Evidence-Based Prescribing

Course Script

PVARF-10652

REVISION HISTORY			
version	Contributor	Description	Date
1	Jerry McCorkle with help from Drs. Stephanie Halvorson and Andrea Cedfeldt	version 1 of 3	4/2/07
2	Same team	version 2 of 3 (Word count: 4185 OST, 2179 narration)	5/24/07
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6	Everybody	final? production version	6/15/07

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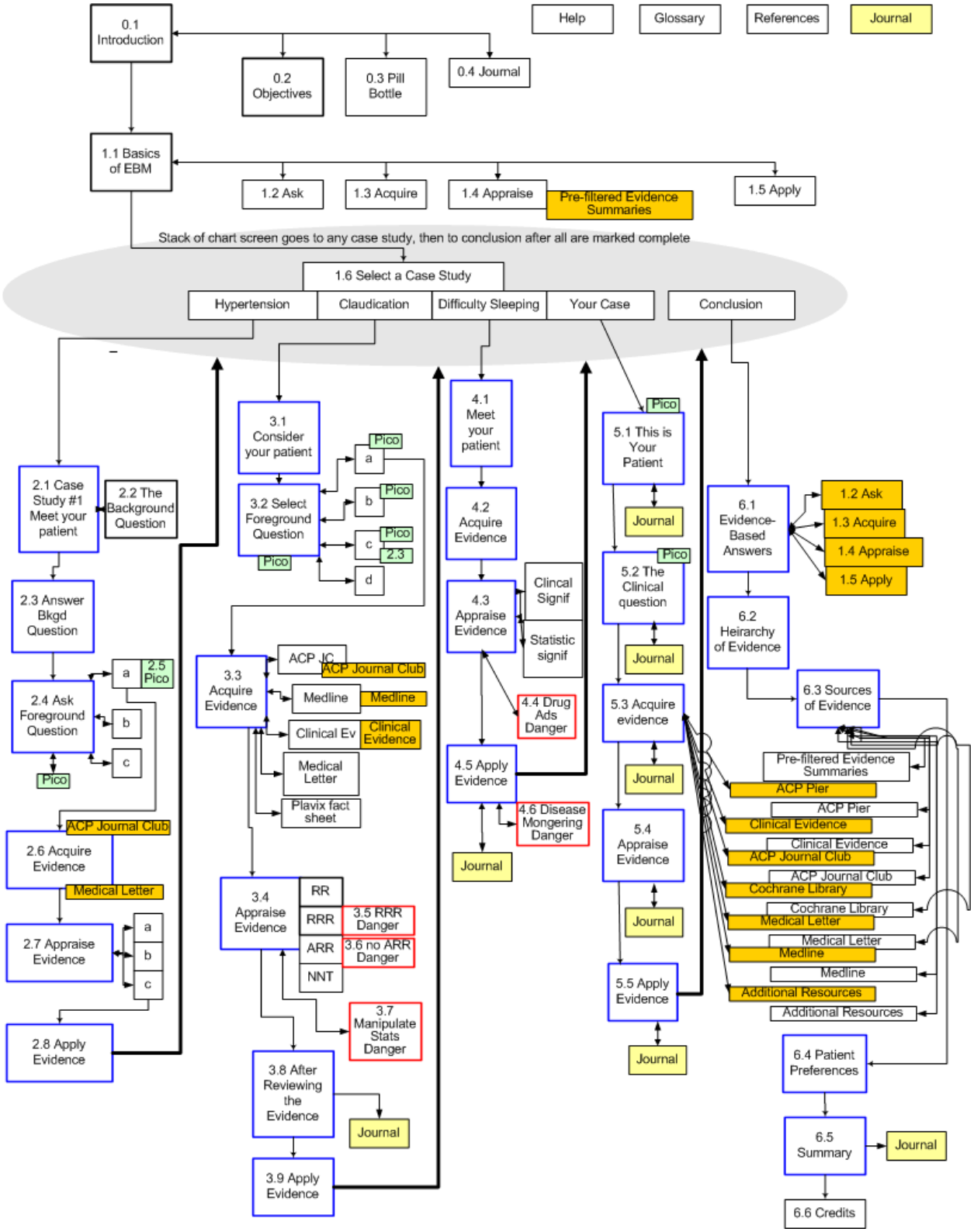
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0. Introduction

0.1. Welcome	3 extra pills
Comments	*The suggested structure is to allow learners to skip straight to the beginning or review the objectives and stuff if they want to.*

Audio	Visual
0.1.1. [music?...] [For all three courses the narrator will be Richard Moore. For clarity the attending should be female. Resident should be male, not Richard.]	Welcome to Evidence-Based Prescribing. How to use the course points to Help Review objectives Goes to Course Objectives What is the Pill Bottle for? Goes to About the Pill Bottle What is the Journal for? Goes to About the Journal Begin course Goes to Overview This program is audio enhanced. If you cannot hear the music please check your speakers.

0.2. Course Objectives		*not required for completion* *includes 4 additional pills*
Comments	*Show the bold text only initially and indicate that the four objectives are clickable. (different color) Clicking on an objective expands the objective to show the detail underneath. Clicking another one closes the first one and opens the second one.* *Back to introduction is same button as on all the others.*	
Audio		Visual

0.2.1.
[narrator]
This course should be valuable to anyone who prescribes medications.
It will help you find information in the medical literature about pharmaceuticals and use it to responsibly and effectively prescribe medications to treat patients.
The following are a list of course objectives.
		Evidence-Based Prescribing Course Objectives
		This course will teach you how to:
		• **Ask/Formulate clinical questions related to drug therapy using evidence-based resources**
		  • Distinguish background from foreground clinical questions
		  • Define foreground clinical questions in PICO format
		• **Acquire best available evidence**
		  • Distinguish need for different resources depending on type of question (background vs. foreground)
		  • List the order, or "hierarchy" of evidence
		  • Demonstrate the ability to answer a clinical question using:
		  Cochrane databases
		  ACP Journal Club
		  Medical Letter
		  Clinical Evidence
		• **Appraise the quality and importance of the evidence**
		  • Calculate Absolute Risk Reduction, Relative Risk Reduction and Number Needed to Treat
		• **Apply the evidence in specific patient care decisions**
		  • Demonstrate the ability to apply the same evidence based research to a variety of different patients
		Back to Introduction

0.3. About the Pill Bottle	
Comments	*No audio.*
Audio	**Visual**
0.3.1.	The course is supported by hundreds of pages of research and documentation. The pill bottle you see tracks your progress and reports it as your course score. It indicates how deeply you explore the course, not what you know. To get the most benefit from the course, explore all of the available choices and resources. Each screen viewed and reference reviewed adds one pill to your pill bottle. The total number of available pills indicates the total amount of information available. You do not need to collect all the pills to complete the course. Signal lights point out potential conflicts of interest. When you see this symbol click on it for more information. *show a warning light (same one as in FDA course)* Back to Introduction

0.4. About the Journal	
Comments	*No audio.*
Audio	**Visual**
0.4.1.	**Journal** • The Journal is a simple way to record learning activities in this course. • You may be asked to print your Journal entries so you can share them in group sessions. • While you are the only one with direct access to the material in your Journal, it is not a place for protected healthcare information. Please respect patient privacy and do not use patient names or other identifiers in the Journal. **My Journal doesn't work** *[Journal with red slash through it?]* • If you are using this course outside of the OHSU environment you may not have access to the Journal. In that case you may choose to use either an electronic or paper-based notebook to complete the exercises in this course. Back to Introduction

0.5. Help	
Comments	

Audio	Visual
0.5.1.  	Progress bar: Shows your relative position in the course. VCR-style navigation controls: Back Pause/Play Repeat Forward Glossary: Defines the terms used. References: Pauses the course to display a list of supporting references. Menu: Click the Menu tab to open the menu. Click any section name to go straight there. Pill Bottle: Tracks the depth of your experience. Journal: Use to respond to questions in the course. Only you can see your Journal. You must print it if you want to show others. There is no limit on how many entries you make or their length. Close

1. Introduction to Evidence-Based Prescribing

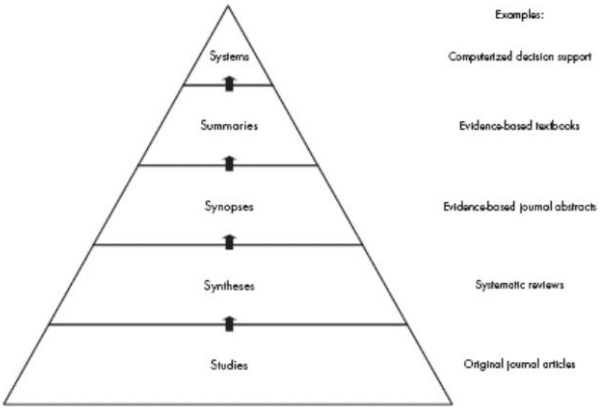
1.1. Basics of Evidence-Based Medicine	*4 extra pills tied to 4 A's required*
Comments	*Comes from the Introduction screen. Links go to subsequent screens. Next continues. This should be a simple, mostly text screen. If it is not too hideous and busy keep building all three sections on the same screen (definition, steps, and types) that way the links are still accessible.*

Audio	Visual
1.1.1. [narrator] Evidence-Based Prescribing is one part of Evidence-Based Medicine.	**Evidence-Based Medicine** The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients Ref: Sackett DL, Rosenberg WM, Gray. EBM: What it is and what it isn't BMJ 1996;312:71-72 http://www.bmj.com/cgi/content/full/312/7023/71
1.1.2. [narrator] Evidence-Based Medicine involves four key steps. *[pause a half second between each of these items]* Ask Acquire Appraise and Apply.	Time these to audio. after narrator says Ask, pause- during the pause the visual ASK will appear, then Acquire, pause- during pause the visual acquire comes up, etc… *Link to subsequent screens* **Evidence-Based Medicine** **Ask** a clinically relevant question **Acquire** the best available evidence **Appraise** the quality and importance of the evidence **Apply** the evidence in patient care decisions. Click each step for more information.
1.1.3. [narrator] Clinical questions can usually be broken down into one of four categories: Therapy, harm, diagnosis and prognosis. Evidence-based prescribing typically involves questions about therapies, and that is the focus of this course.	**4 General Types of Clinical Questions** • Therapy • Harm • Diagnosis • Prognosis

1.2. Ask	*not required*
Comments	*The 4 A screens are sidetracks linked from the terms on the screen above.*

Audio	Visual
1.2.1. [narrator] In the course of an average day a physician answers dozens of questions about therapies.	This course will help you answer clinical questions effectively and efficiently using evidence-based resources. Back

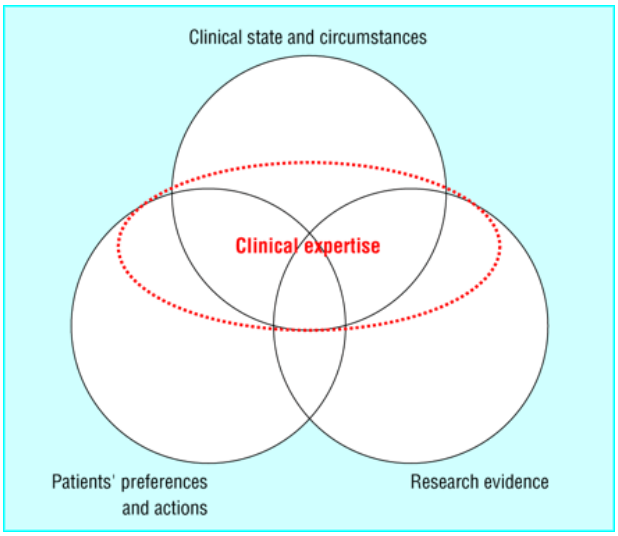
1.3. Acquire	*not required*
Comments	*the "levels" of the pyramid getting labeled or highlighted as the audio is going through them…* *Andrea's guidance: I like how this is outlined with the audio cueing the visual- as we've found out from RR feedback, we need to be sure not to overwhelm with different or with audio/visual dys-synchromy (I just made that term up- Jerry's rubbing off on me)* *Just so we are clear (the spacing confused me) the items go under the italicized heading above it. So – articles, RCTs, Medline and Pub Med etc are Studies.* *Cochrane Library, PubMed, Clinical Queries, treatment guidelines are Syntheses* *-ACP Journal Club is a Synopsis* *-Clinical Evidence and ACP Pier are Summaries* *-Computerized data support is a "system"*

Audio	Visual
1.3.1. [narrator] Evidence-based information is acquired from many different sources including individual randomized-controlled trials, evidence-based guidelines and computerized decision-support tools. Evidence-based resources can be organized into several categories, depending on their level of integration and compilation, such as in the "5S Pyramid." q2 Individual studies are the foundation of the "5-S Pyramid." q3 The next layer, Syntheses, may incorporate numerous studies in the form of a systematic review q4 Synopses are brief descriptions of original articles and reviews, such as those that appear in evidence-based journals. q5 Summaries integrate the lower 3 levels into evidence-based textbooks and guidelines q6 Systems refer to evidence-based decision- support tools	*q1 show just the pyramid with the "S" labels.*  Figure 1. The "5S" levels of organization of evidence from health care research. Haynes ACP JC Nov/Dec 2006;A8-9 *q2 highlight the bottom section and add to Studies section:* Original Articles, Randomized-Controlled Trials: Medline, PubMed *q3Highlight and add to syntheses:* Cochrane Library, PubMed Clinical Queries, treatment guidelines *q4 Highlight and add to synopses* ACP Journal Club *q5Highlight and add to Summaries* Clinical Evidence, ACP PIER *q6 Highlight and add to Systems* Computerized decision support in an electronic medical record)

1.3.2. [narrator] Efficient acquisition of information about pharmaceuticals begins at the top of this pyramid with the most "evolved" EBM sources. No matter what level of the pyramid you use, you need to make sure you understand how the evidence was assembled to be assured of its quality. q2	*q2 corresponding graphics might be a graphic of an arrow starting at the top of the pyramid and moving down through the layers)* At each level the standards for evidence generation, retrieval, selection and analysis should be explicit and at the highest evidence standard possible. For example, authors should state: ▪ Retrieval process used to find the evidence ▪ The appraisal process for rating the quality of evidence ▪ The quality of the evidence Back

1.4. Appraise	*not required*
Comments	
Audio	Visual
1.4.1. [narrator] The amount of appraisal required depends on where in the 5-S pyramid you find the evidence.	**About Pre-filtered Evidence Summaries** goes to 1.4.2 **This document** is an overview of the steps to take in appraising an article about therapy. [link to McMasters Therapy Form.pdf] If you are unfamiliar with these steps, the reference below will walk you through this process. There are similar resources for articles related to harm, prognosis, etc. *Gordon H. Guyatt, David Sackett, Deborah J. Cook, for the Evidence Based Medicine Working Group Users' Guides to Evidence-based Medicine: How to Use an Article about Therapy (1993;270(21):2598-2601) and (1994;271(1):59-63). Copyright 1995, American Medical Association.* *Back*
1.4.2. repeat the Pre-filtered evidence screen 6.3.2	

1.5. Apply		*not required*
Comments	*This is a repeat of the graphics on screen6.4.1 to repeat the visuals.*	*in the summary. Different audio, but we definitely want*

Audio	Visual
1.5.1. [narrator] The application of research evidence always involves a three-way balancing act. q1 It starts with asking "searchable" questions, then gathering and evaluating the available research evidence. q2 Then you must assess the clinical situation and determine the patient's preferences. q3 Lastly, you must apply your own clinical judgment and experience to prioritize the findings and develop a plan.	**Apply** *Build the circles in time with the audio* *q1* *add research evidence* *q2* *add other two circles* *q3* *and end by labeling the center intersection*  *Add citation for diagram:* Haynes RB et al. ACPJC 2002 Mar-Apr;136:A11-14 *In addition to just circles show a clinician (clinical experience), a research result (journal article), and a patient from the course to tie in. Do not use new pictures if possible though because it should be a reinforcement, not something new to think about.* Back

1.6. Select a Case Study	
Comments	*Aa stack of charts labeled as below. In keeping with the non-linear navigation paradigm the stack of charts would show all four chart folders. Learner can pick them in any order. When they are done, they can go to the Conclusion which is probably hidden until they complete all four cases. and indicate in some way that they have been completed. Allow learner to see their progress by checking off the completed ones or something. This should behave like the screen in HOP, though it will look entierely different.*

Audio	Visual
1.6.1. [medical office ambience]	Select the case study 1 Patient with hypertension 2 Patient with claudication 3 Patient with difficulty sleeping 4 Your Patient These cases illustrate the use of Evidence-Based Prescribing. Select any case study when you are ready.
1.6.2. [narrator] You have seen all your patients. Please go the Conclusion for some final words.	*when the learner comes back after completing all four cases add the conclusion ost and the narration pointing to it.* Conclusion

2. Case Study #1

2.1. Meet your patient	*2 extra pills*
Comments	*H&P,*

Audio	Visual
2.1.1. [Add a three second ambience track to set the stage.] [resident, with chart speaking with patient] Well Mr. Moriarty, your dentist was right. Your blood pressure is really quite high. There are several things you can do to help lower your blood pressure. The first and foremost is to quit smoking. [patient, 57 yo male] Yeah, I know. [said with a bored, "I've heard it before" kind of tone]	*show patient and resident in the appropriate clinic setting…* *Perhaps have a button or the chart is labeled* **H&P** *that displays the following OST in a chart.* James Moriarty 57 year old male Dentist informed him he has high blood pressure Self-checked at local drug store:152/94 Patient has no heath insurance and reports smoking 1 pack/day for 40 years. Clinic screening reveals BP 159/85 with no other notable findings. Close
2.1.2. [resident] I would also like to give you some medicine that can help get your hypertension under control. [patient] But I feel fine. I don't like taking pills. What's so important about treating hypertension anyway?	*Show the patient with resident. After the audio finishes add onscreen text (all text on this screen is hyperlink text) as voice bubble of the following question:* What are the risks of untreated hypertension? *q2then label the question* Background Question *q3then define* Provide general information *If click on any part of the voice bubble above go to 2.3 Background question, else skip to next screen.*

2.2. The Background Question	*not required*
Comments	*Soon we will meet the attending. The attending is the "angel" in this course. By angel we mean the person or character that provides the insight or knowledge needed to go forward. We only hear the attending here. Later she actually comes in to consult, but it is not appropriate here.*

Audio	Visual
2.2.1. [Narrator] Background Questions are typically general questions you can answer by using basic reference sources.	**Background Questions** What Disorder How Syndrome Where of Finding When Health State Who Concern Why **Examples of background questions** *[expands on click]* • What are the causes of hypertension? • What is primary versus secondary hypertension? **Appropriate resources for answering background questions** *[expands on click]* Textbooks (including UpToDate) Drug compendia Consultants, colleagues Guidelines **Back**

2.3. Answer the Background Question	*required*
Comments	*resident and patient again*
Audio	Visual
2.3.1. [resident] You may feel fine now but if we do not get your blood pressure under control you will have a significantly higher risk of heart attack, stroke... it could kill you. [patient, appropriately concerned] Oh. If you put it like that, I guess takin' a pill is better than dying. Is it going to be expensive? I don't have insurance so I'll have to pay out of pocket.	*Show resident and patient again.*
2.3.2. [resident, to patient] There are several treatment options available. I'd like to talk to my colleague Dr. Cedorson. If you'll wait here I will be right back.	

2.4. Ask a Foreground Question	*4 extra pills*
Comments	*transition from the resident in the exam room with the patient to the resident in the hallway talking to the attending.* *identify the PICO question. Incorrect options buzz annoyingly and pop up Try Again feedback.* *Throughout the course randomize the question presentation order, and don't use A B C, etc. That is just for script development purposes.*
Audio	Visual
2.4.1. [clinic background noises] q2	*Resident and attending in conference in hallway or office?* You present Mr. Moriarty's case to Dr. Cedorson, the attending. *Perhaps have a button or patient chart labeled* **H&P** *that displays text from H&P on 2.1 over the pictures of the actors.*

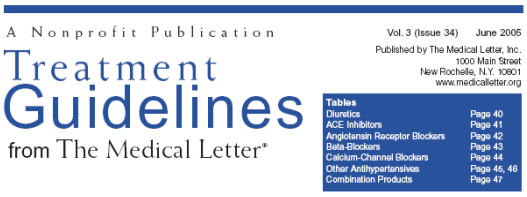
2.4.2. [resident, to attending] ...So I thought maybe I should give him some of those samples of Norvasc® in the cabinet, but thiazide diuretics are pretty cheap too. He's got a lot of cardiovascular risk factors, so I'd like to pick a blood pressure med that will reduce his risk of cardiovascular events.... What do you recommend? [attending: When recorded- this has risk of coming off as somewhat rude- it should be said with effort to help, not to be snide] I recommend, that if you want the right answer you start with the right question.	
2.4.3. [attending/ Each of these questions yields a different answer. Which question do you want to ask?	*attending and resident speaking. This is attempting to get the learner into the resident's shoes, so that when the attending asks the resident which question is the appropriate one, the learner responds from the resident's point of view.* *Have the three questions as OST over prescription pads?* *rip off the sheet to reveal the next bit of text? Robin?* *Make sure that the continue is on the right, pointing out and the try again and see other options buttons go back and to the left. This was not always visually clear for this audience in Competent physician.* **Please indicate which of the following is a foreground question that is structured in the PICO format?** What is PICO? A. In patients with hypertension, do diuretics reduce cardiovascular morbidity and mortality when compared to calcium channel blockers? B. Which medicine is cheaper, Norvasc or a thiazide diuretic? C. Which drug is more effective at reducing high blood pressure: calcium channel blockers or thiazide diuretics?

2.4.4.	A. In patients with hypertension, do diuretics reduce cardiovascular morbidity and mortality when compared to calcium channel blockers? This question uses the PICO format to ask a valid clinical question. The next part of this course describes this format in detail. Continue See the other options anyway What is PICO?
2.4.5.	B. Which medicine is cheaper, Norvasc or a thiazide diuretic? This is more of a background question. A similar question is "does the use of samples reduce patients' out of pocket pharmaceutical costs?" Surprisingly, the answer is no. Use of samples may actually result in increased costs to patients. For more information see: [this list may grow] Adair RF and Holmgren LR. Do drug samples influence resident prescribing behavior? A randomized trial. Am J Med 2005;118:881-884. Chew LD. O'Young TS, Hazlet TK, Bradley KA, et al. A physician survey of the effect of drug sample availability on physicians' behavior. J Gen Intern Med 2000;15:478-483. Try again and remember samples are a marketing tool.
2.4.6.	C. Which drug is more effective at reducing high blood pressure: calcium channel blockers or thiazide diuretics? This is a good question that could be considered a foreground question, however, it is not in the PICO format. Try again and remember to frame your questions in a searchable format (PICO).

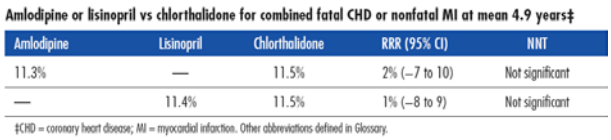
2.5. Foreground Questions/PICO Format	*don't think we can require this one.*
Comments	*This screen comes from the what is PICO link above.* *build the questions by animating the PICO bits coming from the labels above. Perhaps show the word patient expand, etc.* *Andrea: I agree this should be required, but how will they get here? How do we force them to click on What is PICO?*

Audio	Visual
2.5.1. [Attending] Foreground questions ask for specific knowledge to inform clinical decisions or actions, as opposed to background questions that ask for more general knowledge. A well structured foreground clinical question uses the PICO [pronounced PEE-koh] format. Structuring questions in this way allows for more efficient searches of the medical literature. q2 [pause] The most common search strategies incorporate the patient population and the intervention. Q3 However, you also at times might combine your search to include the outcome. Q4 So you see, using PICO allows you to formulate your clinical queries into searchable questions.	P Patient population I Intervention C Comparison O Outcome q2 P- patients with hypertension I- diuretics C- calcium channel blockers O- reduce cardiovascular morbidity and mortality In patients with hypertension, do diuretics reduce cardiovascular morbidity and mortality when compared to calcium channel blockers**?** **Q3** **Have P and I of PICO light up** **Q4** **Have O of PICO light up** **Back**

2.6. Acquire Evidence	*2 extra pills, req*
Comments	*still in the hallway or wherever they were.*

Audio	Visual
2.6.1. [resident, to attending, This should be said nicely/respectfully, not snidely (though working is fine)] So that is my question. Meanwhile my patient is waiting for an answer, and I have three more patients waiting to be seen. I guess I'll look on Medline. [attending] Medline is great but it is not always the best resource available or the best use of your time. If I may make a recommendation, you might want to start with the ACP Journal Club synopsis of a well-known randomized controlled trial called ALLHAT. It should help you answer this question. Also there was a recent Medical Letter that compared their costs. [resident] Thank you. I'll look into these.	*Resident and attending in conference in hallway or office? OST over the shot so that we remember what our question is.* In patients with hypertension do calcium channel blockers reduce cardiovascular morbidity and mortality when compared to diuretics? *show screen shot of ACP Journal Club review of ALLHAT* **Amlodipine or lisinopril vs chlorthalidone for combined fatal CHD or nonfatal MI at mean 4.9 years‡** | Amlodipine | Lisinopril | Chlorthalidone | RRR (95% CI) | NNT | |---|---|---|---|---| | 11.3% | — | 11.5% | 2% (–7 to 10) | Not significant | | — | 11.4% | 11.5% | 1% (–8 to 9) | Not significant | ‡CHD = coronary heart disease; MI = myocardial infarction. Other abbreviations defined in Glossary. *link to Psaty – ALLHAT – ACP journal club.pdf* *q2* *Show abstract of Medical Letter*  link to Medical Letter HTN Guidelines.pdf For more information about ACP Journal Club click here [goes to 2.7.2 which is a replica of 6.3.6] For more information about the Medical Letter click here [goes to 2.7.3 which is a replica of 6. 4. 8]
2.6.2. Repeat the About ACP Journal Club Screen 6.3.6. Only change the "back" functionality.	
2.6.3. Repeat the About Medical Letter screen 6.3.8. Only change the "back" functionality.	

2.7. Appraise Evidence	*req*
Comments	*again, randomize the order of the questions.*

Audio	Visual
2.7.1. [narrator] In this case, your attending was able to direct you to an article review in ACP Journal Club. ACP Journal Club is a "Synopses" resource in the 5S pyramid introduced earlier. Remember, the "higher" up on the pyramid you go, the more time-efficient your search.	link to Psaty – ALLHAT – ACP journal club.pdf  **Amlodipine or lisinopril vs chlorthalidone for combined fatal CHD or nonfatal MI at mean 4.9 years‡** Amlodipine | Lisinopril | Chlorthalidone | RRR (95% CI) | NNT 11.3% | — | 11.5% | 2% (–7 to 10) | Not significant — | 11.4% | 11.5% | 1% (–8 to 9) | Not significant ‡CHD = coronary heart disease; MI = myocardial infarction. Other abbreviations defined in Glossary. Based on the ACP Journal Club summary, you can conclude that: a) amlodipine is more effective than chlorthalidone for preventing coronary heart disease b) chlorthalidone is more effective than amlodipine for preventing coronary heart disease c) amlodipine and chlorthalidone are equally effective in preventing coronary heart disease
2.7.2.	a or b) A relative risk reduction of 2% with a confidence interval of -7 – 10 is not significant Try again
2.7.3.	c That is correct there is not a statistically significant difference in prevention of the primary outcome between chlorthalidone and amlodipine. It is now time to apply this evidence.

2.8. Apply Evidence	*three extra pills*
Comments	
Audio	Visual
2.8.1. [resident] I am going to write you a prescription for a thiazide diuretic. This medicine will treat your high blood pressure, it has been proven to have few side effects and it is relatively inexpensive. [patient] Don't you have some free samples? I don't have a lot of money. [resident] We do have some samples of another medicine called Norvasc®. However, it is no more effective than a thiazide diuretic and after the samples run out it costs ten times as much. In addition, I don't want to make my prescribing decisions based on what we have in the sample cabinet- that's not good medicine. [patient] Thanks Doc.	Return to patient with the answer. show the cost information from the medical letter (Medical Letter HTN Guidelines.pdf) somewhere (just the cost of the 2 drugs we are looking at would suffice; not the whole table) Use of samples may actually result in increased costs to patients, and makes doctors change their prescribing practices. For more information on samples: http://nofreelunch.org/requiredsamples.htm
2.8.2. music?	Record your reflections on this case in your Journal: How would your application of this evidence differ if your patient was: • a long haul trucker with limited access to a bathroom and reluctant to take a diuretic • an elderly woman with chronic hyponatremia • a patient with chronic kidney disease and a baseline creatinine of 3.0 What are your thoughts about samples in medical clinics? Did your thoughts change after reviewing any of listed references? Be prepared to discuss these questions. Select another case *Text above or next returns learner to 1.6*

3. Case Study #2

3.1. Consider your patient	*1 extra pill*
Comments	*H&P, open the chart to show the H&P*

Audio	Visual
3.1.1. [resident speaking with attending] ... and in addition he has peripheral vascular disease with an ankle-brachial index of point seven, so I am going to add clopidogrel [klo-PID-a-grill] to his aspirin. [attending] Why are you going to do that? [resident] When I was on cardiology Dr. Hart said that patients with this degree of PVD should be on both medications to prevent heart attack and stroke. [attending] What evidence supports that? [resident] I'm not sure... [attending] If you wanted to search for the data, what would your clinical question be?	*show attending and resident in the appropriate setting…* *chart labeled or button that says History and Physical or Chart or with a photo of the patient and the following text….* H&P Dean McCrea 63 y.o. Caucasian male with hypertension, hypercholesterolemia, and coronary artery disease (CAD) documented by catherization. Has done well for 2 years on atenol, aspirin, and simvastin. He comes to clinic for follow-up of his exertional leg cramps. ABI is .7 on the left and .5 on the right. Continues to walk daily, needs to stop and rest after 3 blocks to let cramps resolve. [q2]

3.2. Select the Appropriate Foreground Question	*4 extra pills*
Comments	*This screen is just a continuation of the previous one. Still randomizing the questions*

Audio	Visual
3.2.1.	**Which foreground clinical question will help you get the information you need to make an evidence-based prescribing decision?** **What is a foreground question? Link to 2.6** A. In patients with coronary artery disease and peripheral arterial disease is clopidogrel plus aspirin better than aspirin alone in preventing MI and/or stroke? B. Will the combination of clopidogrel and aspirin be better for this patient? C. What is the mortality associated with clopidogrel? D. Does patient need vascular surgery given his ABI's?
3.2.2. correct ding	**a.** In patients with coronary artery disease and peripheral vascular disease is clopidogrel plus aspirin better than aspirin alone in preventing MI and/or stroke? **Correct. This is a foreground question in the PICO format.** **What is PICO? Link to 2.6** **Continue [goes to 3.3]**
3.2.3. wrong buzz	**b.** Will the combination of clopidogrel and aspirin be better for this patient? **Incorrect Question. How will you search this question? "Better" for what? Remember PICO!** **What is PICO? Link to 2.6** **Try again**
3.2.4. wrong buzz	**C.** What are the side effects associated with clopidogrel? Incorrect Question. **This is a background question. Remember: What, How, Where, When, Who, Why?** **What is a background question? Link to 2.3** **What is a foreground question? Link to 2.6** **Try again**
3.2.5. wrong buzz	**d.** Does patient need vascular surgery given his ABI's? Wrong question. **This may be a relevant question, but not related to your medication prescribing question.** **Try again**

3.3. Acquire Evidence	*10 pills total?*
Comments	*where do you look? Make sure the text is supported by the screen shots.* *The Plavix fact sheet should be linked to the website, not the PDF..*

Audio	Visual
3.3.1. [attending] So where will you look for an answer?	In patient with coronary artery disease and peripheral vascular disease, is clopidogrel plus aspirin better than aspirin alone in preventing MI and/or stroke? Where will you look for the evidence to answer the question? • ACP journal club • Medline • Clinical Evidence • The Medical Letter • Plavix fact sheet provided by manufacturer *[see corresponding row below]* Click the evidence sources to see what they reveal. Done looking *goes to final row of this screen 3.4.10* *we have all of these screen shots for the search stuff.*
3.3.2.	ACP journal club *(Screen Shot 3.4.3 ACP No 0)* search terms “peripheral arterial disease”, “clopidogrel and aspirin”, combine and “limit to therapeutics” *screen shot of search page* 6 results *Screen shot 3.4.3 ACP No 1)* #2 appears *to* answer our clinical question. *Screen shot 3.4.3 ACP No 2)* *link to Bhatt* *(Screen shot 3.4.3 ACP No 3)* *ACP J Club PDF Clopidogrel Case.pdf* **For more information on ACP Journal Club click here** Goes to 3.4.7 which is copy of 6.3.6 Go Back to compare to other sources

3.3.3.	Medline (Screen shot 3.4.4 Medline No 0) search terms “peripheral arterial disease” yields 1690 results ”clopidogrel and aspirin” yields 1535 results Combining them yields 85 results (Screen shot 3.4.4 Medline No 1) #19 is the one we want (Screen shot 3.4.4 Medline No 2) *ink to Bhatt* *Clopidogrel and Aspirin.pdf* *screen shot of search page* For more information on Medline click here Goes to 3.4.8 which is copy of 6.3.4 Go Back to compare to other sources
3.3.4.	Clinical Evidence Internal Medicine > Cardiology> Peripheral Arterial Disease> Question: What are the effects of treatments for people with chronic peripheral arterial disease? For more information on Clinical Evidence click here. Goes to 3.4.9 which is copy of 6.3.3 Go Back to compare to other sources
3.3.5.	**Plavix fact sheet** http://products.sanofi-aventis.us/plavix/plavix.html **INDICATIONS AND USAGE** PLAVIX (clopidogrel bisulfate) is indicated for the reduction of atherothrombotic events as follows: **Recent MI, Recent Stroke, or Established Peripheral Arterial Disease** For patients with a history of recent myocardial infarction (MI), recent stroke, or established peripheral arterial disease, PLAVIX has been shown to reduce the rate of a combined endpoint of new ischemic stroke (fatal or not), new MI (fatal or not), and other vascular death. The information from the study we are looking for, the CHARISMA trial, has not been included in this fact sheet.
3.3.6. ACP Journal Club, copy of 6.3.6.	
3.3.7. Medline copy of 6.3.4	
3.3.8. Clinical Evidence Copy of 6.3.3	

3.4. Appraise Evidence	*I pill for each of four equations and each of three dangers*
Comments	*crunch some numbers time. show the table from the abstract and zoom in on the part shown here. We have the learner drag the numbers from the table into the blanks in the formulas to calculate the values shown. Then the computer does the rest for us.* *Make this all very intuitive and easy to do. Follow the layout of the formulas on the back of Andrea's case study! Learner to complete all equations(RR, RRR, ARR, NNT) in a similar manner, building a single screen full of statistics.*

Audio	Visual
3.4.1.	**Table 4. Composite and Individual Primary and Secondary End Points.** End Point | Clopidogrel plus Aspirin (N=7802) | Placebo plus Aspirin (N=7801) | Rela (95 *no. (%)* **Efficacy end points** Primary efficacy end point | 534 (6.8) | 573 (7.3) | 0.93 (CER=7.3 EER=6.8
3.4.2. Control group event rate represents the chances of the event in the control group.	*Highlight the value (7.3) above* Control Event Rate (CCR)
3.4.3. Experimental group event rate represents the chances of the event in the experimental group.	*highlight the value 6.8 above* Experimental Event Rate (EER)`
3.4.4. Divide the experimental event rate by the control event rate to get the relative risk. q2 A Relative Risk of exactly one would mean that there is no difference between the event rates in the control and experimental populations. The Relative Risk for this study is very close to one.	Drag the values from the table into the [make text match the interface]???? Relative Risk (RR) = EER / [over] CER q2 *after dragging both values show the RR of* .93
3.4.5. The relative risk reduction is the percent reduction in events in the treated group event rate (EER) compared to the control group event rate (CER)	Relative Risk Reduction (RRR) = (CER-EER)/CER X 100 OR 1 – RR x 100 **Danger of Relative Risk and Relative Risk Reduction** [nifty red light goes to 3.5] *Complete the rest of these equations by having the learner drop the numbers into the formulas. All of the equations should stay on the screen at the same time, but they probably build in order as they are completed.*

3.4.6. The absolute risk reduction is the difference between the control and experimental event rates.	Absolute Risk Reduction (ARR) = (CER-EER) **(No) Danger of Absolute Risk and Absolute Risk Reduction** [nifty red light goes to 3.6] *Complete the rest of these equations by having the learner drop the numbers into the formulas. All of the equations should stay on the screen at the same time, but they probably build in order as they are completed.*
3.4.7. The number needed to treat represents how many patients would have to receive the treatment to prevent one event over a time period.	Number Needed to Treat= 1 / ARR Again, the learner drags and drops the values to calculate the new values.
3.4.8. As you can see, calculating these numbers can be simple to do and allows you to quickly appraise the quality and significance of the evidence that you are reviewing.	To read more about interpreting the medical literature see these textbooks: User's Guides to the Medical Literature Evidence-Based Medicine- David Sackett **Manipulating Statistics Danger** *nifty read light signal*

3.5. Danger of Relative Risk	*not required*
Comments	
Audio	Visual
3.5.1. Relative risk and relative risk reduction overestimate the impact of a treatment in low prevalence events. Let's say hypothetically, that we found in this study a Relative Risk Reduction of 50%. This could mean the number of MI's in the treatment group was 50 compared to 100 in the control group. Or it could mean that the number of MI's was 1 in the treatment group and 2 in the control group.	*illustrate that the 50% could be 50 of 100 or 1 of 2*

3.6. (No) Danger of Absolute Risk	*not req*
Comments	
Audio	Visual
3.6.1. In contrast to the Relative Risk and Relative Risk Reduction, the Absolute Risk Reduction does discriminate between large and small treatment effect. A relative Risk reduction of 50% could mean a reduction from 100 to 50 or from 2 to 1. The Absolute Risk Reduction however *does* discriminate between these two cases. If the number of MI's in the treatment group was 50, and in the control group 100, the ARR is 50%. However, if the number of MI's in the treatment group is 1 and the control group 2, then the ARR is 1%.	*Compare the two groups again, start with the 50% RRR, then show the ARRs (50 and 1) underneath.* You can see how the ARR takes into account low prevalence events.

3.7. Manipulating Statistics Danger	*not req*
Comments	
Audio	Visual
3.7.1. [attending] As you can see statistics can be manipulated to over- or under-estimate the true effectiveness and safety of a drug. For this reason be cautious when interpreting literature from pharmaceutical representatives and try to appraise the information for yourself.	**This case is good example of slippery statistics** **The RRR is 6.7%, but the ARR 0.5%**

3.8. After Reviewing the Evidence	*req 1 extra pill*
Comments	*no correct answer, just a stem for reflection*

Audio	Visual
3.8.1. [attending] Now that you have appraised the evidence do you think your patient would benefit from adding clopidogrel?	link to Evidence Bhatt DL, Fox KA, Hacke W, et al. Clopidogrel and aspirin versus aspirin alone for the prevention of atherothrombic events. NEJM 2006;354:1706-17 Clopidogrel and Aspirin.pdf In summary: RRR= 6.84% ARR= 0.5% NNT=200 Having appraised the evidence do you think your patient would benefit from adding clopidogrel? Yes No Don't Know Need More Information

3.9. Apply Evidence	
Comments	*Consider patient preferences, etc.*

Audio	Visual
3.9.1. [resident, back with attending] I looked into the question of clopidogrel and aspirin versus aspirin alone and there is no significant cardiovascular benefit for the patient. [attending] Nice job. Our clinical colleagues are great resources of information. However, you can see the importance of going to the primary literature, when available, to answer clinical questions for yourself.	*resident and attending chatting* Select another case *Text above or next returns learner to 1.6*

4. Case Study #3

4.1. Meet your patient	*1 extra pill*
Comments	*H&P as before.*

Audio	Visual
4.1.1. [patient] I've seen the commercials, and I went to their website. I need to ask my doctor... is Lunesta right for me. [resident] That's a good question. To be honest I don't know much about this new medication. Why don't you wait here while I see what I can learn.	*show patient and resident in the appropriate setting. Repeat H&P functionality from before* H&P Linda Evans 72 y.o. female with history of hypertension, GERD and reports trouble falling asleep

4.2. Acquire Evidence	*2 extra pills*
Comments	*2 residents in conference room used before, only this time it is the resident with a second resident ,and not the attending.*

Audio	Visual
4.2.1. [resident] My patient is asking about this new medication Lunesta. I don't know what it is. I'm going to Google it. q1 [resident2] Have you ever tried looking in the Medical Letter on Drugs and Therapeutics? It's a great, unbiased resource and the first place I turn to when I am confronted with questions about a new medication. q2 [resident 1] Oh okay. Let me give it a try and see what I get.	q1 add link to Lunesta.com q2 **Medical Letter on Lunesta** Lunesta in Medical Letter.pdf **Insomnia Treatment Guidelines from Medical Letter** Insomnia Treatment Guidelines Medical Letter.pdf

4.3. Appraise Evidence	*5 extra pills?*
Comments	*we need the resources to reference her that support the 15 minutes/ night extra sleep, or we can just go with what is provided here. I stumbled on the median sleep onset and baseline figures noted below. I thought it was "significant".*
Audio	Visual
4.3.1. [resident1] So if people on the drug got "significantly more" sleep, how much more sleep did they get? [resident 2] You'll have to look at the primary papers to get that kind of information. q2	*show resident looking at study, talking with other resident.* **Medical Letter on Lunesta** Lunesta in Medical Letter.pdf The evidence suggests that a patient can expect to get "significantly" more sleep on Lunesta. How much sleep is that? q2 **Original Study Sponsored by Manufacturer** *Lunesta Study.pdf* *Show the references of the Lunesta medical letter, link the appropriate one to highlight the appropriate table or??*

4.3.2. [resident1] "... hmm, in looking at sleep latency, after 6 months of treatment, the Lunesta group fell asleep only 15 minutes faster than the placebo group..." Q1 [resident 2] "they fell asleep just 15 minutes faster? That's not too impressive. But what about overall sleep duration? [resident 1] "Well... looking at total sleep time, after 6 months of treatment the treatment group slept about 37 minutes longer than the placebo group." Q2 [resident 2] "I would have expected it to be better. Those results may be statistically significant, but are they clinically significant?	*build the onscreen text as indicated* The results of **this study** *Lunesta Study.pdf* demonstrate that nightly use of eszopiclone 3 mg, resulted in "statistically significant" differences in patient-reported measures of sleep onset, sleep maintenance, sleep quality, and next-day function compared with placebo in patients with chronic insomnia. Q1 *Show table from study- for this first dialogue, show table 3 from study, under "Sleep Induction category" highlight Month 6 line.* *Q2* *Show same table 3, here highlight month 6 under the sleep duration category (last line of table)* Compare **Statistical Significance** versus **Clinical Significance** *Danger light* **Other potential problems with drug studies [Danger light to 4.4]**
4.3.3. [resident 2] "What about side effects?" [resident 1] "Generally more side effects in the Lunesta group, unpleasant taste, dry mouth, dizziness. Wow, this is interesting...It seems that 6 percent more of Lunesta patients reported feeling sleepy the next day Q1 [resident 2] "Don't people want to take sleeping pills so they don't feel sleepy the next day?"	**Link to Table 5 from Lunesta study** **Highlight "Somnolence"** **Drug Ads Play Up Benefits, Downsize Risks** http://www.npr.org/templates/story/story.php?storyId=9571484#9572496

4.3.4.	**Statistical Significance** Statistical significance of evidence simply means that the outcome did not occur by chance. It doesn't mean the finding is important or that it has any decision-making utility. In this case you can be fairly certain that the extra 15 minutes of sleep did not occur by chance. Back
4.3.5.	**Clinical Significance** The clinical significance of evidence is determined by the physician and the patient. If a patient is getting only 2 hours of sleep each night, an extra 30 minutes would be very significant! Back

4.4. Drug Ads Danger	*1 extra pill?*
Comments	
Audio	Visual
4.4.1. [resident] I also noticed that all seven authors are linked to the pharmaceutical company that makes Lunesta, and they even sponsored the study. And this person that helped with the manuscript, yup she works for the drug company too.	Critical analysis of research like this raises the following questions: • If 1194 patients were screened (by people on the pharmaceutical company's payroll) and only 791 patients were enrolled, was there any bias in selecting ("Cherry Picking") study participants? • Would an independent statistician have made different choices when handling the data? What conclusions would be reached then? • Should the FDA approve medications when the only data to support their use is funded by the manufacturers of the medication? **Lunesta Study** Lunesta study.pdf **Drug Ads Play Up Benefits, Downsize Risks** http://www.npr.org/templates/story/story.php?storyId=9571484#9572496

4.5. Apply Evidence	*2 extra pills*
Comments	*Consider patient preferences, etc. Moved light bulb to next page. Does it work?*
Audio	Visual
4.5.1. [resident2] Are you sure the patient even has insomnia? [resident 1] Good question.	*Danger Light* **A lot of money can be made from telling healthy people that they are sick** *goes to disease mongering 4.6*
4.5.2. [resident 1] Thank you for waiting. I've looked into the medication you mentioned. Before we talk about treatment options I'd like to hear more about your difficulty sleeping, and would like to ask you some questions about what we call "sleep hygiene"….	*Return to patient with the answer* It turns out that the patient has not tried any lifestyle changes and only occasionally has trouble getting to sleep. Sleep hygiene is a more appropriate place to start than medications. See the Medical Letter's Insomnia Treatment Guidelines section on Cognitive Behavioral Therapy *link to Insomnia Treatment Guidelines Medical Letter.pdf*
4.5.3.	Record in your Journal: Reflect on a time when a patient asked you about a medication you did not know about, or was not indicated. How did you reconcile it? What are your thoughts on Direct to Consumer Advertising? What did you learn from this case? Be prepared to discuss these questions. Select another case Text above or next returns learner to 1.6

4.6. Disease Mongering Danger	*not required*
Comments	

Audio	Visual
4.6.1. [resident2] Are you sure the patient even has insomnia? [resident 1] Good question.	*Danger Light* In a practice now known as "disease mongering," the pharmaceutical industry has turned ordinary ailments into medical problems in an effort to expand markets for new products. For an example see: Lexchin, J. Bigger and better: How Pfizer redefined erectile dysfunction. PLoS 2006;3(4):e132. For more information see: Applbaum K (2006) Pharmaceutical marketing and the invention of the medical consumer. PLoS Med 3(4): e189. Moynihan R, Heath I, Henry D. Selling sickness: the pharmaceutical industry and disease mongering.BMJ. 2002 Apr 13;324(7342):886-91. Select another case *Text above or next returns learner to 1.6*

5. Case Study #4

5.1. This is Your Patient	*1 extra pill*
Comments	*H&P,*
Audio	Visual
5.1.1. [narrator] Now try these steps out on one of YOUR patients. q2 Use the Journal to record your evidence search so you are prepared to discuss it in person.	*show cutout of patient with a question mark and resident in the appropriate setting…* Evidence-Based Medicine Ask a clinically relevant question Acquire the best available evidence Appraise the quality and importance of the evidence Apply the evidence in patient care decisions. *q2* *Show this bit like it is in the hypothetical patient's chart?* For this exercise, please select a patient you saw recently, and a foreground clinical question that arose in relation to this patient. This should be a question you would like to investigate further. *Indicate Journal* Record in your Journal: • What was the foreground question? What is a foreground question? Link to 2.6 (Remember to protect patient privacy. Do not use real names or identifiers.)

5.2. The Clinical Question	*1 extra pill*
Comments	*identify the PICO question.*
Audio	Visual
5.2.1. [narrator] What is the clinical question you need to answer?	In regard to the patient you have in mind, what is the clinical question? • Record the clinical question in your Journal now. *Indicate Journal* Remember to use the PICO format: • Patient • Intervention • Comparison • Outcome What is PICO? Link to 2.6

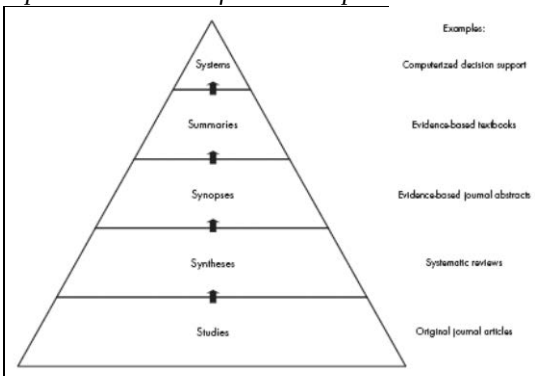
5.3. Acquire Evidence	*1 extra pill*
Comments	*where do you look?*
Audio	Visual
5.3.1. [narrator] Where will you look for evidence?	Which of these resources will you use to research your question? • Clinical Evidence • ACP Journal Club • Cochrane Library • The Medical Letter • Medline • ACP PIER • Others highlight each of these and if they click, have it go to the screen with the "more info" in section 6? In your Journal record: • Where you will start looking • Why you decided to start there • Strategies you will use for the search- did you start with searching the "P" and "I" of your question?
5.3.2. [narrator] Go ahead and conduct your search now.	Consult the sources you have identified to find the evidence to help you answer your clinical question.

5.4. Appraise Evidence	*1 extra pill*
Comments	*crunch some numbers or???*
Audio	Visual
5.4.1. [narrator] After you find evidence to help answer your clinical question, record your answers to the questions provided.	Record in your Journal: • What steps did you take to appraise the evidence you found? • If applicable what are the Relative Risk, , Relative Risk Reduction, Absolute Risk Reduction and Number Needed to Treat Link to formulas Link to McMaster's criteria Effects of Treatment Outcomes Table

5.5. Apply Evidence	*1 extra pill*
Comments	*Consider patient preferences, etc.*
Audio	Visual
5.5.1. [narrator] How will you apply these finding to this patient? How do your patient's preferences and individual physiology factor into your treatment decisions?	*Return to blank patient with the answer* In your Journal: • Record how you would apply the evidence you found with this patient. • Is your decision unique for this patient? • How? • Why? Select another case *Text above or next returns learner to 1.6*

6. Summary

6.1. Evidence-Based Answers	
Comments	
Audio	**Visual**
6.1.1. [narrator] In the course of an average day a physician answers dozens of questions about therapy. q2 In order to answer these clinical questions, remember the 4 steps of evidence-based medicine: Ask, Acquire, Appraise and Apply.	Many decisions are routine , but others require finding answers from other sources. Studies show that questions arise frequently– with 2 questions for every 3 outpatients seen, for example. *q2* **Evidence-Based Medicine** **Ask** a clinically relevant question **Acquire** the best available evidence **Appraise** the quality and importance of the evidence **Apply** the evidence in patient care decisions. Click to review the steps

6.2. Hierarchy of Evidence	
Comments	
Audio	**Visual**
6.2.1. [narrator] This course is intended to help you answer clinical questions about pharmaceuticals quickly and get the strongest, most methodologically sound evidence available. As you've seen, it is often more efficient to use pre-filtered resources, such as synopses and summaries, in which the authors have done the appraisal and integration for you. Individual studies may require that you do your own appraisal.	*Build the hierarchy, start at the bottom, end with the top repeat visual to reinforce concept*  Figure 1. The "5S" levels of organization of evidence from health care research.

6.3. Sources of Evidence	*7 extra pills?*
Comments	
Audio	Visual

6.3.1.
[Narrator]
Here are several places to look for evidence-based answers to questions about therapies. Knowing where to start will save you time. Whenever possible consider using a pre-filtered database such as the Cochrane library, ACP PIER or ACP journal club in which the authors have already reviewed and appraised the literature for you.
	Pre-filtered Evidence Summaries
	• **Clinical Evidence**
	• **ACP Pier**
	• **ACP Journal Club**
	• **Cochrane Library**
	  • Database of Systematic Reviews (DSR)
	  • Database of Abstracts of Reviews of Effectiveness (DARE)
	  • Central Register of Controlled Trials (CCRCT)
	• **Medical Letter**
	  • Treatment Guidelines from the Medical Letter
	  • The Medical Letter on Drugs and Therapeutics
	• **Medline**
	• **Additional Resources and Information**
	add text to the list above that says
	Click each resource to review it's strengths and weaknesses for specific evidence searches.
	Also indicate that the names have become links. Each link goes to the corresponding screen below, and is checked off after reviewing the "more".
	Next still goes to following screen.

6.3.2. [Narrator] Pre-filtered evidence based resources save you time by doing the appraisal for you. Pre-filtered resources may have different criteria for study or research inclusion. In general, the filter criteria for articles involving therapy include random allocation of participants to comparison groups, follow up of a certain percent of participants entering the study, etc.	Pre-Filtered Databases Searching pre-filtered databases is a good place to start when looking for answers to a focused foreground clinical question on therapy. If you find a meta-analysis or systematic review that answers your clinical question, the authors will have already done the work of gathering and summarizing the best of the published (and ideally unpublished) data.

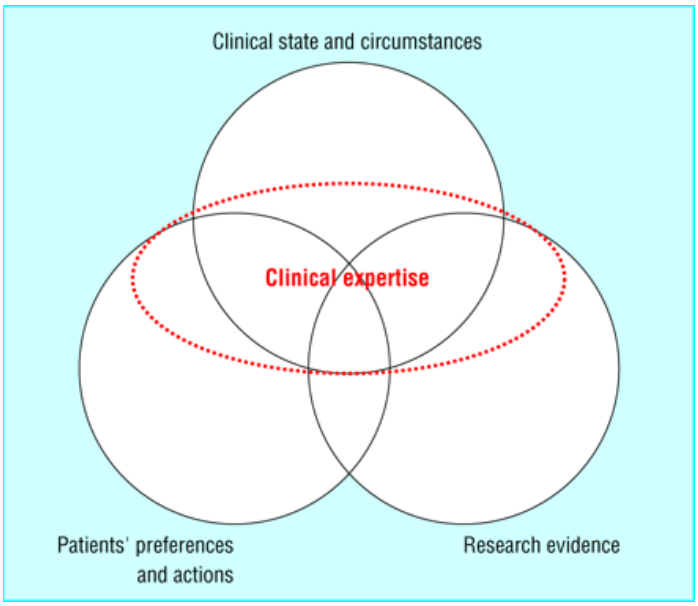
6.3.3. [Narrator] CLINICAL EVIDENCE is most appropriate for answering questions relating to the treatment of common, well-documented medical problems. Clinical Evidence works well as a textbook. Entering search terms is not always as efficient. Instead, start in the appropriate category- usually Internal Medicine or Primary Care. Then focus on the "sub-specialty" to see sub-topics.	**Clinical Evidence** • A **summary** in the "5S" levels of organization • Focuses on outcomes that matter to patients, meaning those that patients themselves are aware of, such as symptom severity, quality of life, survival, disability, walking distance, etc. • Contents are driven by clear clinical questions • Provides clear answers about therapies when the evidence exists (categorizes them as "beneficial," "unknown effectiveness," "unlikely to be beneficial") • Continuously updated • Addresses questions regarding treatments or therapies (not diagnoses) • Is of limited value for very specific questions relating to rare diseases, or very specific patient populations • Does not address issues of cost or cost-effectiveness *screen shots of* Go Back to compare to other sources **Clinical Evidence** http://www.clinicalevidence.com/ceweb/about/index.jsp
6.3.4. [Narrator] Medline is especially valuable for clinical questions involving rare diseases or outcomes, or very specific patient populations-- any question about which there is unlikely to be a large amount of data available. It is of limited value for general clinical questions because a search can turn up thousands of items.	**MEDLINE** • A database of individual **studies** in the "5S" levels of organization For the sake of efficiency start with pre-filtered resources like ACP Journal Club, then look on medline if necessary. Effective search strategies make medline much more valuable. This course is not about how to use medline, but if your are interested, here are some references: Refs: Greenhalgh T. How to read a paper: the Medline database. BMJ. 1997;315:180-183 Hanes, RB et al. Developing optimal search strategies for detecting clinically sound studies in MEDLINE. J Am Med Informatics Assoc. 1994;1:447-458

6.3.5. [Narrator] The COCHRANE LIBRARY is appropriate for questions involving therapies. Similar to other pre-filtered resources, the articles included in the Cochrane Library will have passed strict methodologic criteria. The Cochrane Library is of limited value if your clinical question involves a diagnosis or prognosis, or if your question is such that it is unlikely there is a large Randomized controlled trial or Systematic review on the topic.	**Cochrane Library** • A **synthesis** in the "5S" levels of organization **Cochrane Database of Systematic Reviews (CDSR)-** all systematic reviews done by members of the Cochrane Collaboration **Cochrane Database of Reviews of Effectiveness (DARE)- i**ncludes systematic reviews that were done outside of the Cochrane Collaboration **Cochrane Controlled Trials Registry (CCTR)-** (also called Cochrane Central Register of Controlled Trials) Database of clinical trials that members of Cochrane collaboration obtained via medline and other searches. Mostly limited to RCT's. Link for more info: http://www.cochrane.org/reviews/clibintro.htm PDF of Development of Cochrane Library: http://www.update-software.com/publications/Cochrane/history.pdf *screen shot of search page or abstract* Go Back to compare to other sources
6.3.6. [Narrator] The ACP Journal Club provides synopses of systematic reviews and original studies addressing a focused clinical question. ACP journal club synopses can save you time by completing a thorough appraisal of the evidence for you. Unlike other resources listed the ACP Journal Club addresses prognosis, harm, and diagnosis, as well as questions about therapies.	**ACP Journal Club** • A **synopsis** in the "5S" levels of organization • Filtered review of over 100 journals- internal medicine and other specialties • Includes articles dealing with therapy AND diagnosis, etiology, and prognosis. • Only articles that meet strict methodological criteria are included. making it smaller than other medical databases and easier to search. • Of limited value if a clinical question is unlikely to have been reported in the journals reviewed by ACP Journal Club (link to journals reviewed by ACP J Club: http://www.acpjc.org/shared/journals_reviewed.htm *screen shots of search page* MORE INFO ON ACP JOURNAL CLUB http://www.acpjc.org/shared/purpose_and_procedure.htm Back

6.3.7. [Narrator] ACP PIER© is a web-based, decision-support tool designed to provide point-of-care, evidence-based guidance for clinicians.	ACP PIER© ▪ A **summary** in the "5S" levels of organization ▪ Includes a collection of disease modules that can be searched, found alphabetically or browsed by organ system. ▪ Outlines and provides strength of evidence information for each prevention, work-up and treatment option ▪ Of limited value for rare diseases Back
6.3.8. [Narrator] THE MEDICAL LETTER is most appropriate for clinical questions that pertain to specific medications, [q1] or questions relating to treatment guidelines for a specific medical problem. [q2] Medical Letter publications also explore the cost and cost-effectiveness of medications. The Medical Letter is funded entirely by subscription fees, with no advertising or other support from the pharmaceutical industry, so you can be sure the content is not biased by pharmaceutical industry sponsorship.	**The Medical Letter[q1]** **The Medical Letter on Drugs and Therapeutics** • Describes relevant **studies** in the "5S" levels of organization • Provides critical appraisal of new drugs • Publishes comparative reviews of older drugs [q2] **Treatment Guidelines from the Medical Letter** • A **synthesis** in the "5S" levels of organization • Independent, peer-reviewed, nonprofit publication that offers review articles of drug classes for treatment of common disorders screen shot of search page or abstract Link for more info: http://www.medletter.com/html/who.htm Back

6.3.9. [narrator] Here are some additional evidence-based resources.	Additional resources not covered in detail include: • Evidence-Based Medicine (http://ebm.bmj.com/) • BMJ Updates (http://www.bmjupdates.com/index.asp) • PubMed Clinical Queries http://www.ncbi.nlm.nih.gov/entrez/query/static/clinical.shtml) • Drug Effectiveness Review Project (http://www.ohsu.edu/drugeffectiveness/reports/final.cfm) • PubMed (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?DB=pubmed) For more information see: Haynes RB. Of studies, syntheses, synopses, summaries, and systems: the “5S” evolution of information services for evidence-based health care decisions. ACP J Club. 2006 Nov-Dec;145(3):A8-9.

6.4. Patient Preferences	
Comments	*It might also be nice to show a clinician, a research result, and a patient from earlier in the course to tie back to the original materials. Do not use new pictures though because it should be a reinforcement, not something new to think about.*

Audio	Visual
6.4.1. [Narrator] Evidence-Based Medicine is not "cookbook" medicine. Ultimately the best clinical decisions are those that incorporate an understanding of the clinical state, evidence-based resources and patient preferences, combined with sound clinical expertise.	 *This is the Venn diagram used before. Repeat to reinforce.*

6.5. Conclusion	*req* *1 extra pill*
Comments	

Audio	Visual
6.5.1. [Narrator] Thank you for the care and concern you have demonstrated by reviewing this material. You can access the references at any time. Please be sure you take a few moments to complete the post-test.	You have completed this course. Please take a few moments to complete the post-test via the following link: *(link to surveymonkey here)* You can continue to use your Journal to record your learning. Click **here** for a list of all the Journal exercises in this course (and a few bonus questions.) Credits
6.5.2. [displays on click from previous screen only, OK to scroll] This is a list of all the journal questions presented in this course. Please take a moment to review your journal entries now. When you have answered all of these questions you may wish to print your journal so that you can discuss it in person.	Hypertension Case Study How would your application of this evidence differ if Your patient was: • a long haul trucker with limited access to a bathroom and reluctant to take a diuretic • an elderly woman with chronic hyponatremia • a patient with chronic kidney disease and a baseline creatinine of 3.0 Claudication Case Study Bhatt DL, Fox KA, Hacke W, et al. Clopidogrel and aspirin versus aspirin alone for the prevention of atherothrombic events. NEJM 2006;354:1706-17 Clopidogrel and Aspirin.pdf Having read the article do you think your patient would benefit from adding clopidogrel? Yes/ No/ Don't Know/ Need More Information Difficulty Sleeping Case • Reflect on a time when a patient asked you about a medication you did not know about, or was not indicated. • How did you reconcile it? • What are your thoughts on Direct to Consumer Advertising? • What did you learn from this case? Your Case

	• What was the foreground question? • In regard to the patient you have in mind, what is the clinical question? • Record the clinical question in your Journal now. Remember to use the PICO format Patient Intervention Comparison Outcome Which of these resources will you use to research your question? • Medline • Clinical Evidence • Cochrane Library • ACP Journal Club • The Medical Letter In your Journal record: • Where you will start looking • Why you decided to start there • Strategies you will use for the search • What steps did you take to appraise the evidence you found? If applicable what are the Relative Risk, , Relative Risk Reduction, Absolute Risk Reduction and Number Needed to Treat • Record how you would apply the evidence you found with this patient. • Is your decision unique for this patient? • How? • Why? *Indicate Journal*

6.6. Credits	*not req*
Comments	
Audio	Visual
6.6.1.	This course was made possible by a grant from the state Attorney General Consumer and Prescriber Education Grant Program which is funded by the multi-state settlement of consumer fraud claims regarding the marketing of the prescription drug Neurontin. The following institutions contributed to the course: • OHSU • PVARF • Planet Productions Principle Investigators • Dr. Stephanie Halvorson • Dr. Andrea Cedfeldt Project Support • Heather Crowell Hosting OHSU Integrity Education

7. Glossary

Add a footnote or other reference inside the glossary that reads:

Glossary adapted from the Clinical Epidemiology Glossary developed by the University of Alberta http://www.med.ualberta.ca/ebm/ebm.htm

This is not the same glossary as the FDA course. We need to make the cross references link correctly.

Term	Definition
Absolute risk	The observed or calculated probability of an event in the population under study.
Absolute risk difference	the difference in the risk for disease or death between an exposed population and an unexposed population.
Absolute risk reduction	(ARR): the difference in the rates of adverse events between study and control populations (ie: the difference in risk between the control group and the treated group: ARR=CER-EER)
Bias	(Syn: systematic error) Deviation of results or inferences from the truth, or processes leading to such deviation. See also Referral Bias, Selection Bias.
Blind(ed) study	(Syn: masked study) A study in which observer(s) and/or subjects are kept ignorant of the group to which the subjects are assigned, as in an experimental study, or of the population from which the subjects come, as in a nonexperimental or observational study. Where both observer and subjects are kept ignorant, the study is termed a double-blind study. If the statistical analysis is also done in ignorance of the group to which subjects belong, the study is sometimes described as triple blind. The purpose of "blinding" is to eliminate sources of bias.
Case-series	Report of a number of cases of disease.
Case-control study	Retrospective comparison of exposures of persons with disease (cases) with those of persons without the disease (controls) (see Retrospective study).
Clinical significance	A conclusion about whether or not an observation is of practical meaning to patients and health care providers.
Co-interventions	Interventions other than the treatment under study that are applied differently to the treatment and control groups. Cointervention is a serious problem when double blinding

	is absent or when the use of very effective non-study treatments is permitted.
Cohort study	Follow-up of exposed and non-exposed defined groups, with a comparison of disease rates during the time covered.
Comparison group	Any group to which the index group is compared. Usually synonymous with control group.
Confidence interval (CI)	The range of numerical values in which we can be confident (to a computed probability, such as 90 or 95%) that the population value being estimated will be found. Confidence intervals indicate the strength of evidence; where confidence intervals are wide, they indicate less precise estimates of effect. See Precision
Confounding variable, Confounder	A variable that can cause or prevent the outcome of interest, is not an intermediate variable, and is associated with the factor under investigation. A confounding variable may be due chance or bias. Unless it is possible to adjust for confounding variables, their effects cannot be distinguished from those of factor(s) being studied.
Effectiveness	a measure of the benefit resulting from an intervention for a given health problem under usual conditions of clinical care for a particular group; this form of evaluation considers both the efficacy of an intervention and its acceptance by those to whom it is offered, answering the question, "Does the practice do more good than harm to people to whom it is offered?" See Intention to treat.
Efficacy	a measure of the benefit resulting from an intervention for a given health problem under the ideal conditions of an investigation; it answers the question, "Does the practice do more good than harm to people who fully comply with the recommendations?"
Exclusion Criteria	Conditions which preclude entrance of candidates into an investigation even if they meet the inclusion criteria.
Follow-up	Observation over a period of time of an individual, group, or initially defined population whose relevant characteristics have been assessed in order to observe changes in health status or health-related variables.
Gold standard	A method, procedure, or measurement that is widely accepted as being the best available.
Incidence	The number of new cases of illness commencing, or of persons falling ill, during a specified time period in a given population. See also Prevalence.

Intention to treat analysis	A method for data analysis in a randomized clinical trial in which individual outcomes are analyzed according to the group to which they have been randomized, even if they never received the treatment they were assigned. By simulating practical experience it provides a better measure of effectiveness. (versus efficacy)
Interviewer bias	Systematic error due to interviewer's subconscious or conscious gathering of selective data.
Lead-time bias	If prognosis study patients are not all enrolled at similar, well-defined points in the course of their disease, differences in outcome over time may merely reflect differences in duration of illness.
Likelihood ratio	Ratio of the probability that a given diagnostic test result will be expected for a patient with the target disorder rather than for a patient without the disorder.
Number Needed to Treat (NNT)	the number of patients who must be exposed to an intervention before the clinical outcome of interest occurred; for example, the number of patients needed to treat to prevent one adverse outcome. Equal to the inverse of the absolute risk reduction NNT=1/ARR = 1/CER-EER.
Odds	a proportion in which the numerator contains the number of times an event occurs and the denominator includes the number of times the event does not occur.
Odds Ratio	(Syn: cross-product ratio, relative odds) a measure of the degree of association; for example, the odds of exposure among the cases compared with the odds of exposure among the controls.
p-value	is the probability of obtaining a result at least as extreme as a given data point, *assuming* the data point was the result of chance alone. The fact that p-values are based on this assumption is crucial to their correct interpretation.
Precision	The range in which the best estimates of a true value approximate the true value. See Confidence interval.
Predictive value	In screening and diagnostic tests, the probability that a person with a positive test is a true positive (i.e., does have the disease), or that a person with a negative test truly does not have the disease. The predictive value of a screening test is determined by the sensitivity and specificity of the test, and by the prevalence of the condition for which the test is used.

Prevalence	the proportion of persons with a particular disease within a given population at a given time.
Prognosis	the possible outcomes of a disease or condition and the likelihood that each one will occur.
Prognostic factor	Demographic, disease-specific, or co-morbid characteristics associated strongly enough with a condition's outcomes to predict accurately the eventual development of those outcomes. Compare with risk factors. Neither prognostic or risk factors necessarily imply a cause and effect relationship.
Prospective study	Study design where one or more groups (cohorts) of individuals who have not yet had the outcome event in question are monitored for the number of such events which occur over time.
Randomized controlled trial	Study design where treatments, interventions, or enrollment into different study groups are assigned by random allocation rather than by conscious decisions of clinicians or patients. If the sample size is large enough, this study design avoids problems of bias and confounding variables by assuring that both known and unknown determinants of outcome are evenly distributed between treatment and control groups.
Recall bias	Systematic error due to the differences in accuracy or completeness of recall to memory of past events or experiences.
Referral filter bias	The sequence of referrals that may lead patients from primary to tertiary centres raises the proportion of more severe or unusual cases, thus increasing the likelihood of adverse or unfavorable outcomes.
Relative risk	(RR, or risk ratio) the ratio of the probability of developing, in a specified period of time, an outcome among those receiving the treatment of interest or exposed to a risk factor, compared with the probability of developing the outcome if the risk factor or intervention is not present (ie., the ratio of risk in the treated group to the risk in the control group RR=EER/CER)
Relative risk reduction	(RRR) the extent to which a treatment reduces a risk, in comparison with patients not receiving the treatment of interest (ie., the percent reduction in events in treated compared to controls RRR=[(CER-EER)/CER]).
Retrospective study	study design in which cases where individuals who had an outcome event in question are collected and analyzed after the outcomes have occurred (see also Case-control study).

Risk factor	patient characteristics or factors associated with an increased probability of developing a condition or disease in the first place. Compare with prognostic factors. Neither risk or prognostic factors necessarily imply a cause and effect relationship.
Selection Bias	a bias in assignment or a confounding variable that arises from study design rather than by chance. These can occur when the study and control groups are chosen so that they differ from each other by one or more factors that may affect the outcome of the study.
Sensitivity	(of a diagnostic test) the proportion of truly diseased persons, as measured by the gold standard, who are identified as diseased by the test under study.
Specificity	(of a diagnostic test) the proportion of truly nondiseased persons, as measured by the gold standard, who are so identified by the diagnostic test under study.
Statistical significance	The outcome did not occur by chance. A statistically significant difference means there is statistical evidence that there is a difference; it does not mean the difference is necessarily large, important or significant in the usual sense of the word.
Stratification	division into groups. Stratification may also refer to a process to control for differences in confounding variables, by making separate estimates for groups of individuals who have the same values for the confounding variable.
Strength of Inference	the likelihood that an observed difference between groups within a study represents a real difference rather than mere chance or the influence of confounding factors, based on both p values and confidence intervals. Strength of inference is weakened by various forms of bias and by small sample sizes.
Survival curve	A graph of the number of events occurring over time or the chance of being free of these events over time. The events must be discrete and the time at which they occur must be precisely known. In most clinical situations, the chance of an outcome changes with time. In most survival curves the earlier follow-up periods usually include results from more patients than the later periods and are therefore more precise.
Validity	the extent to which a variable or intervention measures what it is supposed to measure or accomplishes what it is supposed to accomplish.

8. Resources

Description	Source
Planet Productions	http://www.planetproductions.com
	Greenhalgh T. How to read a paper: the Medline database. BMJ. 1997;315:180-183
	Hanes, RB et al. Developing optimal search strategies for detecting clinically sound studies in MEDLINE. J Am Med Informatics Assoc. 1994;1:447-458
	Sackett DL, Rosenberg WM, Gray. EBM: What it is and what it isn't BMJ 1996;312:71-72
	Users' Guides to Evidence-based Medicine: How to Use an Article about Therapy (1993;270(21):2598-2601) and (1994;271(1):59-63). Copyright 1995, American Medical Association.
	Adair RF and Holmgren LR. Do drug samples influence resident prescribing behavior? A randomized trial. Am J Med 2005;118:881-884.
	Chew LD. O'Young TS, Hazlet TK, Bradley KA, et al. A physician survey of the effect of drug sample availability on physicians' behavior. J Gen Intern Med 2000;15:478-483.
	Bhatt DL, Fox KA, Hacke W, et al. Clopidogrel and aspirin versus aspirin alone for the prevention of atherothrombic events. NEJM 2006;354:1706-17
	User's Guides to the Medical Literature
	Evidence-Based Medicine- David Sackett
Drug Ads Play Up Benefits, Downsize Risks	http://www.npr.org/templates/story/story.php?storyId=9571484#9572496
Lunesta Study	Lunesta study.pdf
	Lexchin, J. Bigger and better: How Pfizer redefined erectile dysfunction. PLoS 2006;3(4):e132.
	Applbaum K (2006) Pharmaceutical marketing and the invention of the medical consumer. PLoS Med 3(4): e189.Moynihan R, Heath I, Henry D. Selling sickness: the pharmaceutical industry and disease mongering.BMJ. 2002 Apr 13;324(7342):886-91
Clinical Evidence	http://www.clinicalevidence.com/ceweb/about/index.jsp
	http://www.cochrane.org/reviews/clibintro.htm

Description	Source
PDF of Development of Cochrane Library:	http://www.update-software.com/publications/Cochrane/history.pdf
Journals reviewed by ACP Journal Club	http://www.acpjc.org/shared/journals_reviewed.htm
ACP JOURNAL CLUB	http://www.acpjc.org/shared/purpose_and_procedure.htm
Medical Letter	http://www.medletter.com/html/who.htm
Evidence-Based Medicine	http://ebm.bmj.com/
BMJ Updates	http://www.bmjupdates.com/index.asp
PubMed Clinical Queries	http://www.ncbi.nlm.nih.gov/entrez/query/static/clinical.shtml
Drug Effectiveness Review Project	http://www.ohsu.edu/drugeffectiveness/reports/final.cfm
PubMed	http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?DB=pubmed
	Haynes RB. Of studies, syntheses, synopses, summaries, and systems: the "5S" evolution of information services for evidence-based health care decisions. ACP J Club. 2006 Nov-Dec;145(3):A8-9.
Clinical Epidemiology Glossary	http://www.med.ualberta.ca/ebm/ebm.htm