

Introduction to Evidence-based Medicine (EBM)

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EBM

- "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)
- EBM is the integration of clinical expertise, patient values, and the best evidence into the decision making process for patient care.

The Steps in the EBM Process

The patient	1. Start with the patient -- a clinical problem or question arises out of the care of the patient
The question	2. Construct a well built clinical question derived from the case
The resource	3. Select the appropriate resource(s) and conduct a search
The evaluation	4. Appraise that evidence for its validity (closeness to the truth) and applicability (usefulness in clinical practice)
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

Lifelong learning model

- A process of lifelong, self-directed, problem-based learning in which caring for one's own patients creates the need for clinically important information about diagnosis, prognosis, therapy and other clinical and health care issues.
- Target your reading to issues related to specific patient problems. Developing clinical questions and then searching current databases may be a more productive way of keeping current with the literature.

Why is EBM important?

- Physicians reported that their practice generated about 2 questions for every 3 patients
- Investigators found that physicians had about 5 questions for each patient. 52% of these question could be answered by the medical record or hospital information system. 25% could have been answered by published information resources such as textbooks or MEDLINE
- Studies have also shown that when clinicians have access to information, it changes their patient care management decisions

Is the Evidence Available?

- 145 cases and clinical decisions analyzed:
 - 31 could be supported by a randomized controlled trial
 - 65 were supported by a head-to-head trial (not a placebo-controlled trial)
 - 23 were supported by case-control or cohort studies
 - 4 were supported by case series reports
 - 22 could not be supported with a study from the literature

Evidence-based medicine issues

Opponents	Proponents
<p>EBM is "old hat". Clinicians have been using the literature to guide their decisions for a long time. The label is new.</p>	<p>The new focus on EBM "formalizes" that "old hat" process and filters the literature so that decisions are made based on "strong" evidence.</p>
<p>EBM is "cook book medicine". It suggests that decisions are based solely on the evidence, down playing sound clinical judgement.</p>	<p>EBM should be one part of the process. Decisions must be blended with individual clinical expertise, patient preferences and when available good evidence.</p>
<p>EBM is the mindless application of population studies to the treatment of the individual. It takes the results of studies of large groups of people and tries to apply them to individuals who may have unique circumstances or characteristics, not found in the study groups.</p>	<p>The last step in the EBM process is to decide whether or not the information and results are applicable to your patient and to discuss the results with the patient.</p>

Evidence-based medicine issues

Opponents	Proponents
<p>Often there is no randomized controlled trial or "gold standard" in the literature to address the clinical question.</p>	<p>Clinicians might consider the "evidence pyramid" and look for the next best level of evidence. Clinicians need to understand that there may be no good evidence to support clinical judgement.</p>
<p>There is often great difficulty in getting access to the evidence and in conducting effective searches to identify the best evidence.</p>	<p>Librarians can help identify the best resources and teach clinicians effective searching skills.</p>

The EBM Process

Pauline is a new patient who recently moved to the area to be closer to her son and his family. She is 67 years old and has a history of congestive heart failure brought on by several myocardial infarctions.

She has been hospitalized twice within the last 6 months for worsening of heart failure. At the present time she remains in normal sinus rhythm. 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.

You think she should also be taking digoxin but you are not certain if this will help keep her out of the hospital. You decide to research this question before her next visit.



Pauline

Can you construct a well built clinical question ?

Anatomy of a good clinical question

- **Patient or problem**
 - How would you describe a group of patients similar to yours? What are the most important characteristics of the patient?
- **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? What was the patient exposed to? Asbestos? Cigarette smoke?
- **Comparison**
 - What is the main alternative to compare with the intervention?
- **Outcomes**
 - What can you hope to accomplish, measure, improve or affect?

The structure of the question might look like this:

Patient / Problem	congestive heart failure, elderly
Intervention	digoxin
Comparison, if any	none, placebo
Outcome	primary: reduce need for hospitalization; secondary: reduce mortality



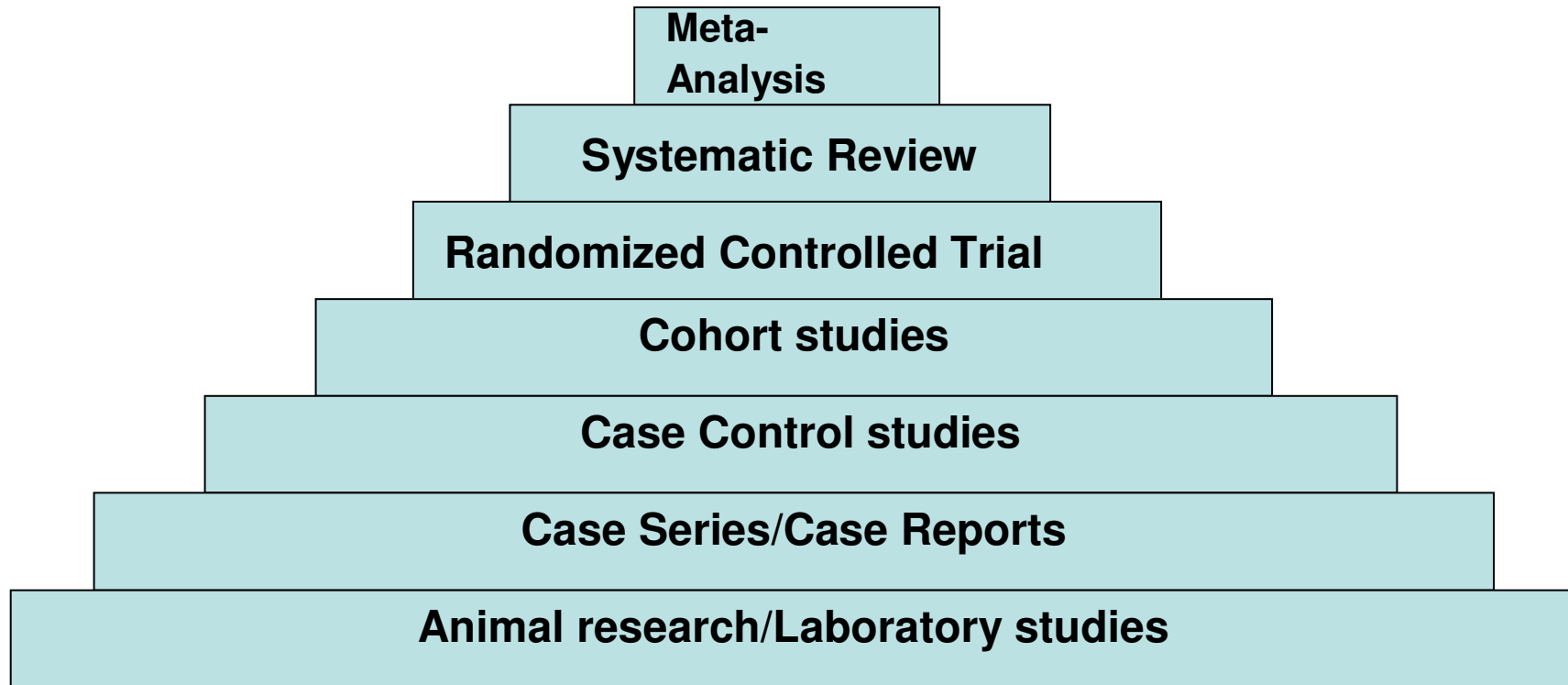
For our patient, the clinical question might be:

In elderly patients with congestive heart failure, is digoxin effective in reducing the need for rehospitalization?

Type of question

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)

Type of Study



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

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



For our patient, the clinical question is:

In elderly patients with congestive heart failure, is digoxin 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.

Clinical question	Clinical Scenario	MEDLINE strategy
Patient Population	congestive heart failure, elderly	heart failure, congestive Limit to Aged
Intervention	digoxin	digoxin
Comparison (if any)	none or placebo	
Outcome	rate of hospitalization	hospitalization
Type of question	therapy	
Type of study	RCT	Limit to randomized controlled trial as publication type

Select a resource

- **Colleagues**
- **Summaries of the primary evidence**
[ACP Journal Club](#) | [Clinical Evidence](#) | [eMedicine](#) | [FPIN Clinical Inquiries](#) | [InfoPOEMs](#) | [UpToDate](#)
- **Databases**
[MEDLINE](#) | [Cochrane Library](#)
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- **Clinical Evidence:**
<http://www.clinicalevidence.com/>
- **eMedicine:** <http://www.emedicine.com>
- **FPIN:** <http://www.fpin.org>
- **InfoPOEMS:** <http://www.infopoems.com/>
- **UpToDate:** <http://www.uptodate.com>
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1	congestive heart failure.mp. or exp Heart Failure, Congestive/	60574	Display

Saved Searches

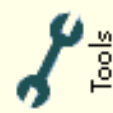
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1	congestive heart failure.mp. or exp Heart Failure, Congestive/	60574	Display
2	exp DIGOXIN/	10168	Display

Saved Searches

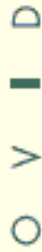
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2	exp DIGOXIN/	10168	Display
3	exp HOSPITALIZATION/ or hospitalization.mp.	108483	Display

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2	exp DIGOXIN/	10168	Display
3	exp HOSPITALIZATION/ or hospitalization.mp.	108483	Display
4	1 and 2 and 3	74	Display

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3	exp HOSPITALIZATION/ or hospitalization.mp.		108483	Display
4	1 and 2 and 3		74	Display
5	limit 4 to (human and english language and randomized controlled trial)		12	Display

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Results of your search: limit 4 to (human and english language and randomized controlled trial)

Results displayed: 11-12 of 12

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11. Hobbs RE. **Digoxin's** effect on mortality and **hospitalization in heart failure:** implications of the DIG study. Digitalis Investigation Group. *Cleveland Clinic Journal of Medicine.* 64(5):234-7, 1997 May.
UI: 9149472

[Complete Reference](#)

12. Anonymous. The effect of **digoxin** on mortality and morbidity in patients with **heart failure.** The Digitalis Investigation Group. [see comment]. *New England Journal of Medicine.* 336(8):525-33, 1997 Feb 20.
UI: 9036306

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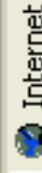
Previous Result(s)



Main Search Page



Done



Internet

Query Translation:

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("heart failure, congestive"[Mesh Terms] OR  
congestive heart failure[Text Word])
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Query Translation:

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("digoxin"[MeSH Terms] OR digoxin[Text Word])
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Search

URL

Query Translation:

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((hospitalization[Text Word] OR hospitalisation[Text Word]) OR "hospitalization"[Mesh Terms])
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Search

URL



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for #1 AND #2 AND #3					
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- ▶ Search History will be lost after eight hours of inactivity.
- ▶ To combine searches use # before search number, e.g., #2 AND #6.
- ▶ Search numbers may not be continuous; all searches are represented.

rch	Most Recent Queries
#4 Search #1 AND #2 AND #3	0:
#3 Search hospitalization	0:
#2 Search digoxin	0:
#1 Search congestive heart failure	0:

Nucleotide Protein Genome Structure PMC Journals

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Practice Guideline
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Review

To

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17: [Hobbs RE.](#)

 Digoxin's effect on mortality and hospitalization in heart failure: implications of the DIG study. Digitalis Investigation Group.

Cleve Clin J Med. 1997 May;64(5):234-7. No abstract available.
PMID: 9149472 [PubMed - indexed for MEDLINE]

[Related Articles, Lir](#)


18: [\[No authors listed\]](#)

 The effect of digoxin on mortality and morbidity in patients with heart failure. The Digitalis Investigation Group.

N Engl J Med. 1997 Feb 20;336(8):525-33.
PMID: 9036306 [PubMed - indexed for MEDLINE]

[Related Articles, Lir](#)

19: [Packer M, Bristow MR, Cohn JN, Colucci WS, Fowler MB, Gilbert EM, Shusterman NH.](#)

 The effect of carvedilol on morbidity and mortality in patients with chronic heart failure. U. S. Carvedilol Heart Failure Study Group.

N Engl J Med. 1996 May 23;334(21):1349-55.
PMID: 8614419 [PubMed - indexed for MEDLINE]

Evaluating the Validity of a Therapy 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?

Are the results of this therapy study valid?

- Was the assignment of patients to treatment randomized?
- Were all the patients who entered the trial properly accounted for at its conclusion?
 - Was follow-up complete?
 - A good study will have better than 80% follow-up for their patients
 - Lost patients should be assigned to the "worst-case" outcomes and the results recalculated
 - Were patients analyzed in the groups to which they were (originally) randomized?
 - "intention to treat" analysis.

Are the results of this therapy study valid?

- Were patients, clinicians, and study personnel "blind" to treatment allocation?
- Were the groups similar at the start of the trial?
- Aside from the experimental intervention, were the groups treated equally?

What's your answer?

- **Are the results of this study valid?**
- **What are the results of the study?**
- **Are the results applicable to your patient?**

Key issues for studies of Therapy:

randomization

follow-up (80% or better)

blinding (the more blinding the better)

baseline similarities (established at the start of the trial)

Key terminology for estimating the size of the treatment effect

	Outcome		Risk of outcome
	+	-	
Treated (Y)	a	b	$Y=a/(a+b)$
Control (X)	c	d	$X=c/(c+d)$

Relative Risk (RR) is the risk of the outcome in the treated group (Y) compared to the risk in the control group.

$$RR = Y / X$$

Relative Risk Reduction (RRR) is the percent reduction in risk in the treated group (Y) compared to the control group (X).

$$RRR = 1 - Y / X \times 100\%$$

Absolute Risk Reduction (ARR) is the difference in risk between the control group (X) and the treatment group (Y).

$$ARR = X - Y$$

Number Needed to Treat (NNT) is the number of patients that must be treated over a given period of time to prevent one adverse outcome.

$$NNT = 1 / (X - Y)$$

Return to the Patient

The study population appears to be similar enough to Pauline that we can consider the results applicable to her case.

The results of this study indicate that digoxin can reduce the need for hospitalizations in patients with heart failure and normal sinus rhythm. Digoxin may be an appropriate therapy to help keep Pauline at home and out of the hospital.

However, if Pauline elects to be treated with digoxin, there will be a need to monitor therapy, draw frequent drug levels, and hold the risk of toxicity. For Pauline, these issues may be offset by the possible benefit of avoidance of hospitalization.



Evaluate your performance with this 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?

Henry is an active 5 year old boy. His mother brought him in for a check-up because Henry has had a fever and a sore throat for several days. You suspect Strep and take a throat culture. The standard treatment for Streptococcal Pharyngitis is oral Penicillin three times a day. However, for Henry and his mother, you are concerned about compliance and the expense of this medication. You recall that a drug representative recently told you that a daily dose of amoxicillin is just as good as penicillin, but costs less. You want to review the literature before you decide on amoxicillin for Henry and possibly changing your standard practice.



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

- A. In children with strep throat, is amoxicillin as effective as penicillin for relief of symptoms?
- B. What is the best treatment for relieving the symptoms of a sore throat?
- C. Is amoxicillin better than penicillin for young children?

Validity Issues: Does the article address:

- **Randomization:** Was the assignment of patients to treatment randomized?
- **Patient follow-up:** Were all patients who entered the trial properly accounted and attributed for at its conclusion?
- **Analysis of patients:** Were patients analyzed in the groups to which they were randomized?
- **Blinding:** Were patients, health workers, and study personnel "blind" to treatment?
- **Baseline characteristics of patients:** Were groups similar at the start of the trial?
- **Treatments:** Aside from the experimental intervention, were the groups treated equally?
- **Are the results of this study valid?**

- This covers the first aspect of evaluating the evidence. There are two additional questions that you need to consider:
 - **What are the Results of the study?**
 - **Are the Results applicable to your patient?**