

VIEWPOINTS

HOW SHOULD THE CLINICIAN APPROACH THE USE OF NEW THERAPIES?

The clinician is faced with a dilemma in approaching the use of new, unproven, or controversial therapies and procedures. To use such procedures is to run the risk that one may waste the patient's time and money, cause harm, be labeled unscientific, and suffer legal consequences. To ignore such therapies, on the other hand, may result in a failure to treat with the most effective method and leave a practitioner lagging behind his or her colleagues in the application of modern approaches to care. In this issue, Drs. Nathan Flax and Steven Cool present their perspectives on the utilization of new therapies. Dr. Cool, a Professor at Pacific University College of Optometry, suggests that clinicians be open-minded and explore the clinical value of new therapies. Dr. Flax, Professor Emeritus at SUNY State College of Optometry and a private practitioner, presents specific guidelines to assist the clinician in determining whether a new therapy is worthy of trial.

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AN APPROACH TO UTILIZATION OF NEW THERAPIES

■ NATHAN FLAX, M.S., O.D.

Abstract

In a dynamic profession, new treatment approaches are continually being introduced. Some of these ultimately will become the conventional wisdom of optometry, others will not. Guidelines are offered to assist the practitioner in deciding which new therapies to incorporate into practice.

Key Words

conventional wisdom, prima facie validity, adequacy of description, veracity, new therapies

One of the burdens of clinical practice is the need to make decisions and take action, often on less than optimal data, utilizing therapeutic strategies that are not rigorously proven. Optometrists share this problem with other health professionals although we are generally spared the life-or-death consequences that others face. A cursory reading of the popular press is sufficient to realize how frequently standard practice is at variance with research facts.

Recent research suggests that estrogen replacement therapy for menopausal women is not being utilized sufficiently, out of a mistaken belief that the cancer potential accompanying estrogen use outweighs the positive effect of estrogen on reducing heart attacks

among the treated women.¹ The cited study, while impressive in the number of subjects involved, does not meet the criteria necessary for a properly controlled clinical trial. Such a research effort would require 10 years or more to complete. This, then, is the dilemma for the clinician: treat now or wait 10 years to be sure.

While perhaps less dramatic, the same judgment call faces the optometric clinician. One conceivable course of action is to offer nothing but "proven" therapies. This sounds proper for a licensed professional who carries responsibility of keeping patient interests foremost. Unfortunately this is not realistic and actually may not serve the patient well. If we limited ourselves to the fully proven, which therapies would remain?

Continued on page 121

VIEWPOINTS

CLINICIANS SHOULD BE OPEN-MINDED AND EXPLORE THE CLINICAL VALUE OF NEW THERAPIES

OR

MYTH AND METAPHOR, FACT AND DATUM IN THE ART AND SCIENCE OF CLINICAL CARE

■ STEVEN J. COOL, PH.D.

Abstract

In day-to-day interactions with patients, clinicians are often the first to make important discoveries about human biological and/or psychological functioning. Likewise, clinicians are frequently the ones to first discover effective therapeutic approaches. Because there is usually a lack of a scientific, data-based explanation to support the clinical findings, these clinical truths are often communicated in a language of "clinical metaphor." When one treats this language as if dealing with one that is scientific and data-based, the clinical metaphor truth fails to "pass the test" of scientific validation. It is suggested that the "art and science of clinical care" consist of skillfully applying new and different treatment approaches in the most scientifically valid manner possible. Each patient presents a unique challenge to the clinician's skills, and the exercise of open-mindedness and clinical intuition in choosing the best intervention (be it "tried and true" or "weird and new") is just as central to clinical success as is the scientifically validated application of treatment.

Key Words

ritual formulary, metaphoric, mythical, new therapies, data-base, factual, neurotransmitter, biogenic amine, plasticity

Joseph Campbell^{1,2} and Jacob Bronowski,³ at different times and in different contexts, have both stressed the idea that the basic truths about the world around us are typically NOT discovered by "basic scientists." Rather, it is the artisans, the craftsmen, the clinicians who, in their day-to-day, "front-line," direct interactions with the world, truly discover the basic truths. Most often, however, there is scant factual data to support or explain what has been discovered. How, then, to pass these truths on to subsequent generations? Bronowski describes it as a process of embedding the truth in a "ritual formulary" which is memorable and can, therefore, preserve the truth. An example he uses is the fashioning of a Samurai sword. One can build an impressive understanding of Samurai sword craftsmanship through detailed analysis of iron/carbon alloys (steel) and their crystal-lattice structures. However, a thousand years ago (when Samurai swords began to be made successfully) no one had access to those factual data analyses, no one had the scientific language to describe and explain the sword-making process. Therefore, the successful sword-maker developed a ritual formulary by which the craft could be passed on: for example, at one point in the process, one must heat the steel "... until it glows the color of the morning sun." Campbell discusses these ritual formularies as "mythology," and he argues that "myth" does not mean "fantasy" and/or "fiction." Rather, he describes myth as truth spoken in "metaphor." For example, if a man, "John," is known to be a fleet and agile runner of the high hurdles, one could describe John's fleetness and

agility in terms of musculo-skeletal biomechanics and neuro-muscular physiological interactions. However, if one does not possess that factual, data-based language, one might simply say that "John is an antelope." Now, verifiably, at the factual, data-based level of discourse, John is NOT an antelope; he IS a human being. Nonetheless, the mythical (metaphorical) statement, "John is an antelope," tells one a great deal about John and conveys a great deal of truth about him. Campbell's point is that there are clearly two distinct levels of discourse here: the factual, data-based level of discourse and the mythological, metaphorical level. Both levels of discourse tell "truth" about John; both levels contain valid information; and both, Campbell concludes, should be honored and valued for the truths that each conveys.

I would strongly argue that new clinical therapies are, most often, exactly like the Samurai sword-making ritual or the mythical metaphor, "John is an antelope." Most often it is practicing clinicians who make significant therapeutic discoveries about patient care and, in many instances, there is little or no factual data-base with which to describe and/or explain the therapeutics. This does not mean, however, that the therapy lacks truth. Rather it indicates that the clinician who strives to share her/his discovery must very often choose the ritual formulary and/or metaphor level of discourse. This leads to a multi-faceted "good news-bad news" situation. On the one hand, the good news is that the truth of the clinical therapeutics is made available to other practicing clinicians and, therefore, made available to patients in

need of the therapeutics. On the other hand, the bad news is that often the RITUAL comes to be "worshipped" as inviolable and unquestionable and is, therefore, often untested or untestable at the factual, data-based level of discourse. On the one hand, the good news is that some discoveries about the nature of clinical therapy have been made and communicated. On the other hand, the bad news is that the truth, spoken in metaphor, is verifiably false, when considered only at the factual, data-based level of discourse. So what's a conscientious clinician to do?

Many would argue that the only safe, wise, and prudent course of action is to very carefully accept into one's therapeutic armamentarium only those techniques and procedures which have been thoroughly tested and scientifically validated: that is, accept and use only those therapeutic procedures which have a factual, data-based level of explanation. This has, of course, become THE accepted scientific method for virtually all clinical specialties during the last half of the 20th century. It IS the "science" in "the art and science of clinical care." Unfortunately, the "science" has seriously threatened to drive out the "art" from clinical patient care. If we had demanded complete scientific validation before clinical applications could be accepted, we would, for example, have only begun using aspirin therapy within the last 15-20 years. If full, independent, scientific validation were to be required, we might still not be performing anything akin to vision therapy. Yet, indeed, there are those who advocate just such severe limitations. At a recent symposium on sensorimotor integration, one of the speakers, a noted physical therapy researcher, declared that ALL neuro-rehabilitation therapy should be halted until such time as a solid, scientific database has been developed, upon which a truly "scientific" therapeutic regimen could be built. This sort of argument implicitly assumes that "the art and science of clinical care" can, in fact, be transformed to "the science of clinical care." I believe that is, patently, an inappropriate assumption.

No two patients can ever present to the clinical situation as two identical entities. Each person brings her/his own unique history. Therefore, no disease or dysfunctional state takes on identical properties from one patient to the next. While there are often constellations of similarities from one patient to another, it

is up to the clinician to exercise her/his own clinical wisdom (clinical intuition, perhaps) and to make the best clinical judgment possible about the most appropriate course of clinical intervention for each patient with whom he/she interacts. In that light, it behooves clinicians to remain abreast of all of the latest clinical findings, whether from a single case study or a national clinical trials study, and to evaluate the possible efficacy of each therapy for the individual patient. This is, I believe, the appropriate application of the "art" of "the art and science." It would, of course, be unwise and imprudent for the clinician to rush out and passionately embrace each new "faddish" therapy which comes along as THE ultimate panacea for all ills. Likewise, it would be equally unwise and imprudent for the clinician to dispassionately turn a "deaf ear" to all new therapies until they have passed the rigors of a national clinical trials study.

One very fertile area of basic science research which can give us some clues regarding the importance to remain open to using the newest and most controversial therapies is the study of brain plasticity. It has become increasingly clear, over the past 10-15 years, that there are certain brain biochemical conditions which are required to exist before effective cortical "plasticity" and new function can occur.^{4,5,6,7} This biochemistry is tied very closely to (triggered by) the class of neurotransmitters known, collectively, as the biogenic amines, and is most closely related to the neurotransmitter norepinephrine. In order for cortical plasticity and new synaptic organizations and connections to occur, appropriate levels of these neurotransmitters must be present to "get the ball rolling." These biochemicals do not, themselves, cause the changes in brain processing, but, rather, arrange conditions so that change can occur. It turns out that the biogenic amines, as a class, are the neurotransmitters most closely correlated with arousal, attentional, motivational, and emotional systems in the primate brain. And, how many times has it been said that the patient who is "motivated" and "attends to the task" is the very patient who will make the largest gains most rapidly in therapy? Today's scientific data-base argues very strongly for the "factual" correctness of this statement. However, I believe every practicing clinician should remain open to the possibility that every new, controversial, "un-

proven" therapeutic regimen that comes along may, indeed, hold within it the behavioral key to "opening the door" of the biogenic amine chemistry of plasticity for the particular patient. Some of the clinical approaches of the past which, to mainstream optometry, have seemed most bizarre, controversial and devoid of scientific validation have later turned out to have enormous clinical, "metaphoric" truth. A prime example is Skeffington's claim that stress plays an interactive role with function/dysfunction in vision.⁸ It is well to remember that a large part of the biochemistry of stress is biogenic amine biochemistry, the same chemistry required for cortical plasticity.

Therefore, I would urge all clinicians to exercise sound clinical judgment in searching for the therapeutic approach which is attentionally sustaining, motivationally relevant, and functionally appropriate for the patient. No matter how bizarre, controversial, or unproven the therapeutic approach may seem to the world at large, if it fits these three criteria, and if it is deemed safe by the clinician involved, the probability of a successful clinical outcome seems very strong indeed. I firmly believe that it is precisely in this exercise of sound clinical judgment that the clinician truly practices both the ART and the SCIENCE of vision care.

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There are almost no clinical procedures that have been tested with the rigor demanded of the vision scientist. This applies to managing binocular problems, treating perceptual dysfunctions, determining the best add for a presbyope, or even prescribing for ametropia.

There are a number of treatment approaches which have survived the test of time. This constitutes the "conventional wisdom" of our profession. This conventional wisdom should be viewed with respect rather than the disdain and disparagement sometimes offered by those who wish to proclaim their own enlightenment. Conventional wisdom is not a static, immutable set of beliefs, but evolves with time and successful application. Many of the almost "heretical" concepts offered by A. M. Skeffington 60 years ago have become part of the conventional wisdom of today.

We all would like proof for every clinical regimen, but this is impossible to achieve with limited time and resources. Some things may never be provable because of the multi-dimensional arena of human performance. This is a real problem in the area of behavioral vision care. Outcome measures are often difficult to specify and the clinical interventions are often both complex and subtle and, therefore, not readily amenable to the controls needed for a rigorous clinical trial. How then should a clinician approach a new innovation that has not yet entered the ranks of conventional wisdom?

There are several criteria that should be applied when contemplating the incorporation of a new or novel approach and one criterion, in particular, that should be avoided. A therapy should NOT be accepted or used simply because it is new. Unfortunately, this is sometimes offered as sufficient reason for using a novel method. It may be fashionable to wear the latest clothing design but it is not consistent with good patient care or professional responsibility to become trendy. Criteria that can help to decide the potential utility of new diagnostic or treatment methods fall into three categories: *prima facie* validity, adequacy of description, and veracity.

Prima facie validity refers to the internal consistency of the procedure or method being offered and the relationship

between the new idea and existing knowledge. The arguments presented should logically flow together. Gaps, where present, should be acknowledged by the advocate of the method. If not, it suggests ignorance, inadequate analysis, or self-deception on the part of the innovator. Any of these is sufficient reason to question whether the new approach will stand the test of time. A new innovation should not violate that which is known, at least not without cogent explanation of why this is so. The presenter of new clinical approaches should not be held to a higher standard than that which the conventional wisdom meets, but the innovator has the responsibility to relate the new to the old whenever possible. This hastens the acceptance of the new and extends the underlying knowledge base.

The second criterion that should be applied before accepting a new therapy is that the procedures, observations, and expected outcomes be sufficiently specified. While this is always important in clinical practice, it is especially important for new therapies. Part of the process by which new ideas become conventional wisdom concerns the establishment of definitions and limits. With time and repetition, things are done in particular ways and a common set of observations emerges. While this is admittedly an imperfect process that does not always work, it usually prevents harmful treatments from being perpetuated. There is a responsibility to do no harm to the patient. New treatments do not bring with them the experience of the old. Therefore, the possibility of adverse effects must be addressed, along with the beneficial outcomes to be anticipated. These must be stated in clear language so that the practitioner can properly inform the patient and adequately monitor and judge the effects of the new intervention. This cannot be accomplished without full description and proper guidance for the practitioner utilizing a new therapy or diagnostic tool.

Determining the veracity of the claims made for the new treatment is perhaps the most difficult and subjective criterion. In a perfect world, there would be appropriate research for each new therapy and no need to deal with the unproven. But this is not a perfect world and often the proper research is unavailable. In many instances it is not likely to become available in time to be useful. Here the

practitioner must rely on common sense. What is the motivation for the presentation of the new treatment? Are the claims consistent with one's own experience? Does the person proposing the new therapy have a track record of ability and credibility? Not all innovators are equal. Although there may be instances in which an unknown or unheralded investigator makes a major breakthrough, they are rare occurrences. There are others who have shown repeated ability to make advances and who thereby earn credibility. Many new approaches fall by the wayside when they are attempted by others. Some have not been properly analyzed by the proponent and the observed changes may have no relationship to the treatment offered. Some are offered for self aggrandizement. Enthusiasm can cloud logic. Before embracing any new approach, these considerations should be addressed.

Not all which is new is better than that which is old. Many approaches that have stood the test of time still deserve to continue on their merits. Openness to new ideas should be combined with a healthy respect for conventional wisdom so that experience can temper novelty. This is the proper way for learned professions to evolve. New therapies are the growth force, but they should be integrated with common sense and caution. Utilization of the criteria of face validity, adequate description and definition, and veracity will assist the practitioner to sensibly evaluate and ultimately incorporate or reject new diagnostic and treatment strategies for the benefit of patients.

Reference

1. Article in *New York Times*, September 12, 1991.

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