The Role of Treatment Theory and Enablement Theory in Shaping Rehabilitation Treatment Studies

John Whyte, MD, PhD

Introduction

Treatment research generally progresses through several stages before a new treatment can be implemented in practice. At an early stage, the goal is to establish proof of principle – the treatment seems to have the effect on some immediate target that its hypothesized mechanism of action predicts. In medical research this would include an in vitro study to demonstrate that a new antibiotic kills a certain bacterial strain. At a later point, clinical trials are performed with carefully selected samples that maximize the ability to detect a clinical benefit. For example, one might exclude patients who are likely to die soon from other causes, or have such mild illness that they are likely to recover quickly without a treatment. Finally, one may study the effectiveness of a treatment on a broader and more heterogeneous sample to ensure that its benefits are more broadly applicable. Such effectiveness studies assess whether the benefits of treatments studied in "pure" samples can be generalized to real world treatment populations and settings. Critics of the drug approval process have noted that this stage is infrequently implemented. Sometimes "real world" is thought of as a continuous dimension as the heterogeneity of the sample increases along many dimensions at once (e.g., as when a treatment studied on relatively young people with few other illnesses is extended to older individuals with multiple comorbidities). At other times, one may be interested in the generalization to specific subpopulations – as, for example, when one studies how a drug works in patients with renal failure.

Rehabilitation research follows a similar developmental sequence, though the stages are less well defined and more variable based on the nature of the treatment, as compared to pharmacologic treatments. Importantly, though, in rehabilitation, "generalization" of treatment benefits to broader and more heterogeneous populations can mean very different things, that have different research design implications. These different meanings of "generalization", in turn, relate to the distinction between treatment theory and enablement theory, as discussed below.

Treatment Theory

A treatment has an immediate or proximal target which it is intended to change, referred to as the treatment object, in analogy with syntax where a verb acts on an object. The verb in this analogy is the essential ingredients or mechanism of the treatment. The treatment theory specifies *how* the essential ingredients alter the object of treatment. The essential ingredients of rehabilitation treatments are extremely variable, ranging from mechanical force applied by a brace to a limb, to learning experiences that modify a pattern of behavior. Accordingly, rehabilitation treatment theories come from many scientific domains and address objects that range from physiologic processes to social systems. Common to all is specification of how a treatment changes the immediate treatment object.

However, many rehabilitation treatments are intended to change things far distal to the treatment object. We may, for example, provide repetitive resistive exercises (object: muscle strength) to improve stair climbing. Or we may train someone in the use of an electronic calendar (object: calendar use skill) to allow more effective social integration. But these treatments have no direct effects on stair climbing or social integration; their impacts in those realms are predicated on a relationship between the treatment object (strength, calendar skill) and a more distal functional outcome (stair climbing, social integration) – a relationship over which the treatment mechanism has no control.

Enablement Theory

Enablement theory addresses interrelationships among functional constructs at different levels of the International Classification of Functioning, Disability, and Health (ICF). That is, enablement theory acknowledges that complex functions are multiply determined, and seeks to model these complex interrelationships. For example, stair climbing requires not just strength, but balance, joint range of motion, pain-free movement, arm movement (depending on the degree of leg weakness and balance loss), etc.; social integration requires not only keeping track of commitments but planning the transportation to get to them, initiating the action, being able to participate in social activities once at the appointment, etc. In principle, a well-developed enablement theory could take as inputs the level of ability of each of these component processes and predict performance of the complex skills. Similarly, it could specify the clinical impact on a complex function of a certain degree of improvement in a component process (i.e., is it *worth* applying a treatment to a component process if it will not impact the desired outcome?). What enablement theory cannot provide, however, is tools to change any of these component processes; it can only predict the ramifications of such changes elsewhere in the enablement model. Moreover, enablement theory doesn't "care" *how* a component is changed. Its predictions would be the same regardless of the mechanism of change.

Combining Theories

Treatment theories give us tools to change treatment objects, but don't tell us the broader impact of any changes we can make. Conversely, enablement theory tells us how changes that we make through treatment will impact broader areas of function, but doesn't tell us how to make those changes. Combining the 2 theoretical frameworks allows us to test the efficacy of a treatment *and* to determine to whom that treatment should be applied, but close consideration demonstrates that these are very different research endeavors.

In rehabilitation, testing the *efficacy* of a treatment (i.e., does it actually induce the change its mechanism is intended to induce?) needs only to address measures of this proximal treatment object or outcome. That is, the ultimate test of the efficacy of a method of training calendar use is whether it enhances the ability to use the calendar. It makes sense to concentrate early phases of clinical research on maximizing the potency of the treatment with respect to its object. What is the fastest and most enduring method for training calendar use? But once the *efficacy* of the treatment with respect to its object has been optimized, the problem shifts focus. *In whom* will the use of this optimized training program result in improved social integration? This problem can't be solved by making the training

program so effective that it has this result in all patients. Rather, it becomes a problem of either: 1) In which patients does treating this problem (inability to keep track of appointments) in isolation have a positive impact on social interaction? or 2) What additional treatments (e.g., transportation services, social communication skills training) must be combined with calendar training *in population X* to have a positive impact on social integration?

Thus, the early stages of efficacy testing are guided largely by treatment theory, but the later stages of effectiveness research and real world impact are guided largely by enablement theory. Importantly, there is no reason that these 2 phases of work must be tightly linked and, indeed, there is reason to think that separating them would have advantages, if means could be found to coordinate the 2 streams of research. Research on treatment theory benefits from expertise on the specific physiological or psychological system being targeted, and on the known and hypothesized mechanisms available to influence that system – e.g., expertise in muscle physiology or anterograde and prospective memory systems in the prior examples. Research on enablement theory, in contrast, benefits from expertise in the performance requirements of the complex real-world tasks that are clinically targeted, and how those performance requirements interact. Thus, different researchers are likely to contribute to these 2 phases of research. Importantly, however, the above conceptualization suggests that there is no need to re-study each treatment for a given treatment object in terms of its real world impact. That is, suppose we know that a method of calendar use training successfully enhances calendar use, and we know that patients with specific patterns of strengths and impairments increase their social integration after calendar use training. If we find a new method of calendar use training that is equally or more effective in enhancing calendar use, we already know that it will also be useful in that patient population. In addition, enablement theory can suggest what *additional impairments* (e.g., writing ability, awareness deficits) may need to be targeted in order to enhance the impact of many calendar-based methods on social integration.

Generalization of Rehabilitation Treatments

In light of the distinction between these 2 theoretical frameworks, we can consider 2 different meanings of the "generalization" of rehabilitation treatment benefits. One is closer to the classic sense of stimulus generalization in animal learning studies. When a pigeon is conditioned to peck a red key but not a green key, we can ask how often the bird pecks an orange key. Similarly, if we train someone to use a calendar to record doctor's appointments, do they record movie dates, or if we do leg strengthening exercises in a seated position, does it also improve strength measured when lying down? But another sense of generalization refers to whether treatments directed at a component process "generalize" to enhanced performance of a complex task or function. Does the person who is trained to use a calendar *show up at appointments*? This clearly relates to domains far beyond the trained domain, and will be largely dictated by enablement theory.

Summary

Rehabilitation treatment research, like biomedical treatment research, proceeds through stages of development. Because of the multifaceted determinants of human function, however, rehabilitation

treatment research shifts focus during development from an emphasis on treatment theory to one on enablement theory. Explicit recognition of this transition could enhance study design at different developmental phases, and highlight the need to involve investigators with different skills at different points.