

Nancy C. Rich, PhD, PT, FACSM\*

The term Evidence-based Practice (EBP) is now being written in stone in the profession of physical therapy. Indeed, in his comments during the opening ceremony for the Annual Conference in June, 2005 the APTA President Ben Massey stated, "We have grown in our mastery of science and in our ability to use evidence to guide practice..."

On the APTA website, the Advanced Clinical Practice course offerings are described as "Evidence-based, hands-on workshops for physical therapists only designed to advance clinical practice knowledge and skills."

The APTA has also developed the Hooked on Evidence program to provide a database of research evidence to support the tests, measurements, and interventions that are practiced everyday in physical therapy clinics.

A quick internet search reveals textbooks and journal articles with the term evidence-based in the title. The listing of presentations at the Combined Sections Meeting and at Annual Conference also includes the qualifier evidence-based... in the title.

Dr. David Sackett is the most cited proponent and author regarding the topic of evidence-based medicine (EBM). Indeed, almost every article written about EBM begins with a definition that was composed by him. It reads, "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 means integrating individual clinical expertise with the best available external clinical evidence from systematic research."<sup>1</sup> Dr. Sackett and 4 of his colleagues simplified the definition in their well-known tutorial text on how to practice and teach EBM. They wrote, "Evidence-based medicine (EBM) is the integration of best research evidence with clinical expertise and patient values."<sup>2</sup> They also offered that, "New evidence from clinical research both invalidates previously accepted diagnostic tests and treatments and replaces them with new ones that are more powerful, more accurate, more efficacious, and safer."<sup>2</sup>

Jules Rothstein gave an explanation regarding what constitutes evidence. He wrote, "...evidence is not faith or tradition. Evidence is viable findings from research, not theories underlying practice. Evidence is data that show

whether treatments make a meaningful difference. Evidence is what is published in credible and respected journals."<sup>3</sup>

However, Rennie cautioned readers of the literature not to automatically trust all that is published. He wrote that there is "... no study too fragmented, no hypothesis too trivial, no literature citation too biased or too egotistical, no design too warped, no methodology too bungled, no presentation of results too inaccurate and too contradictory, no analysis too self-serving, no argument too circular, no conclusion too trifling or too unjustified, and no grammar and syntax too offensive for a paper to end up in print."<sup>4</sup>

As a professor I often emphasized to students to consider the recommendations of Crosby, Stills and Nash in the song they recorded titled, *Wasted on the Way*. I advised all my students to "... question all the answers..."

The task of evaluating published research is daunting to many clinicians. To make the process easier, several scientists have outlined categories of evidence and stratified them in order from strongest to weakest levels. The levels also can be interpreted as starting with the most reliable or most trustworthy or the least vulnerable to bias, to the least trustworthy or the least reliable or the most vulnerable to bias.

The levels of evidence outline by Sackett and his colleagues in 2000 are as follows<sup>2</sup>:

- 1A = Systematic Review of Randomized Controlled Trials (RCTs)
- 1B = RCTs with Narrow Confidence Interval
- 1C = All or None Case Series
- 2A = Systematic Review Cohort Studies
- 2B = Cohort Study/Low Quality RCT
- 2C = Outcomes Research
- 3A = Systematic Review of Case-Controlled Studies
- 3B = Case-controlled Study
- 4 = Case Series, Poor Cohort Case Controlled
- 5 = Expert Opinion

Hadorn and his colleagues outlined another way of classifying categories of evidence.<sup>5</sup> These are the guidelines that were used to rate the quality of evidence that was used to create the Health Care Policy and Research Clinical Practice Guidelines. Only 3 levels are employed with this method.

Level A = Well-conducted RCT with 100 patients or more (including multi-center and

\*Research Director,  
Section on Women's Health,  
American Physical Therapy  
Association,  
Alexandria, Virginia

meta-analyses); well-conducted RCT with fewer than 100 patients (one or institutions and meta-analysis; well-conducted study).

Level B = Well-conducted case-control study, poorly controlled or uncontrolled (including RCT with one or more major or three or more minor methodological flaws), observations studies with high potential for bias (case series with comparison to historical controls), case series or case reports, conflicting evidence with more support.

Level C = Expert opinion.

Several journals are introducing guidelines and instructing authors to label the strength of evidence of their research in terms of rating scales. Indeed, *American Family Physician* has instructed authors to use the ABC scale outlined above. The *Journal of Bone and Joint Surgery* requires authors to state the level of evidence in the abstract.

Following are a few definitions of methodology terms that are used in the levels of evidence guidelines.

Systematic review = When a systematic review is undertaken it is usually restricted to RCTs. A group of reviewers search the available literature via bibliographic databases. They enter common terminologies into the databases and retrieve copies of all the articles written on a specific topic. Next they proceed to critically evaluate the methodologies and content. The final product is a synthesis of the properly completed and meaningful research into information that is relevant to practicing medical practitioners/clinicians. Examples of systematic reviews include:

1. The Cochrane Database of Systematic Reviews:  
<http://www.cochrane.org/cochrane/revabstr/mainindex.htm>
2. The York Database of Abstracts of Reviews of Effects (DARE):  
<http://www.york.ac.uk/inst/crd/darehp.htm>

Meta-analysis = This methodology is a subset of systematic reviews that use statistical methods to combine and analyze multiple investigations.

Randomized Controlled Trials = When a study involves the randomization procedure, subjects in the study are randomly allocated to each group included in the study. Each subject has an equal chance of being assigned into an intervention group, a control group, a placebo group, or a sham treatment group. This eliminates the over-representation of any one characteristic in one group. If the randomization is correctly performed, each group should be similar with respect to baseline characteristics. Furthermore, it eliminates any bias in the assignments of individuals to groups. Without this method it is possible for a researcher to knowingly or unknowingly assign the less involved patient in the intervention group and the more involved patients in the control group. Randomized controlled trials are known to be the 'Gold Standard' for establishing the effects of a treatment.

Cohort Studies = This design is also called a prospective study, or a longitudinal study. It involves the selection of a large population of people who have the same condition and/or receive a specific intervention are followed over time and compared to a group not affected by the condition. This study employs observation as the research method. The interventions are not manipulated.

Matched Case-Controlled Study = This design involves choosing 2 patients, or 2 groups of patients who were exposed to 2 different interventions. The investigator retrospectively looks back to which group or patient achieved a better outcome.

Outcomes Research = For this design a larger group of individuals who receive the same intervention are evaluated retrospectively for their outcomes.

Case-Series = These are reports on a series of patients with a preidentified problem.

Case Report = This involves a report on the intervention and outcome for a single patient/client.

Clinicians may still ask, "What is the best evidence?" The best evidence comes from research that included the randomized assignment of subjects/participants, double-blinded design (the investigators and patients were blinded to the actual treatment group in which the patients were placed), and the use of a control and a placebo group. This type of systematic research significantly increases the confidence with which a medical practitioner can believe in the effectiveness of a treatment. Readers can place more trust in the belief that it was the treatment that caused the outcome of the treatment. In addition, readers should look for an explanation for why participants may have dropped out of an investigation. If they were the more involved patients, then the treatment may appear to be more effective than it was. They should also look for inclusion and exclusion criteria to decide whether the patients/clients included in the study were similar to the patient/client they are treating.

I firmly believe that if we are truly committed to providing patients with the treatments that have the greatest chance at being effective then it is incumbent upon us to start with treatments supported by Level 1 or Level A methodologies. We must search for, and employ first, those interventions that have been shown to have a statistically significant treatment effect with well-controlled research studies. If there are no systematic reviews, or meta-analyses, then one may look for guidance from lower level methodologies.

## REFERENCES

1. Sackett DL. Evidence based medicine: what it is and what it isn't. *Br Med J.* 1996;312:71-72.
2. Sackett DL, Strauss SE, Richardson WS, et al. *Evidence-Based Medicine: How to Practice and Teach EBM.* Philadelphia, Pa: Churchill-Livingstone; 2000.
3. Rothstein JM. It is our choice. *Phys Ther.* 1997;77:800-801.
4. Rennie D. Guarding the guardians: A conference on editorial peer review. *JAMA.* 1986;256:2391-2392.
5. Hadorn DC, Baker D, Hodges JS, Hicks N. Rating the quality of evidence for clinical practice guidelines. *J Clin Epidemiol.* 1996;49:749-754.