



Section on Women's Health

American Physical Therapy Association

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**EVIDENCE-BASED PRACTICE IN WOMEN'S HEALTH: EVALUATION AND
TREATMENT**

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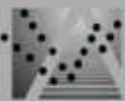
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EVIDENCE-BASED PRACTICE IN WOMEN'S HEALTH: EVALUATION AND TREATMENT

Nancy C. Rich, Ph.D., PT, FACSM

“Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research.”

Evidence-based Medicine Working Group. A new approach to teaching the practice of medicine. *JAMA*. 1992;268:2402-2405.

“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.”

Sackett DL. Evidence based medicine: what it is and what it isn't. *BMJ* 1996;312:71-72.

•“Evidence-based medicine (EBM) is the integration of best research evidence with clinical expertise and patient values.”

ØBest research = “...clinically relevant research ...”

ØØClinical expertise = “... clinical skills and past experience...”

ØØØPatient values = “...unique preferences, concerns and expectations each patient brings to a clinical encounter...”

Sackett DL, Straus SE, Richardson WS et al. *Evidence-Based Medicine: How to Practice and Teach EBM*. Philadelphia: ChurchillLivingstone, 2000.

“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”

Rothstein JM. It is our choice. *Phys Ther*. 1997;77:800-801

Levels of Evidence

Systematic Reviews/Meta-analyses

Randomized Control Trial

Non-Randomized Control Trial

Non-Experimental Studies

Clinical Expertise

Level I Evidence

Systematic Review/Meta-analyses

•Summary of multiple well-designed Randomized Controlled Trials (RCTs)

•Authors use explicit methods to search, critically evaluate and synthesize the literature for a specific topic

Level II Evidence

Randomized Controlled Trial

- “Strong evidence from at least 1 properly controlled randomized trial of appropriate size”

Moore A, McQuay H. Evidence-based everything. *Bandolier*. Available <http://www.jr2.ox.ac.uk/bandolier/band12/b12-1.html>, February 1995.

Randomized Controlled Trials

- Eliminates over-representation of any one characteristic in one group
- Eliminates bias in the assignments of individuals to groups
- “Gold Standard” for establishing the effects of a treatment
- Most valid study design

Level III Evidence

Non-Randomized Trials

- “Evidence from well-designed trials without randomization, single group pre-post, cohort, time series or matched case-controlled studies”

Moore A, McQuay H. Evidence-based everything. *Bandolier*. Available <http://www.jr2.ox.ac.uk/bandolier/band12/b12-1.html>

Level IV Evidence

Nonexperimental Studies

- “Evidence from well-designed nonexperimental studies from more than 1 center or research group”

Moore A, McQuay H. Evidence-based everything. *Bandolier*. Available <http://www.jr2.ox.ac.uk/bandolier/band12/b12-1.html>, Feb 1995.

Level V Evidence

Clinical Expertise

- “Opinions of respected authorities, based on clinical evidence, descriptive studies or reports of expert committees”

Moore A, McQuay H. Evidence-based everything. *Bandolier*. Available <http://www.jr2.ox.ac.uk/bandolier/band12/b12-1.html>

Systematic Review of RCTs

RCT with Narrow CI

Systematic Rev Cohort Studies

Cohort Study/ low quality RCT

Syst Review of Case-Control

Case-control Studies

Case Series, poor Cohort/CC

Expert Opinion

**Levels of Evidence – Level A
(Hadorn et al. 1996)**

- Well-conducted RCT with 100 patients or more (including multi-center & meta-analysis)
- Well-conducted RCT with fewer than 100 patients (one or more institutions & meta-analysis)
- Well-conducted cohort study

Level B Evidence

(Hadorn et al. 1996)

- Well-conducted case-control study
- Poorly controlled or uncontrolled study (including RCT with one or more major or three or more minor methodological flaws)
- Observational 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 Evidence

- Expert Opinion

Hadorn DC, Baker JS, Hicks N. Rating the quality of evidence for clinical practice guidelines. *J Clin Epidemiol.* 1996;49: 749-754.

In order of increasing vulnerability to bias:

- Randomized allocation
- Cohort Studies
- Case-control studies
- Case Series
- Case reports
- Expert opinion

Hadorn DC, Baker D, Hodges JS, Hicks N. Rating the quality of evidence for clinical practice guidelines. *J Clin Epidemiol.* 1996;49:749-754.

“Best” Evidence for Therapies

- Randomized
- Double-Blind
- Placebo Controlled
- Control Group
- Authors Account for all Subjects

VALIDITY CRITERIA

(HADORN ET AL., 1996)

- Selection of patients
- Allocation of patients to treatment groups
- Therapeutic regimen
- Study administration
- Withdrawals from study
- Patient blinding (RCT only)

- Outcome Measurement
- Statistical Analysis

Reliability

- Consistency
- Repeatability
- Measurement device reliability
- Measurer (rater) reliability (intra and inter)
- Response reliability

Reliability Coefficients

- Below 0.50 = poor reliability
- 0.50 to 0.75 = moderate reliability
- Above 0.75 = good reliability

Outcome Measures

“A physical therapy outcome measure is “a test or scale administered and interpreted by physical therapists that has been shown to measure accurately a particular attribute of interest to patients and therapists and is expected to be influenced by intervention”

Mayo N, Cole B, Dowler J, et al. Use of outcome measures in physiotherapy: survey of current practice. *Can J Rehabil.* 1994;81: 82.

Reasons For Improvement Other than the Treatment

- Coincidence
- Regression to the mean
- TLC
- “Believe” in treatment
- Desire to please
- Subjective improvement
- Clinician’s beliefs
- Illnesses wax and wane
- Placebo

Levels of Evidence

Systematic Reviews/Meta-analyses

Randomized Control Trial

Non-Randomized Control Trial

Non-Experimental Studies

Clinical Expertise

•“ When definitive evidence is not available, one must fall back on weaker evidence... and on biologic rationale.”

•Evidence-Based Medicine Working Group. Evidence-based medicine: a new approach to teaching the practice of medicine. *JAMA.* 1992;268:2420-2425.

“We become confident in our educated guesswork to the point where it is easy to confuse personal opinion with evidence, or personal experience with genuine scientific uncertainty.”

Naylor CD. Grey zones of clinical practice: some limits to evidence-based medicine. *Lancet*. 1995;345:840-842.

Red Flags

- If a therapy contradicts well-established laws, principles or empirical findings in physics, chemistry or physiology

“My life experiences have forced me to embrace a radical concept: tissues, cells, even DNA molecules each have their own individual consciousness.”

“It certainly seems worthwhile to try something as harmless as dialoguing with the consciousness of body systems, organs and tissues before taking more invasive steps.”

“Those who sell therapies of any kind have an obligation to prove, first, that their treatments are safe and, second, that they are effective.”

Beyerstein BL. Why bogus therapies seem to work. *Skeptical Inquirer*. 1997;Sept/Oct: 29-34.

Red Flags

- If a therapy contradicts well-established laws, principles or empirical findings in physics, chemistry or physiology
- If a therapy lacks a scientifically acceptable rationale of its own
- If a therapy has insufficient supporting evidence from adequately controlled research

“...using unproven treatments that are not founded in any scientific knowledge is costly and misleading to the patient and, I would argue, borders at times on unethical practice.”

Duncan PW. Evidence-based practice: a new model for physical therapy. *PT Mag*. 1996;4:44-48.

•“In situations where the efficacy of a treatment is being questioned because current knowledge is inadequate, it may actually be more ethical to take the time to make appropriate controlled comparisons than to continue clinical practice using potentially ineffective techniques.”

Portney LG, Watkins MP. *Foundations of Clinical Research: Applications to Practice*. Norwalk,CT: Appleton & Lange, 1993:29.

Only 20% or less of medicine is evidence-based.....

- Source of this assertion = report in U.S. Congressional Office of Technology Assessment (OTA) in 1979
- Based on comments of OTA member Kerr White and his findings from 1963
- Survey of 19 family doctors in a northern British town for two weeks (1960 and 1961)

- Study was to examine the degree to which a prescribed drug was used for the specific condition for which it was intended versus the use of the drug for other conditions
- “Intent was ‘specific’ for the condition for which it was prescribed only about 10% of the time; “probable” in about 22%; “possible” in 26%; “hopeful” in 28%; “placebo” in 10%; and “not stated” in 3.6%

Imrie RH, Ramey DW. The evidence for evidence-based medicine. *Scientific Rev Alternative Med.* 2001;5: 104-108.

- Imrie & Ramey

- “... an average of 37.02% of interventions are supported by RCT...”
- “an average of 76% of interventions are supported by some form of compelling evidence...”
- “... there is emerging evidence that, when EBM is practiced, patients benefit. Clearly, demanding rigorous evidence in evaluating the effectiveness of medical interventions is a good thing.”

6 criteria for treatments [and CE courses]

- Theories underlying treatment are supported by valid anatomical and physiological evidence
- The treatment approach is designed for a specific type of patient population (vs everyone)
- Potential side-effects are provided

6 CRITERIA (CONT'D)

- Studies from peer-reviewed journals are provided that support the treatment efficacy
- Peer-reviewed studies are well-designed, randomized, controlled clinical trials – or well-designed single subject experimental studies
- Proponents of treatment are open and willing to discuss limitations

Harris SR. How should treatments be critiqued for scientific merit? *Phys Ther.* 1996;76:175-181.

1.4 Informed Consent

“Physical Therapists shall obtain patient informed consent before treatment, to include disclosure of: (i) the nature of the proposed intervention, (ii) material risks of harm or complications, (iii) reasonable alternatives to the proposed intervention, and (iv) goals of treatment”

American Physical Therapy Association. Guide for professional conduct and code of ethics (Appendix 3: section 1.4, p. 698). *Guide to Physical Therapist Practice* (2nd edition): 2001.

IN OBTAINING THE INFORMED CONSENT OF THE PATIENT OR CLIENT, THE PHYSICAL THERAPIST:

- Clearly describes the proposed intervention, and delineates the expected benefits and material (decisional) risks as known with the proposed intervention.
- Compares known benefits and risks with and without the proposed intervention, and explains reasonable alternatives to the intervention.

American Physical Therapy Association. Standards of practice for physical therapy and the criteria (Appendix 2: Section III-A, p. 694). *Guide to Physical Therapist Practice* (2nd edition): 2001.

Evidence Based Databases

- PEDro = Physiotherapy Evidence Database
- DARE = Database of Abstracts of Rehabilitation Effectiveness
- CINAHL = Cumulative Index of Nursing & Health Abstracts Allied
- Cochrane Collaboration = International Experts – Systematic Reviews
- MEDLINE = Article Database Produced by National Library of Medicine
- Philadelphia Panel Reviews = Systematic Reviews in *Physical Therapy*, October 2001.

A systematic review of craniosacral therapy: biological plausibility, assessment reliability and clinical effectiveness. *Complimentary Therapies in Medicine*. 1999; 7: 201-207. Green C, Martin CW, Bassett K, Kazanjian A

“This systematic review and critical appraisal found insufficient evidence to support craniosacral therapy.”

Green C, Martin CW, Bassett K, Kazanjian A. A systematic review of craniosacral therapy: biological plausibility, assessment reliability and clinical effectiveness. *Comp Ther Med*. 1999; 201-207.

“...there is limited serious scientific study to assess the efficacy of craniosacral treatment to date. Rigorous clinical and scientific studies will prevent the misuse and marginalization of these techniques and bring them into an appropriate and effective role for the care and rehabilitation of the patient.”

Greenman PE, Mein EA, Andary M. Craniosacral Manipulation. *Physical Med Rehab Clinics NA*. 1996;7:877-896.

• “If one can reliably measure an independent variable whose validity can be verified by experts, then indicators can be incorporated into standard research designs. Reliability can be ascertained regardless of the unconventionality of the phenomenon being assessed provided the respective complementary medical system has an identifiable, systematic, and consistent set of rules for assigning values to quantify attributes of the phenomenon. This is the standard definition of measurement.

Levin et al. Quantitative methods in research on complementary and alternative medicine: a methodological manifesto. *Medical Care*, 1997;35: 1079-1094.

• “Any type of unconventional therapy– and any type of unorthodox mechanism– can be researched productively provided it can be operationalized reliably and validly with appropriately standardized instrumentation (be it mechanical, paper-and-pencil, human,

or otherwise) and also provided that research designs include conventional outcome measures.”

Levin et al. Quantitative methods in research on complementary and alternative medicine: a methodological manifesto. *Medical Care*. 1997;35:1079-1094.

•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.”

Rennie D. Guarding the guardians: A conference on editorial peer review. *JAMA*. 1986;256: 2391-2392.

“Alternative treatments should be subjected to scientific testing no less rigorous than that required for conventional treatments”

Angell M, Kassirer JP. Alternative medicine: the risks of untested and unregulated remedies. *Skeptical Inquirer*, 1999; Jan/Feb: 58-60.

Questions

- Unless a technique has been proven via objective and reliable procedures to be effective, is it ethical to offer it to the public, especially if money is to change hands?
- If a patient reports feeling better from a treatment that has not been shown to be more effective than a placebo, is it ethical to charge money for that treatment?
- Don't we want to know not just what works, but what works best?
- Should we include instruction in measurements and therapies in our curriculum that have been shown to have poor reproducibility or questionable effectiveness at the potential expense of spending more time instructing measurements and techniques with proven reproducibility and effectiveness?

Evidence-Based Practice: How do you do it?

Theresa Spitznagle MHS PT

Goals for Today

- v Familiarize you with what is “Evidence-based Practice”
- v Talk about practical issues related to how to get started using evidence in your everyday clinical practice

Major References

Evidence-based Medicine:

- v How to Practice and Teach EBM⁽¹⁹⁹⁹⁾
 - David L. Sackett
 - W. Scott Richardson
 - William Rosenberg
 - R. Brian Haynes
 - Churchill Livingstone
- v One of the original sources on EBM

Health Sciences Literature Review Made Easy

- v The Matrix Method
 - Judith Garrard⁽¹⁹⁹⁹⁾
 - Aspen Publishers, Inc.
- v Provides easy to follow guidelines on how to review, synthesize, and summarize the literature

What is Evidence-based Practice?

What is it?

- v Evidence-based practice (EBP) is “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.”
 - Sackett, Richardson, Rosenberg & Haynes, 1998 (p. 2)
- v Actually Sackett et al use the term Evidence-based Medicine or EBM
 - Many professions have adopted the EBM model and the term has been generalized to “Evidence-based Practice” EBP

What is required?

- v “Evidence-based practice requires the *integration* of the clinician’s clinical expertise and judgment with the best available, relevant, external evidence on a patient-by-patient basis.”
 - Geyman, Deyo, & Ramsey, 2000 (p.1)

- v Integration of these 2 concepts to provide the best care to an individual patient.

What do they mean by

- v current best evidence?
 - Sackett et al

AND

- v best available, relevant, external, clinical evidence?
 - Geyman et al

They are referring to

- v Research that is “clinically-relevant”
 - previously looked to the basic science studies of medicine for evidence to use in practice,
 - but now**
 - emphasis is on using evidence from patient-centered clinical research studies
 - newer concept

In particular ...

- v Emphasis is on patient-centered clinical research that is directed at 3 primary areas of interest to clinicians
 - the accuracy and precision of diagnostic tests
 - including the clinical examination,
 - the power of prognostic markers, and
 - the efficacy and safety of treatments (therapeutic, rehabilitative and preventive)
Sackett et al, 1998 (p. 2)

So ... what’s really “new” about EBP?

- v *Greatly increased, very strong emphasis on*
 - conducting patient-centered clinical research studies
 - conducting rigorous methodological reviews and synthesis of the evidence
 - typically by a panel of experts, e.g., Cochrane Collection
 - development of guidelines for practice
 - typically by a panel of experts, e.g., AHCPR guidelines

So ... what's really “new” about EBP?

- v *Decreased* emphasis on
 - the “authority” of clinical experts
 - the sufficiency of basic science information

So how do you do this?

Practical Issues

Adopt the 5 Step Strategy

- v Recommended model of 5 steps suggested by Sackett et al to be an evidence-based practitioner
- v 5 steps include
 - **Defining** the question
 - **Finding** the evidence
 - Critically **evaluating** the evidence
 - **Summarizing** the evidence
 - **Applying** the evidence to clinical practice

Step 1: Define the question

Figure out exactly what you are asking.

(improves your efficiency & productivity in searches)

Step 1: Define the question

As physical therapists, often interested in questions related to treatment effects

Example - you might ask a question related to treatment of Urinary Incontinence.

- Is biofeedback more effective than active exercise in the treatment of SUI in females?
- What type of UI? Specific age or gender of interest? Which treatment? E-stim, biofeedback, active ex, resistive ex

Step 2: Find the evidence

Priority considerations with your search

- use electronic media that is periodically updated
- use “patient-centered” studies
- use peer-reviewed sources (primary, secondary, tertiary)
- consider the “quality” instead of “quantity”

Find the evidence

Electronic Data Bases:

- PubMed: Free <http://www.ncbi.nlm.nih.gov/PubMed/>
- 16912: references for UI

Refine Search:

Limits: **Middle Aged: 45-64 years, only items with abstracts, Clinical Trial, Female, Human: 584**

Changed search words:

- biofeedback for stress urinary incontinence
- 19 references were found

Obtain Abstracts

Review Abstracts: Key information

Sample Characteristics

Type of intervention

Duration of intervention

Type of Study

Preferred

Sources of Evidence

Searching for evidence EBP proponents recommend using -

Results of studies conducted on real patients

Rigorous systematic reviews of clinical research reports (e.g. Cochrane Collection)

Practice guidelines based on valid reviews

Step 3:Critically evaluate the evidence

2 Decisions: Whether or not study is:

- v valid, i.e., closeness to the truth (relates to the “quality” of the study)
- v useful to you as a clinician
 - first decision (validity) is the priority
 - if not, then can’t be useful in practice

EBP’s Hierarchy of Sources of Evidence about Treatment

- v Well-conducted RCTs with 100 or more patients
- v Well-conducted RCTs with < 100 patients
- v Well-conducted cohort studies
- v Well-conducted case-control studies
- v Poorly controlled or uncontrolled studies
- v Recommend - When evidence is conflicting ... go with findings from most weighty studies
- ⇒ Expert opinion
 - Adapted from Hadorn DC, J Clin Epidemiol, 1996

Heirarchy for Evaluating Evidence - Treatment Studies

- v Underlying assumption
 - the randomized clinical trial, RCT, is the “gold standard” for treatment studies

- v Hadorn's list reflects
 - a continuum of types of research
 - RCT at one end ⇒ to descriptive research at the other end

Review: 3 Major Characteristics of an RCT

- v Randomization of subjects to groups
 - v Minimum of 2 groups of subjects
 - v Intervention controlled by the investigator
-
- v Anything less than the RCT has less “weight” as evidence

Step 4: Summarize the evidence

Make sure to use more than one study

- Look for effects across studies
- Method of summary - “Matrix method” summarized by Garrard
 - method assists in looking across body of literature to summarize findings

...and finally,

Step 5: Apply the evidence in your practice

- Try a treatment decided most appropriate based on your search
 - Systematically track what happens so that you can evaluate your treatment
 - standardized examination procedures
 - standardized, relevant outcomes conducted regular basis
- (Adapted from Sackett et al, 1998 & Geyman et al, 2000)
- Report on your results

Summary

- v Evidence-based practitioner integrates:
 - best available evidence (emphasis on patient-centered studies)

 - clinical expertise