Gathering and Evaluating Evidence in Clinical Decision-Making

La collecte et l'évaluation de données probantes pour la prise de décision clinique

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Abstract

This paper presents evidence-based clinical decision-making as a process of anticipating therapeutic benefit on the basis of thorough consideration of evidence from a variety of sources. In this process, evidence encompasses the values, beliefs, and experiences of both the client and the clinician, as well as knowledge accrued from all varieties of scientific research. In particular, we suggest structuring the gathering of evidence in terms of Peirce's (1877) classification of sources of evidence. In contrast to expert opinion in evidence-based medicine, we do not advocate the use of a hierarchy in which randomized clinical trials are accepted universally as the most worthy type of evidence. Instead, we suggest evaluating the degree to which the elements of a study fit together to serve a common purpose. Doing so will strengthen clinical practice by providing it with a broader and more dynamic evidence base.

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and the clinician.

Cet article présente la prise de décisions cliniques fondées sur les faits scientifiques comme étant un moyen de prévoir les avantages thérapeutiques. Cette démarche se fonde sur la consultation approfondie de différentes sources pour prendre une décision éclairée. Parmi ces faits, on retrouve les valeurs, les croyances et l'expérience tant du client que du clinicien, ainsi que les connaissances acquises à partir d'un éventail de recherches scientifiques. Notamment, nous proposons de structurer la collecte d'information selon la classification des sources de preuve de Peirce (1877). Par opposition à l'opinion des spécialistes de la médecine fondée sur les résultats cliniques et scientifiques, nous ne valorisons pas le recours à une hiérarchie selon laquelle les essais cliniques aléatoires sont acceptés universellement comme le type de preuves les plus probantes. Au contraire, nous proposons d'évaluer à quel point les éléments d'une étude s'imbriquent les uns dans les autres pour arriver à une fin commune. Cette stratégie renforcera l'exercice clinique grâce à des preuves plus vastes et plus dynamiques.

Keywords: Evidence-Based Practice, Clinical Process, Evaluating Research

herapeutic benefit is the goal of clinical intervention, and evidence based clinical decision-making is a process of anticipating and monitoring therapeutic benefit. Evidence-based clinical decision-making involves gathering and evaluating evidence for use in planning and evaluating the course of treatment. In our view, evidence encompasses the values, beliefs, and experiences of both the client and the clinician, as well as knowledge accrued from scientific research (Lee & Miller, 2003). Expert opinion in evidence-based medicine (e.g., Rosenberg & Donald, 1995; Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996; Sackett, Straus, Richardson, Rosenberg, & Haynes, 2000) suggests that clinical decision-making entails systematic appraisal of the best research evidence. In comparison, our view is that clinical decision-making involves gathering and evaluating the diverse varieties of evidence that are brought to the therapeutic process by both the client

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Gathering Evidence

The aim in gathering clinically relevant evidence is to examine the values, beliefs, experiences, and knowledge that clients and clinicians bring to the therapeutic process. We have previously suggested structuring the gathering of evidence in terms of Peirce's (1877) classification of sources of evidence (Lee & Miller, 2003). In his classic paper, entitled *The Fixation of Belief*, Peirce describes four general methods that serve to substantiate belief; he identifies these as the method of tenacity, the method of authority, the *a priori* method, and the method of science. In the clinical context, each of these methods represents a different kind of evidence that may be introduced into the therapeutic process by the client and clinician.

The method of tenacity refers to the unwavering acceptance of an idea because it is what one already believes; it is the continuing adherence to a belief on the basis of its longstanding acceptance by an individual or group. In terms of client beliefs, it is important to recognize that some beliefs are resilient aspects of a client's construction of self, and these central beliefs will shape a client's perspective of therapeutic goals and outcomes. Similarly, there exists in each health care profession a set of core beliefs about practice that are held on the basis of tenacity. Speech-language pathologists and audiologists believe that the ability to communicate is an important component of one's health and well-being, and this core belief underwrites a clinician's perspective of therapeutic goals and outcomes. The perspectives of the client and clinician are not always aligned. They may have different ideas about what will happen during therapy and they may hold different expectations about the outcome of therapy. A mutual set of therapeutic goals and outcomes should be carefully negotiated as part of the clinical decision-making process.

The method of authority refers to the uncritical acceptance of an idea because it is advocated by a respected individual, group, or institution. In large part, the method of authority perpetuates common beliefs in a culture. As Peirce (1877) notes, "it is mere accident of their having been taught as they have, and of their having been surrounded with the manners and associations they have, that has caused them to believe as they do and not far differently" (p. 10). In terms of client beliefs, a peer with related experiences can be a compelling source of information affecting therapeutic goals and outcomes. For instance, a peer who uses a hearing aid can represent an authoritative source of evidence about the utility of a particular type of hearing aid, and a peer's negative evaluation of a particular device can be a barrier to its use by the client despite the recommendations of the audiologist. Similarly, clinicians demonstrate beliefs that are based on authority when practices are modeled in accord with the ideas of clinical specialists or individuals highly regarded for their expertise on particular issues. Institutional guidelines or mandates also may serve as a source of authority for clinicians insomuch as they establish the set of common practices at a particular institution. It is possible for what

is considered to be standard practice to vary across institutions or service provider agencies.

The *a priori* method refers to the acceptance of an idea on the basis of some personal rationale; that is, it is an idea that "we find ourselves inclined to believe" (Peirce, 1877, p. 10) because a reason can be given for it. Although the a priori method "is far more intellectual and respectable from the point of view of reason than either of the others" (p. 10), it remains the case that what one person is inclined to believe as reasonable is not necessarily the same as what another person is inclined to believe. As Peirce notes, it "is always more or less a matter of fashion" (p. 11) to determine whether a conclusion is reasonable. Consider the example of a woman who is reluctant to use a communication strategy that a speech-language pathologist recommended for facilitating conversation with her husband who has dementia of the Alzheimer's type. The woman finds conversation with her husband to be demanding, but she reasons that there is no benefit to using the recommended strategy because it places even more demands on her. Although such reasoning is not rigorous, the conclusion is reasonable to the client. In terms of clinical beliefs, the a priorisource of evidence refers to the use of clinical experience to inform practice. Clinical experience is an important repository of information gained from working with other clients and with other therapists, and it represents a suitable place to begin the process of gathering evidence.

The fourth method described by Peirce (1877) is science. Peirce viewed science as a method of overcoming the "accidental and capricious element" (p. 11) characteristic of the other methods discussed previously. However, in contemporary accounts, science is no longer attributed this level of fidelity. For instance, in his influential historical analysis of science, Thomas Kuhn (1970) argues that "an apparently arbitrary element, compounded of personal and historical accident, is always a formative ingredient of the beliefs espoused by a given scientific community at a given time" (p. 4). As a consequence, all scientific beliefs are subject to revision or replacement over time. Furthermore, Kuhn notes that "few philosophers of science still seek absolute criteria for the verification of scientific theories" (p. 145) because "no theory can ever be exposed to all possible relevant tests" (p. 145). Thus, in considering science as a method of appraising belief, it is important to acknowledge the provisional nature of scientific evidence.

Clients frequently encounter brief reports of scientific research in the mass media. In particular, the Internet enables clients to access a variety of information about their particular health concerns and the range of potential treatment options. Although not always accurate, the information available on the Internet and in the mass media is frequently compelling and persuasive. For instance, it is conceivable that a brief account of the results of treatment for stuttering provided on the Internet or in yesterday's newspaper will affect a parent's beliefs about the method, and outcome, of treatment of her or his child's fluency disorder if such treatment is pursued.

Research as a Source of Evidence

The professions of speech-language pathology and audiology encompass a wide variety of peer-reviewed research. However, the accounts of evidence-based practice that one encounters in medical and epidemiological journals creates the impression that speech-language pathologists and audiologists should consider the randomized clinical trial (RCT) as the best evidence of the therapeutic benefit of an intervention. Unfortunately, this impression is misleading. In speech-pathology and audiology, as in rehabilitation in general, treatment interventions are most aptly described as dynamic processes in which the client plays a participatory role. Medical treatments, on the other hand, are often more aptly described as controlled procedures in which the patient has a more passive role. For example, when fitted with a hearing aid, the client with a hearing impairment makes decisions about when to use the hearing aid on the advice of an audiologist, but when fitted with a pacemaker, a cardiologist's patient has no such role in the intervention's efficacy. The person fitted with a hearing aid has a participatory role whereas the person fitted with a pacemaker has a passive role.

Insomuch as the nature of medical and rehabilitation interventions differ, the methods appropriate for evaluation of rehabilitation interventions should not be assumed to be the same as those appropriate for the evaluation of medical treatments. As explained below, we maintain that the randomized clinical trial is less appropriate for the evaluation of rehabilitation interventions than for the evaluation of medical treatments.

The Randomized Clinical Trial

The randomized clinical trial has two basic characteristics (Day & Altman, 2000). The first characteristic is random assignment of participants to treatments; the second characteristic is concealment of the assigned treatment from the participant, the investigator, or both. The purpose of randomly assigning participants to different treatments is to examine the effect of treatments while controlling for the effect of intervening variables. Randomization can control an indefinite number of intervening variables without consideration of which variables actually intervene in treatment outcomes. In rehabilitation research, the nature of these intervening variables is of considerable importance in anticipating the therapeutic benefit that a particular client is likely to experience as a consequence of a particular treatment. In a rehabilitation process in which the client plays a participatory role, there is a clear need to examine and understand the individual differences among clients that mediate intervention outcomes rather than simply to control them by means of random assignment. For example, one could investigate the nature of personal factors that mediate the extent to which a particular communication strategy is effective, rather than simply examining whether, on average, the communication strategy is effective.

The concealment of the assigned treatment from participants or investigators is often referred to as blinding. It is intended to control the effect that knowledge of the treatment may have on the therapeutic outcome. It should be recognized, however, that blinding is no longer a reasonable strategy once the participatory role of the rehabilitation client is acknowledged. That is, clients cannot have a participatory role in a therapeutic process that is concealed from them. In addition, it is not possible for a clinician to be blinded to the treatment when the treatment she or he is administering is a process that unfolds over several weeks of interaction with the client and necessitates at least a minimal amount of expertise with the therapeutic approach. Thus, it is not surprising that speech-language pathologists and audiologists have looked to research methods and designs other than randomized clinical trials to study the process of rehabilitation. The research designs appropriate for evaluating the effectiveness of medical treatments should not be assumed to be universally appropriate for evaluation of the intervention processes used in speech-language pathology or audiology.

Evaluating Research Evidence

There is an assumption in many discussions of evidencebased practice that particular kinds of research should be regarded as providing the best evidence of therapeutic benefit. There have been many attempts to develop scales and checklists to evaluate the quality of research evidence (Moher, Jadad, Nichol, Penman, Tugwell & Walsh, 1995), but there is limited evidence that such measures of methodological rigor are related to the scientific validity of research findings (Fletcher, 2002). For instance, randomized clinical trials and observational studies can often yield similar results despite being ranked very differently in hierarchies of best evidence (Benson & Hartz, 2000; Concato, Shah, & Horwitz, 2000). Therefore, it is important to recognize that the research design alone does not ensure scientific validity.

In our opinion, the scientific merit of research should be viewed as a gestalt rather than in terms of a hierarchy. In other words, one should consider the degree to which the elements of a study fit together to serve a common purpose, rather than consider the rank of individual elements in a hierarchic list. We suggest that the following elements of a study are important to consider when evaluating how well a study fits together to serve a common purpose.

First, a study should address a clearly articulated research question, supported by a thoughtful rationale derived from thorough consideration of theory and previous research. Second, the method used in a study should suit the research question. For example, investigations of the subtle complexity of a client's personal experiences are facilitated by in-depth interviews, and studies informing the appropriate use of standardized assessments are well served by descriptive and correlational methods. One cannot assume that one research method suits all research questions without depreciating the dynamic and

multifaceted nature of rehabilitation. Third, and as noted earlier, there is a clear need to understand the personal factors that mediate rehabilitation outcomes. It is important to view these individual differences as relevant predictors of intervention outcomes rather than as sources of experimental error to be controlled. Fourth, the tests and measures employed in a study should be appropriate to the research question. As Pedhazur and Schmelkin (1991, p. 15) state, "scientific advances are largely predicated on the measurement procedures used." To the extent possible, the methods of measurement should minimize the effects of unreliability and threats to validity. Fifth, the analysis of the data should be determined by the research question because the appropriateness of the analysis cannot be judged without direct reference to the research question. In addition, it is valuable for quantitative studies to provide information regarding potential clinical significance and effect size, as well as reporting statistical significance. Last, the conclusions derived from a study must clearly be related to the data and supported by the analyses performed. Conclusions and interpretations must be defensible on the basis of the analyses performed within the study, and should be restricted to addressing the research question. Any interpretations that exceed the results of the analyses should be acknowledged as speculative at best.

It is our opinion that all research has the potential to contribute to a fuller understanding of the rehabilitation process in speech-language pathology and audiology. No one kind of research can be judged universally to be the best source of evidence; even studies with recognized limitations can contribute to the understanding of rehabilitation when serving as part of the diverse array of evidence that clinicians and clients bring to the therapeutic process.

Arguably, the most justifiable clinical decisions are those based on multiple sources of evidence. In assimilating a diverse array of evidence, it is important to demonstrate a convergence of findings across a variety of methodological and measurement approaches (Campbell & Fiske, 1959). Cross-validation occurs when a number of different studies provide convergent support for a common conclusion. As Kuhn (1970) has noted, there is an arbitrary element in all research findings because no hypothesis can be tested under all possible relevant conditions. In the context of research, cross-validation demonstrates the extent to which a particular conclusion is tenable under a variety of research conditions. In the context of clinical practice, cross-validation is exemplified when the client's beliefs are (1) in agreement with evidence drawn from research, and (2) consistent with the clinician's prior experiences.

Conclusion

In describing approaches to gathering and evaluating evidence for use in the planning and monitoring of therapeutic intervention, we maintain that the rehabilitation client has an important and necessary participatory role. Consequently, we envision evidence-based clinical decision-making as a process of anticipating therapeutic benefit on the basis of thorough consideration of evidence from a variety of sources. In our perspective, evidence encompasses the values, beliefs, and experiences of both the client and the clinician, as well as knowledge accrued from all varieties of scientific research. Evidence-based practice should be a thoughtful process that is not amenable to cursory review using checklists or other rote methods of gathering and evaluating evidence. Rather, evidence-based clinical decision-making is a dynamic process in which the clinician may sometimes need to synthesize incongruent pieces of evidence, giving priority to the client's values and beliefs, while simultaneously weighing evidence drawn from research employing a variety of research methods. Doing so will strengthen clinical practice by providing it with a broader and more dynamic evidence base.

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