

Guidelines, Clinical Practice, and Uncertainty Finding Direction When the Maps Do Not Work

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Clinical guidelines provide a map that funding agencies and managed care organizations encourage physicians to follow, just as travel guides suggest preferred routes for motorists. The suggested route of the clinical guideline is determined using scientific evidence. The assumption is that if all physicians take the same route and reduce practice variations, quality will increase and unnecessary expenditures will decrease.

However, if you have ever consulted a map that does not acknowledge the road you are on, you will understand the frustration experienced by many primary care physicians when using clinical guidelines. Maps may be constructed in many different ways, depending on their purpose and function. A map of the nation will not have the detail necessary to navigate city streets. The map may be correct, but if it does not provide the information you need, it is of little use.

Have you ever examined directions given to a colleague for a destination that you know well? These directions may not include the roads you would normally take. Landmarks may be different from the ones you usually rely on. And some people prefer to sightsee rather than travel express. Such is the world where clinical guidelines and practicing clinicians meet, where variation in the clinical landscape abounds.

In this issue of the *Journal*, O'Connor and colleagues¹ report their application of an upper respiratory infection (URI) guideline designed to reduce antibiotic use and health care expenditures. They followed the recommendations developed using the results of valid clinical trials, and measured the impact on clinical practice. Though the authors may be disappointed that the findings did not reward their hard work with cost savings and measures of improved quality, they have established a benchmark for research that applies evidence-based guidelines in practice. This effectiveness study describes the difficulty of applying a guideline and also teaches important lessons about primary care practice.

VALIDITY: FINDING THE USEFULNESS IN RESEARCH

In research, 2 types of validity compete for our attention: internal and external.² Internal validity is the important attribute of usefulness for studies of *efficacy*. In experimental studies, such as randomized clinical trials, methods that enhance internal validity allow the testing of a hypothesis by controlling for extraneous variables that may con-

found the measures of interest. However, variables of interest to family doctors, such as personal characteristics of patients that may guide diagnosis and treatment, are randomized away or excluded. In doing so, internal validity remains intact. Guideline recommendations are usually developed on the basis of studies of efficacy.

External validity is the degree to which the usefulness of a study can be generalized to other environments. This is the important attribute of usefulness for studies of *effectiveness*. Unfortunately, as internal validity increases (ie, the more tightly controlled the experimental environment and variables are), external validity is likely to decrease.^{3,5} Thus, studies with the strongest internal validity may be less generalizable and applicable to primary care populations.

ISSUES OF EXTERNAL VALIDITY

The study by O'Connor and coworkers is an example of an effectiveness study that can be used to examine the application of a guideline and problems of external validity. The authors list 3 possible reasons for the guideline's failure: poor implementation, different microbial patterns, and misjudged patient expectations. In addition we should consider the role of uncertainty in clinical practice and its relation to scientific evidence.

Effective implementation of a guideline is often related to the appropriate selection of patients, begun in this study by identifying those with symptoms of URI. Then the authors used inclusion and exclusion criteria to enhance the validity of the study. They excluded comorbidities and competing diagnoses, both important confounders. Yet, although these exclusions enhanced the study's internal validity, this limited the external validity.

Clinicians and insurers may be concerned about the costs of appropriately applying a guideline. This study examined a highly prevalent disease in primary care, yet applying the guideline was inefficient. Of the 3163 patients examined in the study, only 408 patients met criteria for inclusion. Thus, the guideline could be applied to only 13% of the population with URI symptoms.

COMPETING DISEASES AND DIAGNOSIS

Comorbidities accounted for many of the patients eliminated according to the exclusion criteria. Unfortunately, researchers do not know the impact of comorbidities on the clinical decisions of physicians and patients. Comorbidities can reduce the validity of studies that show high efficacy. Yet, their prevalence in our practices and their impact on our decisions are central to questions of effectiveness. We seldom see diseases in isolation, and certain diseases travel in groups. In this study, URIs are accompanied by sinusitis, bronchitis, and ear infections.

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THE IMPORTANCE OF TIME AND TIMING

The actual implementation of a guideline may be difficult because scientific evidence rarely tells us when to intervene, especially with chronic diseases. Most research on efficacy does not address the longitudinal aspects of patient care. Even with URIs, the time frame is important. The authors established a time frame of 21 days (though probably not based on scientific evidence, it seems well reasoned) to examine the outcomes in this study. Stopping measurement any earlier may have led to optimistic claims about the reduction in antibiotic use of the intervention.

THE PATIENT'S ILLNESS

The possibility that the microbial patterns changed represents factors about the disease being studied and the reliability of measuring them adequately. Although the authors focus on the biomedical aspects of disease, an important contributor to variability in this study may be the effect of the disease on the patient (illness). The variable host response and any symptoms associated with a viral URI may confound uniform pathways in a guideline.

PATIENT EXPECTATIONS VERSUS GUIDELINE GOALS

Patient expectations are important to health care delivery and quality care. Guidelines are disease centered, and attempts to make them sensitive to patient preferences may work educationally. However, when guidelines are used to monitor quality performance, controlling for patient preferences dilutes the rigor of the measurement for adherence to the guideline.

Patients may have goals that compete with the goals of a guideline. This is particularly true for chronic diseases.⁶ Patients' goals are related to past experiences, their desire to relieve suffering, and beliefs about the efficacy of interventions. In this study, patients' goals did not likely include a reduction in antibiotic use or physician visits. Developers of guidelines and those who measure guidelines must ensure that patients' goals and expectations are incorporated.

THE ROLE OF UNCERTAINTY IN CLINICAL PRACTICE

A map indicates what is known about the ways to navigate through a territory. What do we do when a map fails? Rather than look to the mapmaker, we should explore the terrain ourselves. Clinical practice remains relatively unexplored. The limits of evidence-based medicine and guideline use in clinical practice may be found in the gray zones of uncertainty where science meets art.⁷

For example, when a patient has URI symptoms, physicians address the problem with a disease-centered approach, applying evidence-based principles. Yet, when patients express dissatisfaction with the approach, the symptoms seem out of proportion to our findings, or the course of illness is protracted, we are left with uncer-

tainty. Guidelines do not help us through this terrain. Astute clinicians spend more time with the patient, looking for clues to relieve the "dis-ease." Can primary care research offer insights?

If the science of medicine allows clinicians to practice with some certainty because it provides quantifiable evidence, then the art of medicine describes the practice of medicine surrounded by uncertainty. The goal of researchers in primary care should be to develop methods and models of measurement that can at least explain, if not reduce, the uncertainties in practice. The Direct Observation of Primary Care Study⁸ is one example of a study that used qualitative and multimethod research to maximize external validity.⁹

Applying evidence-based guidelines may provide an opportunity for researchers to better understand clinical practice. By using interventions derived from experimental studies in actual practice, we may see the emergence of new models that may improve the usefulness of our current maps. Guidelines and the measurement of their use can be improved. Researchers must be sensitive to patient preferences and goals, understanding that good clinicians are responsive to these factors.¹⁰

Examining external validity also gives direction to other areas for research. The effect of comorbidities on care and outcomes is important. We should explore the appropriate timing of interventions and how their effectiveness can be maximized. We should determine when unique patient factors should force a departure from the map provided by science. To what degree should we be guided by scientific evidence that is internally valid but not applicable to our patients? We will not know until more effectiveness studies like this are done. Only then will newer maps incorporate the paths taken by primary care clinicians and lead us to improved patient care quality.

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