"Ask Dr. J"

The "Ask Dr. J" columns are authored monthly by Jennifer Christian, MD, MPH, President of Webility Corporation. See previous columns at www.webility.md.

Dr. J's columns also appear in the monthly Bulletin of the Disability Management Employer Coalition (DMEC). To purchase a book of Dr. J's collected columns, go to www.dmec.org.

The columns often summarize issues discussed by the Work Fitness and Disability Roundtable, a free, multi-disciplinary e-mail discussion group moderated by Dr. Christian. Apply to join the Roundtable at www.webility.md.

June 2008 – The Challenge of Evidence-based Guidelines

Dear Dr. J:

Can you help me understand the term "evidence-based guidelines?" Various organizations are all saying they have them – and in fact seem to be competing over whose is the best. If they're all evidence-based, why shouldn't we just use the most user-friendly or cheapest one?

Evelyn in Evanston

Dear Evelyn:

Your question is a good one. To most people, all the guidelines look pretty similar. This is an arena in which "buyer beware" is the correct motto, because the average buyer won't be able to tell a good guideline from a bad one. There are several good choices out there along with some "pseudo-evidence-based guidelines". I suggest you get expert advice.

First, your expert needs to know methodology. The "evidence-based medicine" movement is driving the development of a new kind of expert: the methodologists. These are people who are deeply interested in the technical aspects of the scientific method. They can look at research studies and tell us whether they are well-designed enough that we can rely on their findings. Poor research designs produce weak results; well-designed studies produce information that is more reliable. Guidelines with fancy-looking bibliographies may actually be relying on poor quality science. As you evaluate options, the question is: How thoroughly did the guideline developers analyze the quality of the evidence?

Second, your expert has to have a sense of perspective. Beyond design and methodology issues, there looms another problem: time. Well-designed studies can't guarantee certainty. Because the frontiers of science are continually moving forward, today's best and most "up-to-date" knowledge is often not as reliable – simply because it's new. The usual process of addressing a research topic is to test, re-test and confirm, to look at things from a slightly different angle, and apply increasingly sophisticated experimental methods over time. A great

example is the hormone replacement therapy for post-menopausal women. Based on a lot of previous studies, we thought we knew the answer – "it is good" – until a larger study with a different design was completed, and showed that hormone replacement therapy actually harmed instead of helped the women who were taking it. In your case, ask whether the guideline developers have accepted new evidence with enthusiasm or a grain of salt?

Lastly, your expert has to be able to tell how well the guidelines "fill the holes" between the evidence. It turns out that guideline developers have a lot of holes to fill. How good is the clinical judgment and consensus opinion portion of the guideline, and what principles, if any, is it based on?

As an example, I'm going to share a portion of a message Dr. Elizabeth Genovese sent to the Work Fitness & Disability Roundtable, the free email discussion group I run. (You are welcome to join us!) She is describing how the ACOEM* Evidence-based Practice Committee develops its recommendations on what to do when a clinical issue needs to be addressed but the science is missing or weak. Here is what she wrote. I have made a few comments [in brackets].

> "The problem is often not about the literature per se. It is easy to decide to recommend an intervention when the literature strongly supports its use. By support from the literature, we mean (a) improved functional outcomes OR (b) clear evidence of substantive [change in clinical condition] which presumably would allow for pursuit of those interventions that can increase function AND (c) a low risk of harm (which includes the opportunity cost that is engendered by not pursuing OTHER alternative interventions that might be of equal efficacy).
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> "The issue is that in our quest for the best possible grounds for our recommendations, we must use as our basis the research studies that have already been done – the best available evidence. However, in aggregate, more often than not, the best available evidence is incomplete, spotty, and provides answers to only some of the questions that need to be answered. As a group, the studies often ask some but not all of the important questions, fail to compare and weigh the relative merit/ risks of things that need to be compared, omit an important patient population or subset, are poorly designed, too small or short-lived, flawed in a critical way, or otherwise are incomplete, inadequate, or insufficient. It is rare rather than common for the existing evidence to provide us with a crystal clear black and white answer.
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> "In short, ACOEM has realized that if we are going to provide USEFUL recommendations to clinicians, we must provide recommendations that fill the gaps between the bits of 'solid' evidence – AND we must have a rational, clinically sound, commonsensical, defensible, responsible, and unbiased method for developing and updating that material.
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> "Anyway, when struggling with how to set up our recommendations, the ACOEM methodology committee looked to work already done by agencies such as Medicare and others who have been involved in guideline work for the general population.
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> "Based on their work, we have developed what are referred to as our First Principles to guide us in developing recommendations when the 'evidence base' must be supplemented with advice based on our group's combined clinical judgment. These are:
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> 1. Imaging or testing should generally be done to confirm a clinical impression [in other words, not be a 'fishing expedition'].
> 2. Tests should affect the course of treatment.

3. Treatments should improve on the natural history of the disorder, which in many cases is recovery without treatment.
4. Invasive treatment should be preceded by adequate conservative treatment and may be performed if conservative treatment does not improve the health problem.
5. The more invasive and permanent, the more caution should be exerted in considering invasive tests or treatments and the stronger should be the evidence of efficacy.
6. The more costly the test or intervention, the more caution should be generally exerted prior to ordering the test or treatment and the stronger should be the evidence of efficacy.
7. Testing/ treatment decisions should be a collaboration between the clinician and patient with full disclosure of benefits and risks.
8. Treatment should create neither dependence nor functional disability [but rather should empower the patient to take responsibility for his/her own recovery].

"Despite this guidance, the evidence-based practice panels sometimes spend inordinate amounts of time and energy debating what to do in situations when there is anecdotal (or low quality) evidence of benefit for an intervention and the literature acceptable for use in an 'evidence-based' guideline indicates that it is either not efficacious or is indeterminate.

"Bottom line – there are no easy answers. But what we can do is understand WHY this is the case, and do our best to make responsible decisions based on both knowing what we know, and admitting what we do not know, in the context of the ACOEM First Principles (above). We want to help steer our patients (or those of other physicians) toward interventions that are low in risk and cost-effective when compared to other interventions that have the same likelihood of leading to improved outcomes.

"Our gold standard in terms of looking at any intervention, whether in workers compensation or personal healthcare, should always be 'Does it improve function or allow the resumption of, or participation in, activities that DO improve function?' That's because enabling our patients to go back to living their lives (which includes work in most instances) is what we really want to achieve.

"For those who are unfamiliar with how the ACOEM guidelines work, there are 9 categories for recommendations. Each recommendation category is driven by the quality of evidence supporting it. Thus of the four categories of recommendations FOR treatment, the evidence ratings proceed from best to weakest. The four categories of recommendations AGAINST treatment have evidence ratings that proceed from weakest to best.

4 Levels of RECOMMENDATIONS FOR the Treatment

Strongly recommended
Moderately recommended
Recommended
Consensus opinion

No recommendation

4 levels of RECOMMENDATIONS AGAINST the Treatment:

Consensus opinion
Recommended
Moderately recommended
Strongly recommended"

[end of quotation]

So, Evelyn, I'm assuming you want to select the best guideline to use because you want patients to get the safest and most effective care – care that the evidence says has the best chance to get them better, and lets them get on with their lives. You should pick the guideline with the most solidly-based and wisest recommendations, rather than the one that is more convenient or cheaper. You should ask real experts to help you evaluate the alternative offerings. They must know what they are doing and you must be confident they are unbiased rather than political.

Personally, I would recommend focusing on the method the guideline developers have used (in detail) more than whether I agree with what they have come up with – because the solidity of the evidence base for the recommendations is my primary concern. Is the method designed to winnow out weak science? Have the developers made an earnest effort to find the best available current truth? Will the guidelines stand up under scrutiny or a challenge? Are they selecting the simplest, safest, most effective and most economical methods of care? If the methodology for coming up with recommendations is not "crystal clear", why not?

A few years ago, a client asked me to do a head-to-head comparison of a commonly used tool that provides aggregated data for use in clinical decision-making. There were four competitors in the marketplace, each with their own version. Two of them were deficient in one or more major ways, so I eliminated them. The remaining two looked roughly equivalent, although with some differences in the detailed data. Where I found the "pay dirt" was in the methodology section. The explanation for how one of the tools came up with their data was nearly impossible to follow and simply didn't make sense – it was clinically improbable or impossible. I decided that the data looked good, but was based on junk. A methodology section shouldn't be opaque. It should be crystal clear what the evidence is, what it says, and how you got from here to there. There should be no "black boxes" anywhere in evidence-based science.

Even though I'm a member of the ACOEM evidence-based practice committee, I'm a ruthless merit-o-crat. If I had doubts, I'd have quit. As it is, I am really proud of ACOEM's ever-improving methodology and the "pure" motives of the committee of volunteers who are continually developing and updating its guidelines. And, if you're curious, you can read the WHOLE methodology section yourself.

I guess I can't be called neutral. I have a bias for quality. Hope this explanation will help you sort things out, Evelyn.

Smiling,
Dr. J

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