

Commentary

A need for an augmented review when reviewing rehabilitation research

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Abstract

There is a need for additional strategies for performing systematic reviews (SRs) to improve translation of findings into practice and to influence health policy. SRs critically appraise research methodology and determine level of evidence of research findings. The standard type of SR identifies randomized controlled trials (RCTs) as providing the most valid data and highest level of evidence. RCTs are not among the most frequently used research design in disability and health research. RCTs usually measure impairments for the primary research outcome rather than improved function, participation or societal integration. It forces a choice between “validity” and “utility/relevance.” Other approaches have effectively been used to assess the validity of alternative research designs, whose outcomes focus on function and patient-reported outcomes. We propose that utilizing existing evaluation tools that measure knowledge, dissemination and utility of findings, may help improve the translation of findings into practice and health policy. © 2016 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

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The Institute of Medicine published a report critical of the quality of medical care in the United States.¹ This was followed by discussions about improving quality and facilitating translation of research into practice.² Since then, evidence and evidence-based practice have become the sine qua non for high quality and efficient medical care. The assurance that studies are reliable and the level of evidence is high is often based on systematic reviews (SRs), which have also informed the process of guideline development.³ Guidelines are constructed from SRs using a prospective, methodical approach to reviewing the literature; and using a process designed for grading the strength of evidence and the quality of the study. There has been a significant increase in the number of these treatment guidelines, with several thousand reported by the National Guideline Clearinghouse.⁴

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Despite the contribution of SRs to many of the medical specialties, there have been shortcomings to their benefit for identifying a high level of evidence for rehabilitation research. There are primarily two explanations for this. One reason is that clinical researchers often measure impairments and use objective measures for primary outcomes. This type of research outcome, which may increase the likelihood of demonstrating statistical significance, may not be preferred for outcomes by the rehabilitation community and may not be clinically meaningful. Functional outcome measures and assessments pertaining to participation in activity needed and desired by individuals are considered important goals for this research. Findings from secondary outcomes are often based on patient-reported outcomes (PROs) and may be under-reported because they do not reach statistical significance and/or the study is inadequately powered for these measures.

The second issue is that the standard SR, such as Cochrane,^{5,6} assigns the highest level of evidence to studies that use randomized controlled trials (RCTs). This design is difficult to use in many rehabilitation trials reasons for which are discussed in more detail below. Adhering to RCTs may drive the kind of research performed, restrict the types of research design selected in order to reach a high level of evidence and form the foundation for treatment guidelines. Development of review methods that assess the soundness of qualitative,

descriptive research may add to the identification of sound and relevant outcomes.

This commentary presents the view that in order to influence practice, rehabilitation research should address the issue of relevance of the research in addition to meeting high standards for methodological strength. In order to do that, reviews must address both issues. To defend this position, we will briefly review the standard approach to SRs and how level of evidence is determined, present additional approaches for grading published research as part of an SR and review some of the difficulties encountered when applying the standard SR approach to rehabilitation research. Finally, we present examples of how to apply an augmented approach, referred to as knowledge, diffusion and utilization.^{7,8} This discussion may help increase awareness of the importance of performing research that includes assessments of utility/relevance to functional and patient desired outcomes and using review techniques that address these important outcomes, as well.

Standard systematic reviews

Two recently published reports from the IOM suggested that medical practice has advanced significantly from an expert opinion/experienced-based approach to one based on reviews of peer-reviewed, published literature.⁹ There is now a commitment to try to link the results of literature searches to prescribed pathways that assure methodological soundness to the review process that will enable the health care providers, recipients of health care, and payers to be confident that decisions are informed and evidence-based.

SRs have provided much needed analyses for practitioners. The introduction of greater rigor into the review process has helped them learn about what has been done, what has been done well, and what may not have reached a level of evidence to inform practice. These gaps open opportunities for future research.

SRs have several aims¹⁰: 1) synthesize the results of multiple original studies by using strategies that reduce bias, 2) identify gaps in the literature that may need to be filled before treatment recommendations can be endorsed, and 3) provide a score indicating the level of evidence, hence boosting confidence in the quality of the research. By applying a methodologically sound approach that enables the reader to determine the reliability and validity of the trials' results, one can decide if data are sufficient to be implemented into practice, possibly by generating evidence to establish practice guidelines and/or policy.¹¹ The process begins with a hypothesis and contributions of SRs to rehabilitation outcomes include all of the above mentioned.

SRs usually identify randomized controlled trials (RCTs) as the most likely to reach a level of evidence to inform practice. As has been reported, it is unlikely that level of evidence, alone, will change practice. RCTs frequently address treatment effects on impairments (e.g.

loss of strength, motion, sensation), but not on the full spectrum of the human experience. This has proven to be a particular problem for rehabilitation researchers because improved function (physical, psychological and social) is an important goal of treatment and is difficult to measure for many reasons.¹²

Limitations of standard systematic reviews for rehabilitation research

There are limitations to using SRs. To cite Green,¹³ "Most of the research qualifying as worthy of systematic reviews that lead to best practice guidelines disseminated to practitioners and policy makers is highly controlled research under unrepresentative circumstances."

This problem has generated considerable discussion in the rehabilitation literature in an effort to determine what the barriers are to changing practice.^{14,15} Some researchers have stated that research should "include a broad range of participants, ... and measure outcomes (both benefits and harms) that are important to patients, and reflects results in settings similar to those in which the intervention is used in practice."¹⁰ Key features include the fact that conceptually, disability involves the interaction of a person with a wide range of complex factors in the environment.¹⁶ This requires patient participation, often quite individually and not treatment driven. Controlling for these variables and properly "blinding" treatments, which may include assistive devices, often leads to small sample sizes for studies at any one local site. Another significant challenge for rehabilitation research is defining a true control group when it may not be feasible to deny people with disabilities functional assistance.¹⁷ Additionally, it is extremely difficult to perform RCTs when there are multiple interventions and therapies are performed by different specialists.¹⁸

Interventions that address broader issues of health and include the social, physical, and/or economic environment cannot be manipulated experimentally (e.g. universal design, accessibility, public attitudes, legal rights, effects of culture, economic factors), removing the possibility of conducting RCTs. The hallmarks of current SR grading systems, objective primary outcomes and standardized treatments, do not incorporate the complexity and contextual factors inherent in interventions that address broader issues. It has been challenging to design and implement high quality RCTs that use meaningful measures of function with the reliability and credibility needed to support clinical pathways. Thus, there are fewer RCTs in rehabilitation treatment research than in other fields of medicine and they receive a lower rating for level of evidence when performing standard SRs.

Specialties that rely upon individualized therapies are difficult to standardize. Rehabilitation and psychiatry are two such examples.^{18,19} Identification of shortcomings in the use of Cochrane reviews (standard SRs) for the

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