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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

mental health field have been described before.^{20,21} The result of such SRs is that a paucity of useful information reaches a high level of evidence and relatively few practice guidelines can be recommended for changing practice.²²

Therefore, when applying standard SRs, the trials that demonstrate a high level of evidence are the trials that address impairments as primary outcomes. However, if the outcome is only looked at with respect to its impact on impairment, it falls short of an important goal for rehabilitation, namely its impact on health outcomes, function and participation in daily activities of value to the individual.²³ Some researchers have commented that changing practice and informing policy should include indices that measure these aspects of health as outcomes,²⁴ and RCTs often lack these features.¹⁷

An example of this might be that a specific SR identifies a high level of evidence for studies of trials that use functional electrical stimulation (FES) for strength improvement for people with stroke. In this hypothetical review, the primary outcome sought is increased strength, which is an objective measure. Several studies demonstrate a high level of evidence for a positive effect of FES. However, there are no data in the trial pertaining to ambulation, functional activity, symptom relief, participation in social and vocational activities or quality of life, etc. The authors do not link the strength improvement to functional measures or outcomes of value to the participants. In this example, there were other studies that have a lower level of evidence for the primary outcome, yet present findings that support utility of the intervention for function, participation and societal integration that would be excluded from standard SRs.²⁵ Several rehabilitation researchers have reported these difficulties in performing standard SRs²⁶ and that this limits the value of SRs to rehabilitation practice.^{18,19,27}

Several grading systems have been developed that offer a varied approach to SRs and meet high standards. These include GRADE²⁸ and STROBE,^{29,30} among others. GRADE and STROBE share some fundamental characteristics with Cochrane reviews. They rate quality of evidence and the strength of the recommendations; they devise a protocol with a requirement for a clearly formed question, inclusion and exclusion criteria for the pool of reviewed publications; and a consistent plan for reviewing and reporting findings. These methods are designed to rate level of evidence, give much heavier weight to RCTs than to observational research, and favor objective measures. They expand the review to include outcomes of interest to and preferences of patients, signaling interest in a broader base for outcome measures. This is a refinement of the SR approach and does not fully address the need to provide assessment that identifies relevance.

Some disciplines use methodology developed from the social sciences,³¹ and use a broad range of constructs for evaluating research. This may include qualitative research,

quasi-experimental designs, survey data and consensus building. Social scientists apply a rigorous means of analysis for rating studies, but include many different techniques for data gathering including: a) Delphi approach; b) nominal groups; c) signal/noise evaluations which depend upon a quantitative meta-analysis and a qualitative meta-synthesis; and d) an interpretive assessment (hermeneutic). These aim to analyze the impact of multi-domain information (e.g. biological, behavioral, cognitive, affective) on diverse people in varied settings. Evidence from qualitative research has “an important role in ensuring that SRs are of maximum value to policy, practice and consumer decision-making.”^{32–34} Qualitative components are often built into the evaluation of health interventions³⁵ and therefore it is increasingly likely that outcome studies included in SRs may have qualitative research embedded within, or associated with them.^{c,36–41}

Application of alternative review strategies to rehabilitation research

Application of other approaches may help reduce some limitations of the standard SR, as applied to rehabilitation research, and increase the chances that studies include outcome measures of function, participation specifically sought by patients.^{42,43} This may rebalance the need for internal validity with external validity.⁴⁴ It may allow the inclusion of studies that are descriptive and include both primary and secondary outcomes in the analysis. Such augmentation allows for evaluation of the level of evidence for new knowledge generated, value to patients, and utility for informing practice or policy.

We performed a limited search of published reviews of publications between 2010 and 2015 in which the search terms included spinal cord injury and treatment and bladder/bowel dysfunction. Twenty systematic reviews were identified with bladder/bowel dysfunction as primary outcomes. There were 3 of the 20 SR's that identified secondary outcomes that improved function or quality of life as a result of the treatment, but the level of evidence was low compared to the more impairment driven outcomes.^{45–47} Hence, these data would not reach a level of evidence to establish efficacy of the studies' interventions about functional outcomes. However, in our opinion, this does not necessarily eliminate the value of the findings. It does highlight the issue mentioned above that in seeking to demonstrate a high level of evidence, objective measures are selected by researchers often to the detriment of finding useful and valued outcomes. Secondary outcomes may be of interest, but as in the case of these studies are most likely underpowered. While only one small sample, this supports the view that a relatively small number (3 of the

^c http://handbook.cochrane.org/chapter_20/20_2_1_definition_of_qualitative_research.htm and <http://www.equator-network.org/reporting-guidelines/coreq/>.

20 reviewed) use functional measures as primary outcomes.

In order to examine the utility of the standard SR, we conducted a post hoc evaluation of selected SRs in order to compare results from a standard Cochrane approach with the KDU alternative approach.^{7,8} The intent was to determine whether the two simultaneously conducted reviews might identify both overlaps and differences in the results between the two types of reviews. It is understood that the intent of the two reviews differs. The Cochrane review is designed to answer an hypothesis about what level of evidence is reached by the publication and the other, whether the study is likely to have elements that promote knowledge diffusion, utilization and have relevance.

We selected an article for review to test this, entitled “Assessing quality of life in relation to physical activity participation in persons with spinal cord injury: A systematic review.”⁴⁸ This SR used PubMed and CINAHL databases. All studies used a quality of life (QOL) measurement tool and assessed physical activity (PA) or employed a

PA intervention to determine a relationship between PA and QOL. Thirteen articles met inclusion criteria and used 9 QoL outcomes. Short Form-36 [SF-36] and Quality of Well-being [QWB], Perceived QOL [PQoL], Satisfaction with Life Scale [SWLS], QOL Index SCI Version III, Life Satisfaction [LISAT], QOL Feedback, QOL Profile: Physical and Sensory Disabilities Version [QOLP-PSD] and Subjective QOL [SQOL]. The SR demonstrated a positive link between physical activity and QoL in 12 studies.

The KDU rubric (Table 1) was applied to the specific references that had been included in the standard SR conducted by Ravenek et al described above.⁴⁸ KDU scores were measured by the number of “yes” designations in each of the general topics included in the KDU rubric. Topic 1 (conduct and design of study), addresses research design, how the study was performed and who made input into its development (e.g. patients, caregivers research professionals etc) directly. Topic 2 (implications of findings), asks whether the study has potential for applying findings to change practice. Topic 3 (utility), assessed whether

Table 1
KDU rubric

Topic	Scale II: Rating meaning in disability research (1–30)	Evidence of indicator		
		Yes	No	Comment
I. Conduct, design	1. Involvement of individuals with disabilities a) Consumer involvement in conduct and design study? b) Individuals with a disability were involved in determining the research question? c) Individuals with a disability were given opportunity to review results? 2. Dimensions studied are congruent with W.H.O. Framework for functioning, disability and health a) Data are presented on indicators of health? (e.g. thoughts, feelings, behaviors, physical health/impairment etc) b) Data are presented on indicators of task or activity? (e.g. cooking, grooming, greeting) c) Data are presented on indicators of participation in residential, vocational, educational or social domains? (e.g. roles such as worker, student, resident, homemaker etc) d) Data are presented on environmental factors in activity or participation?			
II. Implications of the findings for use specifically identified	a) Implications for policy/systems development specifically identified in the article or report? b) Implications for programs or services specifically identified in the article or report? c) Implications for provider practice specifically identified in the article or report? d) Implications for daily life of individuals with disabilities, specifically identified in the article or report? e) Implications for families or other supports outside the health/mental health/rehabilitation system, specifically identified in the article or report? f) Implications for minority populations or underserved geographic areas specifically identified in the article or report?			
III. Support available to put finding to use	a) Does the study identify any values underpinning the service, intervention/choice of outcomes/phenomenon studied, to support the translation of the findings/results into use? b) Does the study identify available materials or tools (e.g. legislative brief, instrument, manual, intervention curriculum, protocol etc), to support the translation of the findings/results into use? Or are links to this type of info provided? c) Does the study identify the cost for implementing the findings/results (e.g. start-up costs, costs of changing policy; training, consultation etc) or are links to this type of info provided? d) Does the study identify the cost of maintaining the findings/results in practice? Or are links provided to this type of info? e) Does the study identify activities or services available to support personnel, programs, or systems wishing to translate the findings/results into practice (e.g. training programs, consultation)? Or are links to this type of info provided? f) Does the study identify any support available for the translation of the findings/results into use by minority populations or underserved geographic areas? Or are links to this type of info provided?			

Table 2

Summary of KDU analysis of selected manuscripts.

KDU dimensions	Accomplishments of the paper	Scope for excellence
I		
a) Involvement of individuals with disabilities	The paper understands the target individuals with disabilities and tries to extract best possible information from the available sources.	Target population could have been involved in conduct and design of the study to truly understand the effect of interventions.
b) Dimensions studied are congruent with W.H.O. Framework for functioning, disability and health	Effective measures were recruited to collect data on indicators of health. Study indicates the relation between depression & pain and supports it with descriptive and inferential statistics.	The data could have been utilized to reflect on change in task, activity or participation. The study could have potentially identified how depression or pain interferes with normal lives.
II		
Implications of the finding for use in provider practice	The study successfully correlates depression and pain and informs rehabilitation service providers, the role of trauma in level of pain post SCI that would help in designing early interventions in severe cases, preventing secondary complications.	Could have gone a step further to provide implications for individuals and families on anticipating depression and pain symptoms associated with SCI.
III		
Support available, in terms of activities, values underpinning the service or outcomes of interventions, to put findings to use.	Interrelates patient characteristics, etiology and neurological impairments with severity of pain and depression in SCI patients. The study also implicitly identifies preventive treatment approaches as a measure to inhibit symptoms.	The paper is restricted to identifying correlations between depression, pain, & etiology of SCI. Analysis and association of findings with possible favorable outcomes would help in better utilization of the intensive research.

Title of the paper – Depression and pain among inpatients with spinal cord injury and spinal cord disease: differences in symptoms and neurological function. Authors – Denise G. Tate, Martin B. Forchheimer, Dunia Karana-Zebari, Anthony E. Chiodo & Jennifer Young Kendall Thomas.⁴⁹

studies determined if resources were available to develop programs or practices that were demonstrated to be effective and was rarely included among outcomes of clinical trials.

The analysis identified several interesting findings. First, the most frequently identified factor that authors included in their studies was health indicators and their implications with respect to daily life. This was found in 6 studies. The next most frequently identified factor

was whether the findings support translation of findings into use (present in 5). As for the other variables, investigators rarely include patients, families and/or caregivers in any capacity. Similarly, only 1 study mentioned the cost of the intervention or what one would need to promote findings into practice or policy.

Application of the KDU rubric (Table 1) to 2 manuscripts helped identify areas where an augmented approach could have been used to identify aspects of design,

Table 3

Summary of KDU analysis of selected manuscripts.

KDU dimensions	Accomplishments of the paper	Scope for excellence
I		
a) Involvement of individuals with disabilities	The paper acknowledges and recommends the documentation of participants' pre-injury psychological status to establish a better understanding of their mental health.	Target population could have been involved in conduct & design of the study to truly understand the effect of interventions.
b) Dimensions studied are congruent with W.H.O. Framework for functioning, disability and health	Comprehensive instruments were used to collect information on indicators of health. The study relates the occurrence of depressive episodes with TBIs and provides effective measures to fight depression supporting its research statistically.	The research limits itself to measuring the severity of depression and ignores its impact on normal working lives of the disabled. It could have gone a step further to include the impact of depression on their ADLs and IADLs.
II		
Implications of the finding for use in provider practice	The study very well identifies and presents the findings of research to the clinical practices. It provides evidence-based suggestions on pharmacological treatments and rehabilitative programs to fight depression post TBI.	Could have included implications for individuals themselves and families on anticipating depression and means to overcome the painful episodes.
III		
Support available, in terms of activities, values underpinning the service or outcomes of interventions, to put findings to use.	Outcomes of pharmacological and psychological interventions studied are included in the paper. It also provides valid points and guidelines for future researches that could be helpful in analyzing the various interventions to overcome depression following TBI.	Besides mentioning use of a cost effective approach to depression management, the paper could have identified interventions and medicines that are cost effective.

Title of the paper – Treatment for Depression After Traumatic Brain Injury. Authors – Jesse R. Fann, Tessa Hart, and Katherine G. Schomer.⁵⁰

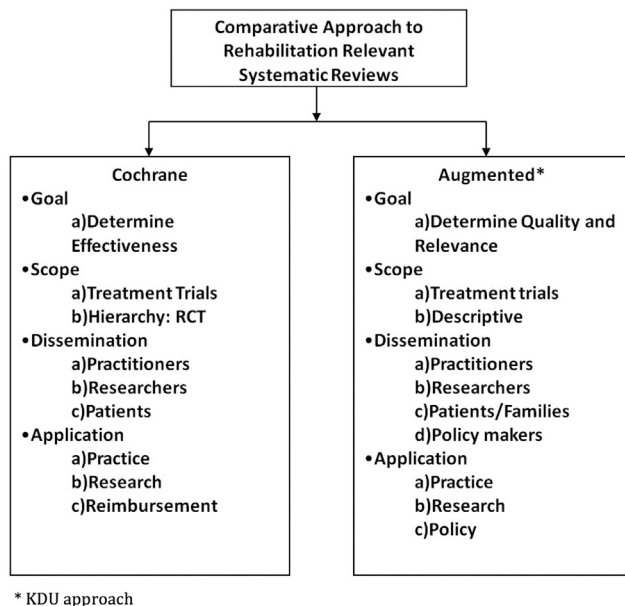


Fig. 1. Comparative approach to rehabilitative relevant systematic reviews.

relevance and possible implementation strategies to facilitate knowledge translation. The analysis demonstrates what the value of using an alternative strategy to assess the study⁴⁹ and the review⁵⁰ might add to the knowledge base and its utility (Tables 2 and 3).

It is likely that SRs and KDU assessments address different parameters. Standard clinical trial methodology addresses the level of evidence for determining effectiveness and relies heavily on randomized, controlled trials. KDU methodology addresses questions that have been shown to influence relevance and possibly translation of findings into practice or policy. In the authors' opinion, opportunities to evaluate the additional criteria that address impact on practice or policy; how to operationalize the findings and what resources would be needed for implementation, might be helpful in increasing the likelihood that the findings will be translated into changes in practice or policy.

The classic SR approach is not altered by applying a KDU assessment. In our experience, while performing these parallel analytic reviews, we observed that studies could have included data gathering or further analyses that would encompass some of the domains identified in the KDU process with little additional effort. It is our hope that in the future rehabilitation researchers would include the assessment of these domains. Adding measures of KDU may raise the awareness of a study's contribution to utility of the knowledge gained and possibly influence future clinical research design.

A flowchart (Fig. 1) demonstrates a summary of the two types of reviews.^{6–8} Running these in parallel may be able to make explicit level of evidence and relevance and utility of findings. Both may be of value to patients and health care professionals.^{51–53}

This article suggests there may be value in using an augmented approach to performing SRs for clinical rehabilitation research. While the focus of the analysis is on an approach to evaluating rehabilitation outcomes, the broader issue of health outcomes is highly relevant. Measures of overall health must include self-reports and reflect the values and needs of patients. It is valuable for reviews of clinical research to apply a method of analysis that uses a reliable process for assessing the validity of several research designs and outcomes that may not be exclusively objective. This approach can be performed in parallel with the standard review and serve to raise awareness about the utility and likelihood of diffusion of knowledge resulting from clinical research. It is hoped that using an augmented review may, expand the range of outcomes, increase diffusion of knowledge and increase the likelihood of bringing change in clinical practice and policy while providing assurance of a high level of evidence; and ultimately improve overall health and manage disability.

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