroom teaching session might involve describing the 3 cases that are used for the chapter on community-acquired pneumonia in adults. The learners could be broken up into 3 small groups, each assigned to discuss one of the patient cases. As a first step, the learners could be asked to discuss the cases without any further information and to estimate the probability that each patient has community-acquired pneumonia.

These estimates can be written on a flip chart and discussion can take place about what elements went into the decision making for each group.

Teaching Tip #4

Ask learners to commit to probabilities. Creating a safe learning environment in which learners can discuss their initial assessments is important to help them build on their base knowledge in each session.

The educator can then discuss the concept of the likelihood ratio, the prior probability of disease and the individual likelihood ratios for the clinical examination items. The educator should ask whether this information would alter the learners' assessment of the likelihood of disease.

Teaching Tip #5

Focus on learner interaction, minimizing or eliminating didactic teaching. The teaching tools should serve as substrate interactive teaching. Educators can combine some didactic teaching for emphasis, orientation and reinforcement of principles, but primary strategies should be interactive.

In the example of community-acquired pneumonia, the likelihood ratios for the individual findings are not very useful so this creates an opportunity for discussing multivariate analyzes and clinical prediction rules. The learners could be given summaries of the Diehr multivariate model and the Heckerling clinical prediction model and break into their 3 groups to repeat their discussion on the assessment of the probability of pneumonia.

Teaching Tip #6

Focus the clinical examination on useful items while pointing out findings that may not be helpful. As learners familiarize themselves with likelihood ratios, educators should identify clinical examination that impacts those assessments and also dispel myths about examination items that don't.

Using the Diehr multivariate model as an example, the educator could have each group come up with the likelihood ratio to apply to their patient. The educator can then hand out a blank nomogram such as the one that is included in the PRIMER (A Primer on the Precision and Accuracy of the Clinical Examination: Introduction) and have the trainees plot the results for each case. The nomogram serves as a visual tool to illustrate the concept that a likelihood ratio, applied to a prior probability, generates the posttest probability of disease.

Teaching Tip #7

Use the nomograms to illustrate movement from pretest to posttest probabilities. The nomogram can be a valuable visual and conceptual tool when working through individual patient cases.

Planning for delivery: Finding ways to practice the skill of taking history and physical examination

For optimal professional development, trainees require orientation to key concepts of clinical examination, skills practice and feedback from their faculty mentors and role models. Some of the topics are particularly suited for classroom practice of clinical exams, such as examination of the shoulder or knee. To facilitate these learning exercises, the Rational Clinical Examination and Education Guides have pictures and illustrations that highlight the technical points of clinical maneuvers.

Some of the clinical examination items will require teaching directly in the context of patient care, for example, learning to assess central venous pressure or ascites. Patient-centered teaching can be complemented by bringing the evidence from the Education Guides to a teaching session or rounds either proceeding or following a trip to the bedside. Educational assignments written on a prescription pad, called education prescriptions, encourage the learner to follow up on a finding identified during

ward rounds or clinic sessions. The prescription should note the clinical question and suggest the relevant Rational Clinical Examination articles. Just as in clinical medicine where the physician follow-up on the treatment response, the education prescriber should follow-up with the learner at their next clinical session.

Teaching Tip #8

Find ways to practice hands-on maneuvers with your learners in both the classroom and clinical settings. Learners need to practice and receive feedback on clinical examination. When patients are respectfully included, skills can be refined in the clinical environment as well as in the classroom setting.

A barrier when trying to incorporate evidence into clinical teaching is discomfort with statistical principles and the frequent misperception that evidence-based practice is equivalent to statistics. Throughout the Education Guides, we included descriptions of common statistical concepts that the teachers and learners will encounter. The PRIMER includes an entire set of descriptions and teaching strategies that can serve to assist educators in confronting these principles.

However, we emphasize that while understanding the statistical concepts is helpful, it should not take away from the clinical application and focus of a teaching session. The Education Guides should help educators and learners become better users of the medical literature on the clinical examination, rather than to become statisticians or researchers.

Teaching Tip #9

Avoid statistical jargon. The goal is to assist learners to become effective at incorporation of evidence into clinical practice.

More than any other goal in the creation of the Education Guides for the Rational Clinical Examination, we hope that educators and learners will have fun with the book and the tools it supplies. The Rational Clinical Examination series provides a plethora of teaching opportunities that uniquely combine evidence and the medical literature with direct patient care. Enjoy yourself and good things will follow.

Teaching Tip #10

Have fun. Strive to employ new and creative ways to engage your learners, involve them in the excitement of clinical decision making and the fun of lifelong learning.

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[i] Calaprice, Alice. The new quotable Einstein. Princeton, NJ: Princeton University Press; 2005, p. 66.

[ii] Wyer PC, Keitz SA, Hatala R, Hayward R, Barratt A, Montori V, Wooltorton E, Guyatt G. Tips for learning and teaching evidence-based medicine: introduction to the series. CMAJ. 2004;171(4):347-348.

Educational Prescription: Duke University Medical Center

What is an educational prescription?

It's a learning assignment co-written by preceptor and learner that

- specifies the clinical problem that generated the question.
- states the question, in all 4 of its key elements (PICO).
- specifies who is responsible for answering it.
- reminds everyone of the deadlines for answering it (taking into account the urgency of the clinical problem that generated it).

Why use educational prescriptions?

Questions arise but they don't always get followed up because clinical constraints and fatigue often limit our opportunities. Using educational prescriptions helps us keep track of our questions so that we can answer them when an opportunity develops. Prescriptions help learners practice the important lifelong habit of using EBM on a daily basis to help answer clinical questions.

Tips for using educational prescriptions

- Include them as a regular part of rounds, sign-outs, and supervision.
- Ask your learners to write educational prescriptions for you.
- Keep a copy of the prescription for you and the service's chief resident.
- Use the opportunity to introduce the learner to a University librarian who can help 'fill' the prescription.
- Follow-up with the learner on the pre-specified date.
  Resources: https://guides.mclibrary.duke.edu/ebm/home

(Modified from http://www.cebm.utoronto.ca/practise/formulate/eduprescript.htm)

Patient's Initials/MRN: _____ Learner: _____

Clinical Question

Patient or Problem:
Intervention:
Comparison:
Outcome(s):
Type of question:
Study type:

Date and place to present findings: _____

Presentation will cover:

1. search strategy
2. search results
3. appraisal of the validity of the evidence
4. appraisal of the importance of the results
5. application to the patient/problem
6. your self-evaluation of this process

First copy to learner; second copy to attending; third copy to chief resident

Appendix

Critical Appraisal Forms

Clinical Decision Analysis

Citation:

Is this a newly derived instrument? (Level IV)	
Was validation restricted to the retrospective use of statistical techniques on the original database? (If so this is a Level IV rule). If so, consider the following standards for initial development of a decision rule.	
Were all important predictors included in the derivation process?	
Were all important predictors present in significant proportion of the study population?	
Does the rule make clinical sense?	
Has the instrument been validated? (Level II or III) If so, consider the following:	
Did validation include prospective studies on several different populations from that used to derive it (II), or was it restricted to a single population (III)?	
How well did the validation exercise meet the following criteria? Were the patients chosen in an unbiased fashion and do they represent a wide spectrum of severity of disease?	
Was there a blinded assessment of the criterion standard or outcome event (or was the outcome all-cause mortality) for all patients?	
Was there an explicit and accurate interpretation of the predictor variables and the actual rule without knowledge of the outcome?	
Was there 100% follow-up of those enrolled?	
How powerful is the rule (in terms of sensitivity and specificity; likelihood ratios; proportions with alternative outcomes; or relative risks or absolute outcome rates)?	
Has an impact analysis demonstrated change in clinical behavior or patient outcomes as a result of using the instrument? (Level I)	
How well did the study guard against bias in terms of differences at the start (concealed randomization, adjustment in analysis) or as the study proceeded (blinding, cointervention, loss to follow-up)	
What was the impact on clinician behaviour and patient-important outcomes?	

Adapted from McMaster Evidence-based Clinical Practice Workshops and Users' Guide to the Medical Literature 3rd Ed.

Clinical Practice Guidelines

Citation:

Is the clinical question clear and comprehensive?	
Is the recommended intervention clear and actionable?	
Is the alternative clear?	
Were all of the relevant outcomes important to patients explicitly considered?	
Was the recommendation based on the best current evidence?	
Are values and preferences associated with the outcomes appropriately specified?	
Do the authors indicate the strength of their recommendations?	
Is the evidence supporting the recommendation easily understood?	
For strong recommendations, is the strength appropriate?	
For weak recommendations, does the information provided facilitate shared decision making?	
Was the influence of the conflict of interests minimized?	

Adapted from McMaster Evidence-based Clinical Practice Workshops and Users' Guide to the Medical Literature 3rd Ed.

Diagnostic Test

Citation:

How serious is the risk of bias?	
Did participating patients constitute a representative sample of those presenting with a diagnostic dilemma?	
Did investigators compare the test to an appropriate, independent reference standard?	
Were those interpreting the test and reference standard blind to the other results?	
Did all patients receive the same reference standard irrespective of the results of the test results?	
What are the results?	
What likelihood ratios were associated with the range of possible test results?	
How can I apply the results to patient care?	
Will the reproducibility of the test results and its interpretation be satisfactory in my clinical setting?	
Are the study results applicable to patients in my practice?	
Will the test results change my management strategy?	
Will patients be better off as a result of the test?	

Adapted from McMaster Evidence-based Clinical Practice Workshops and Users' Guide to the Medical Literature 3rd Ed.

Differential Diagnosis

Citation:

How serious is the risk of bias?	
Did the study patients represent the full spectrum of those with this clinical problem?	
Was the diagnostic evaluation definitive?	
What are the Results?	
What were the diagnoses and their probabilities?	
How precise are the estimates of disease probability?	
How can I apply the results to patient care?	
Are the study patients and clinical setting similar to mine?	
Is it unlikely that the disease possibilities or probabilities have changed since this evidence was gathered?	

Adapted from McMaster Evidence-based Clinical Practice Workshops and Users' Guide to the Medical Literature 3rd Ed.

Citation:

Are the results valid?	
Did the recommendations consider all relevant patient groups, management options, and possible outcomes?	
Did the investigators adopt a sufficiently broad viewpoint?	
Are results reported separately for relevant patient subgroups?	
Is there a systematic review and summary of evidence linking options to outcomes for each relevant question?	
Were costs measured accurately?	
Did investigators consider the timing of costs and outcomes?	
What are the results?	
What were the incremental costs and effects of each strategy?	
Do incremental costs and effects differ between subgroups?	
How much does allowance for uncertainty change the results?	
How can I apply the results to patient care?	
Are the treatment benefits worth the harms and the costs?	
Can I expect similar costs in my setting?	

Adapted from McMaster Evidence-based Clinical Practice Workshops and the Users' Guide to the Medical Literature 3rd Ed.

Harm, Cohort Study

Citation:

How serious is the risk of bias?	
Aside from the exposure of interest, did the exposed and control groups start and finish with the same risk for the outcome?	
Were the patients similar for prognostic factors that are known to be associated with the outcome (or did statistical adjustment level the playing field)?	
Were the circumstances and methods for detecting the outcome similar?	
Was the follow-up sufficiently complete?	
What are the Results?	
How strong is the association between exposure and outcome?	
How precise is the estimate of risk?	
How can I apply the results to my patient care?	
Were the study patients similar to patients in my practice?	
Was follow-up sufficiently long?	
Is the exposure similar to what might occur in my patient?	
What is the magnitude of the risk?	
Are there any benefits that are known to be associated with the exposure?	

Adapted from McMaster Evidence-based Clinical Practice Workshops and Users' Guide to the Medical Literature 3rd Ed.

Harm, Case-Control Study

Citation:

How serious is the risk of bias?	
Did the cases and control group have the same risk (chance) for being exposed in the past?	
Were cases and controls similar with respect to the indication or circumstances that would lead to exposure?	
Were the circumstances and methods for determining exposure similar for cases and controls?	
What are the Results?	
How strong is the association between exposure and outcome?	
How precise is the estimate of risk?	
How can I apply the results to my patient care?	
Were the study patients similar to patients in my practice?	
Was follow-up sufficiently long?	
Is the exposure similar to what might occur in my patient?	
What is the magnitude of the risk?	
Are there benefits that offset the risks of the exposure?	

Adapted from McMaster Evidence-based Clinical Practice Workshops and Users' Guide to the Medical Literature 3rd Ed.

Prognosis

Citation:

How serious is the risk of bias?	
Was the sample of patients' representative?	
Were patients classified into prognostically homogeneous groups?	
Was follow-up sufficiently complete?	
Were outcome criteria objective and unbiased?	
What are the results?	
How likely are the outcomes over time?	
How precise are the estimates of likelihood?	
How can I apply the results to patient care?	
Were the study patients and their management similar to those in my practice?	
Was the follow-up sufficiently long?	
Can I use the results in the management patients in my practice?	

Adapted from McMaster Evidence-based Clinical Practice Workshops and Users' Guide to the Medical Literature 3rd Ed.

Qualitative Methods

Citation:

Is the qualitative research relevant?	
Are the results credible?	
Is there a specific qualitative research method cited?	
Was the choice of participants or observations explicit and comprehensive?	
Were research ethics approval obtained?	
Was data collection sufficiently comprehensive and detailed?	
Were the data analyzed appropriately and the findings corroborated adequately?	
What are the results?	
What are the results?	
How can I apply the results to patient care?	
How does the study offer helpful theory?	
Does the study help me to understand the context of my practice?	
Does the study help me to understand social phenomena in my practice?	

Adapted from McMaster Evidence-based Clinical Practice Workshops and Users' Guide to the Medical Literature 3rd Ed.

Screening

Citation:

How serious is the risk of bias?	
Is there randomized controlled trial evidence that the intervention benefits people with asymptomatic disease?	
What are the recommendations, and will they help you in caring for patients?	
Were the data identified, selected, and combined in an unbiased fashion?	
What are the benefits?	
What are the harms?	
How do benefits and harms compare in different people and with different screening strategies?	
What is the effect of individuals' values and preferences?	
What is the effect of uncertainty associated with the evidence?	
What is the cost-effectiveness?	

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Citation:

Assessing the Credibility of the Systematic Review Process	
Did the review address a focused clinical question (i.e. can be framed in PICO format)?	
Was the search for relevant studies detailed and exhaustive?	
Were selection and assessment of studies reproducible?	
Was the risk of bias of the primary studies assessed?	
Did the review address possible explanations of between-study differences in results using prespecified hypotheses?	
Did the review describe a process to assess confidence in effect estimates? (e.g. GRADE tool to assess quality of the body of evidence)	
Understanding the Summary Estimate of a Meta-analysis	
What is the magnitude of treatment effect? (what is the pooled estimate?)	
How precise are the results? (i.e. confidence interval around the pooled estimate)	
Rating Confidence in the Estimates (the Quality of a Body of Evidence)	
How serious is the risk of bias in the body of evidence?	
Are the results consistent across studies? (i.e. heterogeneity or inconsistency)	
Do the results directly apply to my patient? (i.e. PICO, generalizability, indirectness)	
Is there a concern about reporting or publication bias?	
Are there reasons to increase or decrease the confidence of the rating? (*Randomized trials start high and observational studies start low)*	
Overall, what is the quality of the body of evidence by outcome? (High, moderate, low, very low)	
How can I apply the results to my patient care?	
Did the review present results that are ready for clinical application? (e.g. patient important outcomes, absolute benefit /risk)	
Are the study patients similar to my patient and are likely benefits worth potential harms/costs?	

Adapted from McMaster Evidence-based Clinical Practice Workshops and the Users' Guide to the Medical Literature 3rd Ed.

Therapy

Citation:

How serious is the risk of bias?	
Did intervention and control groups start with the same prognosis?	
Were patients randomized?	
Was randomization concealed?	
Were patients in the study groups similar at baseline with respect to prognostic factors?	
Was prognostic balance maintained as the study progressed?	
To what extent was the study blinded?	
Were groups prognostically balanced at the study's conclusion?	
Was follow-up complete?	
Were patients analyzed in the groups to which they were randomized?	
Was the trial stopped early?	
What are the results?	
How large was the treatment effect?	
How precise was the treatment effect?	
How can I apply the results to my patient care?	
Were the study patients similar to my patient?	
Were all patient-important outcomes considered?	
Are the likely benefits worth the potential harms and costs?	

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Citation:

How serious is the risk of bias?	
Did intervention and control groups begin the study with a similar prognosis?	
Were patients randomized?	
Was randomization concealed?	
Were patients similar at baseline with respect to known prognostic factors?	
Was prognostic balance maintained as the study progressed?	
Were patients, caregivers, collectors of outcome data, adjudicators of outcome, and data analysts aware of group allocation?	
Were groups prognostically balanced at the study's conclusion?	
Was follow-up complete?	
Was the trial stopped early for benefit?	
Were patients analyzed in the groups to which they were randomized?	
Did the investigators guard against an unwarranted conclusion of non-inferiority?	
Was the effect of the standard treatment preserved?	
Did the investigators analyze patients according to the treatment they received, as well as to the groups to which they were assigned?	

What are the results?	
How large was the treatment effect?	
How precise was the estimate of the treatment effect?	
How can I apply the results to my patient care?	
Were the study patients similar to my patient?	
Were all patient-important outcomes considered?	
Are the likely advantages of the novel treatment worth the potential harms and costs?	

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