
 Commentary

Evidence-based Medicine Meets Goal-directed Health Care

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Evidence-based medicine and goal-directed, patient-centered health care seem, at times, like parallel universes, though, at a conceptual level, they are perfectly compatible. Part of the problem is that many of the kinds of information required for decision making in primary care are often unavailable or difficult to find. Several case examples are used to illustrate this problem, and reasons and solutions are suggested. The goal-directed health care model could be helpful for directing the search for evidence that is relevant to the decisions that patients and their primary care physicians must make on a regular basis.

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Evidence-based medicine is:

the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine requires integration of individual clinical expertise and patient preferences with the best available external clinical evidence from systematic research.¹⁻⁴

The best evidence of treatment effects is believed to come from randomized, controlled trials. Epidemiological studies (cohort, case-control, and cross-sectional) and expert opinion are of lesser value, and anecdotal information is considered to be unreliable.⁵⁻⁶ Recognizing that the most useful clinical evidence involves outcomes of importance to patients, Slawson,

Shaughnessy, and colleagues coined the phrase “patient-oriented evidence that matters” (POEMs).⁷⁻¹¹

Goal-directed health care is a conceptual model of care in which the goals and objectives are determined prior to deciding on diagnostic and treatment strategies.¹²⁻¹⁴ This approach contrasts with problem-oriented care in which identification and correction of problems is assumed to result in desirable outcomes. Goal-directed health care is most applicable to primary care settings in which longitudinal physician-patient relationships are of central importance and where patients see physicians for preventive care and natural occurrences such as pregnancy that cannot be accurately characterized as problems. The focus on goals and objectives (which are values driven) rather than problems (which are value neutral) puts greater emphasis on the relationship between physician and patient. The result is patient-centered care.¹⁵⁻¹⁸

Evidence-based medicine and goal-directed health care are perfectly compatible at a conceptual

level. Physicians and patients ought to consider the available evidence when determining goals and objectives and when choosing among strategies for achieving them. Unfortunately, the evidence required to practice goal-directed care is often unavailable or hard to apply because of the way it is currently being collected, analyzed, and reported.¹ The following scenarios highlight some of the challenges associated with finding and using the best available evidence to inform goal-directed care. Suggestions are made regarding the types of additional information required, and some examples are provided of methods for analyzing and organizing information to make it more useful.

Cases

Case #1: Clarence

Clarence, a 46-year-old tax attorney, visited a health fair where his serum cholesterol was measured. Because it was high, he was told to consult his physician. When a fasting lipid panel confirmed the abnormality—total cholesterol 260 mg/

dL, LDL 170 mg/dL, HDL 38 mg/dL—Dr Mosely suggested that Clarence come in. The conversation went something like this.

Doctor: Your cholesterol is too high. While you have no symptoms of heart disease, you are 46 years old, and your HDL (good cholesterol) level is a little low. I suggest that you modify your diet and walk 20–30 minutes three times a week. Eat less red meat, avoid fried foods, drink low-fat milk, and use polyunsaturated oils or olive oil when cooking. I will give you some written material to take home to your wife, and if she has questions, have her call me. We'll repeat your tests in 6 weeks.

Clarence: Actually, I already eat a pretty good diet, and I play full court basketball twice a week and walk the dog for 30 minutes every night.

Doctor: That's good, but look through this material on a healthy heart diet and see if there are some things that you can do to improve. I'll check your cholesterol again in 6 weeks.

Three months later, Clarence's lipid levels were the same.

Doctor: Well, it appears that diet isn't going to be sufficient. I think that you should start taking a cholesterol-lowering medicine.

Clarence: I don't like to take medicine. I rarely ever take an aspirin.

Doctor: Actually, you probably *should* take an aspirin every day to reduce the chance of heart disease.

Clarence: If I take the cholesterol medicine, what will it do for me?

Doctor: It will reduce your risk of having a heart attack.

Clarence: By how much?

Doctor: Well (pulling out his handheld computer), if we can get your LDL cholesterol below 130, we can lower your risk of a heart attack over the next 10 years by 20%.¹⁹

Clarence: What's my risk now?

Doctor: About 10%.

Clarence: So, I can lower my risk of a heart attack from 10% to 8% over the next 10 years. That doesn't sound like much, and I was counting on living beyond 56. By how much will I reduce my risk over the next 25 years?

Doctor: That's beyond the range of my calculator, but I'm sure we will have better ways to deal with heart disease by then. Why don't you go home and think about it. Discuss it with your wife. I'm sure that she and the kids don't want you to have a heart attack. Call me with your decision.

One week later, Clarence called his doctor.

Clarence: I have a few more questions. When I thought about it some more, I remembered that heart attacks can sometimes be reversed with clot-busting drugs, right? And even when they can't be reversed, I assume that many heart attacks don't result in death or serious disability.

Doctor: That's true.

Clarence: Also, can you estimate my life expectancy with and without the medicine? Remember I have a family history of cancer.

Doctor: Only because it's you, Clarence. You're really making me earn my money.

Clarence: I appreciate our relationship, but I would think that most patients would want the same information. By the way, we haven't really talked about the cost and side effects of the medicine.

Doctor: Well, unfortunately these medicines—"statins"—are somewhat expensive, but they rarely cause side effects, though liver and muscle problems sometimes occur. They will cost you about \$85 a month.

Clarence: That would be about \$10,000 over the next 10 years. And I assume I will also see you more often and have periodic blood tests.

Doctor: (beginning to show signs of fatigue) Yes. I will need to see you and do blood tests every 6 months. I don't know how much

that will cost, but you can probably figure it out.

Clarence: OK. Give me another week, and I will get back to you. Call me if you find the life expectancy figures.

One week later, Clarence contacted his doctor.

Doctor: What do you say, Clarence? Are you convinced?

Clarence: I am close to making a decision. First, let me review my understanding of the decision.

Doctor: Go ahead.

Clarence: If I take the medicine for the next 10 years at a cost of \$10,000 (assuming the cost of office visits and labs are balanced by the potential cost savings associated with treatment of preventable heart attacks), I can reduce my risk of a heart attack by 2%, from 10% to 8% and, based on my own research, increase my life expectancy by about 2 weeks. I could find no quantifiable information regarding the effect of heart attacks on quality of life, so I couldn't take that into account.

Doctor: Don't forget that the 1 month of life is an average. You actually have a 2% chance of gaining years of additional life. Also, consider the effect on heart attack rates throughout the country if everyone like you took the medicine.

Clarence: Whoa! I'm as altruistic as the next guy, but I'm not going to take an expensive medicine to improve population statistics.

Doctor: Fair enough.

Clarence: I have one final question. When it's my time to go, I would like to die in my sleep. How will taking the cholesterol medicine affect my chances of dying that way?

Case #2: Mildred

Mildred, who was 79 years old, had been Dr Mosley's patient for more than 20 years. The doctor had treated her for hypertension, osteoarthritis, and recurrent sinusitis. Her blood pressure, which had been well controlled on hydrochlor-

thiazide 25 mg daily, had increased gradually to 190/90 but was now averaging 155/85 after the addition of lisinopril 40 mg and amlodipine 5 mg daily. Her renal function was normal, and a computerized tomographic angiogram of her renal arteries was normal as well. She was only covered by Medicare and said she couldn't afford more medications. She had noticed ankle edema since she started the amlodipine and didn't want to increase the dose. She followed a DASH diet, avoided excess sodium, and walked four times a week for 30 minutes.

At her most recent visit, she asked whether she was likely to live long enough to benefit from more-aggressive treatment of her hypertension and whether she had already gotten most of the benefit of treatment by lowering her blood pressure from 190 to 155 systolic. Dr Mosley wondered how to weigh the value of treatment against the cost and side effects of additional medications and the extra visits required to adjust them.

Case #3: Harvey

Harvey was 50 years old, divorced, overweight (body mass index=29), sedentary, and smoked one pack of cigarettes per day. His average blood pressure was 160/95. He had diabetes, and his most recent hemoglobin A1C was 8.1. His LDL and HDL cholesterol levels were 160 mg/dl and 33 mg/dl, respectively. His homocysteine level was 10% above the upper reference limit. He was asymptomatic, saw Dr Mosley only occasionally, and was generally nonadherent to his recommendations.

Dr Mosley had a new plan for Harvey's next visit. Instead of listing all of the ways that Harvey could lower his heart attack risk (see Table 1), he would focus on one or two of them and try to relate their value more directly to Harvey's own values and priorities. He wished he had better information about the relative effect of each intervention

Table 1

Possible Strategies to Reduce Harvey C's Heart Attack Risk

1. An aerobic exercise program/routine
2. Weight reduction
3. A low saturated fat, low cholesterol diet
4. Smoking cessation
5. Blood pressure reduction
6. Blood glucose reduction
7. Aspirin 81 mg per day
8. LDL cholesterol reduction using a statin
9. HDL cholesterol elevation using niacin
10. Vitamin supplementation to reduce homocysteine level
11. An exercise thallium scan or dobutamine echocardiogram with angioplasty or stenting if indicated

on life expectancy. He wondered if he should suggest the strategies that would be easiest to initiate (eg, aspirin and vitamin supplementation), the one not requiring a long-term commitment (exercise testing), or the ones with benefits beyond heart attack prevention (eg, blood sugar control and smoking cessation). Or should he simply ask Harvey which strategies he would be most likely to carry out?

Discussion

What Kinds of Evidence Do We Need?

While most of us would agree that Clarence did make his physician "earn his money," we must also acknowledge that many patients might want the same information if they could get it.

Much of the evidence being collected and valued today pertains to the efficacy of clinical interventions. However, the proper application of this evidence to individual patients requires other types of information. For example, we need to know which outcomes are of greatest importance and what risks and costs are generally acceptable to most patients, how to identify patients whose values differ substantially from the majority, the optimal timing of different interventions, the relative effects of different interventions, the most effective ways to articulate information and

recommendations to patients, and the most efficient ways to facilitate changes in behavior. These kinds of information may not be easily obtainable from randomized controlled trials.

Applying Evidence to Individual Patients

Harvey and Mildred asked relevant questions to which answers probably exist, but the data haven't been analyzed in ways that would make it maximally useful. We know that control of blood pressure in 79-year-old patients reduces the rate of strokes, heart failure, and renal failure. What isn't clear, however, is whether most of the benefit occurs as a result of the initial 10–20 mm Hg reduction or whether each additional 10 mm Hg is of equal importance. This is important, because the final 10–20 mm Hg reduction is the hardest to achieve, often requiring the use of multiple medications at side effect-producing doses. We could find only one study that shed any light at all on this issue, and it was done for an entirely different purpose.²⁰

A handful of studies of blood pressure reduction have included total mortality as an outcome, but meta-analyses have suggested that treatment is associated with a reduction in mortality rate from 29 deaths per 1,000 person years to 25 deaths per 1,000 person years over a 5-year

period.²¹ Is that degree of benefit enough to be important to an individual with a 7-year life expectancy? And, is the benefit greatest initially, constant throughout the course of treatment, or does it increase with duration of treatment? Should we wait to treat hypertension until the risk of stroke and heart failure reach a certain level or begin treatment as early as possible?

Prioritization

Physicians often try to address every risk factor and solve every problem in much the same way that a mechanic fixes a car. But human beings aren't cars, and it isn't often possible to eliminate every risk factor and resolve every problem. Many interventions require behavioral change, which requires motivation. Motivation relates directly to personal goals and objectives, which are determined by values, strengths, resources, limitations, and action constraints.^{22,23}

In practice, problems with easily measurable outcomes and requiring little physician effort (eg, hypertension) tend to be addressed before those that require more time and effort (eg, smoking cessation) unless patient priorities intervene. The relative benefit of interventions is taken into account only if the patient is symptomatic. In fact, accurate information on benefit is rarely available, though methods by which to estimate it have existed for more than 25 years.

When the goal is prevention of premature death and disability, we should have at our fingertips estimated life expectancies and causes of premature disability for patients with various combinations of age and risk factors, and we should be able to estimate the relative benefit of available interventions on those outcomes. Health risk appraisal methods can be used to prioritize interventions by quantifying their effect on life expectancy.²⁴ Electronic databases documenting the

experiences of large numbers of patients can be used to predict outcomes of individuals.

When we are trying to maximize quality of life, we should be able to estimate the effects of treatment on function, taking into account such things as cost, side effects, and the adverse effects of diagnostic labeling. Many clinical trials now include quality-of-life measures, and that is a step forward. However, as stated by Carr and Higginson, quality of life is an individual construct, and most of the currently available measures don't take account of individual values and preferences.²⁵ Instruments that do are available but are not in widespread use.²⁶⁻²⁸ Patient preference trials and "N-of-1" studies are other options that can be considered.²⁹⁻³³

Before explaining benefits and risks, and certainly before making recommendations, we should take into account patients' readiness to change. The transtheoretical (stages of change) model can help predict the likelihood of behavioral change.³⁴⁻³⁶ It was developed 25 years ago and is only recently receiving the attention of practicing physicians.

Patients and their primary care physicians need lots of information of many kinds to make evidence-based decisions. There is no reason that this information cannot be obtained and disseminated in ways that maximize its value. At least two obstacles stand in the way, the notion that many of these issues that we have discussed constitute "the art of medicine" and are therefore not amenable to study and the reliance on a problem-oriented medical model that depersonalizes care, hiding many important elements of patient-centered decision making. The use of a goal-directed health care model to drive the search for evidence may help us overcome these obstacles.

Summary

Our goal was to evoke discomfort and stimulate thinking about the kinds of evidence that primary care physicians need. Viewing primary care as a goal-directed activity could help focus these efforts. Substantial progress has been made in gathering evidence. Researchers are more often including total mortality and quality of life as outcome measures. Before evidence-based medicine can be incorporated within a goal-directed framework, however, the concept of evidence must be expanded to include the many other important strategic issues involved in primary care practice, and the sources of that evidence must be extended beyond the traditional research methods.

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