

EVIDENCE-BASED-MEDICINE (EBM)

Gordon Brock, M.D., F.C.F.P., F.R.R.M.S.

Medical Director MedExtra

Rural Physician, Eldee, Ontario

Ontario Lic. #31580

Associate Scientific Editor, Canadian Journal of Rural Medicine

Family Medicine can be complex and at times, frustrating for all. As opposed to more narrowly based specialties, the patient may enter the physician's office with any of a wide range of problems. Sometimes the course-of-action for the physician is clear, sometimes less clear:

- A healthy 51-year-old male comes requesting a 'Statin' for elevated cholesterol on recent lab tests. The physician has to decide if this lifelong treatment is beneficial.
- A 46-year-old comes in with a cough. The physician needs to decide if a chest X-Ray and antibiotics are required for acute bronchitis
- A 42-year-old comes in with a congestion and a 'runny nose' for a few days. The physician needs to decide if antibiotics are required for sinusitis.

EBM is the deliberate and judicious bringing of "Current-Best-Practice Recommendations" (CBPR) derived from Scientific evidence and Research, into the care of individual patients, to produce the best possible "Outcome" for the patient.

EBM – WHAT IT ALL MEANS

- 1) Optimizes physician medical decision making by emphasizing the use of evidence from well-conducted, scientific studies.
- 2) Integrates the physician's clinical expertise (years in the making) with the patient's values and this best-available scientific evidence from well-conducted research studies.
- 3) Equally importantly, **EBM** classifies **CBPRs** by their "strength", i.e. how confident the physician can be that following such a given recommendation will achieve the best "Outcome":
 - a. A "**Strong Recommendation**" means that test/treatment benefits clearly outweigh the risks.
 - b. A "**Weak Recommendation**" means that the scientific evidence is less clear on whether the benefits outweigh the risks.
- 4) **EBM** thus differs from "Traditional Medicine", whereby the Physician used his own knowledge, experience and preferences to make recommendations to his or her patients.
- 5) **EBM** is NOT "cookbook-style-medicine" with a one-size-fits-all recipe for a given patient. It must also incorporate consideration of (often non-quantifiable) things such as:
 - a. Patient desires and social factors
 - b. Individual physician preferences
 - c. Medical resources available for the treatment plan
- 6) **EBM** is NOT a total replacement for traditional medical care and decision-making, rather it's an adjunct and supplement to quality medical professional care and decision-making.

- 7) **EBM** is NOT:
- A magical panacea to get good care for patients
 - A tool for government health planners or for the cheapest possible medical care
 - Nor can it ever completely replace medical expertise and judgement
- 8) In the end, of course, the proverbial “acid test” is: Did the care given by the Physician produce the best possible “Outcome” for his or her patient in a Cost-effective manner:
- The quickest-possible return to prior health status?
 - The greatest chance of “cure”?
 - The least side-effects?
 - The best chance of quick return-to-health and work? etc.

HOW LONG HAS EBM BEEN WITH US?

EBM is neither new nor old: The use of scientific methods and statistics to determine the best possible care dates to at least 1835, when research papers using what today would be described as modern scientific methods began to be published. EBM truly came of edge in the 1970’s when research tools to evaluate the effectiveness of treatments became more and more refined. In the 1980’s, groups such as **RAND** in the U.S. and **The Cochrane Collaboration** in the U.K. formed to do the arduous work of reviewing the often-complicated and multiple research studies to distill them into clear “**Best Practice Recommendations to Physicians**”, and importantly, grade these Recommendations with respect to their “strengths.” Finally, the Internet Age in the 1990’s allowed physicians instant access to these Recommendations in real time in the comfort of their own offices.

EVIDENCE-BASED-MEDICINE

- 1) Improves Physician decision-making by providing clear Best-Practice-Recommendations
- 2) Integrates the best-scientific evidence with the physician’s expertise and patient desires
- 3) Is designed to produce the best-possible “Outcomes” for patients in a Cost-effective manner
- 4) Does not completely replace individual Physician expertise and experience

EVIDENCE-BASED MEDICINE CASE 1: A 51-YEAR-OLD MACHINIST WITH AN ELEVATED CHOLESTEROL

A 51-year-old machine operator came to see me for an opinion about his cholesterol. He has had his cholesterol checked at a clinic and thought that it was “elevated”. He says that he has a couple of uncles who take a “statin” (a class of medicine designed to lower cholesterol) and wonders if he should take a “statin” too?

In front of me, sitting comfortably in an office chair, I see a slightly obese man wearing jeans and a T-shirt, sitting comfortably in a chair. He looks older than his stated age.

In most patients, a quick series of 6-8 questions give a good indication of where we are headed:

- Has a doctor ever told you that you had heart disease? *The patient says No.*
- Do you have any chest-pain or shortness-of-breath when you climb stairs? *He again says no.*
- He does not smoke.
- Do you have high blood pressure? *He says not as far as he knows.*
- His father died at age 78 of cancer. His mother is alive at age 74 and is reasonably well.
- Do you have any other illnesses? *He has had mild asthma since childhood.*
- Do you have your results with you? *He shows me a paper and I notice quickly that his cholesterol level is 5.1 mmol/L which is above normal.*
- I next examine his heart and it is normal. His Blood Pressure is 124/84 (also normal)

At this stage, my “**Traditional Medicine**” would say: *“I see many patients like this...cholesterol a bit high.... They don’t have heart disease; they are more worried than anything else. There is no family history here to be worried about, you don’t smoke or have high blood pressure, so your risk of developing heart disease seems to me to be low. If you really want a “statin” I can prescribe one, but you then commit to taking a pill every day for the rest of your life, you can get side effects. Overall, I don’t think a statin will help you very much.”*

What would Evidence-based Medicine say?

- I run his age, blood pressure and cholesterol values through a Risk-assessment tool called “The Framingham”, developed in Framingham, Massachusetts by a group of Harvard physicians who have been following 5,209 men since 1948 for heart disease. It states that a man with his cholesterol levels and blood pressure has a 9.4% risk of developing heart disease over the next 10 years. This is classified as “**low-risk**”.
- **My question now is: If I prescribe a “statin”: What benefits can he expect? What risks?**
For this, I have to turn to the massive studies done in the 1990s, involving tens of thousands of men. They treated half of them with a “statin” (the “treatment group”) and the other half with a sugar pill (the “control group”) then “followed” them all for 5 years, and, basically, saw how many in each group developed heart disease.
- The studies showed that out of every 1,000 men in the “control group” (who got a sugar pill): 38 of the men had died over the 5 years of a variety of causes, including, cancer, heart disease and accidents, and 94 of them had developed heart disease.
- In the “treatment group” (the ones who got a “statin”): 38 of the men died (identical to the “control group”!!!) and 74 of them had developed heart disease, a bit less than in the “control group” – so maybe the “statin “worked???”

Now the hard part, as always in statistics, what does it all mean?

Take the 1,000 men in the “treatment group”: The exact same number died as in the “control group”. So.....**taking a “statin” for those 5 years did not save any of their lives.**

Taking a “statin” did seem to prevent about 20 cases of heart diseases in those 1,000 men (recall the “control group” had 94 cases while the “treatment group” had 74 cases): So 20 cases of heart disease were prevented in 1,000 men.....or 2 cases/100

Put another way: 100 men took a “statin” every day and it indeed seemed to save 2 of them from having heart disease.....the other 98 received no benefit at all; they did not do obviously any better or worse than the men taking the sugar pill. So, **Number Needed to Treat (NNT) to prevent one case of heart disease was 2 per hundred prevented case of heart disease or 1/50.**

But... in Medicine, there is always another side to the “Benefit side”: the “Harm” side. In the men taking a “statin”: 10% had muscle damage due to the drug and 2% developed diabetes.

So, now, my Evidence-based Medicine answer would be:

“If I had 100 men like you and I gave all of them a “statin” for 5 years like your uncles are taking: out of every one hundred men, only 2 would receive any benefit from the drug. The other 98 would have received no benefit from the “statin” and would have taken it, in effect, for nothing.....On the other side of the equation, 10 of those men would have sustained muscle damage from the drug and 2 would develop diabetes.

So, what do you think I should do?”

EVIDENCE-BASED-MEDICINE – LOW RISK INDIVIDUALS STATIN TREATMENT FOR 5 YEARS

- 1) No lives saved
- 2) 20 cases of heart disease were prevented (NNT 1/50 - 2 cases/100)
- 3) 10% had muscle damage, 2% (2/100) developed diabetes due to the Statin

EVIDENCE-BASED MEDICINE CASE 2: A 46-YEAR-OLD COMPUTER OPERATOR WITH A COUGH FOR 3 DAYS

A 43-year-old paper-mill computer operator is my next patient. The Nurse’s Triage Note says that he has had a cough for three days, and that his “vital signs”: heart and breathing rates, temperature, and blood oxygen saturation (the amount of oxygen getting from his lungs into his blood stream) are all Normal. He takes only a pill called hydrochlorothiazide for blood pressure.

Sitting comfortably in an office chair, wearing a shirt and tie, I see an average-built man who looks about his age. He looks “well” and not obviously having any difficulty breathing or pain.

In most patients, a quick series of 6-8 questions give a good indication of where we are headed:

- How long have you had this for? *Patient confirms “about three days”*
- Have you had any fever or chills? *Fever or chills means I have to worry if he has a pneumonia*
- Do you have a runny nose or sore throat? *If so, this might mean he has a simple “cold”*
- Are you spitting up any sputum? *He says no; Generally speaking, the more sputum, the sicker the patient...*
- Do you have any trouble breathing? *He says no.*
- Do you have any chest pain? *He again says no. Trouble breathing or chest pain mean the possibility of more serious disease.*
- Have you ever been diagnosed with lung disease, such as asthma or emphysema? *He says no, indicating that pre-existing lung disease is unlikely to be the cause of his symptoms*

- Do you smoke cigarettes? *Smokers are prone to serious lung disease.*

I then listen to the patient's chest and his lungs sound normal to me.

At this stage, my **"Traditional Medicine"** would say: I have seen many patients such as this in my 42 years of rural practice, and I think I have a lot of expertise and experience here. I believe that, with what I have seen, he does not have a pneumonia (my prime concern) and so I don't think a Chest-X-ray is really all that necessary. I often prescribe antibiotics, in my experience, many patients do want them, and they often tell me that they feel better when they have been prescribed.

My Traditional Medicine-what-I-would-tell-the-patient: *"You have acute bronchitis; I will write you a prescription for Biaxin (a "lung" antibiotic). Go home, rest and most patients are better in 5-7 days or so."*

What would Evidence-based Medicine say?

Study # 1: A study looked at the "vital signs" of 115 patients with pneumonia and found that almost 90% of them had either fever or a rapid heart rate or a low blood oxygen saturation, or else abnormal sounds when the physician listened to the chest. **Moral:** *Put another way, the risk that the patient has a pneumonia is substantially lowered if I find that he or she has normal temperature, heart rate and oxygen saturation, and his or her lungs sound normal when I examine the chest.*

CONCLUSION: **So, I seem to be supported in my assumption that, as he has normal "vital signs" and his chest seems normal: He is unlikely to have a pneumonia.**

I decided not to do an X-ray.

Study #2 reviewed the Chest-X-Rays done on 1819 patients with an acute cough. They asked the physician what they would prescribe before he or she could look at the X-Ray, then showed him or her the Chest-X-Ray and asked now what they would prescribe. **In 97% of the cases, doing a Chest-X-Ray did not change what the physician prescribed.** **Moral:** *Chest X-rays in patients who seem to have acute bronchitis only rarely change what the physician will prescribe.*

CONCLUSION: **I am supported in my decision that the patient did not need a Chest-X-ray. It would keep him here longer, expose him to radiation, have a cost, and in the end, would be unlikely to change very much.**

Antibiotics: Study #3 reviewed 17 studies with a total of 5099 patients with acute bronchitis; About half the patients were prescribed antibiotics, the other half got a sugar pill. At best, antibiotics made the patient better about half-a-day-faster and got him or her back to work, again about half-a-day faster. 1/24 of the patients given antibiotics had a "harmful side effect".

At this stage, my **Evidence-based Medicine** would say that I can be reasonably sure (90% ??? – pretty good but not quite 100%, maybe I should be a bit cautious) that the patient has acute bronchitis and does not have a pneumonia, and that a Chest-X-ray would be unlikely (97%) to change what I will tell the patient. Antibiotics might, at best, get him better a half-a-day quicker, but there is some risk of a side effect.

My Evidence-based-what-I would-tell-the-patient: *"I am reasonably sure, 90% or so, that you don't have a pneumonia, you have an acute bronchitis. X-rays are really not all that helpful here, so I do not think it is necessary to keep you here any longer or expose you to unnecessary radiation-risk. On the question of antibiotics, I can prescribe them, but, at best, they only make half-a-day's difference, and expose you to side effects, so I generally do not prescribe them. As I mentioned, it is hard to be 100% certain in medicine, but for now, go home, rest and most patients are better in 5-7 days or so. But, in the next few days, if your temperature or heart rate shoot up, or if you feel really unwell: Come back to see me and I will do a Chest-X-Ray ASAP".*

Now, which approach sounds better to you????

EVIDENCE-BASED-MEDICINE – X-RAYS & ANTIBIOTICS

ACUTE BRONCHITIS

- 1) In 97% of cases chest x-ray did not change treatment
- 2) Antibiotics at best accelerated return to health/work by one-half (1/2) day
- 3) 1/24 patients taking antibiotics had a 'Harmful side effect'

EVIDENCE-BASED MEDICINE CASE 3: A 42-YEAR-OLD ACCOUNTANT WITH SINUSITIS

A 42-year-old Accountant came in with a runny nose and mild cough for 5 days. Her regular Family Physician was away and that is why she was seeing me that day; She says this is a "sinusitis" that she gets once a year or two, and her regular Family Physician always prescribes her antibiotics for this, and these makes her feel better in a few days.

In front of me, sitting comfortably in an office chair, I see a well-dressed woman, looking about her age and not seeming sick. In most patients, a quick series of 6-8 questions give a good indication of where we are headed:

- How long have you been sick for? *About 5 days*
- How did it start? *Like always, it started as a mild "cold" for a day or two, but has been worsening slowly...*
- Do you have a runny nose? *Yes, more on the left side, with thick greenish mucous.*
- Is your nose blocked? *Yes, a bit more on the left side.*
- Cough or fever? *No fever, but a bit of a cough, especially at night.*
- Any pain? *The left cheek is painful and sore since I awoke this morning.*
- Are you a well-person generally? *Yes*
- I examine her: *Her left nostril is swollen inside. The left cheek area is tender when I touch it.*

At this stage, I agree that she indeed has sinusitis.

At this stage, my "Traditional Medicine" would say: *"I see lots of cases of this. Many of the patients say that antibiotics make them get better quickly, and antibiotics seem harmless enough. So why not just write her a prescription for antibiotics and send her on her way?"*

What would Evidence-based Medicine say?

I consult the Cochrane Review, a medical think-tank in the UK which reviewed the files of 3057 patients with sinusitis. They found that:

- 1) Even without antibiotics, most patient recovered quickly. About half of them (46%) were better in one week and two-thirds (64%) were better within two weeks. So, most patients get better quickly, even without antibiotics.
- 2) Patients given antibiotics did only minimally better, about 6%, so say, in those patients who were antibiotics: 52% were better in one week and 70% better within two weeks.

Now the hard part, as always in statistics, what does it all mean?

Take 100 patients with sinusitis and let us give them all antibiotics and call them all back in a week: 52 will say that they are better, but from the studies above, 46 of them would have gotten better anyway, even without antibiotics. The 'extra' 6 above that will say they are better, is perhaps the placebo effect or the antibiotics.

Put another way: 100 patients took antibiotics to cure an extra 6 people over and above those who would have gotten better "anyway". So, **the Number Needed to Treat (NNT) one case of sinusitis was 17 (100 ÷ 6).**

17 patients took antibiotics and, in the end, only one benefitted. The other 16 did not do any better than the patients who were not given antibiotics.

But... in Medicine, there is always another side to the “Benefit side”: the “Harm” side. In the patients who got antibiotics, about one-in-eight (1/8) had a harmful side effect, most often diarrhea.

So, now, my Evidence-based Medicine answer would be:

“Antibiotics really do not help very much in sinusitis, most people get quickly better without them in a week or two. In fact, 17 patients will have to take antibiotics to help cure one of them, the other 16 will get no real benefit from the antibiotics, and two or so of them will have side effects, including diarrhea.

Perhaps a case of harm outweighing good.....If you really want them, perhaps I can give you some antibiotics, but it is maybe wiser to give you a prescription for a cortisone nose spray to decongest your nose and some Tylenol for now. I should see you in a week or so, and if you are not better then, we can re-evaluate.

So, what do you think I should do?”

EVIDENCE-BASED-MEDICINE – ANTIBIOTICS FOR SINUSITIS

- 1) 52% of patients were ‘better’ versus 46% not treated (6/100 – NNT 1/17)
- 2) 1/8 patients taking antibiotics had a ‘Harmful side effect’