Welcome!

Objectives:

This tutorial is intended for any health care practitioner or student who needs a basic introduction to the principles of Evidence-Based Practice.

Upon completion of this self-paced tutorial, you will be able to:

- define Evidence-Based Practice (EBP)
- identify the parts of a well-built clinical question
- identify EBP searching strategies that could improve PubMed retrieval
- identify key issues that help determine the validity of the results of a study

How to use this Tutorial

This tutorial includes five major units. We recommend that you go through them in sequence. They will give you an overview of the Evidence-Based Practice process as well as give you an opportunity to practice with new cases. The five units are:

- **What is EBP?** provides definitions and explains the steps in the EBP process.
- **Clinical Question** introduces you to a patient, illustrates the anatomy of a good clinical question, and defines the types of questions and studies.
- **Literature Search** constructs a well-built literature search and identifies potentially relevant articles.
- **Evaluating Evidence** identifies criteria for determining the validity of a study.
- **Testing your Knowledge** gives you an opportunity to practice the EBP process with several new cases.
- **Glossary** links to definition of EBP terms from the Centre for Evidence-Based Medicine in Toronto
- **References** points you to additional sites for continued study of the EBP process. and defines some of the terms used in EBP.
- **Feedback** gives you the opportunity to provide feedback about this tutorial. We ask that you take the time to give us your thoughts and suggestions for improvement. All comments will be greatly appreciated.

Within this tutorial, you have several opportunities to follow links to other Web sites. The external sites open in a new window. Close the second window to return to this tutorial.

We hope this tutorial will be easy to use as well as give you a foundation for the practice of Evidence-Based Practice (EBP). Allow approximately 1 hour to complete the tutorial and 1 practice case.

Click on this **link** for a pdf file of the tutorial for printing.

Credits

This tutorial was developed by Connie Schardt (connie.schardt@duke.edu), Duke University Medical Center Library and Jill Mayer (Jill_Mayer@unc.edu), University of North Carolina at Chapel Hill Health Sciences Library. Robert Ladd, HSL at UNC-Chapel Hill, designed the graphics and the user interface. Please contact Connie Schardt (919-660-1124) or Jill Mayer (919-966-0960) if you have difficulties using this program.

Thank you to Sheri Keitz, MD, Senior Associate Dean for Faculty Affairs, University of Miami Miller School of Practice, and Christopher Klipstein, MD, Clinical Associate Professor, Department of Medicine, UNC-Chapel Hill, who served as content evaluators for the original project.

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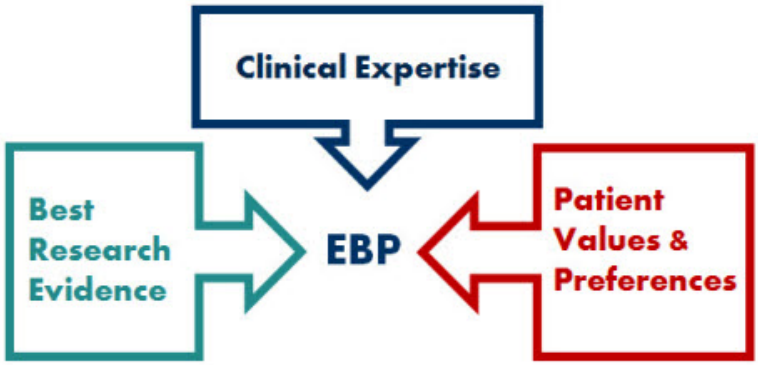
What is Evidence-Based Practice (EBP)?

The EBP Process

The most common definition of EBP is taken from Dr. David Sackett, a pioneer in evidence-based practice. EBP is "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient. It means integrating individual clinical expertise with the best available external clinical evidence from systematic research." (Sackett D, 1996)

EBP is the integration of clinical expertise, patient values, and the best research evidence into the decision making process for patient care. Clinical expertise refers to the clinician's cumulated experience, education and clinical skills. The patient brings to the encounter his or her own personal and unique concerns, expectations, and values. The best evidence is usually found in clinically relevant research that has been conducted using sound methodology. (Sackett D, 2002)



The evidence, by itself, does not make a decision for you, but it can help support the patient care process. The full integration of these three components into clinical decisions enhances the opportunity for optimal clinical outcomes and quality of life. The practice of EBP is usually triggered by patient encounters which generate questions about the effects of therapy, the utility of diagnostic tests, the prognosis of diseases, or the etiology of disorders.

Evidence-Based Practice requires new skills of the clinician, including efficient literature searching, and the application of formal rules of evidence in evaluating the clinical literature.

The Steps in the EBP Process

ASSESS the patient	**1. Start with the patient -- a clinical problem or question arises from the care of the patient**
ASK the question	**2. Construct a well built clinical question derived from the case**
ACQUIRE the evidence	**3. Select the appropriate resource(s) and conduct a search**
APPRAISE the evidence	**4. Appraise that evidence for its validity (closeness to the truth) and applicability (usefulness in clinical practice)**
APPLY: talk with the patient	**5. Return to the patient -- integrate that evidence with clinical expertise, patient preferences and apply it to practice**

Self-evaluation	6. Evaluate your performance with this patient

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The Well-Built Clinical Question

ASSESS the Patient	**1. Start with the patient: a clinical problem/question arises from the care of the patient**
ASK the Question	**2. Construct a well-built question derived from the case**

EBM always begins and ends with the patient. To begin this process, consider the following clinical scenario:

This is a new patient who recently moved to the area to be closer to her son and his family. Pauline is 73 years old and has a history of congestive heart failure and a left ventricular ejection fraction of 40%.

She has been hospitalized twice within the last 9 months for worsening of heart failure. She is extremely diligent about taking her medications (enalapril, aspirin and simvastatin) and wants desperately to stay out of the hospital. She lives alone with several cats and a canary.

She comes to you with an advertisement for Avapro (Irbesartan) and wants to know if this would help her. You are not certain of the evidence supporting this drug. You decide to research this question before discussing this with her during the next visit.

The next step in this process is to take the identified problem and construct a question that is relevant to the case and is phrased in such a way as to facilitate finding an answer.

Anatomy of a good clinical question: PICO

PICO is a mnemonic that helps one remember the key components of a well focused question. The question needs to identify the key problem of the patient, what treatment you are considering for the patient, what alternative treatment is being considered (if any) and what is the outcome you want to avoid or promote.

P = Patient or problem

How would you describe a group of patients similar to yours? What are the most important characteristics of the patient? This may include the primary problem, disease, or co-existing conditions. Sometimes the sex, age or race of a patient might be relevant to the diagnosis or treatment of a disease.

I = Intervention, prognostic factor, or exposure

Which main intervention, prognostic factor, or exposure are you considering? What do you want to do for the patient? Prescribe a drug? Order a test? Order surgery? What factor may influence the prognosis of the patient? Age? Co-existing problems? Has the patient been exposed to something? Asbestos? Cigarette smoke?

C = Comparison

What is the main alternative to compare with the intervention? Are you trying to decide

between two drugs, a drug and no medication or placebo, or two diagnostic tests? Your clinical question does not always need a specific comparison.

O = Outcomes

What can you hope to accomplish, measure, improve or affect? What are you trying to do for the patient? Relieve or eliminate the symptoms? Reduce the number of adverse events? Improve function or test scores?

The structure of the PICO might look like this:

Patient / Problem	heart failure, ejection fraction 40%, elderly
Intervention	irbesartan or avapro
Comparison, if any	none, placebo, standard care
Outcome	primary: reduce need for hospitalization; secondary: reduce mortality

For our patient, the clinical question might be:

In elderly patients with heart failure and an ejection fraction of 40%, is irbesartan effective in reducing the need for rehospitalization?

Two additional elements of the well-built clinical question are the **type of question** and the **type of study**. This information can be helpful in focusing the question and determining the most appropriate type of evidence or study.

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Types of Questions and Types of Studies

Types of Questions:

Two additional elements of the well-built clinical question are the **type of question** and the **type of study**. This information can be helpful in focusing the question and determining the most appropriate type of evidence or study.

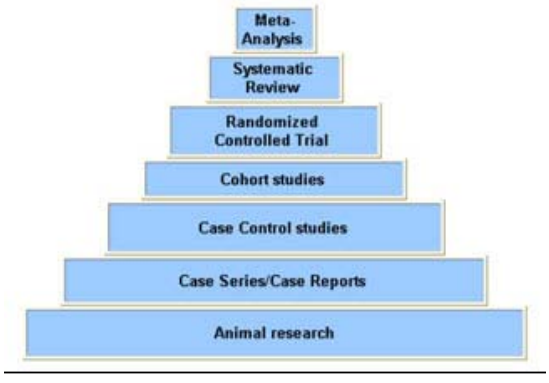
The most common types of questions related to clinical tasks are:

Diagnosis	how to select and interpret diagnostic tests
Therapy	how to select treatments to offer patients that do more good than harm and that are worth the efforts and costs of using them
Prognosis	how to estimate the patient's likely clinical course over time and anticipate likely complications of disease
Harm/Etiology	how to identify causes for disease (including iatrogenic forms)

The type of question is important and can help lead you to the best study design:

Type of Question:	**Suggested best type of study**:
Diagnosis	prospective, blind comparison to a gold standard
Therapy	RCT > cohort > case control > case series
Prognosis	cohort study > case control > case series
Harm/Etiology	RCT > cohort > case control > case series
Prevention	RCT > cohort study > case control > case series
Clinical Exam	prospective, blind comparison to gold standard
Cost Benefit	economic analysis

Types of Studies:



This is one example of what is often referred to as the evidence pyramid or the hierarchy of study design. It is used to illustrate the evolution of the literature. The base of the pyramid is where information usually starts with an idea or laboratory research. As these ideas turn into therapies and diagnostic tools they are tested with laboratory models, then in animals, and finally in humans. The human testing may begin with volunteers and go through several phases of clinical trials before the therapy or diagnostic tool can be authorized for use within the general population. Controlled trials are then done to further test the effectiveness and efficacy of a drug or therapy. As you move up the pyramid the amount of available literature decreases, but increases in its relevance to the clinical setting. As you move up the pyramid the study design is more rigorous and allows for less bias or systematic error that may distract you from the truth.

Case series and **Case reports** consist of collections of reports on the treatment of individual patients or a report on a single patient. Because they are reports of cases and use no control groups with which to compare outcomes, they have no statistical validity.

Case control studies are studies in which patients who already have a specific condition are compared with people who do not have the condition. The researcher looks back to identify factors or exposures that might be associated with the illness. They often rely on medical records and patient recall for data collection. These types of studies are often less reliable than randomized controlled trials and cohort studies because showing a statistical relationship does not mean than one factor necessarily caused the other. **A case control study starts with patients who already have the outcome and looks backwards to possible exposures.**

Cohort studies take a large population who are already taking a particular treatment or have an exposure, follow them forward over time, and then compare them for outcomes with a similar group that has not been affected by the treatment or exposure being studied. Cohort studies are observational and not as reliable as randomized controlled studies, since the two groups may differ in ways other than in the variable under study. **A cohort study starts with the exposure and follows patients forward to an outcome.**

Randomized, controlled clinical trials are carefully planned projects that introduce a treatment or exposure to study its effect on real patients. They include methodologies that reduce the potential for bias (randomization and blinding) and that allow for comparison between intervention groups and control groups (no intervention). A randomized controlled trial is an experiment and can provide sound evidence of cause and effect. **A RCT randomly assigns the exposures and then follows patients forward to an outcome.**

Systematic Reviews usually focus on a clinical topic and answer a specific question. An extensive literature search is conducted to identify studies with sound methodology. The studies are reviewed, assessed, and the results summarized according to the predetermined criteria of the review question.

A **Meta-analysis** will thoroughly examine a number of valid studies on a topic and combine the results using accepted statistical methodology to report the results as if it were one large study. The Cochrane Collaboration has done a lot of work in the areas of systematic reviews and meta-analysis.

The pyramid serves as a guideline to the hierarchy of study design. You may not always find the highest level of study to answer your question. In the absence of the best evidence, you then need to consider moving down the pyramid.

Other types of Clinical trials:

Clinical Trial [Publication Type]
Work that is the report of a pre-planned clinical study of the safety, efficacy, or optimum

dosage schedule of one or more diagnostic, therapeutic, or prophylactic drugs, devices, or techniques in humans selected according to predetermined criteria of eligibility and observed for predefined evidence of favorable and unfavorable effects. While most clinical trials concern humans, this publication type may be used for clinical veterinary articles meeting the requisites for humans. Specific headings for specific types and phases of clinical trials are also available.

Clinical Trial, Phase I [Publication Type]
Work that is the report of a pre-planned, usually controlled, clinical study of the safety and efficacy of diagnostic, therapeutic, or prophylactic drugs, devices, or techniques based on a small number of healthy persons and conducted over the period of about a year in either the United States or a foreign country.

Clinical Trial, Phase II [Publication Type]
Work that is a report of a pre-planned, usually controlled, clinical study of the safety and efficacy of diagnostic, therapeutic, or prophylactic drugs, devices, or techniques based on several hundred volunteers, including a limited number of patients, and conducted over a period of about two years in either the United States or a foreign country.

Clinical Trial, Phase III [Publication Type]
Work that is a report of a pre-planned, usually controlled, clinical study of the safety and efficacy of diagnostic, therapeutic, or prophylactic drugs, devices, or techniques after phase II trials. A large enough group of patients is studied and closely monitored by physicians for adverse response to long-term exposure, over a period of about three years in either the United States or a foreign country.

Clinical Trial, Phase IV [Publication Type]
Work that is a report of a planned post-marketing study of diagnostic, therapeutic, or prophylactic drugs, devices, or techniques that have been approved for general sale after clinical trials, phases I, II, and III. These studies, conducted in the United States or a foreign country, often garner additional data about the safety and efficacy of a product.

Cross-sectional studies describe the relationship between diseases and other factors at one point in time (usually) in a defined population. Cross sectional studies lack any information on timing of exposure and outcome relationships and include only prevalent cases.

Qualitative Research answers a wide variety of questions related to human responses to actual or potential health problems.The purpose of qualitative research is to describe, explore and explain the phenomena being studied.

Studies that show the efficacy of a diagnostic test are called **prospective, blind comparison to a gold standard** study. This is a controlled trial that looks at patients with varying degrees of an illness and administers both diagnostic tests -- the test under investigation and the "gold standard" test -- to all of the patients in the study group. The sensitivity and specificity of the new test are compared to that of the gold standard to determine potential usefulness.

Retrospective cohort (or historical cohort) follows the same direction of inquiry as a cohort study. Subjects begin with the presence or absence of an exposure or risk factor and are followed until the outcome of interest is observed. However, this study design uses information that has been collected in the past and kept in files or databases. Patients are identified for exposure or non-exposures and the data is followed forward to an effect or outcome of interest.

For our patient, the clinical question is:

In elderly patients with heart failure and an ejection fraction of 40%, is irbesartan effective in reducing the need for rehospitalization?

It is a **therapy question** and the best evidence would be a **randomized controlled trial (RCT)**. If we found numerous RCTs, then we might want to look for a systematic review.

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The Literature Search

ACQUIRE the evidence	**3. Select the appropriate resource(s) and conduct a search**

In the previous module, we learned how to construct a well-built clinical question. Using that question, we will move on to the literature search.

For our patient, the clinical question is:

In elderly patients with heart failure and an ejection fraction of 40%, is irbesartan effective in reducing the need for rehospitalization?

It is a therapy question and the best evidence would be a randomized controlled trial (RCT). If we found numerous RCTs, then we might want to look for a systematic review.

Constructing a well-built clinical question can lead directly to a well-built search strategy. Note that you may not use all the pieces of the well-built clinical question in your MEDLINE strategy. In the following example we did not use the term "ejection fraction 40%" or "elderly." We also did not include the word ***therapy***. Instead we used the publication type, **randomized controlled trial**, to get at the concept of treatment. However, you may consider the issue of ejection fraction or age later when you review the articles for applicability to your patient.

PICO	Clinical Question	Search Strategy
Patient / Problem	heart failure, elderly ejection fraction 40%	heart failure Limit to Aged
Intervention	irbesartan or avapro	irbesartan OR avapro
Comparison (if any)	none, placebo, standard care	
Outcome	reduce need for hospitalization reduce mortality	 hospitalization
Type of Question	therapy	(see below)
Type of Study	RCT	Clinical Query - Therapy/narrow or Limit to randomized controlled trial as publication type

Select a resource

The practice of Evidence-Based Practice advocates that clinicians search the primary literature to find answers to their clinical questions. There are literally millions of published reports, journal articles, correspondence and studies available to clinicians. Choosing the best resource to search is an important decision. Large databases such as PubMed/MEDLINE will give you access to the primary literature. Secondary resources such as ACP Journal Club,

Essential Evidence, FPIN Clinical Inquiries, and Clinical Evidence, will provide you with an assessment of the original study. These are often called "pre-appraised" or EBP resources. The Cochrane Library provides access to systematic reviews which help summarize the results from a number of studies.

Detailed list of resources for practicing EBP

To quickly find an answer, we might first look at an appraised resource, such as *ACP Journal Club*. *ACP Journal Club's* general purpose is to select from the biomedical literature articles that report original studies and systematic reviews that warrant immediate attention by physicians attempting to keep pace with important advances in internal medicine. These articles are summarized in value-added abstracts and commented on by clinical experts. Studies included in this small database are relevant, newsworthy and critically appraised for study methodology.

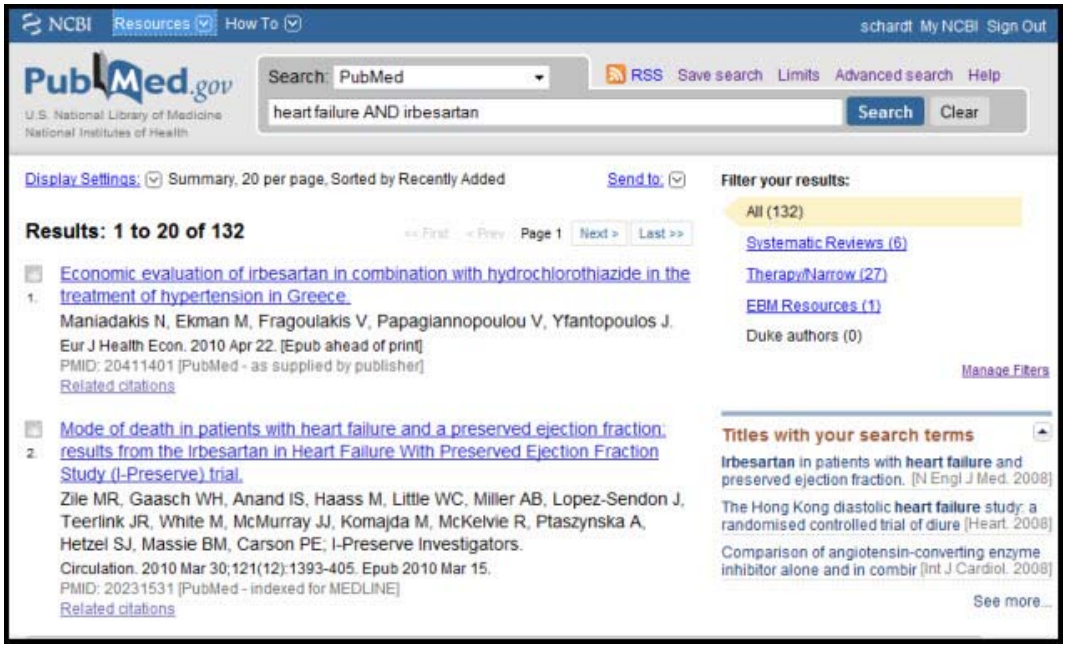
A search of irbesartan and heart failure identified this citation: *2008 - Irbesartan did not reduce all-cause death or CV hospitalization in heart failure and preserved ejection fraction.* This is a critical appraisal of Massie BM, Carson PE, McMurray JJ, et al. Irbesartan in patients with heart failure and preserved ejection fraction. N Engl J Med. 2008;359:2456-67. The conclusion is that Irbesartan did not reduce the composite endpoint of mortality or hospitalization for cardiovascular events in patients with heart failure and preserved ejection fraction.

If you do not have access to *ACP Journal Club* or other EBP resources you will need to do the search in PubMed or MEDLINE. PubMed/MEDLINE is a very large database with over 17 million citations. You will need your focused question and search strategy for this database.

Conduct the search in PubMed:

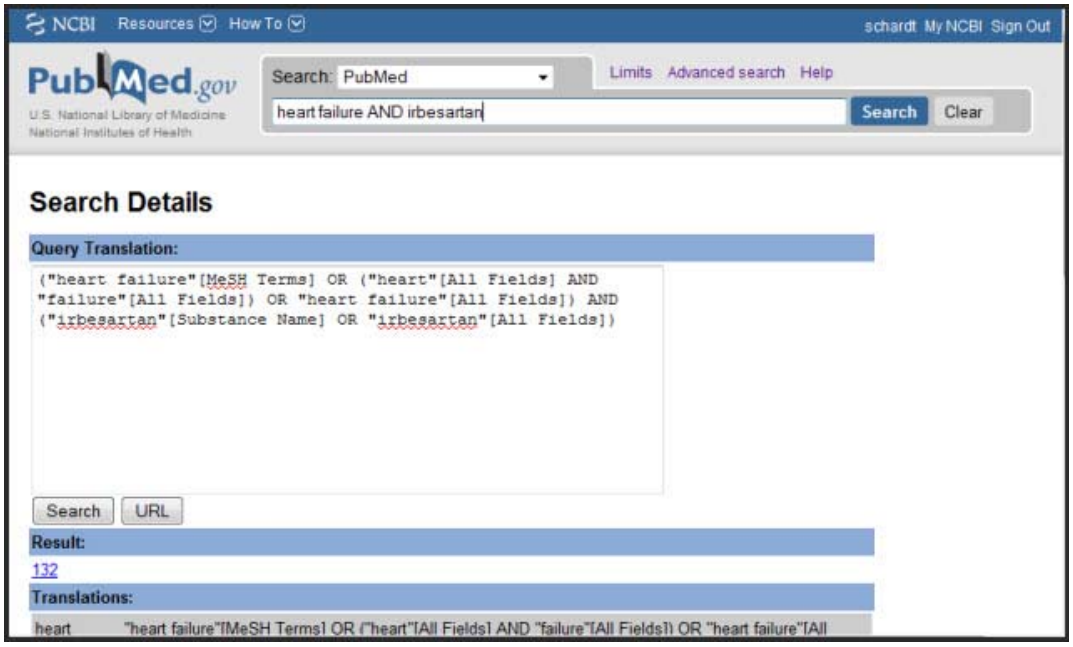
Step 1: Use PICO to formulate the search strategy; start with the Patient problem and Intervention

Enter the term for the patient problem and the intervention: **heart failure AND irbesartan**. PubMed attempts to map your terms to appropriate Medical Subject Headings (MeSH). MeSH is the standard terminology used by the indexer and helps find articles on the topic, regardless of the exact wording used by the authors.

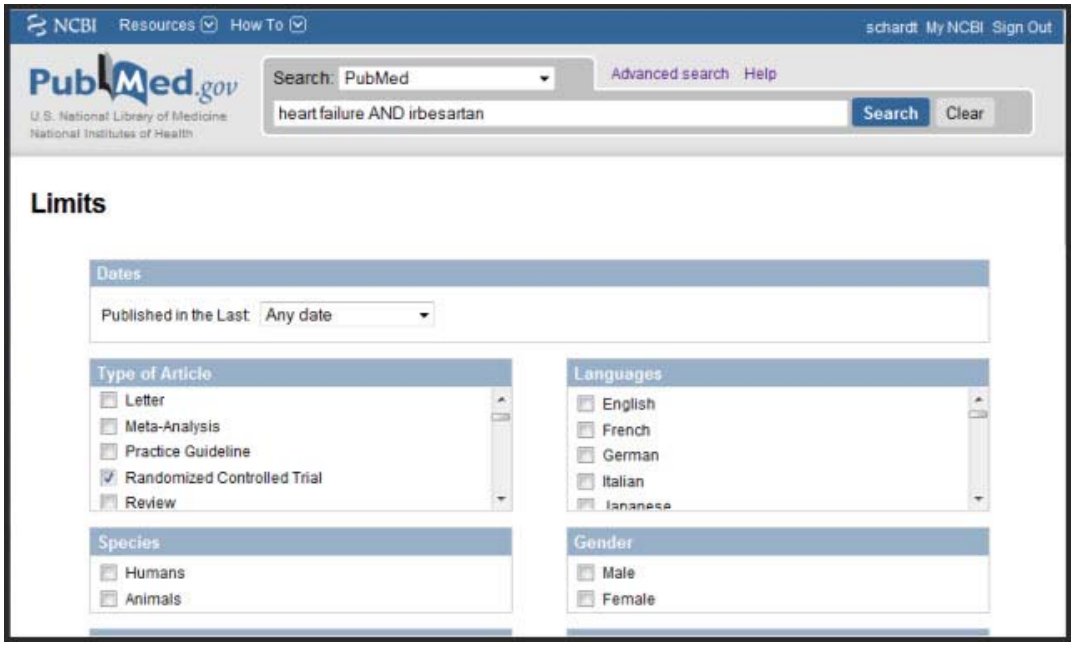


Step 2. Look at Details to verify MeSH terms

Click on **Details** (from the *Advanced search* page) to see the terms that PubMed actually used in its search. You want to be sure PubMed found the appropriate MeSH terms. PubMed will automatically also search for your terms as words in the title and abstract. **Heart failure** is a MeSH term and **irbesartan** is a Substance Name.

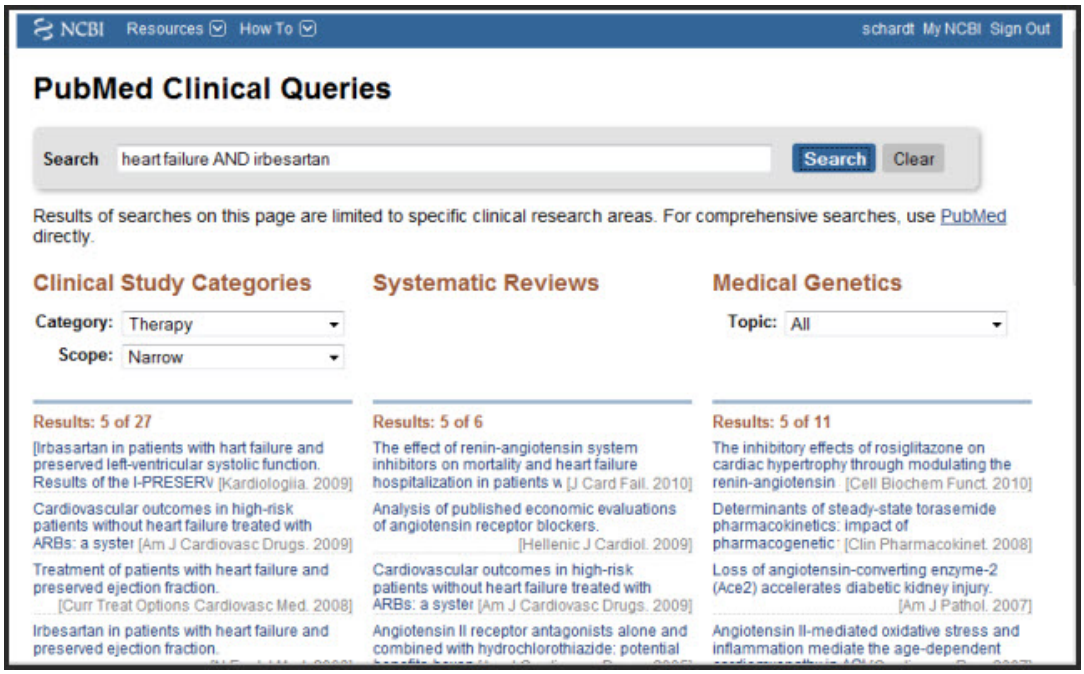


Step 3. Limit to appropriate study design
This is a therapy question. We know from the previous discussion that the best evidence for a therapy question is a randomized controlled clinical trial (RCT). Use the Limits function from the advanced page to limit to RCT as a publication type.



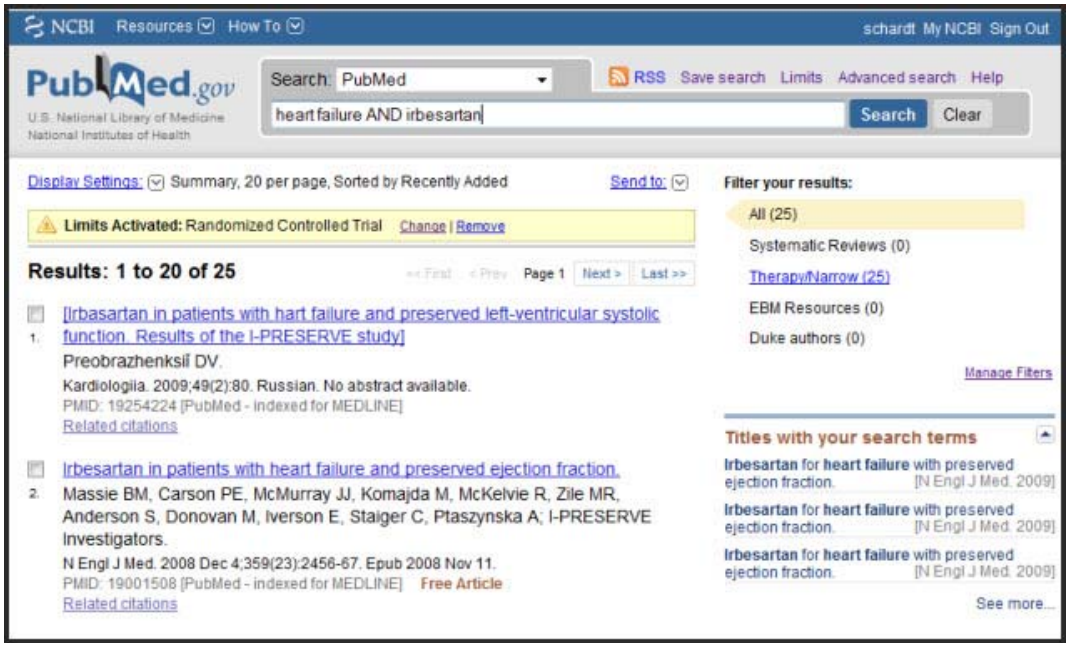
You can also use the **Clinical Queries** function to limit the results to study methodologies relevant to therapy questions. Copy your last search strategy **heart failure AND irbesartan**. Click on *Advanced search*; near the end of the page under ***More Resources*** there will be a link to the **Clinical Queries**. Paste the search strategy in the Clinical Query search box and select the type of question (***Therapy***) and the default ***narrow, specific search***. Click on GO.

You may get more results using the **Clinical Queries**.



Step 4. Review the results

Both methods limit your results to RCTs. The second citation is the Massie article that we found in ACP Journal Club.



If you are not familiar with searching PubMed, you may want to review the PubMed tutorials at http://www.nlm.nih.gov/bsd/disted/pubmedtutorial

The next step is to read the study and determine if the methodology is sound so that we can consider the results.

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Resources for Practicing EBP

EBP Resources | EBP Websites

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What is the ideal resource?

- Located in the clinical setting
- Easy to use
- Fast, reliable connection
- Comprehensive /Full Text
- Effective search engine
- Provides primary data

EBP Resources

The following is a list of some valuable resources for practicing EBP. Descriptions of these resources appear below the list.

- **Summaries of the primary evidence**
  ACP Journal Club | Clinical Evidence | Dynamed | eMedicine | Essential Evidence Plus | FPIN Clinical Inquiries | UpToDate
- **Databases**
  PubMed | Cochrane Library | Center for Reviews & Dissemination:
- **Electronic textbooks and libraries**
  AccessMedicine | ACPMedicine | ACP PIER | Stat!Ref | First Consult MDConsult
- **Meta-Search Engines**
  SUMSearch | TRIP Answers

Summaries of the primary evidence:

ACP Journal Club
This Web site comprises a 10-year archive (from 2000 to the present) of the cumulative electronic contents of "ACP Journal Club", with recurrent weeding of out-of-date articles. The content is carefully selected from over 100 clinical journals through reliable application of explicit criteria for scientific merit, followed by assessment of relevance to medical practice by clinical specialists. For more information, go to http://www.acpjc.org

Clinical Evidence
Clinical Evidence describes the best available evidence from systematic reviews, RCTs, and observational studies were appropriate. For more information, go to:
http://www.clinicalevidence.bmj.com/

Dynamed
Dynamed is a point-of-care reference resource designed to provide clinicians with the best available evidence to support clinical decision-making. For more information, go to
http://www.ebscohost.com/dynamed/aboutUs.php

eMedicine
eMedicine is a point-of-care medical reference available to health care professionals on the internet. The evidence-based content is updated regularly by more than 8,000 physician or health care provider authors and editors. For more information go to:
http://www.emedicine.com

Essential Evidence
Essential Evidence is a one-stop reference that includes best-evidence answers to your most important clinical questions concerning symptoms, diseases, and treatment. For more information go to: http://www.essentialevidenceplus.com/

FPIN Clinical Inquiries
Clinical Inquiries provides answers to clinical questions by using a structured search, critical appraisal, clinical perspective, and rigorous peer review. FPIN Clinical Inquiries deliver best evidence for point of care use. For more information see FPIN at http://www.fpin.org

UpToDate
UpToDate is an evidence-based, peer reviewed information resource available via the Web, desktop/laptop computer, and PDA/mobile device. For more information, see UpToDate at http://www.uptodate.com

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Databases:

PubMed
PubMed comprises more than 19 million citations for biomedical articles from MEDLINE and life science journals. Citations may include links to full-text articles from PubMed Central or publisher web sites. FREE Access PubMed at: http://www.ncbi.nlm.gov

Cochrane Library
The Cochrane Library contains high-quality, independent evidence to inform healthcare decision-making. It includes reliable evidence from Cochrane and other systematic reviews, clinical trials, and more. Cochrane reviews bring you the combined results of the world's best medical research studies and are recognized as the gold standard in evidence-based health care. For more information see Cochrane Library at: http://www.thecochranelibrary.com/view/0/index.html

Center for Reviews and Dissemination:
The databases DARE, NHS, EED and HTA assist decision-makers by identifying and describing systematic reviews and economic evaluations, appraising their quality, and highlighting their relative strengths and weaknesses. For more information see CRD at: http://www.crd.york.ac.uk/crdweb

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Electronic textbooks and libraries:

AccessMedicine
AccessMedicine is an online resource that provides students, residents, clinicians, researchers, and all health professionals with access to "Harrisons Online". For more information see Access Medicine at http://www/accessmedicine.com

ACP Medicine
ACP Medicine is a publication from the American College of Physicians. Online content includes "Best New Evidence" and drug information. ACP Medicine is also available from Stat!Ref. For more information see ACP Medicine at http://www.acpmedicine.com

ACP PIER
ACP PIER is an online clinical tool that provides evidence-based clinical guidance improve to clinical care. PIER has contracted with McMaster University to conduct continual literature searches on topics contained in PIER. For more information, go to: http://pier.acponline.org/index.html

First Consult
First Consult provides evidence based answers at the point of care. For more information see First Consult http://www.mdconsult.com/das/pdxmd/lookup/0/

MD Consult
MD Consult offers comprehensive information available in one online resource. Access includes full-text articles, medical references across a wide range of specialties, clinically relevant drug information, and over 10,000 patient handouts. For more information see MD Consult at http://www.mdconsult.com/

Stat!Ref
STAT!Ref is a collection of online electronic resources for healthcare professionals. For more information see Stat!Ref at http://www.statref.com/

Meta-Search Engines:

SUMSearch
SUMSearch selects the best resources for your question, formats your question for each resource, and makes additional searches based on results. For more information see SUMSearch at http://sumsearch.uthscsa.edu/

TRIP Answers:
The TRIP Database is a clinical search tool designed to allow health professionals to rapidly identify the highest quality clinical evidence for clinical practice. For more information see TRIP Answers at http://www.tripdatabase.com/

EBM Websites:

*JAMA*Evidence
Fundamental tools for understanding and applying the medical literature and making clinical diagnoses. http://www.jamaevidence.com

NC Evidence-Based Medicine Education Center of Excellence:
http://library.ncahec.net/ebm/pages/index.htm

Duke University Medical Center Library: Evidence-Based Medicine (EBM):
http://www.mclibrary.duke.edu/subject/ebm

Lamar Soutter Library, UMass Medical School, Worcester, MA
Evidence-Based Medicine Tutorials: http://library.umassmed.edu/EBM/tutorials/index.cfm

University of Illinois at Chicago, Evidence Based Medicine: Finding the Best Clinical Literature:
http://www.uic.edu/depts/lib/lhsp/resources/ebm.shtml

University of Rochester Medical Center, Nesbit Guide to Evidence Based Resources:
http://www.urmc.rochester.edu/hslt/miner/digital_library/evidence_based_resources.cfm

Centre for Evidence-Based Medicine http://www.cebm.net/

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Evaluating the Evidence

APPRAISE the evidence	**4. Appraise that evidence for its validity (closeness to the truth) and applicability (usefulness in clinical practice)**

Step 1: Evaluating the Validity of a Therapy Study

We have now identified current information which can answer our clinical question. The next step is to read the article and evaluate the study.

There are three basic questions that need to be answered for every type of study:

- Are the results of the study valid?
- What are the results?
- Will the results help in caring for my patient?

This tutorial will focus on the first question: are the results of the study valid? The issue of validity speaks to the "truthfulness" of the information. The validity criteria should be applied before an extensive analysis of the study data. If the study is not valid, the data may not be useful.

The evidence that supports the validity or truthfulness of the information is found primarily in the study methodology. Here is where the investigators address the issue of bias, both conscious and unconscious. Study methodologies such as randomization, blinding and accounting for all patients help insure that the study results are not overly influenced by the investigators or the patients.

Evaluating the medical literature is a complex undertaking. This session will provide you with some basic criteria and information to consider when trying to decide if the study methodology is sound. You will find that the answers to the questions of validity may not always be clearly stated in the article and that clinicians will have to make their own judgments about the importance of each question.

Once you have determined that the study methodology is valid, you must examine the results and their applicability to the patient. Clinicians may have additional concerns such as whether the study represented patients similar to his/her patients, whether the study covered the aspect of the problem that is most important to the patient, or whether the study suggested a clear and useful plan of action.

Note: The questions that we used to test the validity of the evidence are adapted from work done at McMaster University. See the References/Glossary unit: 'Users' Guides to the Medical Literature.'

Read the following article to determine if the article meets the criteria for validity.

Massie BM, Irbesartan in patients with heart failure and preserved ejection fraction. N Engl J Med. 2008 Dec 4;359(23):2456-67. PubMed PMID: 19001508. **Click here** to view or print a copy of the article that is marked to show you where the validity information is found.

Are the results valid?

These questions address the issues of validity and the methodology of the study:

Did intervention and control groups start with the same prognosis?

1. Were patients randomized?

The assignment of patients to either group (treatment or control) must be done by a random allocation. This might include a coin toss (heads to treatment/tails to control) or use of randomization tables, often computer generated.

Research has shown that random allocation comes closest to insuring the creation of groups of patients who will be similar in their risk of the events you hope to prevent. Randomization balances the groups for known prognostic factors (such as age, weight, gender, etc.) and unknown prognostic factors (such as compliance, genetics, socioeconomics, etc.). This reduces the chance of over-representation of any one characteristic within the study groups.

More information: Treatment allocation in controlled trials: why randomise? Douglas G Altman & J Martin Bland BMJ 1999;318:1209-1209 (1 May)

> Massie article: Study procedures: Eligible patients were treated with single-blind placebo for 1 to 2 weeks before randomization; those who successfully completed this run-in phase and whose condition remained clinically stable were randomly assigned in a 1:1 ratio to receive irbesartan or matching placebo. The randomization schedule was implemented with the use of an interactive voice-response system. [page 2457]

2. Was group allocation concealed?

The randomization sequence should also be concealed from the clinicians and researchers of the study to further eliminate conscious or unconscious selection bias. Concealment (part of the enrollment process) ensures that the researchers cannot predict or change the assignments of patients to treatment groups. If allocation is not concealed it may be possible to influence the outcome (consciously or unconsciously) by changing the enrollment order or the order of treatment which has been randomly assigned. Concealed allocation can be done by using a remote call center for enrolling patients or the use of opaque envelopes with assignments. This is different from blinding which happens AFTER randomization.

More information: Concealing treatment allocation in randomised trials Douglas G Altman & Kenneth F Schulz BMJ 2001;323:446-447 (25 August)

> Massie article: Study procedures: The randomization schedule was implemented with the use of an interactive voice-response system. [Page 2457] This methodology would conceal the randomized allocation scheme.

3. Were patients in the study groups similar with respect to known prognostic variables?

The treatment and the control group should be similar for all prognostic characteristics except whether or not they received the experimental treatment. This information is usually displayed in Table 1, which outlines the baseline characteristics of both groups. This is a good way to verify that randomization resulted in similar groups.

> Massie article: Table 1: The study groups did not differ significantly in baseline characteristics. [Page 2460]

Was prognostic balance maintained as the study progressed?

4. To what extent was the study blinded?

Blinding means that the people involved in the study do not know which treatments were given to which patients. Patients, researchers, data collectors and others involved in the study should not know which treatment is being administered. This eliminates bias and preconceived notions as to how the treatments should be working. When it is difficult or even

unethical to blind patients to a treatment, especially a surgical treatment, then a "blinded" clinician or researcher is needed to interpret the results.

More information: Blinding in clinical trials and other studies Simon J Day & Douglas G Altman BMJ 2000;321:504 (19 August)

> Massie article: Patients were blinded using a matched placebo. All investigators and committee members who were involved in the conduct of the study (except for members of the data and safety monitoring board) were unaware of study-group assignments. Data analysts were blinded. The sponsors or a contract research organization collected the trial data, which were then analyzed at the Statistical Data Analysis Center at the University of Wisconsin, Madison, independently of the sponsors and according to a predefined statistical analysis plan. Adjudicators were blinded. Deaths and hospitalizations were adjudicated by members of an independent end-point committee who were unaware of study-group assignments and used pre specified criteria. [Page 2458]

Were the groups prognostically balanced at the study's completion?

5. Was follow-up complete?

The study should begin and end with the same number of patients in each group. Patients lost to the study must be accounted for or risk making the conclusions invalid. Patients may drop out because of the adverse effects of the therapy being tested. If not accounted for, this can lead to conclusions that may be overly confident in the efficacy of the therapy. Good studies will have better than 80% follow-up for their patients. When there is a large loss to follow-up, the lost patients should be assigned to the "worst-case" outcomes and the results recalculated. If these results still support the original conclusion of the study then the loss may be acceptable.

> Massie Article: The mean follow-up time was 49.5 months, and the trial included 16,798 patient-years of follow-up. At the end of the study, vital-status data were not available for 29 patients (1%) in the irbesartan group and 44 patients (2%) in the placebo group. [Page 2459]

6. Were patients analyzed in the groups to which they were first allocated?

Anything that happens after randomization can affect the chances that a patient in a study has an event. Patients who forget or refuse their treatment should not be eliminated from the study results or allowed to “change groups”. Excluding noncompliant patients from a study group may leave only those that may be more likely to have a positive outcome, thus compromising the unbiased comparison that we got from the process of randomization. Therefore all patients must be analyzed within their assigned group. Randomization must be preserved. This is called "intention to treat" analysis.

More information: The effects of excluding patients from the analysis in randomised controlled trials: meta-epidemiological study. Nüesch E. et al. BMJ. 2009 Sep 7;339:b3244

> Massie article: Statistical analysis: Data from all patients who underwent randomization were analyzed according to the intention-to-treat principle. [Page 2458] In addition, Table 2 shows results for primary outcomes that includes all patients in the trial. [Page 2463]

7. Was the trial stopped early?

Stopping a trial early may provide an incomplete picture of the real effect of an intervention. Trials ended early may compromise randomization if they stop at a “random high” when prognostic factors may temporarily favor the intervention group. When study size and the number of events are small, stopping early may overestimate the treatment effective.

Massie article: The study was not stopped early.

Are the results of this study valid?

Yes. This study methodology appears to be sound and the results should be valid.

Key validity issues for studies of Therapy:

- randomization
- concealed allocation
- baseline similarities
- blinding
- follow-up complete
- intention-to-treat

Source:
Guyatt, G. Rennie, D. Meade, MO, Cook, DJ. *Users' Guide to Medical Literature: A Manual for Evidence-Based Clinical Practice, 2nd Edition 2008.*

Next - Step 2: What are the results?

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Step 2: What are the results?

How large was the treatment effect?
What was the relative risk reduction?
What was the absolute risk reduction?

How precise was the estimate of the treatment effect?
What were the confidence intervals?

From the abstract: During a mean follow-up of 49.5 months, the primary outcome occurred in 742 patients in the irbesartan group and 763 in the placebo group. Primary event rates in the irbesartan and placebo groups were 100.4 and 105.4 per 1000 patient-years, respectively (hazard ratio, 0.95; 95% confidence interval [CI], 0.86 to 1.05; P = 0.35).

Overall rates of death were 52.6 and 52.3 per 1000 patient-years, respectively (hazard ratio, 1.00; 95% CI, 0.88 to 1.14; P = 0.98).

Rates of hospitalization for cardiovascular causes that contributed to the primary outcome were 70.6 and 74.3 per 1000 patient-years, respectively (hazard ratio, 0.95; 95% CI, 0.85 to 1.08; P = 0.44). There were no significant differences in the other pre specified outcomes. [Page 2456]

The irbersartan and placebo groups did not differ for the primary composite endpoint, its individual components or the secondary composite endpoints. Irbesartan did not improve the outcomes of patients with heart failure and a preserved left ventricular ejection fraction.

Table 2. Primary Outcome with Component Events.*

Outcome	Placebo (N=2061)		Irbesartan (N=2067)		Hazard Ratio (95% CI)	P Value
	No. of Patients with Event	Event Rate per 1000 Patient-Yr	No. of Patients with Event	Event Rate per 1000 Patient-Yr		
Primary outcome	763	105.4	742	100.4	0.95 (0.86–1.05)	0.35
Death	226		221			
Hospitalization for protocol-specified cardiovascular cause	537		521			
Worsening heart failure	314		291			
Myocardial infarction	54		60			
Unstable angina	19		20			
Stroke	79		68			
Atrial arrhythmia	68		77			
Ventricular arrhythmia	3		5			

2 x 2 Table for Calculating the Effect Size for CV Hospitalizations

	Hospitalization for CV	**Not Hospitalized for CV**	Totals
Irbesartan Group	521	1546	2067
Placebo Group	537	1524	2061

Experimental Event Rate (EER) = 521 / 2067 = 25.2%
outcome present / total in experimental group

Control Event Rate (CER) = 537 / 2061 = 26%
outcome present / total in control group

Absolute Risk Reduction (ARR) = 26% - 25.2% = .8%
is the *arithmetic difference* between the rates of events in the experimental and control group. An Absolute Risk Reduction (ARR) refers to the decrease of a bad event as a result of the intervention. An Absolute Benefit Increase (ABI) refers to the increase of a good event as the result of the intervention. [ARR = EER-CER]

Relative Risk Reduction (RRR) = .8% / 26% = 4%
is the *proportional reduction in risk* between the rates of events in the control group and the experimental group. Relative Risk Reduction is often a larger number than the ARR and therefore may tend to exaggerate the difference. [RRR = EER - CER/CER]

Numbers Needed to Treat (NNT) = for this study not significant
is the number of patients who need to be treated to prevent one bad outcome or produce one good outcome. In other words, it is the number of patients that a clinician would have to treat with the experimental treatment to achieve one additional patient with a favorable outcome. [NNT = 1/ARR]

Confidence Intervals
are a measure of the precision of the results of a study. For example, "36 [95% CI 27-51]", a 95%CI range means that if you were to repeat the same clinical trial a hundred times you can be sure that 95% of the time the results would fall within the calculated range of 27-51. Wider intervals indicate lower precision; narrow intervals show greater precision.

P value
refers to the probability that any particular outcome would have arisen by chance. The smaller the P value the less likely the data was by chance and more likely due to the intervention. Standard scientific practice, usually deems a P value of less than 1 in 20 (expressed as P=.05) as "statistically significant". The smaller the P value the higher the significance.

Clinical versus Statistical Significance
"Although it is tempting to equate statistical significance with clinical importance, critical readers should avoid this temptation. To be clinically important requires a substantial change in an outcome that matters. Statistically significant changes, however, can be observed with trivial outcomes. And because statistical significance is powerfully influenced by the number of observations, statistically significant changes can be observed with trivial (small) changes in important outcomes. Large studies can be significant without being clinically important and small studies may be important without being significant." [[http://www.acponline.org/clinical_information/journals_publications/ecp/julaug01/primer.htm]

Clinical significance has little to do with statistics and is a matter of judgment. Clinical significance often depends on the magnitude of the effect being studied. It answers the question "Is the difference between groups large enough to be worth achieving?" Studies can be statistically significant yet clinically insignificant.

For example, a large study might find that a new antihypertensive drug lowered BP, on average, 1 mm Hg more than conventional treatments. The results were statistically significant with a P Value of less than .05 because the study was large enough to detect a very small difference. However, most clinicians would not find the 1 mm Hg difference in blood pressure large enough to justify changing to a new drug. This would be a case where the results were statistically significant (p value less than .05) but clinically insignificant.

Source:
Guyatt, G. Rennie, D. Meade, MO, Cook, DJ. *Users' Guide to Medical Literature: A Manual for Evidence-Based Clinical Practice, 2nd Edition 2008.*

Next - Step 3: How can I apply the results to patient care?

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Step 3: How can I apply the results to patient care?

Were the study patients similar to my population of interest?
Does your population match the study inclusion criteria?
If not, are there compelling reasons why the results should not apply to your population?

Were all clinically important outcomes considered?
What were the primary and secondary endpoints studied?
Were surrogate endpoints used?

Are the likely treatment benefits worth the potential harm and costs?
What is the number needed to treat (NNT) to prevent one adverse outcome or produce one positive outcome?
Is the reduction of clinical endpoints worth the increase of cost and risk of harm?

It appears from our brief analysis that this article meets the criteria for validity. To complete the analysis you would need to review the results and determine if they are applicable to Pauline. Our patient is a 73 year old female with heart failure and a left ejection fraction of 40%. She has no other remarkable past medical history and is living on her own. She meets the inclusion criteria for this study. The results show that irbesartan may not be effective for our patient. There are also drug interactions to consider. The next step is to talk with the patient.	

Take a moment to reflect on how well you were able to conduct the steps in the EBM Process.

Did you ask a relevant, well focused question? Do you have fast and reliable access to the necessary resources? Do you know how to use them efficiently? Did you find a pre-appraised article? If not, was it difficult to critically evaluate the article?

Source:
Guyatt, G. Rennie, D. Meade, MO, Cook, DJ. *Users' Guide to Medical Literature: A Manual for Evidence-Based Clinical Practice, 2nd Edition 2008.*

Note: For validity criteria for other types of studies, see the following supplements: Diagnosis | Prognosis | Etiology/Harm | Systematic Review

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Evaluating the validity of a Diagnostic study

Are the results valid?

1. Did participating patients present a diagnostic dilemma?

The group of patients in which the test was conducted should include patients with a high, medium and low probability of having the target disease. The clinical usefulness of a test is demonstrated in its ability to distinguish between obvious illness and those cases where it is not so obvious or where the diagnosis might otherwise be confused. The patients in the study should resemble what might be expected in a clinical practice.

2. Did investigators compare the test to an appropriate, independent reference standard?

The reference (or gold) standard refers to the commonly accepted proof that the target disorder is present or not present. The reference standard might be an autopsy or biopsy. The reference standard provides objective criteria (e.g., laboratory test not requiring subjective interpretation) OR a current clinical standard (e.g., a venogram for deep venous thrombosis) for diagnosis. Sometimes there may not be a widely accepted reference standard. The author will then need to clearly justify their selection of the reference test. Those who are conducting or evaluating the other test should not know the results of any of the tests.

3. Were those interpreting the test and reference standard blind to the other results?

To avoid potential bias, those conducting the test should not know or be aware of the results of the other test.

4. Did the investigators perform the same reference standard to all patients regardless of the results of the test under investigation?

Researchers should conduct *both* tests (the study test and the reference standard) regardless of the results of the test in question. Researchers should not be tempted to forego either test based on the results of only one of the tests. Nor should the researchers apply a different reference standard to patients with a negative results in the study test.

Key issues for Diagnostic Studies:

- diagnostic uncertainty
- blind comparison to gold standard
- each patient gets both tests

What are the results?

What likelihood ratios (LRs) were associated with the range of possible test results?
How much will different levels of the diagnostic test result raise or lower the pretest probability of disease?

	Reference Standard Disease Present	**Reference Standard Disease Absent**
New Test positive	**a**	**b**

New Test negative	**c**	**d**

Sensitivity: measures the proportion of patients with the disease who also test positive for the disease in this study. It is the probability that a person with the disease will have a positive test result.
Sensitivity = true positive / all disease positives [a / (a + c)]

Specificity: measures the proportion of patients without the disease who also test negative for the disease in this study. It is the probability that a person without the disease will have a negative test result.
Specificity = true negative / all disease negatives [d / (b + d)]

Sensitivity and specificity are characteristics of the test but do not provide enough information for the clinician to act on the test results.

Likelihood ratios (LR): indicate the likelihood that a given test result would be expected in a patient with the target disorder compared to the likelihood that the same result would be expected in a patient without that disorder.

Likelihood ratio of a positive test result (LR+) increases the odds of having the disease after a positive test result.

Likelihood ratio of a negative test result (LR-) decreases the odds of having the disease after a negative test result.

How much do LRs change disease likelihood?

LRs greater than 10 or less than 0.1	cause large changes
LRs 5 - 10 or 0.1 - 0.2	cause moderate changes
LRs 2 - 5 or 0.2 - 0.5	cause small changes
LRs less than 2 or greater than 0.5	cause tiny changes
LRs = 1.0	cause no change at all

How to use a nomogram with a likelihood ratio

More about likelihood ratios: Diagnostic tests 4: likelihood ratios. JJ Deeks & Douglas G Altman BMJ 2004 329:168-169

How can I apply the results to patient care?

Will the reproducibility of the test result and its interpretation be satisfactory in your clinical setting?
Does the test yield the same result when reapplied to stable participants?
Do different observers agree about the test results?

Are the study results applicable to the patients in your practice?Does the test perform differently (different LRs) for different severities of disease?
Does the test perform differently for populations with different mixes of competing conditions?

Will the test results change your management strategy?
What are the test and treatment thresholds for the health condition to be detected?
Are the test LRs high or low enough to shift posttest probability across a test or treatment threshold?

Will patients be better off as a result of the test?

Will patient care differ for different test results?
Will the anticipated changes in care do more good than harm?

Based on: Guyatt, G. Rennie, D. Meade, MO, Cook, DJ. *Users' Guide to Medical Literature: A Manual for Evidence-Based Clinical Practice, 2nd Edition 2008.*

Note: For criteria for other types of studies, see the following supplements:
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Evaluating the validity of a Prognosis study

Are the results Valid?

1. Was the sample of patients representative?

The patients groups should be clearly defined and representative of the spectrum of disease found in most practices. Failure to clearly define the patients who entered the study increases the risk that the sample is unrepresentative. To help you decide about the appropriateness of the sample, look for a clear description of which patients were included and excluded from a study. The way the sample was selected should be clearly specified, along with the objective criteria used to diagnose the patients with the disorder."

2. Were the patients sufficiently homogeneous with respect to prognostic factors?

Prognostic factors are characteristics of a particular patient that can be used to more accurately predict that patient's disease course. These factors, which can be demographic (age, sex, race, etc.), disease specific (e.g., stage of a tumor or disease), or comorbid (other conditions existing in the patient at the same time), can also help predict good or bad outcomes.

In comparing the prognosis of the 2 study groups, researchers should consider whether or not the patient's clinical characteristics are similar. It may be that adjustments have to made based on prognostic factors to get a true picture of the clinical outcome. This may require clinical experience or knowledge of the underlying biology to determine if all relevant factors were considered.

3. Was the follow-up sufficiently complete?

Follow-up should be complete and all patients accounted for at the end of the study. Patients who are lost to follow-up may often suffer the adverse outcome of interest and therefore, if not accounted for, may bias the results of the study. Determining if the number of patients lost to follow up affects the validity depends on the proportion of patients lost and the proportion of patients suffering the adverse outcome.

Patients should be followed until they fully recover or one of the disease outcomes occurs. The follow-up should be long enough to develop a valid picture of the extent of the outcome of interest. Follow-up should include at least 80% of participants until the occurrence of a major study end point or to the end of the study.

4. Were objective and unbiased outcome criteria used?

Some outcomes are clearly defined, such as death or full recovery. In between, can exist a wide range of outcomes that may be less clearly defined. Investigators should establish specific criteria that define each possible outcome of the disease and use these same criteria during patient follow-up. Investigators making judgments about the clinical outcomes may have to be "blinded" to the patient characteristics and prognostic factors in order to eliminate possible bias in their observations.

Investigators making judgments about the clinical outcomes may have to be "blinded" to the patient characteristics and prognostic factors in order to eliminate possible bias in their observations.

Key issues for Prognosis Studies:

- well-defined sample
- similar prognosis
- follow-up complete

- objective and unbias outcome criteria

What are the results?

How likely are the outcomes over time?
* What are the event rates at different points in time?
* If event rates vary with time, are the results shown using a survival curve?

How precise are the estimates of likelihood?
* What is the confident interval for the principle event rate?
* How do confidence intervals change over time?

Issues of prognosis
Prognosis of a disease refers to its possible outcomes and the likelihood that each one will occur.

Prognostic Results are the numbers of events that occur over time, expressed in:

- **absolute** terms: e.g. 5 year survival rate
- **relative** terms: e.g. risk from prognostic factor
- **survival curves**: cumulative events over time

A **Prognostic Factor** is a patient characteristic that can predict that patient's eventual outcome:

- **demographic**: e.g. sex, age, race
- **disease-specific**: e.g. tumor stage
- **comorbidity**: other co-existing conditions

Articles that report prognostic factors often use two independent patient samples:

- **derivation sets** ask - what factors might predict patient outcomes?
- **validation sets** ask - do these prognostic factors predict patient outcomes accurately?

How can I apply the results to patient care?

Were the study patients and their management similar to those in your practice?
Were disease therapies applied equally across subgroups in the study?
Were disease therapies applied equality over time?

Was the follow-up sufficiently long?
Were patients followed long enough to detect outcomes of interest to your practice?

Can you use the results in the management of patients in your practice?
Does the impact of a prognostic factor on outcome events cross a therapeutic threshold?

Source: Guyatt, G. Rennie, D. Meade, MO, Cook, DJ. *Users' Guide to Medical Literature: A Manual for Evidence-Based Clinical Practice, 2nd Edition 2008.*

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Evaluating the validity of a Etiology/Harm study

Are the results of this article valid?

COHORT Studies: Aside from the exposure of interest, did the exposed and control groups start and finish with the same risk for the outcome?

1. Were patients similar for prognostic factors that are known to be associated with the outcome (or did statistical adjustment level the playing field)?
The two groups, those exposed to the harm and those not exposed, must begin with the same prognosis. The characteristics of the exposed and non-exposed patients need to be carefully documented and their similarity (except for the exposure) needs to be demonstrated. The choice of comparison groups has a significant influence on the credibility of the study results. The researchers should identify an appropriate control population before making a strong inference about a harmful agent. The two groups should have the same baseline characteristics. If there are differences investigators should use statistical techniques to adjust or correct for differences.

2. Were the circumstances and methods for detecting the outcome similar?
In cohort studies determination of the outcome is critical. It is important to define the outcome and use objective measures to avoid possible bias. Detection bias may be an issue for these studies, as researchers may look deeper to detect disease or an outcome.

3. Was follow-up sufficiently complete?
Patients unavailable for complete follow-up may compromise the validity of the research because often these patients have very different outcomes than those that stayed with the study. This information must be factored into the study results.

CASE-CONTROL STUDIES: Did the cases and control group have the same risk (chance) of being exposed in the past?

1. Were cases and controls similar with respect to the indication or circumstances that would lead to exposure?
The characteristics of the cases and controls need to be carefully documented and their similarity needs to be demonstrated. The choice of comparison groups has a significant influence on the credibility of the study results. The researchers should identify an appropriate control population that would be eligible or likely to have the same exposure as the cases.

2. Were the circumstances and methods for determining exposure similar for cases and controls?
In a case control study determination of the exposure is critical. The exposure in the two groups should be identified by the same method. The identification should avoid any kind of bias, such as recall bias. Sometimes using objective data, such as medical records, or blinding the interviewer can help eliminate bias.

Key issues for Etiology Studies:

- similarity of comparison groups
- outcomes and exposures measured same for both groups
- follow-up of sufficient length (80% or better)

What are the results?

How strong is the association between exposure and outcome?

* What is the risk ratio or odds ratio?
* Is there a dose-response relationship between exposure and outcome?

How precise was the estimate of the risk?

* What is the confidence interval for the relative risk or odds ratio?

Strength of inference:

For RCT or Prospective cohort studies:

	Cases Outcome present	**Controls Outcome not present**
Exposure Yes	**a**	**b**
Exposure No	**c**	**d**

Relative Risk (RR) is the risk of the outcome in the exposed group divided by the risk of the outcome in the unexposed group:

RR = a /(a + b) divided by c/(c + d)

RR = (exposed outcome yes / all exposed) /
(not exposed outcome yes / all not exposed)

"RR of 3.0 means that the outcome occurs 3 times more often in those exposed versus unexposed."

For case-control or retrospective studies:

	Cases Outcome present	**Controls Outcome not present**
Exposure Yes	**a**	**b**
Exposure No	**c**	**d**

Odds Ratio (OR) is the odds of previous exposure in a case divided by the odds of exposure in a control patient:

OR = (a / c) divided by (b / d)

OR = (exposed outcome yes / not exposed outcome yes) / (exposed outcome no / not exposed outcome no)

"OR of 3.0 means that cases were 3 times more likely to have been exposed than were control patients."

Confidence Intervals are a measure of the precision of the results of a study. For example, "36 [95% CI 27-51]", a 95%CI range means that if you were to repeat the same clinical trial a hundred times you can be sure that 95% of the time the results would fall within the calculated range of 27-51. Wider intervals indicate lower precision; narrow intervals show greater precision.

Confounding Variable is one whose influence distorts the true relationship between a potential risk factor and the clinical outcome of interest.

More information on odds ratios: The odds ratio Douglas G Altman & J Martin Bland BMJ 2000;320:1468 (27 May)

How can I apply the results to patient care?

Were the study subjects similar to your patients or population?
Is your patient so different from those included in the study that the results may not apply?

Was the follow-up sufficiently long?
Were study participants followed-up long enough for important harmful effects to be detected?

Is the exposure similar to what might occur in your patient?
Are there important differences in exposures (dose, duration, etc) for your patients?

What is the magnitude of the risk?
What level of baseline risk for the harm is amplified by the exposure studied?

Are there any benefits known to be associated with the exposure?
What is the balance between benefits and harms for patients like yours?

Source: Guyatt, G. Rennie, D. Meade, MO, Cook, DJ. *Users' Guide to Medical Literature: A Manual for Evidence-Based Clinical Practice, 2nd Edition 2008.*

Note: For criteria for other types of studies, see the following supplements:
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Evaluating the validity of a Systematic Review

Are the results of this article valid?

1. Did the review explicitly address a sensible question?

The systematic review should address a specific question that indicates the patient problem, the exposure and one or more outcomes. General reviews, which usually do not address specific questions, may be too broad to provide an answer to the clinical question for which you are seeking information.

2. Was the search for relevant studies detailed and exhaustive?

Researchers should conduct a thorough search of appropriate bibliographic databases. The databases and search strategies should be outlined in the overview. Researchers should also show evidence of searching for non-published evidence by contacting experts in the fields. Cited references at the end of articles should also be checked.

3. Were the primary studies of high methodological quality?

Researchers should evaluate the validity of each study included in the systematic review. The same EBM criteria used to critically appraise studies should be used to evaluate studies to be included in the systematic review. Differences in study results may be explained by differences in methodology and study design.

4. Were selection and assessments of the included studies reproducible?

More than one researcher should evaluate each study and make decisions about its validity and inclusion. Bias (systematic errors) and mistakes (random errors) can be avoided when judgment is shared. A third reviewer should be available to break a tie vote.

Key issues for Systematic Reviews:

- focused question
- thorough literature search
- include validated studies
- selection of studies reproducible

What are the results?

Were the results similar from study to study?
How similar were the point estimates?
Do confidence intervals overlap between studies?

What are the overall results of the review?
Were results weighted both quantitatively and qualitatively in summary estimates?

How precise were the results?
What is the confidence interval for the summary or cumulative effect size?

Deciphering a forest plot for a systematic review/meta-analysis

More information on reading forest plots:

Ried K. Interpreting and understanding meta-analysis graphs--a practical guide. Aust Fam Physician. 2006 Aug;35(8):635-8. PubMed PMID: 16894442.

Greenhalgh T. Papers that summarise other papers (systematic reviews and meta-analyses). BMJ. 1997 Sep 13;315(7109):672-5. PubMed PMID: 9310574.

How can I apply the results to patient care?

Were all patient-important outcomes considered?
Did the review omit outcomes that could change decisions?

Are any postulated subgroup effects credible?
Were subgroup differences postulated before data analysis?
Were subgroup differences consistent across studies?

What is the overall quality of the evidence?
Were prevailing study design, size, and conduct reflected in a summary of the quality of evidence?

Are the benefits worth the costs and potential risks?
Does the cumulative effect size cross a test or therapeutic threshold?

Based on: Guyatt, G. Rennie, D. Meade, MO, Cook, DJ. *Users' Guide to Medical Literature: A Manual for Evidence-Based Clinical Practice, 2nd Edition 2008.*

Note: For criteria for other types of studies, see the following supplements:
Therapy | Diagnosis| Prognosis | Etiology/ Harm

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Testing Your Knowledge

The purpose of this exercise is to practice the steps in the EBP process with a new case. You will be given a case scenario to read. Then you should choose the best well-built clinical question and Medline search strategy to answer that question. Finally you will be asked to read a relevant article that addresses the clinical question and identify the validity issues for that study.

Choose among:

Case 1: Tamiflu for the seasonal flu

Case 2: Physical therapy for the knee

Case 3: Nursing staff and the cardiac surgery patient

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Case 1: Tamiflu for the seasonal flu

This is a self-correcting exercise. Click on **Answer** for a pop-up box with the response.

Note: If you do not see a pop-up box, check your pop-up blocker settings in the browser. If that is not the problem, try closing the previous pop-up box or check to see if the pop-up box is behind your browser window. If you still do not see the pop-up box, you may need to update your browser.

ASSESS the patient	**1. Start with the patient -- a clinical problem or question arises out of the care of the patient**

You just graduated from medical school and are getting ready to start your internship. Your brother calls you to ask for your advice. He thinks he has the flu. Three of his co-workers are home with the flu and he is sure he has it now.

He's headed to the Urgent Care Clinic but wants to hear from you before he sees the doctor. Should he insist on a prescription to Tamiflu? Will it make him feel better and get back to work sooner? Is it worth the cost?

You have heard the reports on the news but need to review the evidence for yourself before advising him. You tell him you will call him right back.

ASK the Question	**2. Construct a well-built clinical question derived from the case**

Based on this scenario, choose the best, well-built clinical question:

A. Is Tamiflu more effective than bed rest and Tylenol for the flu? Answer

B. In healthy adults, does Tamiflu reduce the severity of acute influenza? Answer

C. How much does Tamiflu cost? Answer

ACQUIRE the Evidence	**3. Select the appropriate resource(s) and conduct a search**

Based on question B, choose the best search strategy to address the question.

A. Search: Tamiflu Answer

B. Search: influenza AND tamiflu AND adult Limits: randomized controlled trial, Core clinical journals Answer

C. Search tamiflu AND severity of illness Answer

APPRAISE	**4. Appraise the evidence for its validity (closeness to the truth) and**

the Evidence	its applicability (usefulness in clinical practice)

Read the following article to determine if the article meets the criteria for validity. As stated previously, evaluating the medical literature is a complex undertaking. You will find that the answers to the questions of validity may not always be clearly stated in the article and that you may have to use your own judgment about the importance and significance of each question.

Article: Treanor JJ. Efficacy and Safety of the Oral Neuraminidase Inhibitor Oseltamivir in Treating Acute Influenza: A Randomized Controlled Trial; JAMA 2000;283(8):1016-1024 FREE article.

Are the results valid?

1. Randomization: Were patients randomized? Answer

2. Concealed allocation: Was group allocation concealed? Answer

3. Similar baseline characteristics of patients: Were patients in the study groups similar with respect to known prognostic variables? Answer

4. Blinding: To what extent was the study blinded? Answer

5. Follow-up: Was follow-up complete? Answer

6. Intention to Treat: Were patients analyzed in the groups to which they were first allocated? Answer

7. Was the trial stopped early? Answer

Notable strengths included: a strong methodology, a reasonable sample size, good follow-up and compliance, and the use of multiple clinical sites across the Unites States. They perform appropriate statistical testing for multiple comparisons. Their choice of intention-to-treat analysis for efficacy and non-intention-to-treat analysis for safety are the conservative choices, so positive findings are that much more robust.

Weaknesses: No reporting of racial characteristics, no summary of over-the-counter medication use, exclusion of patients with preexisting pulmonary or other chronic disease.

Overall, this trial demonstrates no major threats to validity.

This covers the first aspect of evaluating the evidence. There are two additional questions that you need to consider:

What are the results?

How large was the treatment effect?
What was the relative risk reduction?
What was the absolute risk reduction?

How precise was the estimate of the treatment effect?
What were the confidence intervals?

Tamiflu results: A total of 374 individuals (59.6%) were infected with influenza. Their duration of illness was reduced by more than 30% with both oseltamivir, 75 mg twice daily (median, 71.5 hours; *P*,.001), and oseltamivir, 150 mg twice daily (median, 69.9 hours; *P* =

.006), compared with placebo (median, 103.3 hours).

Among all 629 subjects, oseltamivir reduced illness duration (76.3 hours and 74.3 hours for 75 mg and 150 mg, respectively, vs 97.0 hours for placebo; *P* = .004 for both comparisons) and illness severity (686 score-hours and 629 score hours for 75 mg and 150 mg, respectively, vs 887 score-hours for placebo; *P*,.001 for both comparisons).

Secondary complications such as bronchitis and sinusitis occurred in 15% of placebo recipients compared with 7% of combined oseltamivir recipients (*P* = .03).

2x2 table for dichotomous results from Table 4: complications in confirmed influenza patients

	Secondary infections - YES	**Secondary infections - NO**	**Totals**
Tamiflu Combined	17	228	245
Placebo	19	110	129

Experimental Event Rate: 17/245 = 6.9%

Control Event rate: 19/129 = 14.7%

Absolute Risk reduction: 14.7% - 6.9% = 7.8%

Relative Risk reduction: 7.8 / 14.7% = 53%

Number Needed to Treat: 1/ 7.8% = 13 patients with confirmed influenza need to be treated with tamiflu for 5 days (and take at least one pill) to prevent one complication.

How can I apply the results to patient care?

Were the study patients similar to my population of interest?
Does your population match the study inclusion criteria?
If not, are there compelling reasons why the results should not apply to your population?

Were all clinically important outcomes considered?
What were the primary and secondary endpoints studied?
Were surrogate endpoints used?

Are the likely treatment benefits worth the potential harm and costs?
What is the number needed to treat (NNT) to prevent one adverse outcome or produce one positive outcome?
Is the reduction of clinical endpoints worth the increase of cost and risk of harm?

When generalizing this study, keep in mind it was only performed in healthy people who completed the course of therapy and were confirmed to be infected with influenza. Only 60% of patients with an “influenza-like illness” actually were infected with influenza.

The current cost of 5 days of Tamiflu is $50 to $130, depending on your state and pharmacy.

The major benefit is the reduction in the duration of illness from 4 to 3.125 days. [See Table 2 - All Treated Participants]

No significant harms were reported, although this is a relatively small study.

APPLY: talk with the patient	**5. Return to the patient -- integrate the evidence and clinical expertise, patient preferences and apply it to practice**

Think about your brother, the results of the study, the benefits, the risks, the costs, and what you would discuss with him.	

If you are not going on to another test case, please take a few minutes to give us feedback about this tutorial. Thank you!

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Case 2: Acupuncture for the old knee

This is a self-correcting exercise. Click on **Answer** for a pop-up box with the response.

Note: If you do not see a pop-up box, check your pop-up blocker settings in the browser. If that is not the problem, try closing the previous pop-up box or check to see if the pop-up box is behind your browser window. If you still do not see the pop-up box, you may need to update your browser.

ASSESS the patient	**1. Start with the patient -- a clinical problem or question arises out of the care of the patient**

George is an active 83 year old male. He used to swim three times a week for 45 minutes, garden, and walk to church. But for the last several months, he has had trouble walking and bending his knees. It has made gardening difficult and restricted his daily activities.

His family physician made the diagnosis of osteoarthritis and prescribed Voltaren (diclofenac), a nonsteroidal anti-inflammatory drug. He is still in pain and wants to know if acupuncture would help. He says he would like to stay away from more medication. You are not sure about the effectiveness of acupuncture for this patient and need to do a little research before you can address his question.

ASK the question	**2. Construct a well-built clinical question derived from the case**

Based on this scenario, choose the best, well-built clinical question:

A. Can acupuncture help an elderly 83 year-old male? Answer

B. Is acupuncture or diclofenac effective for a painful knee? Answer

C. In elderly patients with osteoarthritis of the knee, can acupuncture combined with an anti-steroidal inflammatory agent, improve mobility and reduce pain? Answer

ACQUIRE the evidence	**3. Select the appropriate resource(s) and conduct a search**

Based on question C, choose the best search strategy to address the question.

A. Search: acupuncture AND osteoarthritis knee Limits: Aged: 65+ years, Randomized Controlled Trial Answer

Search: B. acupuncture AND Anti-inflammatory agents, non-steroidal AND osteoarthritis, knee Limits: Aged: 65+ years, Randomized Controlled Trial, Answer

C. knee AND acupuncture AND diclofenac Answer

APPRAISE the evidence	4. Appraise the evidence for its validity (closeness to the truth) and its applicability (usefulness in clinical practice)

Read the following article to determine if the article meets the criteria for validity. As stated previously, evaluating the medical literature is a complex undertaking. You will find that the answers to the questions of validity may not always be clearly stated in the article and that you may have to use your own judgment about the importance and significance of each question.

Vas J. Acupuncture as a complementary therapy to the pharmacological treatment of osteoarthritis of the knee: randomised controlled trial. BMJ. 2004 Nov 20;329(7476):1216. PubMed PMID: 15494348. Free PMC article.

Are the results valid?

1. Randomization: Were patients randomized? Answer

2. Concealed allocation: Was group allocation concealed? Answer

3. Similar baseline characteristics of patients: Were patients in the study groups similar with respect to known prognostic variables? Answer

4. Blinding: To what extent was the study blinded? Answer

5. Follow-up: Was follow-up complete? Answer

6. Intention to Treat: Were patients analyzed in the groups to which they were first allocated? Answer

7. Was the trial stopped early? Answer

What are the results?

How large was the treatment effect?
What was the relative risk reduction?
What was the absolute risk reduction?

How precise was the estimate of the treatment effect?
What were the confidence intervals?

RESULTS: 88 patients completed the trial. In the intention to treat analysis, the WOMAC index presented a greater reduction in the intervention group than in the control group (mean difference 23.9, 95% confidence interval 15.0 to 32.8) The reduction was greater in the subscale of functional activity. The same result was observed in the pain visual analogue scale, with a reduction of 26.6 (18.5 to 34.8). The PQLC results indicate that acupuncture treatment produces significant changes in physical capability (P = 0.021) and psychological functioning (P = 0.046). Three patients reported bruising after the acupuncture sessions.

NOTE: Because these are continuous variables, we cannot calculate absolute risk reduction or relative risk reduction or number needed to treat.

How can I apply the results to patient care?

Were the study patients similar to my population of interest?
Does your population match the study inclusion criteria?
If not, are there compelling reasons why the results should not apply to your population?

Were all clinically important outcomes considered?
What were the primary and secondary endpoints studied?
Were surrogate endpoints used?

Are the likely treatment benefits worth the potential harm and costs?
What is the number needed to treat (NNT) to prevent one adverse outcome or produce one positive outcome?
Is the reduction of clinical endpoints worth the increase of cost and risk of harm?

Do these patients in this study match George for age, physical conditioning, or previous treatment? Note that the mean age of patients in this study was 65 to 68 years and primarily women.

APPLY: talk with the patient	**5. Return to the patient -- integrate the evidence and clinical expertise, patient preferences and apply it to practice**

Think about George, your treatment recommendation for him and what you would discuss with him on his next visit.	

If you are not going on to another test case, please take a few minutes to give us feedback about this tutorial. Thank you!

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Case 3: Nursing staff and Cardiac Surgery Patients

This is a self-correcting exercise. Click on **Answer** for a pop-up box with the response.

Note: If you do not see a pop-up box, check your pop-up blocker settings in the browser. If that is not the problem, try closing the previous pop-up box or check to see if the pop-up box is behind your browser window. If you still do not see the pop-up box, you may need to update your browser.

ASSESS the patient	**1. Start with the patient -- a clinical problem or question arises out of the care of the patient**

The setting is a large community hospital. The transition from discharge to home is a high-risk period for patients. This is a time when patients experience complications and adverse drug effects, often many weeks before they can access their primary care provider. As the Assistant Head nurse, you have been assigned to a process improvement group looking at ways to increase medication compliance and decrease adverse events and hospitalizations for these patients.

In talking to your colleagues in other units, you find out that the hospital has recently purchased an interactive voice response (IVR) system for reminding patients about upcoming appointments. You think this might be helpful in tracking cardiac surgical patients.

You want to request additional budget support to use this system with discharged patients. However, hospital administration wants to see a justification for this and information about its potential effectiveness before providing additional funding. You have been tasked with reviewing the research on IVR.

ASK the Question	**2. Construct a well-built clinical question derived from the case**

Based on this scenario, choose the best, well-built clinical question:

A. What is the best way to follow patients for compliance and reporting adverse effects? Answer

B. Is an interactive voice response system useful to follow discharged surgical or hospitalized patients? Answer

C. In patients discharged after surgical procedures, is an IVR system more effective at reducing adverse effects and medication non compliance than following standard care? Answer

ACQUIRE the Evidence	3. Select the appropriate resource(s) and conduct a search

Based on question C, choose the best search strategy to address the question.

A. Search: ivr AND hospitalizations OR adverse reactions Answer

B. Search: (ivr OR interactive voice response) AND (medication compliance OR hospitalization OR adverse effects) Limits: Randomized Controlled Trial Answer

C. Search: Cardiac Surgical Procedures AND (ivr OR interactive voice response) AND (medication compliance OR hospitalization OR adverse effects) Limits: Randomized Controlled Trial Answer

APPRAISE the Evidence	4. Appraise the evidence for its validity (closeness to the truth) and its applicability (usefulness in clinical practice)

Read the following article to determine if the article meets the criteria for validity. As stated previously, evaluating the medical literature is a complex undertaking. You will find that the answers to the questions of validity may not always be clearly stated in the article and that you may have to use your own judgment about the importance and significance of each question.

Article: Sherrad H. Using technology to create a medication safety net for cardiac surgery patients: a nurse-led randomized control trial. Canadian Journal of Cardiovascular Nursing, 2009 19(3):9-15. PDF file.

Are the results valid?

1. Randomization: Were patients randomized? Answer

2. Concealed allocation: Was group allocation concealed? Answer

3. Similar baseline characteristics of patients: Were patients in the study groups similar with respect to known prognostic variables? Answer

4. Blinding: To what extent was the study blinded? Answer

5. Follow-up: Was follow-up complete? Answer

6. Intention to Treat: Were patients analyzed in the groups to which they were first allocated? Answer

7. Was the trial stopped early? Answer

What are the results?

How large was the treatment effect?
What was the relative risk reduction?
What was the absolute risk reduction?

How precise was the estimate of the treatment effect?
What were the confidence intervals?

An analysis of the composite primary outcome of increased compliance with medications and decreased AEs (emergency room visits and hospitalization) at six months revealed

that patients in the IVR group were significantly different from the patients in the UC group (RR and 95% CI: 0.60 [0.37, 0.96], p = 0.041) as shown in Table 4.

In the IVR group, 51.1% remained compliant with their medications and did not have an AE, compared to 38.5% in the UC group.

	Positive composite outcome YES	**Positive composite outcome NO**	**Totals**
IVR Group	70	67	137
Usual care Group	55	88	143

Experiment Event Rate: 70 / 137 = 51%
Control Event Rate: 55/143 = 38.5%

Absolute Reduction Risk (compliant with their medications and did not have an AE): 51% - 38.5% = 12.5%.

Relative Risk Reduction: 12.5% / 38.5% = 32%.

Number Needed to Treat: 1 / 12.5% = 8 patients

The number of cardiac surgical patients that would need to be treated with (use) the IVR in order to prevent one additional bad outcome is 8 patients.

Analysis of the discreet secondary outcomes determined a significant difference for medication compliance (RR: 0.34 [0.20, 0.56], p < 0.0001), whereas there was no impact on the emergency room visits (RR: 1.04 [0.63, 1.73], p = 0.897) and hospitalization (RR: 0.77 [0.41, 1.45], p = 0.519)

How can I apply the results to patient care?

Were the study patients similar to my population of interest?
Does your population match the study inclusion criteria?
If not, are there compelling reasons why the results should not apply to your population?

Were all clinically important outcomes considered?
What were the primary and secondary endpoints studied?
Were surrogate endpoints used?

Are the likely treatment benefits worth the potential harm and costs?
What is the number needed to treat (NNT) to prevent one adverse outcome or produce one positive outcome?
Is the reduction of clinical endpoints worth the increase of cost and risk of harm?

APPLY: talk with patient	**5. Return to the patient -- integrate the evidence and clinical expertise, patient preferences and apply it to practice**

The intervention is something that is available within the hospital. And while the study was not as rigorous as we would have liked, the intervention is reasonable, cost effective and relatively harmless.	

Please take a few minutes to give us feedback about this tutorial. Thank you!

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JAMAEvidence
Fundamental tools for understanding and applying the medical literature and making clinical diagnoses. Includes online version of the Users' Guide to the Medical Literature (2008) and The Rational Clinical Examination (2009). http://www.jamaevidence.com/

Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice, 2nd Edition Gordon Guyatt, Drummond Rennie, Maureen O. Meade, and Deborah J. Cook. 2008

Sharon E Straus, W. Scott Richardson, Paul Glasziou and R. Brian Haynes. *Evidence-based Medicine: How to Practice and Teach EBM.* 3nd edition. Elsevier, 2005.

What is EBM?

Evidence-Based Medicine Working Group Evidence-Based Medicine: A New Approach to Teaching the Practice of Medicine. JAMA 1992 Nov 4;268(17):2420-5. http://www.cche.net/text/usersguides/ebm.asp

Sackett, D. *Evidence-based Medicine - What it is and what it isn't.* BMJ 1996; 312:71-72. http://www.bmj.com/cgi/content/full/312/7023/71

Lang, Eddy. The why and the how of evidence-based medicine. McGill Journal of Medicine 2004 8:90-94. http://www.mclibrary.duke.edu/training/courses/ebm600/lang.pdf

Well-Built Clinical Question

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;A12.

The Literature Search

PDQ Evidence-Based Principles and Practice, 2nd Edition,by Ann McKibbon, is not only an excellent introduction to EBP but also provides search strategies for doing a literature search using MEDLINE, CINAHL Database of Nursing and Allied Health Literature, PsycINFO, and EMBASE/Excerpta MEDICA. Order information from http://www.amazon.com

The FPIN Consortium has developed over the past ten years in response to a need to make evidence-based family medicine and clinical scholarship more accessible to family physicians in clinical practice. For more information see: http://www.fpin.org/mc/page.do?sitePageId=71500

Evaluating the Evidence

These articles are from the first Users Guide series published in JAMA in 1994:

How to Use an Article About Therapy or Prevention
http://www.cche.net/text/usersguides/therapy.asp

How to Use an Article About a Diagnostic Test
http://www.cche.net/text/usersguides/diagnosis.asp

How to Use an Article About Prognosis
http://www.cche.net/text/usersguides/prognosis.asp

How to Use an Article About Harm
http://www.cche.net/text/usersguides/harm.asp

How to Use an Overview (Systematic Review)
http://www.cche.net/text/usersguides/overview.asp

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