

## Putting the Patient First

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Ideas that challenge our current way of doing things are never welcomed initially,<sup>9</sup> but if a new method is valuable, it will be adopted over time by most. The term *evidence-based practice* (EBP) was first coined by McMaster University professors [Gordon Guyatt and Dave Sackett](#) in the early 1990s. Essentially, they suggested adding relevant research findings to the clinical decision-making process. They noted that often there is a gap between research conclusions and their implementation in clinical practice.

We now know that, on average, it takes approximately 15 years for a cutting-edge effective intervention to become a standard of practice or for practitioners to stop using interventions that research studies have found to be ineffective.<sup>1</sup> These delays lead to patient suffering, because ineffective strategies are neither benign nor cost-free.

Thus, EBP is imperative in order to align patient care with the best practices of the day. One example of a practice that became popular based on promising initial findings is selenium supplementation. This practice is still widely used, despite evidence that selenium poses serious health risks. (For more information, See "Selenium Risks" sidebar below).

### Evidence-Based Practice

EBP integrates four key components into a clinical decision-making framework: patient values, patient circumstances, clinical expertise and relevant clinical research.<sup>18-21</sup>

*Patient values:* Each patient has their own personal preferences and unique concerns, expectations and values.<sup>18-21</sup> EBP acknowledges that the patient's preferences, rather than the clinician's, should be considered first when possible. Thus, EBP must always be patient-centered.

*Patient circumstances:* The patient's clinical state is obviously a key factor in clinical decisions.

## Evidence-Based Care and What the Research Says About Selenium

Selenium is a trace mineral essential to good health, but necessary only in small amounts. Before it was found to be an essential nutrient, selenium was considered remarkably toxic to humans. Early research was optimistic that selenium supplementation might help prevent cancer and certain cardiovascular problems. A breakthrough occurred in 1973, when a research team observed that selenium protected against oxidative damage in selenium-deficient rats.<sup>4</sup> But recent research has found that selenium supplementation might be more harmful than beneficial to humans.

An international medical research team reported in *Annals of Internal Medicine* that selenium supplements are likely to increase the risk for diabetes. In this study, 1,202 participants were given either oral selenium or placebo. During a follow-up of more than seven years, type 2 diabetes occurred in 8.9 percent of the selenium recipients, but in only 5.9 percent of the placebo recipients.<sup>6</sup>

Another study examined the relationship between the use of selenium and the risk of prostate cancer. The study investigated 295,344 men with a mean age of 62 years who were cancer free at enrollment.<sup>2</sup> The researchers discovered that subjects taking high levels of selenium had increased risks of advanced and fatal prostate cancers. This finding is supported by another study.<sup>1</sup>

Yet another study investigated selenium for the prevention of cardiovascular disease. In this trial, more than 1,000 subjects were given either oral selenium or placebo.<sup>5</sup> These researchers found no overall effect of selenium on cardiovascular disease.

An international research team conducted a systematic review to investigate the effects of selenium for primary prevention of cardiovascular disease and the potential adverse effect on type 2 diabetes.<sup>3</sup> More than 19,000 participants were involved in the studies reviewed. Selenium supplementation did not reduce all-cause mortality, cardiovascular disease mortality or non-fatal cardiovascular disease events. But it did increase the risk of type 2 diabetes.

Selenium supplementation might be beneficial in certain populations, such as those with HIV or those with severe gastrointestinal problems, such as Crohn's disease. It may also be beneficial in regions where diets are low in selenium, such as China, because the soil is lacking in selenium. But there is no selenium deficiency in the United States.

More than 1 percent of Americans take selenium supplements, and more than 35 percent take multivitamin/mineral supplements that often contain selenium. In light of the available research, practitioners should recommend that their patients avoid selenium due to increased health risks and lack of benefits.

*Clinical expertise:* Knowledge accrued through professional practice makes up an important part of evidence-based decision-making.<sup>4-5,8,18-21,24</sup> Clinical expertise includes clinical skills, critical thinking and proficiency in clinical reasoning. In the absence of clear and compelling research evidence, clinicians have to rely mostly on their experience and patient preferences.<sup>23</sup> Moreover, without clinical expertise, evidence may inappropriately be applied to an individual patient.<sup>15,19</sup>

*Relevant clinical research:* The research literature can provide a source of information for clinical decision-making, but it should not be the sole factor. The best evidence is usually found in clinically relevant patient-centered research that has been designed and conducted using sound methodology.<sup>18-21</sup> Research evidence should not be taken at face value and adhered to uncritically, but should be given appropriate weight, depending on its internal and external validity.<sup>7,14</sup>

This requires a good understanding of the strengths and limitations of research: what it can and cannot tell us. Three foundational questions should be asked: Are the results of the study clinically important? Are the results valid? Are the results applicable to my patient?

Not all evidence is equally useful.<sup>13</sup> Different types of evidence are more relevant to different questions, but each type can provide important insights for optimal patient outcomes.<sup>25</sup> For example, a randomized, controlled trial can be used to examine the effectiveness of a new treatment. But research into causes of illnesses and prognoses is usually best done with observational studies, and the evaluation of diagnostic tests is most effectively done with an observational study and decision model.

In fact, every type of study has a place, even the case report. Moreover, even though a randomized, controlled trial is considered the best design to examine treatment effectiveness, a well-designed and conducted observational study can be more useful than a poorly designed and executed randomized, controlled trial.

### Integrating the Components

Fully integrating the four components of EBP into clinical decisions optimizes clinical outcomes and enhances patients' quality of life. Such integration requires that practitioners thoughtfully assign relative weights to each component, depending on the circumstances, in order to answer the pivotal question: What is the best course of action, all things considered?

Integrating the four components of EBP can be a daunting task, because the individual components cannot be measured in a way that facilitates comparing their relative importance. How many units of doctor's clinical expertise are equivalent to how many of units of patient values, and how does either of these compare with a certain quantity of research literature? Although we cannot easily define the units in question, nor derive any equations for assigning relative importance, there is no doubt that the clinical consequences of appropriately integrating the components of EBP is of paramount importance.

For example, a parent whose child requires a life-saving surgery may hold values against blood transfusions, but substantial literature strongly suggests the surgery cannot be done without a blood transfusion. In this case, the research should trump the parent's values. As a counter-example, spinal manipulation usually outperforms mobilization in head-to-head studies, but what if the patient strongly prefers mobilization? Both strategies are clinically effective, cost-effective and safe, so the patient's values should trump the research literature.

Clinical decision-making is a process involving critical thinking, evaluating evidence, applying

judgment and problem solving.<sup>22</sup> Some decisions are straightforward, while others are more complex. But in all cases, we want to select the management strategy that optimizes a patient's health and minimizes any potential harm.

We need to consider and balance the patient's values, the current clinical situation, our experience and the best relevant information. We need to connect the dots in order to make the best decision, keeping in mind that this is not a "cookbook" approach or a "one-size-fits-all" methodology.

### Common Misunderstandings

EBP has been criticized by some based on the erroneous assumption that it relies exclusively on evidence from randomized, controlled trials, and ignores practitioner expertise and patient values. In fact, some have coined alternative terms like *evidence-informed*, *knowledge translation* or *knowledge exchange* to reflect their preferences. Although there are scores of different definitions for EBP, most share a common thread.<sup>2-3,6,10-12,14,16-22</sup> But regardless of the term or definition employed, the key elements of EBP, as outlined above, include patient values, patient circumstances, clinical expertise and relevant clinical research.

Some doctors, seeing that EBP includes doctor's clinical expertise and experience, may be tempted to think of this as an "escape clause" that permits them to practice however they see fit, using the principle of EBP as a shield for *de facto* practicing outside of its principles. It would be hard to find a doctor who would knowingly and explicitly reject EBP, yet we all know practitioners who insist its place is "not in my backyard."

In the chiropractic profession, we see this among some advocates of proprietary technique systems who want to practice their largely evidence-free techniques, while demanding that other technique proprietors cite evidence to support what they do.

The twin pillars providing the foundation for modern health care are patient-centered care and evidence-based care. The major objective behind EBP is to help doctors provide the best possible care and treatment to patients. Practitioners who add relevant research to the decision-making model will increase the probability that their patients will experience better results. This is important, because the patient should always come first.

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