



## Volume 7

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## Evidence-based medicine (EBM) and what it means to you

### TAKING OUR PULSE

We often reference the concept of EBM (or EBP: evidence-based practice) in this newsletter, but this time let's dig a little deeper to define what it is, and illustrate it with a recent real-life example that demonstrates its importance to our company and industry. This is the process that Broadspire follows in evaluating medical practice issues.

The most common definition of EBP is taken from Dr. David Sackett, a pioneer in evidence-based practice. EBP is "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient. It means integrating individual clinical expertise with the best available external clinical evidence from systematic research". (Sackett D, 1996)

EBP is the integration of clinical expertise, patient values, and the best research evidence into the decision making process for patient care. Clinical expertise refers to the clinician's cumulated experience, education and clinical skills. The patient brings to the encounter his or her own personal and unique concerns, expectations, and values. The best evidence is usually found in clinically relevant research that has been conducted using sound methodology. (Sackett D, 2002)

So how is evidence developed in a way that ensures that clinical decisions can be made with confidence? The evidence pyramid below shows the progression from poor evidence to excellent evidence and consensus, from bottom to top.



Case studies are very low on the scale. This consists of a physician or group of physicians performing a certain treatment on one or several patients, describing the results, and drawing conclusions about effectiveness of the intervention. These can be more or less sophisticated, but nevertheless are, at best, a building block to a more robust study. Case studies should not be used to make policy/coverage decisions.

The randomized controlled trial (RCT) is the gold standard of clinical research. It may not always be feasible, but is certainly preferred. Patients are randomly assigned to a group that receives the treatment or intervention being evaluated, and another group (the control group) receiving placebo or sham treatment. The study is 'blinded' so that patients are unaware of whether they are receiving a real treatment or a placebo treatment. These studies are designed so that sufficient numbers of matched patients are in both groups so as to ensure statistical analysis will be meaningful.

But even RCT's on the same treatment may differ in their results, so at the top of the pyramid are systematic reviews and meta-analyses that combine the data from all the applicable, well-designed RCTs to yield aggregate outcomes. These studies are then reviewed by a panel of experts to yield consensus-based authoritative guidelines, such as ACOEM, ODG, Clinical Evidence and the Cochrane Collaboration.

### **JUST WHAT THE DOCTOR ORDERED**

We recently received a bill from a treating physician, Dr. W.Y., who ordered, and performed, an "intradiscal fibrin sealant injection at L5-S1", i.e. the physician injected a product called Tisseel into a disc in the spine, for a somewhat vague diagnosis he referred to as "internal disc disruption". (This incidentally is a controversial diagnosis and many would argue that no treatment at all is advisable; but that's a topic for another issue.) Tisseel is derived from human blood, and is FDA approved only for sealing bleeding sites in blood vessels or in the bowel at surgery. So this constituted an off-label (non-FDA approved) use of the product.

Our very alert medical bill review team noted that the physician had billed an unlisted CPT code for this service, and that the fee of \$5700 was extraordinary. "Unlisted" means that the procedure is not a specifically coded and defined service accepted by the American Medical Association, and that is often a red flag in terms of representing a potentially experimental procedure. The case was referred to the Medical department for review.

It is not really clear why Dr. W.Y. first decided that injecting fibrin sealant into spinal discs was a good idea. Nevertheless, he and several colleagues tried this out on 15 patients and concluded that it "appears safe and may improve pain and function in selected patients with discogenic pain."

This was a case series, with no control group, and as noted above, is not an optimal research tool. To these physicians' credit, they did proceed to participate in a randomized controlled trial. In this trial 220 patients received injections into discs, half receiving fibrin sealant and half receiving placebo injections of saline (salt water). The study revealed that there was no benefit from fibrin sealant; in fact, the patients getting the placebo actually did slightly better! The study was terminated earlier than anticipated due to the clear lack of benefit. The results were convincing because of the RCT design. Dr. W.Y. was quoted as concluding that "The findings do not demonstrate a superiority of intradiscal fibrin sealant over intradiscal saline."

### KEY TAKE AWAY POINTS

- One must have a healthy skepticism about new treatments and technologies and defer judgment and adoption until sufficient time and effort has been dedicated to high-quality evidence-based research. Simple anecdotal results, or case studies, are insufficient. RCTs, particularly in conjunction with systematic reviews by physician experts, are optimal.
- Broadspire's clinical policies (in the Medical department database), and Utilization Review department/peer review panel (PRS) are resources for ensuring that only medically appropriate services are delivered, and experimental/investigative services are not authorized.
- In the case above, the treatment was deemed experimental/investigative by the medical department, and this determination will apply to any future instances of services of this type. (It should be noted that this procedure was not authorized by Broadspire either before or after it was performed and was denied payment.)

### CIRCULATING IN THE PRESS

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Unfortunately, a great deal of research reported in journal articles is poorly done, poorly analyzed or both, and thus is not valid. A great deal of research is also irrelevant to our patients and practices. Separating the clinical wheat from the chaff can take skills that many of us never were taught.

### THREE STEPS TO AN EVIDENCE-BASED ANSWER

When faced with a clinical question, follow these steps to find an evidence-based answer:

1. Search the Web site of one of the evidence review organizations, such as Cochrane (<http://www.cochrane.org/cochrane/revabstr/mainindex.htm>), Bandolier (<http://www.jr2.ox.ac.uk/bandolier>) or Clinical Evidence (<http://www.clinicalevidence.com>), described in "Making Evidence-Based Medicine Doable in Everyday Practice," *FPM*, February 2004, page 51. You can also search the TRIP+ Web site (<http://www.tripdatabase.com>), which simultaneously searches the databases of many of the review organizations. If you find a systematic review or meta-analysis by one of these organizations, you can be confident that you've found the best evidence available.
2. If you don't find the information you need through step 1, search for meta-analyses and systematic reviews using the PubMed Web site (see the tutorial at [http://www.nlm.nih.gov/bsd/pubmed\\_tutorial/m1001.html](http://www.nlm.nih.gov/bsd/pubmed_tutorial/m1001.html)). Most of the recent abstracts found on PubMed provide enough information for you to determine the validity and relevance of the findings. If needed, you can get a copy of the full article through your hospital library or the journal's website.
3. If you cannot find a systematic review or meta-analysis on PubMed, look for a randomized controlled trial (RCT). The RCT is the "gold standard" in medical research. Case reports, cohort studies and other research methods simply are not good enough to use for making patient care decisions.

You may not be performing this kind of research on your own, but this provides insight on the deliberate approach to evaluating the effectiveness of medical services.