

CASE AND COMMENTARY

Should a Physician Offer Recommendations Based on Experience but Contrary to Current Practice Guidelines?

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Abstract

This case of a patient whose physician refuses to prescribe statins for high cholesterol raises ethical issues about a physician's decision to offer clinical recommendations contrary to current practice guidelines. Our response summarizes social forces that have led to the rise of evidence-based medicine, the development of clinical guidelines, and the evolution of the roles of physicians and patients in decision making. We conclude that there are times when a physician can justifiably make a recommendation to a patient that contravenes a current clinical guideline. In making such a recommendation, we suggest that a physician should communicate a rationale for deviating from clinical guidelines and respect a patient's autonomy. We consider the need for and limitations of clinical guidelines, numerous factors influencing shared decision making, and key ethical principles of nonmaleficence and respect for patient autonomy.

Case

Mr S is a 50-year-old man who presents to his primary care physician in rural Pennsylvania. He is here to see Dr O for his annual physical examination. Dr O took care of Mr S's parents and now cares for Mr S's wife and their 3 adult children. Mr S has known Dr O for a long time and considers him not just his physician, but a friend.

Mr S and Dr O begin with some social conversation, then discuss his current health and concerns and proceed to the physical exam, which suggests no abnormalities. Dr O reviews Mr S's recent bloodwork. Despite 6 months of lifestyle modifications, Mr S continues to have elevated low-density lipoprotein (LDL) and total cholesterol levels, and lower than normal high-density lipoprotein (HDL) cholesterol. Dr O thinks that Mr S should continue with the current plan and recheck his lipid panel in 6 months. However, Mr S is concerned that his high cholesterol will not significantly improve in another 6 months and asks Dr O, "Shouldn't I be taking statins or some kind of medication for my high cholesterol at this point, Doc?" Dr O answers as follows: "I don't prescribe statins, which are a class of cholesterol-lowering medications recommended by the American Heart Association. I have taken them myself and experienced terrible muscle pain, which

is a well-documented side effect, to the point where it affected my ability to walk. I have had a couple of other patients who were on statins and stopped taking them because of severe side effects. Given my personal experiences with statins, I've stopped prescribing them altogether. My role as a good physician is to help improve your quality of life, not worsen it. Statins negatively affected my quality of life and I think they will negatively affect yours, too. Rather than statins, I recommend that you continue with lifestyle changes including increased exercise and a low-fat diet."

Mr S sat in silence contemplating his response. Dr O has been his trusted physician for nearly all his adult life, but he wonders why Dr O is recommending something inconsistent with well-established practice guidelines.

Commentary

This case raises 2 fundamental and interrelated issues of doctoring: On what basis should physicians make treatment recommendations? And what is the role of the patient and the physician in formulating treatment decisions? These questions pertain to the epistemology and relational foundations of medicine. Epistemology is a branch of philosophy concerned with sources of knowledge and what constitutes truth. Philosophers diverge on the question of which criteria should be regarded as justifying a belief. Some ("evidentialists") require evidence sufficient to prove that the cause of a phenomenon is not the result of chance.¹ Others ("reliabilists") maintain that a belief is justified if it arises from reliable cognitive faculties and considers the probability of a phenomenon's occurrence.¹ These ideas have important applicability to health care. For example, ideally a physician should make treatment recommendations based, at a minimum, on a thorough understanding of the best available evidence of potential benefits and harms of treatment options while considering the patient's goals, preferences, and social context. A physician also needs to maintain awareness of how his or her own cognitive and affective biases might affect his or her decision making. We conclude that Dr O would be justified in making a recommendation contrary to clinical guidelines if he accomplished all the above and met specific obligations to his patient. We do not believe Dr O met these requirements in this case.

Statin Guidelines and Possible Explanations of Dr O's Recommendation

The relevant guidelines are the 2013 American College of Cardiology/American Heart Association (ACC/AHA) statin guidelines.² These guidelines changed the previous risk assessment model and lowered the risk threshold considered sufficient to warrant primary prevention statin therapy to levels below those of other leading international guidelines. Per the ACC/AHA guidelines, statins are recommended for persons without clinical atherosclerotic cardiovascular disease (ASCVD) or diabetes who are 40 to 75 years of age, have LDL cholesterol levels between 70 and 189 mg/dL, and have an estimated 10-year ASCVD risk of $\geq 7.5\%$. The guidelines also advise against specific cholesterol target levels, advocating instead for treatment intensity according to risk

category.² The US Preventive Services Task Force advises therapy based on the presence of 1 or more CVD risk factors and a 10-year CVD risk of 10% or greater.³ There is no consensus among national or international guidelines about these recommendations.⁴ Disagreement among experts rightfully raises questions among practicing physicians about whether a specific treatment recommendation consistent with one of these guidelines would be based on a justified belief.

The case does not indicate whether Dr O believes there is sufficient evidence to support the ACC/AHA guidelines. Assuming he does and that Mr S falls within recommended treatment thresholds, recommending a statin would be based on Dr O's justified belief that this would be beneficial. Alternatively, suppose Dr O does not agree that sufficient evidence supports the guidelines or is skeptical in view of differences in guideline risk models and treatment thresholds. He would not be obliged to recommend statins in this situation, as a recommendation would not be based, in his mind, on a justified belief. In this case, however, Dr O seems unaware that his exclusive focus on his negative personal experiences with statins may reflect cognitive bias, hijacking his decision-making process and influencing his recommendations. More specifically, his personal experience as a patient may have generated cognitive availability bias (judging a phenomenon as more likely to occur because it springs readily to mind) and base rate neglect (ignoring the known prevalence of a condition because one is focused on a specific case).^{5,6} Both possibilities may have led him to weigh the harms of statins more heavily than their benefits. If so, his recommendations would not rest on a justified belief and would be unsupported. It is also possible that Dr O is not familiar with the guidelines.

Regarding the second question about the role of patient and physician in decision making, although Dr O seems genuinely concerned for the patient's quality of life, he fails to integrate the patient's concerns and preferences into his recommendations. This omission does not emerge from issues related to the evidence upon which the guidelines are based. Rather, it may emerge from a physician-centered orientation to decision making, lack of knowledge about the impact of patients' active involvement in their care on health outcomes, or lack of interpersonal and communication skills.

As we discuss next, the challenge of justifying clinical recommendations led to the evolution of clinical practice guidelines.

Challenges in the Development of Medical Standards

The American College of Surgeons published the first professional guidelines regarding cancer care services and fracture management in 1931, followed by the American Academy of Pediatrics, which produced practice guidelines regarding immunizations for children in 1938.⁷ After World War II, the evolution of randomized, controlled trials offered new tools to assess the efficacy of newly developed therapeutics.⁸ Subsequent expansion of federal funding for research and the expanded role of government as health

care provider, purchaser, and overseer of the public's health contributed significantly to the mandate for standards to ensure the quality of care.⁷

Professional standards review organizations, established in 1972 through amendments to the Social Security Act, enabled the development of data systems that uncovered wide variations in practice and care quality,⁷ leading to calls for more rigorous application of research-based evidence to clinical care. David Sackett, acknowledged as the father of [evidence-based medicine](#) (EBM), defined it as "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients."⁹ The practice of EBM involves integrating the physician's clinical expertise (knowledge, proficiency, and judgment acquired through experience and reflective practice) with the best available evidence from systematic research.^{9,10} EBM pioneers acknowledged that appropriate variations in practice might arise from physicians' using their clinical judgment and knowledge of patients' circumstances in addition to the results of rigorous research to guide care.⁹ Some variations, of course, might arise from lack of awareness of research findings.

Proponents of EBM and clinical guidelines encountered considerable backlash from physicians who objected to formulaic, "cookbook medicine."^{9,11} Tensions emerged among those who viewed [evidence-based guidelines](#) as a means to consolidate professional power and others who viewed them as impinging on physicians' autonomy.¹² Nevertheless, the convergence of rapidly expanding medical knowledge, technology, and treatments and the desire to reduce variation and improve quality of care has led to the development of myriad clinical practice and prevention guidelines by medical organizations and specialty societies.⁷ The relationship between physicians and guidelines has become even more complex as guidelines have become measures of accountability, enforced and incentivized by insurers, governmental agencies, and the courts.¹³

Physician adherence to guidelines remains low, and interventions to enhance adherence have yielded mixed results.^{14,15} One review suggests that this lack of adherence is attributable to multiple factors: skepticism about guidelines in general, lack of familiarity with guidelines, lack of belief that a guideline will result in expected outcomes, presence of contradictory guidelines, and lack of self-efficacy or motivation to implement guidelines.¹⁶ External barriers also impede physicians' adherence to guidelines, including lack of time and resources, organizational constraints, and inability to reconcile patient preferences with guideline recommendations.¹⁴ In this case, it's Dr O's preference, not the patient's, that contradicts current guidelines. This difference in preferences brings us to a discussion of the relational foundations of medicine and how the evolution of the patient-physician relationship has affected decision making.

Decision Making in the Patient-Physician Relationship

Scholars and researchers have described various models of the patient-physician relationship and proposed recommendations about what might be “ideal,” particularly regarding the decision-making process.¹⁷ For years, the beneficent *paternalistic* model prevailed, with physicians making decisions and presenting patients with information sufficient to obtain assent to the intervention she or he believed best. In the late 20th century, at around the time that the EBM movement was gaining steam, the rise of consumerism and consumer protections motivated patients and physicians to begin considering other approaches that expanded patients’ involvement in making decisions about their medical care.¹⁷

Although many models of the patient-physician relationship have been proposed, we discuss two here. In the *informative* model, the physician serves as a technical expert who provides relevant information and implements the patient’s choice of treatment.¹⁷ This model overlooks the physician’s need to participate in decisions in caring relationships with patients and patients’ needs to feel they have a supportive guide when decisions are difficult.^{18,19} The *shared decision making* model evolved to address how to find balance between physician power and patient choice.²⁰ The process involves, at a minimum, sharing of information and preferences by both physician and patient and an attempt to reach a shared understanding about the nature of the problem and what to do.^{20,21} The physician’s [communication tasks in shared decision making](#) include building a partnership with the patient (or family); understanding the patient’s social circumstances, preferences, and expectations; and providing information about the patient’s condition as well as the benefits and potential harms of available treatments. Communication tasks also include discussing uncertainty about how available research evidence might apply to the patient, explaining the rationale for one’s recommendations, checking for understanding, and reaching agreement with the patient about how to proceed.²²⁻²⁵ [Applying population-based guidelines to an individual patient](#) while integrating a patient’s preferences can be daunting. This task, however, is the essence of patient-centered care.²⁶

The steady increase in people accessing medical information on the internet is changing the physician-patient relationship. For example, research based on the 2015 Health Information National Trends Survey notes that, among all racial groups, the internet is the most utilized first source of health information; health care practitioners come in second.²⁷ Mr S, who wonders why his physician is recommending “something inconsistent with well-established practice guidelines,” probably read about them on the internet if he did not receive information about them from Dr O. Physician responses to patients asking about health-related internet information have been mixed. Some are threatened, some view interpretation of this information as their responsibility, and others view it as an opportunity for partnership, particularly with activated patients.^{28,29} Researchers define patient “activation” as having the knowledge, skills, and confidence

to manage one's health.³⁰ They posit that positive health behaviors emerge, in part, from actively seeking information to inform choices and behavior change.³¹ Current evidence suggests that highly activated patients are significantly more likely to be aware of treatment guidelines for their condition and have improved health outcomes compared with less activated patients.^{31,32}

The Physicians' Obligations and the Patient's Options

Dr O has several obligations. He is obligated to remain informed about developments in medical knowledge, treatments, and guidelines. He is obligated to be self-aware and transparent. Dr O should acknowledge—to himself and to his patients—areas in which he has overwhelming cognitive and affective biases and that his personal experience may not be generalizable to others. Of course, biases are not always accessible to our conscious awareness, which makes acknowledging them and uncoupling them from decision making difficult.⁶ Dr O is also obligated to respect patient autonomy and to involve the patient in decisions when the patient so desires. He should acknowledge that Mr S may weigh the potential benefits and harms of a statin differently than he does. Dr O might choose to say something like this: "First and foremost, I want you to enjoy good health. The research I'm aware of supports recommending a statin in your case to reduce your risk of cardiovascular disease. Some people who take statins develop muscle pains, which is a known side effect. My own experiences with muscle pains while on statins have made me sensitive to that problem, but the published statistics say that most patients take statins without any problems. What's most important is how *you* weigh the benefits and harms of taking a statin. Let's talk about that and make a decision about what might be best for you."

If, however, Dr O has reviewed the research and disagrees with the guidelines (because he believes the evidence is flawed, for example), has addressed any personal biases influencing his interpretation of the data, and has explained the reasoning behind his recommendations to the patient, he is not obligated to prescribe a medication or follow guidelines which he believes, professionally, are not in the best interest of his patient.³³ Under these circumstances, he can choose, following the ethical principle of nonmaleficence, to "do no harm."

Mr S is an informed, activated patient who is perplexed by his physician's deviation from recommended guidelines. What might he do in this situation? Mr S might respond to Dr O's recommendations by saying, "I appreciate that you are looking out for me, but I'm still worried about having a heart attack or stroke. Is there someone else I could talk to who might have a different opinion?" Or, if highly activated, he might say, "I'm willing to try a statin medication, even though you're not enthusiastic about prescribing one." However, unless Dr O explicitly invites his input, Mr S might simply contemplate Dr O's bias and wonder if it is time to change physicians.

Obligations, Evidence-Based Guidelines, and the Physician-Patient Relationship

The convergence of EBM and incentivized guidelines, patient-centered care, and shared decision making, consumerism, and patient engagement is changing our concepts of agency for both patients and physicians. Competent physicians remain well informed about scientific developments and new evidence in their field of practice and strive to be aware of the influence of their cognitive and affective biases. They are obliged to provide high-quality care and to uphold the ethical principles of beneficence, nonmaleficence, and respect for autonomy and to do so within the context of caring, compassionate relationships. For reasons perhaps not fully elucidated, Dr O was unable to fulfill these obligations. We do not agree with his decisions or recommendations but would hope to discuss this with him if he were a colleague.

In summary, in cases in which physicians recommend deviating from a guideline, they are obligated to ensure, to the best of their ability, that their recommendations are based on justified belief, not driven by bias or conflict of interest. They are obligated to present clear information about risks and benefits of available treatment options and alternatives to patients. Physicians and patients may then share the responsibility to reach agreement on decisions that are best for the patient. Done well, clinical decision making integrates the physician's expertise, the best evidence relevant to the patient's needs, and the patient's preferences to arrive at a shared plan. Ultimately, of course, the patient is responsible for the decision about whether to act on the plan.

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