E D I T O R I A L

Take-Home Messages

very time we attend a continuing education meeting, there is a hope that at the end of the meeting there will be a distinct "take-home" message. Even if the presentations are designed to be theoretical or philosophical, there should be a link toward continuous improvement in the knowledge base or skills of the attendees. Understanding the desire to always take something home, we need to appreciate that some of the things we carry with us from a weekend meeting may not be pertinent to our clinical practice on Monday.

When sitting in the audience, we most likely make the assumption that the speakers' presentations have been reviewed to ensure accuracy and the recommendations have been evaluated to ensure safety and efficacy. Of all the factors associated with a continuing education program, it is the question of safety and efficacy that creates the foundation for any of the messages that go home with the audience.

This raises the question of how presentations are evaluated. In research, this is actually a pretty easy process, because research institutions (universities, hospitals, etc) evaluate every research protocol through a form of institutional review board (IRB). Institutions are very diligent in ensuring that research protocols go through review. It is not just hospitals and universities, however; non-institutionally aligned clinical practices can go through review processes that mimic those of traditional IRBs. An example of such a program may be seen on the web at the Western IRB (www.wirb.com).

Different IRBs will determine their own individual goals; however, there are some goals that are virtually universal. Review boards will protect the rights of subjects involved in research, assess the risks and benefits of research, ensure patient confidentiality, and assess the appropriateness of informed consent. The IRB will also address questions regarding the maintenance of data, the type of data that may be maintained, the type of information that must be de-identified, and what may or may not constitute research.

Research is sometimes conducted on products, techniques, or devices that are used for purposes that differ from the original descriptions, often described as "offlabel" usage. This occurs with the use of pharmaceutical agents in indications that were not approved when the drug received its approval for marketing. Conversely, in some cases the drugs may be used for the approved indication, but the dosage, age group, or route of administration may differ from the original recommendations.

The "take-home" messages from presentations derived from research protocols that had undergone IRB assessment and approval are as strong as the research was stringent. The presence of review board approval does not ensure that the outcomes of the research provided definitive answers to the research question. Often, research is inconclusive because of small sample sizes, short study duration, or simply because the tested intervention was truly no better or worse than previously documented approaches. In some situations, the presentation may demonstrate an alternative treatment approach that offers no specific therapeutic advantages. In such a situation, the

decision to use the newly described intervention may depend on tangential factors such as ease of use, cost, packaging, convenience of dosing, or a myriad of other factors that may lead the audience members to consider the newly described intervention.

All of the previous comments are relevant to research that has been developed and evaluated using institutional review boards. Many therapeutic approaches have been introduced outside of traditional research settings. In some situations, clinicians may utilize products or devices that are readily available in situations that had not been previously described. When procedures are performed on patients who sought the services of that clinician, it is possible that the clinician might use off-label approaches to address specific clinical presentations. These "one-off" approaches to treatment may eventually develop into new treatment protocols if the first clinical application went well. You may even see such approaches in scientific journals in "case report" format. Indeed, if such procedures are performed repeatedly, this may allow a series of patient presentations known as a "case series." Obviously, the more patients enrolled in a case series for an appropriate period of time, the more confidence one would have in such reports.

The problem with case series is that subtle changes in treatment approaches may develop over time and may not be reported as a developing treatment approach. This may occur as a simple oversight, or it could represent intentional obfuscation. Moreover, the clinician describing a treatment approach may simply forget the evolution of the method over the duration of the case series. A presentation of an evolving case series may actually be an accumulation of a number of different approaches that are grouped together as if all treatments were quite similar, while a series of nuances contributed to improvement of the overall treatment outcomes.

Whenever an individual develops a scientific presentation, publication, or investigation, there is always a desire to provide a message that benefits those who see, read, or hear the information that is shared. This is particularly true at scientific meetings where speakers provide the audience with important information that could result in changes in clinical practices.

Obviously, there are many ways for treatment to evolve. When "take-home" messages are gained from a comprehensive presentation of all the steps and modifications that were used in developing the recently described intervention and when the audience truly appreciates the steps taken, the message may truly be worth the effort to take it home. Failure to appreciate all the nuances, however, could make the audience discard the messages on the way out the exit. Here's wishing your attendance at meetings where all messages find their way into your home.

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