Creating a Manual to Better Define Rehabilitation Treatments

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ABSTRACT

Background: Stakeholders in the health care enterprise are interested in the comparative effectiveness of treatment alternatives. Rehabilitation is a key component of the health care system that is expected to grow as the population ages and increasing numbers of patients survive with chronic illnesses and disabilities. At present, however, rehabilitation lacks sufficient rigorous research to guide clinicians and consumers toward effective treatments. The field has a plethora of measures of case mix and outcome, but the treatment process itself is a "black box" specified only crudely with metrics such as *length of stay*, *sessions of physical therapy*, and *course of vocational rehabilitation*. The rehabilitation treatments that must be compared in effectiveness research are not specified in sufficient detail to be measured and studied with respect to their differential impact on outcomes important to consumers. In 2008, we embarked on a NIDRR (National Institute on Disability and Rehabilitation Research)-funded 5-year effort to improve classification and measurement of rehabilitation interventions. This culminated in a conceptual framework for a rehabilitation treatment **taxonomy** [a] (RTT), described in a January 2014 supplement to *Archives of Physical Medicine and Rehabilitation.* This work in progress has received enthusiastic support, commentary, and dissemination from many rehabilitation disciplines. We included representatives of these disciplines in periodic discussions and workshops to help shape the effort described in this report.

Objectives: The objective of this project was to incorporate the conceptual framework of the RTT into standardized operational procedures so that clinicians, educators, and researchers across all rehabilitation disciplines could define and specify rehabilitation treatments according to their immediate effects, mechanisms of action, and hypothesized **active ingredients**. Thus, one tangible objective was the development, initial testing, and dissemination of a *Manual for Rehabilitation Treatment Specification* (see Methods). A further objective, using the results of that testing, was to continue developing the RTT toward the goal of achieving a common language and classification system for all rehabilitation interventions (now renamed the **Rehabilitation Treatment Specification System—RTSS**), thus allowing meaningful grouping of similar treatments and meaningful comparisons across distinct treatment approaches. The ultimate goals of the RTSS, once adopted, are to

- enhance the ability of clinical educators and supervisors to ensure that treatments are delivered as intended;
- improve the ability to replicate and disseminate effective treatment research;
- improve the ability to synthesize treatment evidence across replications of the same or similar treatments;
- support cross-cutting research on treatment principles that apply to larger categories of treatment;
- enhance communication among members of different disciplines coordinating care; and

[a] Technical terms are in bold when first used and are defined in the Glossary in the Appendix.

- increase the value of administrative datasets in treatment research by increasing the information value of treatment documentation.

Methods: Directed by the principal investigator and 2 senior co-investigators, a multidisciplinary core team and 5 work groups compiled a sample of 51 treatments that a multidisciplinary sample of rehabilitation clinicians was most interested in evaluating and comparing. We built vignettes, which contained brief clinical summaries, around these treatments and used them as the basis for treatment specification. The vignettes focused on a range of treatments delivered in both inpatient and outpatient settings to adults as well as children in the following disciplines: occupational therapy (13), physical therapy (13), speech-language pathology (12), nursing (7), and psychology (6). Core team members attempted specification of these treatment vignettes, identified ambiguities and gaps in the set of rules and procedures that were drafted to guide them, and recommended refinements to those procedures in an iterative manner. The core team discussed the challenges encountered in these attempted specifications in weekly meetings, and one team member was assigned to draft written resolutions or revisions to existing manual rules. After multiple cycles of attempted specification, rule revision, and respecification, the core team arrived at a full draft of the *Manual for Rehabilitation Treatment Specification*, which described the key concepts of treatment specification and provided a reproducible procedure for such specification, along with a set of 5 fully specified vignettes as teaching illustrations. We provided a group of 40 rehabilitation clinicians from mixed disciplines with web-based training in using the manual. We used feedback from trainees about the manual's clarity and utility to shape a final version. The project advisory board met by teleconference and in 2 face-to-face meetings to provide feedback on the evolving manual, suggestions for design of the RTSS clinician training cycle, and final input on next steps toward implementing the specification system.

Results: Despite the previous period of NIDRR funding, a number of challenging conceptual obstacles emerged during the process. Developing and revising rules to guide the specification of **volitional treatments**—treatments that require effort and engagement on the part of the patient—were among the most challenging tasks. In addition, we developed procedures and rules for (1) determining the number of treatment components, (2) defining the **target of treatment** for each **treatment component**, (3) determining the **treatment group** to which each treatment component belongs, and (4) specifying the treatment component's active ingredients and their **dosing parameters**. Feedback obtained from the advisory board, from participants in the RTSS clinician training cycle, and from attendees at multiple professional presentations confirmed that the concepts contained in the manual were valuable and useful in supporting clinical education and supervision, clinical reasoning, and research reporting and synthesis. Advisory board members and training participants also agreed that repeated practice with feedback and discussion would be necessary to allow development of independent skills in treatment specification. Thus, the advisory board recommended continued efforts to implement these concepts into curricula for rehabilitation clinicians and researchers as well as a series of focused implementation projects that could document the positive impact of the RTSS and encourage its broader adoption.

Conclusions: We developed and summarized the conceptual framework for the RTSS in the *Manual for Rehabilitation Treatment Specification.* Those who have engaged with the concepts have found them valuable for both clinical reasoning and research reporting, but the rules and procedures needed for independent treatment specification require practice and skill development. We will need to take additional steps to train relevant stakeholders to implement this system.

BACKGROUND

Rehabilitation is in urgent need of a stronger evidence base to guide the provision of clinically effective treatments and services and to allow consumers of rehabilitation services to make informed choices.[1-8] Building the evidence base in rehabilitation, as in other areas of health care, requires rigorous treatment research using randomized controlled trials, quasi-experimental studies, health services observational research, and other study designs. However, unlike health care fields that rely heavily on pharmacologic and surgical treatments, whose active ingredients are clearly defined, the treatments that must be studied in rehabilitation commonly are not themselves specified in sufficient detail to be operationalized, measured, and compared accurately.[9-12]

Treatment Specification for Comparative Effectiveness Research

Comparative effectiveness research (CER) and informed selection of rehabilitation treatments by consumers are limited until the treatments being compared or selected are operationally defined. CER of treatments that are defined at the institutional level (eg, *inpatient rehabilitation* vs *subacute rehabilitation*) or discipline level (eg, *16 hours of PT* [physical therapy] *vs 4 hours of PT*) may produce null results because of the variable contents of those labels. Even when CER studies demonstrate differences in the impact of treatments defined in these ways, it is difficult to generalize those results to new instances of those institutions or disciplines, since the actual treatment **ingredients** delivered may vary. We argue that the most useful way of defining rehabilitation treatments, like pharmacologic and surgical treatments, is with reference to their active ingredients. Whereas one can productively ask about the relative effectiveness of aspirin and metoprolol (active ingredients) in preventing recurrent myocardial infarction, framing the question in terms of *pills vs capsules* (**inactive ingredients**) would not advance clinical research. This project addressed a critical gap in the specification and measurement of rehabilitation interventions, which must be resolved in order to fill the many specific gaps in the evidence base within this branch of health care.

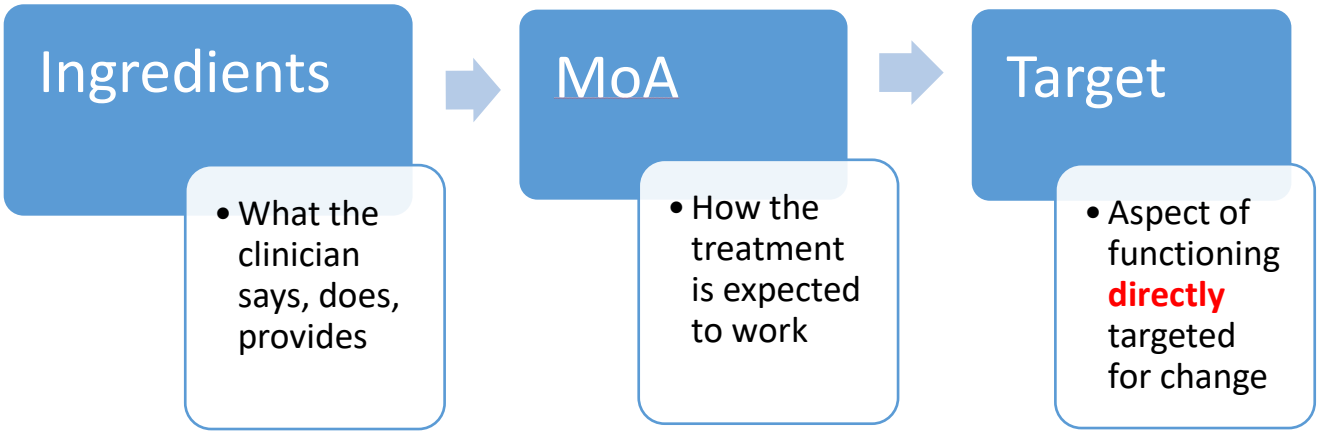
Clear specification of rehabilitation treatments is not sufficient to guarantee useful patient-centered comparisons, but we would argue that it is a necessary step. Many treatment targets in rehabilitation are of immediate patient relevance (eg, the ability to be safely mobile, to dress and feed oneself, to be free of pain, to communicate with friends and loved ones). Comparing treatments intended to achieve those targets requires the potential treatments to be defined in an objective and replicable way. Doing so does not guarantee that well-conducted CER will be completed, or that evidence will be sufficient to make an informed choice. Failing to clearly define the treatments under study makes it impossible to advance CER. Some rehabilitation treatments address targets (eg, joint range of motion, gait biomechanics, working memory capacity) that are not of immediate patient relevance but that relate to treatment aims that *are* patient relevant (eg, ability to dress oneself, walking speed, ability to follow a conversation). In these instances, the clinician will need to assist the patient in weighing and comparing treatment alternatives by clarifying how they relate to meaningful patient outcomes. This is no different from many areas of medical practice in which the **target of treatment** (eg, lowering cholesterol) is not of direct patient relevance, but the treatment aim (avoiding myocardial infarction and stroke) is, and the clinician should clarify the link.

The Importance of Treatment Theory in Treatment Specification

A critical assumption of this work is that all rehabilitation treatments and services are best specified with reference to the **treatment theory** underlying each component of an intervention. Treatment theory has been defined as a "set of propositions that describe what goes on during the transformation of input into output, that is, the actual nature of the process that transforms received therapy into improved health."[13] As such, treatment theory hypothesizes that specific active ingredients are required for a given functional change. We have further defined 3 components of a treatment theory that together are necessary and sufficient to explain the treatment's effects.[14] This **tripartite structure** consists of (1) a treatment target, which is a *specific* and *measurable* aspect of patient functioning targeted for change; (2) a set of active ingredients that, in some combination, are hypothesized to effect the desired changes in the target (note that inactive ingredients may also be present but do not

change the target); and (3) the **mechanism of action**, which specifies the hypothesized processes by which ingredients bring about these changes, as illustrated in Figure 1. In this scheme, the ingredients and the target are both observable and measurable, while the mechanism of action is often invisible and must be inferred.

Figure 1. Tripartite structure of a treatment theory for a single treatment component



Abbreviation: MoA = mechanism of action.

Treatment theory, which explains the direct effects of treatment, may be distinguished from **enablement theory**, which refers to the more distal functional changes (treatment aims) that may occur because of a treatment-induced change in one or more treatment targets. For example, prescription eyeglasses might be provided to increase visual acuity (target). Improved vision *may* result in better driving, but that relationship is indirect (an aim), since driving performance may also be affected by attention, processing speed, aspects of motor control, etc. A central tenet of our work is that *the specification and measurement of rehabilitation treatments should be organized around the concept of treatment theory*. Enablement theory, in contrast, is useful for the selection of a treatment likely to have a desired distal impact on an

individual patient, as shown in Figure 2. In one case, the treatment is directed toward a target of improved vision, and thus driving performance would be an aim. One might not prescribe eyeglasses to enhance the aim of better driving in a patient who also has extreme distractibility or upper extremity weakness. However, there may be adapted driver training approaches that would consider driving performance itself as a target, as illustrated by the arrow in the third row of Figure 2. Thus, driving is an aim for the first treatment but a target for the second.

Figure 2. Enablement theory related to treatment targets and aims

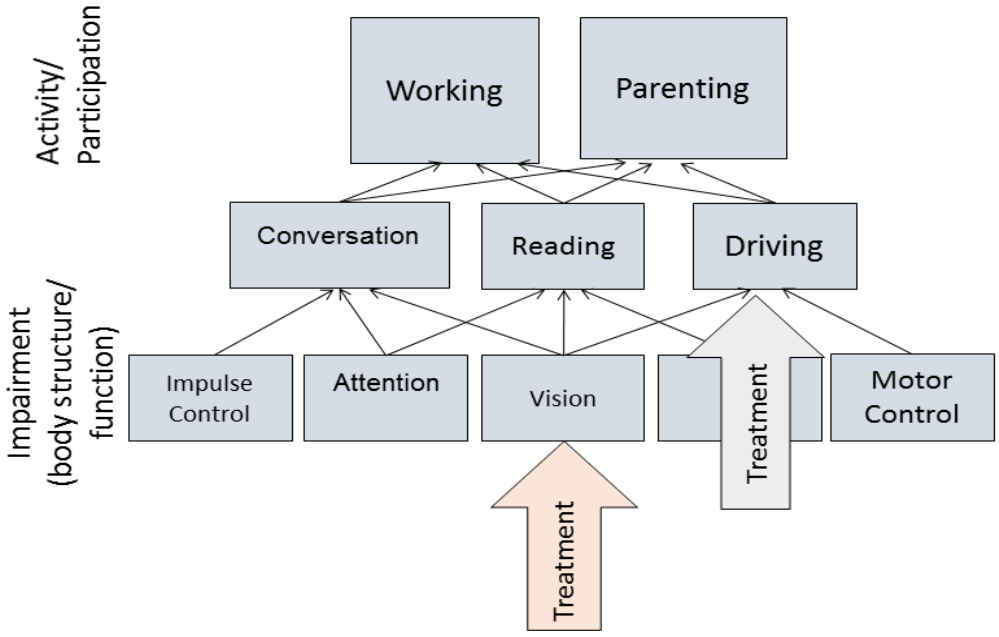


Figure 2 provides a schematic illustration of enablement theory. With respect to the ICF (International Classification of Functioning, Disability and Health) framework, multiple factors at the impairment (ie, body structure/function) level may determine function at the activity level, and multiple factors at the activity level may affect factors at the participation level. Two potential treatments are illustrated with targets at 2 different levels. Even a highly effective treatment at one level cannot guarantee successful accomplishment of an *aim* at a distal level because of the additional causal factors relevant to that aim.

In rehabilitation, ingredients are clinician actions and behaviors, verbalizations, substances (eg, drugs), procedures, and other entities selected for their ability to affect a target via a prespecified mechanism of action. By specifying the active ingredients of treatment, a

treatment theory also specifies which ingredient variations constitute meaningful variations in treatment dose. Ingredients vary qualitatively (eg, a clinician may provide explicit feedback or not, or terminal vs concurrent feedback) and sometimes quantitatively as dosing parameters (eg, feedback may be delivered on a specific schedule of frequency/intensity).

We also argue that treatment targets need to be better specified to measure rehabilitation with the precision needed to evaluate its effects empirically. In clinical parlance, treatment targets may be framed as, for example, "improved ambulation," but for some patients it may be important to ambulate faster; for others, it may be to use a more symmetrical gait pattern, to incorporate an assistive **device** correctly, or to be able to ambulate for a longer distance. The clinician is likely to select different ingredients for these different specific targets. Our use of the word *target* connotes a more exact conceptualization of the immediate outcome of treatment, one that allows for precise measurement and precise selection of the types of ingredients (aids, instructions, cues, error feedback, reinforcement, environmental setup, etc) that will bring about the desired result.

Current Approaches to Rehabilitation Treatment Specification

Thought leaders in this field have long noted the "black box" problem of rehabilitation,[15-19] meaning that its ingredients have not been sufficiently specified and quantified nor their effects compared in ways that will assist in treatment selection. Attempts to compare services with reference to the level of *facilities* (eg, inpatient rehabilitation unit vs skilled nursing unit), *disciplines* or *staff training levels* (eg, services from physical vs occupational therapy, or a physical therapist vs a physical therapy aide), or *time* (eg, length of stay, hours of treatment) fail to unpack the black box because they provide no information about the actual content and process of the treatment experienced by patients. The common clinical practice of defining treatment by the problem it is meant to address (eg, gait training, memory remediation, vocational rehabilitation) similarly provides no information about the methods or processes used to address the problem. Thus, the current state of affairs affecting rehabilitation research, program evaluation, and ultimately practice is analogous to asking whether, for example, cancer treatment is effective or ineffective without considering the

differences among the many available formulas and intervention modalities that are targeted to specific forms of the disease.

Rehabilitation is not alone in this dilemma. The difficulties in specifying so-called complex interventions, many of which depend on active intrapersonal and interpersonal processes such as **volition**, learning, and the therapeutic relationship, have been recognized in other fields, including psychotherapy, behavioral medicine, public health, and nursing.[20-29] Accordingly, the UK Medical Research Council's guidance for developing and evaluating complex interventions calls for improved methods of specifying and reporting intervention content to address the problems of lack of consistency and consensus.[30] In influential early work, Donabedian called attention to the importance of *structure* and *process* factors in determining health care outcomes.[31] In his scheme, *structure* includes physical facilities, health care technology, and financing. *Process* refers to such factors as the nature of assessment procedures, frequency of team meetings, and adherence to care pathways. Although measured structure and process factors have been shown to be associated with rehabilitation outcomes in a number of studies, they are rather crude predictors of outcomes overall.[32] This is likely because such processes as team meetings can bring together wider expertise and increase the probability that a good treatment plan will emerge, but the team meeting itself doesn't enhance the patient's functioning, and not every team meeting results in the selection of an optimal treatment.[32] In addition, even the best treatment plans need to be specified in enough detail for team members to carry them out accurately and consistently. Thus, there remains a need to better define and operationalize rehabilitation treatments in order to determine which are optimal for specific patients and specific functional problems amenable to rehabilitation services.

An example from the research team's experience may help highlight this need as well as the gaps waiting to be addressed. In 2011, the Department of Defense commissioned the Institute of Medicine (IOM) to analyze the evidence base supporting cognitive rehabilitation for traumatic brain injury (TBI).[33] As the panel began reviewing the available evidence, the issue of treatment definition and specification became an immediate obstacle. For example, *memory*

remediation consisted of repetitive drills, training in the use of internal mnemonic strategies, training in the use of external memory aids such as notebooks and cellphones, and other methods. In assessing the evidence base for memory remediation, should all of these disparate treatments be meta-analyzed together? Is the target of treatment really the same for all of them? Treatments such as drills appear to be intended to build *memory capacity*. But a memory notebook has no direct effect on memory capacity. Instead, it is designed to facilitate the successful completion of a set of everyday activities that are limited by memory deficits, such as keeping appointments and completing the tasks on to-do lists; a memory notebook would not be predicted to improve facial recognition or memory for routes traveled. Thus, the effectiveness of a treatment involving a memory notebook should be measured against completion of the intended activities rather than, for example, standardized memory testing or evaluation of facial recognition.

This example represents one instance in which lack of a meaningful method for defining and specifying treatment posed a major obstacle to useful synthesis of rehabilitation treatment research, thus precluding the development of reliable guidance for clinicians regarding which interventions to offer their patients. But a problem exists not only in the synthesis of research; if in the primary research the investigator fails to accurately specify the treatment target, he or she may miss important treatment effects. As in the example of the IOM panel, a memory notebook might be judged ineffective by assessing its impact with respect to patients' abilities to remember people's faces. If the wrong ingredients are chosen to represent the rehabilitation treatment, the same problem may occur (eg, if a smartphone were selected on the basis of size and shape rather than the usability and relevance of its internal features). Since efficacy or inefficacy of a rehabilitation treatment depends on the actual ingredients received by the patient, the field of rehabilitation needs an approach to treatment definition based on the nature and quantity of *ingredients* used for affecting specified functional *targets*.

Project Objectives

The overall objective of this project was to advance the conceptual framework for rehabilitation treatment specification, developed with previous funding, and to transform it

into a procedural manual (the *Manual for Rehabilitation Treatment Specification*) that could guide clinicians and researchers in performing treatment specification in a standardized fashion—that is, to develop a Rehabilitation Treatment Specification System (RTSS). We addressed this overall objective with the following specific aims:

Aim 1

Develop a reliable and effective *Manual for Rehabilitation Treatment Specification* and associated training materials describing a standardized set of steps that will guide researchers, clinical educators, and clinicians in applying the tripartite structure of treatment theory to

- determine whether to decompose a treatment into mechanistically distinct treatment components;
- specify the treatment target for a particular treatment component, and distinguish it from additional ("downstream") clinical aims; and
- specify in observable/measurable form the ingredients required to initiate the known or hypothesized mechanism of action of the treatment component.

Aim 2

Provide training based on the *Manual for Rehabilitation Treatment Specification* to a multidisciplinary cohort of rehabilitation professionals, use the evaluation of training outcomes to assess the reliability and utility of the method for treatment specification, and subsequently make final revisions to the manual and associated training materials.

Aim 3

Use 50 well-defined treatment examples produced in the first phase of the project (aim 1) to make recommendations for further development of a rehabilitation treatment taxonomy (RTT).

We intended for these aims to result in the full development of a specification system, based on known or hypothesized active ingredients, which is supported by clear and rule-based

procedures. We anticipate a number of positive impacts of this kind of treatment specification system, once broadly adopted by clinicians, clinical educators, and researchers. From the perspective of research, such a system ensures that the elements of treatment thought to drive its efficacy are clearly described and that attempts to replicate research ensure delivery of those same ingredients. This system also ensures that evidence reviews in their synthesis phase sample studies of *the same treatment* (in a mechanistic sense) for analysis so that their conclusions help inform the treatment theory that those treatments share. Finally, once strong evidence exists for the effectiveness of a given form of treatment, an ingredients-based specification system ensures that clinical practitioners can deliver well-defined active ingredients.

With respect to clinical education and practice, such a system allows educators to highlight the essential aspects of delivering the effective treatment ingredients, allows clinical supervisors to evaluate appropriate adherence to treatment delivery plans and standards, and facilitates clinical reasoning about what ingredients are able to modify what aspects of functioning. By employing discipline-neutral nomenclature, the system also fosters interdisciplinary communication about shared treatment theories and active ingredients. These potential benefits are illustrated by a complete specification of a simple treatment in Table 4. However, this detailed illustration will be easier to appreciate after review of the key RTSS concepts.

Ideally, an ingredients-based specification system also should support clinical documentation and billing. Doing so would enhance the value of administrative datasets as sources of evidence about treatment effectiveness, since treatments would be documented in categories pertinent to their effectiveness. However, a very simple and quick system would be needed for this purpose, and the potential tension between the accuracy needed to guide research and the simplicity needed for documentation has not been explored in detail.

STAKEHOLDER ENGAGEMENT

Unlike many PCORI-supported projects, the primary stakeholders for this project are rehabilitation clinicians, educators, researchers, and editors/publishers rather than patients or consumers of rehabilitation services. This reflects the technical nature of the "black box problem" in that better treatment specification requires reflection on treatment theories and hypothesized mechanisms of action with which consumers of rehabilitation services are unlikely to be familiar. Achieving the project aims will result in a set of rehabilitation treatments that are operationally defined with respect to their hypothesized active ingredients. This, in turn, is expected to improve the training and supervision of clinicians to reliably deliver those active ingredients and to enhance the ability of researchers to aggregate evidence about the efficacy and effectiveness of the treatments so defined. Only then will it be possible for patients and consumers to weigh the pros and cons of different well-defined treatment alternatives.

With this in mind, we designed 4 primary methods for engaging relevant stakeholders: (1) creation of an advisory board; (2) conduct of multiple focus groups; (3) training of a multidisciplinary group of clinicians; and (4) presentation and discussion of the work in progress at professional meetings. These methods complemented the experience of the multidisciplinary team of rehabilitation clinicians and researchers that conducted the project. Below, we describe the impacts of the advisory board and of our presentations at professional meetings. We describe the impacts of the clinician focus groups and the clinician training cycle under Methods and Results, as these were data collection methods described in the original grant methodology.

Advisory Board

We created an advisory board of 18 senior clinicians, rehabilitation educators, professional association leaders, researchers, and journal publishers, as well as 2 rehabilitation consumers who are also involved as rehabilitation professionals or advocates (see Table 1). We selected these individuals to represent multiple disciplines and practice settings, to provide insight regarding the likely users of the system we developed, to provide feedback on ideas and

drafts, and to assist in dissemination and implementation of project findings. Early in the project, we held meetings of the advisory board by teleconference to discuss the results of our focus groups and to receive guidance on how to address the challenges of specifying volitional treatments (treatments that depend on the patient's effortful behavioral performance for their efficacy). In January 2017, we held a 2-day in-person meeting of the advisory board to review an initial draft of the *Manual for Rehabilitation Treatment Specification,* to attempt manual-guided treatment specifications, and to plan for the cycle of RTSS clinician training. Late in the third year, we conducted our final in-person advisory board meeting to summarize the feedback received from the cycle of RTSS clinician training and our efforts at professional education and to discuss next steps for implementing the developments of the project.

Table 1. Advisory Board Members and Their Affiliations

Member	Affiliation
Bill Boissonault, PhD	American Physical Therapy Association staff
Keith Cicerone, PhD	JFK Johnson Rehabilitation Hospital; prominent cognitive rehabilitation clinician–researcher
Rebecca Craik, PhD, PT, FAPTA	Dean, Arcadia University; former editor of *Physical Therapy*
Susan Fasoli, ScD, OTR/L	Occupational therapy researcher, MGH Institute of Health Professions
Anne Forrest, PhD	Individual with TBI; liaison to Brain Injury Association of America
Robert Forsyth, PhD, BMBch, MA	Newcastle University; pediatric neurorehabilitation clinician–researcher
Neil Harvison, PhD	American Occupational Therapy Association staff
Allen Heinemann, PhD	Northwestern University; rehabilitation outcomes researcher; editor, *Archives of Physical Medicine & Rehabilitation*
Julie Hensler-Cullen, RN, MSN	Rehabilitation nurse; clinical educator, MossRehab
James Lenker, PhD, OTR/L, FAOTA	University of Buffalo; clinical educator, assistive technology specialist; occupational therapy researcher
Susan Lin, ScD, OTR/L	Occupational therapist, MGH Institute of Health Professions
Ben Lippincott	Individual with spinal cord injury; staff on Georgia Tech/Shepherd Center Rehabilitation Engineering Center
Joan C. Rogers, PhD	University of Pittsburgh (emeritus); occupational therapy clinical educator
Margaret Rogers, PhD	American Speech Hearing Language Association staff
Sue Ann Sisto, PT, MA, PhD	Stonybrook University; physical therapy researcher; former president, American Congress of Rehabilitation Medicine
Mary Slavin, PhD, PT	Boston University; clinical educator, physical therapy researcher
Marieke Van Puymbroeck,	Clemson University; chair of Recreation Therapy

Member	Affiliation
PhD, CTRS	department
Carolee Winstein, PhD, PT, FAPTA	University of Southern California; clinical educator, physical therapy researcher

Professional Society Presentations

Because the primary users of the RTSS will be rehabilitation clinicians, educators, and researchers, presentations of this work at professional society meetings are an opportunity not only for dissemination but also for meaningful engagement of project stakeholders. Accordingly, members of our team have presented the work at 20 professional meetings in the United States, Canada, multiple European countries, and Australia to audiences of physical therapists, occupational therapists, speech-language pathologists, and psychologists (see Table A in the Appendix). The format of these sessions varied, depending on conference schedule and space constraints. However, in many of the presentations, we built in interactive experiences with attendees that allowed us to obtain feedback about the perceived value of the RTSS, concerns and criticisms, and opportunities for implementation. In some instances, this simply involved reserving substantial discussion time to invite reactions to the conceptual material provided didactically. In other cases, we conducted participatory exercises intended to elicit feedback on specific points. For example, at a meeting of the American Congress of Rehabilitation Medicine, we ran a session on organ function treatments at which we invited participants to nominate standardized targets that they treat in particular functional areas. This allowed us to explore the feasibility of developing standard target menus in the future and to promote reliability in specification and standardized communication.

Stakeholders had significant impact on the project at multiple points. Much of this impact will be evident from the discussion of methods and results that follows, but we will briefly summarize 2 specific changes that resulted from interaction with our advisory board: our handling of volitional treatments and our design of the RTSS clinician training cycle. The project team found specification of volitional treatments to be extremely challenging. We attempted

several different sets of procedural rules to balance the precision of specifying volitional treatments with the clerical burden of doing so. With each change, we presented the new set of procedures to our advisory board (we presented one of these iterations to the RTSS clinician trainees for feedback) and asked them to attempt treatment specifications using those procedures. Their feedback allowed us to settle on a workable compromise for volitional treatment specification. Second, our advisory board heavily influenced the design of the clinician training cycle. The board felt that it was important to make archived presentations available since many clinicians would not be able to commit to 6 meetings at a fixed time point. The board also recommended offering the small-group discussions in the evening (so as not to interfere with people's daytime responsibilities) on different nights (we offered "sections" of the same material on 4 days of the week) and recommended treating these small-group discussions as sources of qualitative feedback rather than applying quantitative measures of learning. Finally, advisory board members helped publicize and recruit participants for the RTSS clinician training cycle.

METHODS

Overview of Original and Revised Methods

This project did not involve collection of original empirical data about treatment ingredients or the way they have been specified in the literature, but rather involved an intertwined process of clarifying and refining underlying concepts, developing specification rules and procedures based on those concepts, applying the concepts to various specification tasks, and revising concepts and/or procedures in response to challenges in their application. In contrast to the implementation of a more traditional methodology, almost from the very beginning these methods resulted in unanticipated findings and challenges that necessitated changes in subsequent procedures. Consequently, the originally proposed methods for this project underwent significant revision during the performance period (each reviewed and approved by the principal investigator). In the end, data collection took the form of intermittent solicitation of qualitative data from advisory board members, participants in the RTSS clinician

training cycle, and attendees at professional society presentations. Here we briefly discuss the original methodology of the proposed project and the methods actually used to accomplish its aims.

Proposed Project Methodology

We proposed that, during the first 6 months, we would convene work groups of rehabilitation professionals to (1) generate a heterogeneous list of commonly used rehabilitation treatments administered within a single treatment episode, and (2) generate assessment items with which to construct a scale to measure the quality of treatment specification. This phase resulted in a list of 50 commonly used rehabilitation treatments selected to represent multiple disciplines and settings. We proposed that the core project team would work to specify these treatments in batches of 10 at a time, with *specification* meaning identification of the number of treatment components, the target of the treatment, the ingredients, and the known or hypothesized mechanism of action by which the ingredients exerted their effects. These 50 treatment specifications would allow the creation of menus of targets and ingredients to be expanded as new treatments were specified. We successively tested the inter-rater agreement among team members to confirm the reliability of specification methods as they were developed.

At the conclusion of this phase, we proposed to complete version 1 of the *Manual for Rehabilitation Treatment Specification*, the written document that operationalizes the process of treatment specification. We also developed a training curriculum to support the use of the manual. Both the manual and the curriculum, as well as the quality rating scale developed in the first phase, would receive stakeholder input and revision in an in-person workshop involving our advisory board. We proposed that, after suitable revision, we would embark on a program of training for clinicians, clinical educators, and clinical researchers from all disciplines involved in rehabilitation, delivered in a series of biweekly web-based sessions. We would deliver this training series 3 times over a 10-month period, with about 40 participants in each cycle (ie, approximately 120 individuals trained altogether), affording the opportunity to edit and clarify the material in response to trainee feedback between cycles. We would assess the

effectiveness of the training by masked ratings of the quality of attendees' treatment specifications before and after participation in the series, and participants would be asked for suggestions on improving the clarity and quality of the training and the specification materials, to inform version 2 of the manual.

In the final phase of the project, we proposed to reconvene our advisory board for a final meeting to address the future of the specification system (eg, the nature of the further work needed, who will undertake it [using what means], and how this specification system should interface with related efforts undertaken by other professional organizations).

Actual Project Methodology

The actual methods we used to achieve the aims of the project followed the proposed methods in terms of their intended outcomes, but in certain phases we elected to forgo the proposed quantitative methods (eg, statistical testing of pretraining and post-training ratings of specification quality) in lieu of qualitative data that we judged to be more appropriate to the stage of development of the treatment specification system.

Summary of Methods by Project Phase

Phase 1 (quarters 1-2)

Identifying treatments and measures of the quality of treatment specification.

We shifted the planned in-person work groups with rehabilitation clinicians to teleconference format due to logistic constraints. We conducted an in-person, multidisciplinary pilot focus group at MossRehab, which helped shape the questions for the subsequent teleconferences. Teleconference focus groups were organized by a core team or advisory board member of that discipline. We conducted separate focus groups with physical therapists, occupational therapists, speech-language pathologists, rehabilitation nurses, and rehabilitation psychologists to solicit nominations of treatments that the core team could begin to specify. We worked to ensure variability within each focus group in terms of populations treated (adult/child, neurologic, musculoskeletal, etc) and practice setting (hospital, outpatient). The

discussion format encouraged participants to nominate treatments that multiple patient groups commonly use. The core team collectively reviewed notes from these focus groups as well as potential treatment nominations. In addition, we received structured feedback about the draft Likert-type ordinal rating scale for measuring specification quality. The proposed ratings focused on whether the reader of a specified treatment would be able to implement that treatment as described.

In these focus groups, we discovered that it was rare for clinicians to nominate specific standardized or protocol-based treatments and much more common for them to discuss approaches or treatment activities in general. Setting aside how well named or operationalized these examples were, it was difficult to extract 50 identifiable treatments. Rather, clinicians tended to talk in terms of the problems or goals they were likely to address and some of the ingredients or approaches they used to address them. Interestingly, in speech-language pathology, in which a number of named and manualized treatments do exist (eg, semantic feature analysis[34]; VNeST[35] [Verb Network Strengthening Treatment]), focus group members did not nominate any of these. The facilitator probed whether clinicians were familiar with and used these treatments. Responses took the form "Yes, I use some of that" or "Yes, I sometimes apply those principles," suggesting that many rehabilitation clinicians think of treatment planning less as the selection of standardized treatment elements and more as an improvisational cooking task in which the chef has significant latitude to select and add ingredients "to taste."

Because of this, the core team abandoned the plan to arrive at 50 discrete and well-specified treatments in common use. Instead, we elected to insert a step of developing brief clinical vignettes written around a specific patient problem, rather than a well-characterized treatment, with the idea of specifying the likely treatment options that might be used for such a patient. Although this concretized the process of attempted treatment specification, it introduced a variety of irrelevant issues related to the unknown characteristics of the hypothetical patients in the vignettes. Thus, in our later attempts to use these vignettes for specification, it was sometimes difficult to determine whether the challenge was in the

specification process itself or in not knowing, from the vignette, exactly which patient characteristics affected ingredient selection. In real-world treatment specification, the researcher or treating clinician would have access to the full set of facts and observations about a patient and his or her own opinions about the treatment being pursued.

During these focus groups, we received general endorsement of the proposed approach to rating specification quality as well as several helpful edits and clarifications for specific items, which allowed us to revise the scale for use later in the project.

Phase 2 (quarters 3-5) and Phase 3 (quarters 6-7)

Phase 2: Defining and specifying a set of treatments and operationalizing the process of treatment definition and specification.

Phase 3: Incorporating the rules and procedures for defining and specifying rehabilitation treatment components into a manual and associated training materials that will equip researchers, clinicians, and clinical educators to apply treatment definitions and specifications.

For several reasons, we abandoned the plan for quantitative evaluation of inter-rater agreement in these phases. First, we discovered that it was difficult to apply inadequate specification rules to a full treatment specification. Rather, as we attempted specifications based on the early rules in place at that moment, specifiers were unable to complete the specifications with the rules available. Thus, it was uncommon for 2 team members to complete specifications that disagreed and more common that they both recognized obstacles to completing the specifications in the first place. Accordingly, the most productive way to identify issues that required new specification rules or rule clarification was through discussion of attempted specifications and the disagreements and challenges that arose.

We moved to a plan of assigning pairs of core team members to specify a treatment vignette and then to discuss with the whole group where they disagreed and what challenges they faced. This often led to modifying the specification rules to accommodate the most recent

challenge and frequently to revisiting previously specified vignettes that required revision. In this way, the specifications of the vignettes and the development of the specification procedures and rules proceeded in parallel, but complete specification of treatments was difficult to achieve until near the end of the manual's development. In lieu of formal testing of inter-rater agreement, core team members typically achieved a consensus on the optimal rule and specification through repeated discussion. When the core team faced particular challenges in agreeing on an optimal solution, they selected these challenges for targeted discussion and resolution with the advisory board.

Phase 4 (quarters 8-11)

Evaluation and revision of the Manual for Rehabilitation Treatment Specification *and associated training materials.*

We revised the proposed plan for 3 sequential rounds of clinician training to a single cycle with 40 participants, largely due to time constraints, and we shifted the emphasis of the training cycle to prioritize qualitative feedback on the manual's utility and clarity rather than empirical evidence of its impact on skill development. We made the latter change after realizing that the original plan to obtain empirical evidence of skill development was unrealistic. We learned during our first in-person advisory board meeting that skillfully applying the rules and procedures we had developed was challenging and required a degree of practice and feedback that might not be feasible during a short web-based training cycle. Thus, whether a measurable improvement in specification skill was a reasonable goal for such a brief training interaction was unclear. In addition, during discussions with many clinicians, it became clear that our conceptual framework changed perceptions of what *implement the treatment as directed* means. In other words, if clinicians, prior to our training, believed that performing the same activity today that was performed yesterday constituted *treatment as directed*, then they would rate a specification that described the nature of the activity as "good." After training, they might come to see that they didn't really know what treatment target was being pursued with that activity, what level of challenge for the patient it should have had, what form of cuing or correction they should have used, etc. As a result, training might affect not only the quality

of treatment specification but also the interpretation of the rating scale. Finally, it was difficult to design a quality rating process that was blind to whether the specification was completed pretraining or post-training, since specific technical words and concepts would be likely to appear only in the post-training specifications.

Because the goal of the training became qualitative rather than quantitative feedback, we reduced the training to a single cycle with 40 experienced rehabilitation clinicians and 4 weekly small-group sections. With help from our advisory board, we solicited clinicians from around the country who came from all rehabilitation disciplines and had experience in varied patient populations and treatment settings. Initial dissemination of information about the training cycle resulted in contacts from 105 individuals. We eliminated 6 due to their limited experience (4 had < 2.5 years) or the fact that they were therapy assistants (2). We sent surveys of schedule availability to the remaining 99 clinicians and eliminated 28 for failing to return the survey or because of their limited availability as indicated by their survey responses, leaving 71 individuals. We invited 48 of these individuals to participate based on a match between their availability and when we could schedule the sessions, but 9 of these ultimately withdrew, leaving 39 who participated in the full training cycle. They received three 1-hour web-based lectures on the conceptual framework. The lectures were given in real time but archived for later viewing for those who could not attend the scheduled sessions. The individuals also received 3 homework assignments involving target and ingredient specification from vignettes provided. The vignettes and documentation sheets were distributed after each lecture and returned by email prior to the sessions when they would be discussed. Members of the core team reviewed the homework for specification errors and composed a discussion outline for the small-group sessions. We divided the 3 small-group discussions of their attempted specifications and of the manual into 4 evening sections held from Monday to Thursday to allow for schedule flexibility. Members of the executive committee facilitated the homework discussions via teleconference, supported by web-based slides summarizing the key points. Core team members served as scribes for the discussions and consolidated the notes from the 4 sections into a single summary of each assignment. (The 3 homework assignments are provided

in the Appendix, along with an example of the summary slides created to discuss each of the assignments.)

The characteristics of the RTSS clinician training participants are shown in Table 2.

Table 2. Characteristics of Participants in the RTSS Training Cycle

Length of time in practice	Mean: 16.4 years; median: 14 years
Discipline	Physical therapy (9), occupational therapy (7), speech-language therapy (7), therapeutic recreation (6), clinical/rehabilitation psychology (5), vocational counseling (2), nursing (2), social work (1)
Practice setting	Varied: adult and pediatric; inpatient and outpatient; acute and chronic; congenital and acquired; neurologic, sports/musculoskeletal, and general
Role	Clinician (32), educator (5), clinician–educator (2)

Phase 5 (quarter 12)

Informing further development of an RTT.

We obtained extensive feedback on the *Manual for Rehabilitation Treatment Specification* and the concepts it contains from the RTSS clinician trainees through multiple methods. As noted, 2 scribes attended small-group sessions to record qualitative feedback, and their feedback was reconciled into a single summary that the full core team discussed to determine which changes in the specification rules and/or manual were warranted. The core team identified and reviewed participants' specification homework errors (defined by instances when their homework specifications deviated from consensus specifications prepared by the core team in advance), as these errors informed topics requiring further explication in the manual. We asked training participants to complete a post-training survey that solicited structured feedback about the clarity and utility of various sections of the manual. Finally,

trainees were invited to send specific proposed edits to the manual to the team at the conclusion of the training. We obtained feedback on iterations of the manual and many other issues via telephone and in-person meetings of the project advisory board. In addition, project team members presented on the evolving RTSS at multiple professional meetings, as mentioned previously, often including participatory activities that elicited feedback from potential stakeholders at these meetings. We synthesized all these sources of feedback and brought them for discussion to the final advisory board meeting in November 2017, along with a final revision of the manual that resulted from the feedback received up to that point.

This last phase of the project evolved largely as anticipated. The advisory board members participated in a final round of specification based on the updated procedures defined in the last version of the manual in order to provide feedback on the status of the concepts and the clarity of the procedures at the project's close. Importantly, the agenda of the final advisory board meeting was primarily devoted to feedback on 2 further steps for advancing this line of work: production of a set of manuscripts summarizing the key developments of the project during this funding cycle (4 manuscripts and an editorial are now in press) and discussion of next steps for advancing and implementing the products and concepts that we developed.

RESULTS

Conceptual Developments

Enduring Concepts from the Prior Project Period

Many important concepts that developed during a previous round of funding by the National Institute on Disability and Rehabilitation Research (now the National Institute on Disability, Independent Living, and Rehabilitation Research) remained intact. However, this project emphasized development of a Rehabilitation Treatment Specification System (RTSS), rather than a rehabilitation treatment taxonomy (RTT). A taxonomy is any rule-based classification system. The more important issue for our purposes is what kind of taxonomy is likely to be most useful in advancing treatment research and practice, and we argue that it is a taxonomy built around treatment theory–defined active ingredients of treatment. At the same time, we recognized that developing a method for specifying treatments with respect to their active ingredients supports the development of such a taxonomy but does not achieve it. We still required a subsequent step to decide how to organize well-specified treatments into categories or dimensions. Thus, for the near term, we defined our work as focused on the specification process itself.

We remained committed to a specification system based on known or hypothesized active ingredients of treatment and relying on treatment theory. We based our commitment on the premise that only this kind of system can lend order to the attempt to organize and synthesize evidence regarding treatment efficacy and effectiveness. We also knew from our work on the previous project that no other specification system incorporated this perspective. The International Classification of Health Interventions (ICHI), the closest in purpose to the RTSS, defines treatments in gross terms, primarily with respect to the goal of treatment rather than the ingredients used to achieve that goal. Within the framework of treatment specification, we retained the core concept that the tripartite structure of treatment theory should underlie the RTSS, with enablement theory informing the selection of treatments that will have the desired distal effects in particular patients. We also retained and further

developed the important concept of a treatment component, which is the largest unit of treatment with a single target. Thus, for example, a treatment for depression might consist of 4 distinct components focused on different targets and employing different ingredients: (1) increased patient understanding of the nature of depression; (2) more accurate patient knowledge of the name and properties of a prescribed antidepressant; (3) increased patient skill to reliably take the antidepressant medication; and (4) improved patient mood (from the antidepressant chemical prescribed).

Other concepts from the previously funded research were retained if they continued to prove workable as tools for unambiguous treatment specification, but we modified them, if necessary, in response to specification obstacles.

Treatment Groups

We retained the notion of distinct treatment groups, composed of mutually exclusive sets of targets and characteristic ingredients. However, we reduced our original treatment groups from 4 to 3 and renamed them in response to feedback from our stakeholders. We previously had a treatment group focused on changing organ structures and one focused on changing organ functions (parallel to the ICF's [International Classification of Functioning, Disability and Health's] categories of "functional levels").[36] However, with the exception of a few cosmetic treatments (such as providing a nonfunctional prosthetic hand or a facial prosthesis), rehabilitation treatments rarely pursue changes in organ structure except to achieve changes in organ function. Accordingly, we eliminated the structure group. This resulted in the 3 treatment groups shown in Table 3, along with typical examples.

Table 3. Key Characteristics of the 3 Treatment Groups

Name of Group	Typical Targets	Typical Ingredients	Mechanisms of Action	Clinical Examples
Organ functions	Changed or replaced organ functions	Varies by organ system: • Energy applied to soft tissues • Exercise schedules for strengthening/ endurance training • Stimulus exposure parameters for habituation • Devices for limb replacement	Varies: • Up- or down-regulation of organ system • Passive learning mechanisms • Replacement of organ with artificial one • Tissue stretch	Aerobic exercise, muscle strengthening, hearing aid, prosthetic limb, deep brain stimulation, serial casting
Skills and habits	Improved ability to perform (at both ICF function and activity/ participation levels and both mental and physical tasks) New habits	Provision of opportunities for repeated practice (with or without increasing demands) Instruction, cues, guidance, feedback, etc	Learning by doing	Gait training, activities of daily living training, training in use of a compensatory memory device, training in **habit** formation
Representations	Enhanced knowledge Modified attitudes/ emotional responses Changed probability	Didactic instruction Prompts to process new or previously acquired information Persuasion, motivational techniques	Cognitive/affective information processing	Patient education, adjustment counseling, instruction on how to perform an activity, motivational interviewing

Name of Group	Typical Targets	Typical Ingredients	Mechanisms of Action	Clinical Examples
	of specific behaviors	Prompts for action		

Another important conceptual development was the addition of *habits* to the skills and habits group (formerly called skilled performances). We recognized that the development or adoption of new behavioral routines enacted on an automatic or quasi-automatic basis—ie, new habits—is an important but sometimes neglected aspect of rehabilitation and one in which the desired behaviors respond to many of the same ingredients as skill development. A focus on the concept of habit development within this treatment group will encourage clinicians and researchers to attend to not only the ingredients responsible for improving skills in the short term but also the internal and external cues ("triggers") that will maximize the long-term deployment of these skills habitually in the patient's natural environment.

Specifying Volitional Treatments

The core group spent a great deal of its energy on the challenging task of developing rules for specifying volitional treatments—that is, treatments that depend on the patient or consumer enacting certain effortful behaviors such as exercising, practicing tasks, or processing information. In contrast to passively applied treatments, which allow the clinician to specify in advance precisely which ingredients will be delivered to the patient, volitional treatments require the patient to self-administer some of the ingredients if the treatment is to be effective. For example, a clinician may design a set of exercises for a patient to perform, but the patient must repetitively lift the assigned weights in order to build strength. This introduces several challenges:

- The clinician does not have full control over the ultimate delivery of effective ingredients in volitional treatments, yet formally acknowledging the patient's control over the receipt of these ingredients threatens to undermine the specification process altogether (only the patient could "specify" some of the ingredients).
- In some volitional treatments, the only ingredients actually delivered by the clinician are instructional or motivational (eg, directions for a home exercise program), which have no mechanism of action on functional entities such as muscle strength. To adhere tightly to the tripartite structure of treatment theory, such treatments could have *only* targets of performing the assigned activity, which would completely leave out the important clinical question of whether the activity selected by the clinician was, itself, likely to be effective if performed.
- One can identify pairs of treatment targets for volitional treatments: the **volition target**, which refers to whether the patient performed the treatment activity as instructed (eg, performed the exercises), and the **direct target**, which refers to whether the performance of that activity resulted in the functional change that was predicted (eg, increased strength). However, in many instances, it is difficult to determine whether the clinician's ingredients influence the volition target or the direct target. For example, when a clinician educates a patient about the purposes of his or her medications, which of the clinician's behaviors are ensuring that the patient is attending to and processing the information (the volition target), and which are ensuring that accurate medication information is conveyed (the direct target)?

We ultimately concluded that there was no perfect resolution to the specification of volitional treatments—that it was ultimately a balance between theoretical purity and practical utility. The core team drafted several versions of the procedures for specifying volitional treatments and discussed the pros and cons of the resulting specifications. We also solicited feedback on 2 of these iterations from the advisory board and on 1 iteration from the participants in the RTSS clinician training cycle. Finally, we arrived at a compromise in which supervised treatments specifically included *volition ingredients* but not a separate volition

target, whereas unsupervised treatments required separately articulated volition and direct targets.

Specification of Treatment Targets

The core team also discussed rule-based specification of treatment targets. In particular, we explored whether finite menus of treatment targets could be developed to facilitate treatment specification with less clerical burden and with greater agreement. We began by exploring whether the *body function* codes of the ICF could serve as predefined treatment targets for our organ function treatment group and for the function-like entities in our skills and habits group (eg, improved balance, improved attention). Discussion of the existing ICF codes revealed several challenges in applying them:

- To the knowledge of core team members, many ICF-defined body functions do not have corresponding treatments, so at best a subset of these codes could be used as treatment targets.
- These codes do not address the *measurable aspect* of change, as required of RTSS targets. Thus, an ICF code of *muscle power* would have to be supplemented with a measurable dimension, such as *increased*.
- In some cases, ICF entities do not map onto current scientific understanding of functional areas. For example, the way the ICF divides the cognitive domain of *attention* does not correspond to current concepts of neural network control of attention, such that it is unlikely that biologically informed treatments could target aspects of attention as defined by the ICF.
- In many treatment areas, the precise entity being treated is difficult to determine without detailed discussions with treatment experts. For example, are certain voice exercises focused on the strength of the relevant muscles or the coordination of those muscles? Thus, we felt that treatment experts should develop predetermined menus of organ function targets in various areas, and that they should build on ICF categories if possible but not be confined by them.

In the case of activity-like skills and habits targets and representations targets, we recognized that the number of potential targets is infinite and, therefore, a comprehensive menu is unlikely. However, the targets in these groups can change in only a finite number of ways (eg, accuracy, speed). Thus, we will need to individually specify the targets in these areas, though we can draw the measurable aspect of change from a finite menu. We distilled the guidance we developed for specifying treatment targets into the manual both as a set of procedures and rules and as a set of example specifications from the original vignettes, which mapped descriptions onto well-articulated targets.

Specification of Treatment Ingredients and Dosing Parameters

We made similar advances in the guidance for the specification of treatment ingredients and their dosing parameters. We determined that active ingredients in the organ functions category were organ-specific physical stimuli. We proposed asking the same treatment experts who are engaged in articulating consensus-based organ functions targets to generate a list of the ingredients that actively alter the functioning of the organ(s) relevant to their treatment expertise. We determined that the key ingredient for the skills and habits group was the clinician's facilitation of performance, often coupled with various forms of guidance and feedback. The key ingredient in the representations group was the clinician's facilitation of information processing, either in the form of delivering new information or encouraging reflection and reprocessing of existing information. This information can be more neutral (as in education) or contain more emotional valence (as in motivational or behavior change discussions). Importantly, we determined that the ingredients that are active in achieving a volition target (ie, the successful performance of a treatment activity) are the same as those that are also associated with representations targets; in fact, volition targets are a special case of representations targets, in which the clinician intends for the information to lead to action rather than simply to understanding. In addition, we proposed that the **COM-B framework**,[37] developed in health psychology, is a useful way to organize and conceptualize volition ingredients. The COM-B framework stresses the importance of Capability, Opportunity, and Motivation in leading to health-related Behavior change, and we have incorporated these

dimensions into our guidance about the specification of ingredients for representations group targets as well as specifically for volition targets.

In addition to clarifying the types of ingredients associated with the 3 treatment groups, we also developed rules for specifying dosing parameters for different kinds of ingredients. Dosing parameters range from quantitative measures of ingredients on a ratio or interval scale (eg, number of practice repetitions, load during a muscle contraction) to those on an ordinal scale (eg, moderate tension applied during serial casting), and from those reflecting settings on an ingredient delivery vehicle (eg, the wattage setting and head size for an ultrasound transducer) to those reflecting treatment **progression** (eg, systematic changes in dosing during treatment that are planned in advance). We stress that the relevant notion of *dose* differs for different kinds of ingredients. Currently, the notion of dose is often framed with respect to time, as in specifying the number of hours of physical therapy or the number of days in inpatient rehabilitation. We have specifically discouraged specifying dose with respect to time, except in contexts in which the ingredient's mechanism of action does depend on duration of exposure (eg, duration of heating prior to tendon stretch). In other contexts, dose specification should rely on measurable quantities of the active ingredient(s), such as number of performance repetitions or the specific information content delivered.

We distilled the conceptual developments related to ingredient specification, like those related to targets, into the manual along with illustrative examples. We provide one such example in Table 4 to illustrate a number of the concepts and potential impacts discussed previously.

In this specification, what a speech-language pathologist traditionally might consider a single treatment (instruction in use of TEP [tracheoesophageal puncture] prosthesis) is divided into 4 distinct treatment components. Although the TEP and prosthesis affect organ functions (voicing), there is no organ functions treatment component. This is because orthotic and prosthetic devices have their own organ functions treatment components only when they exert their effects passively. In this case, the TEP prosthesis is unlikely to achieve any target unless it is incorporated into the performance of a skill and becomes one of the necessary ingredients

for acquiring this skill. The first 2 components listed address performance skills and therefore are classified as skills and habits treatment components. There are 2 distinct skills and habits targets because the skills, materials required to execute them, and criteria for judging independence are different. As expected, however, the clinician provides opportunities for repeated performance of each skill, along with verbal, visual, and/or tactile instruction and feedback. Each target is named for the skill to be acquired, and target achievement is measured by correct performance without the need for assistance. Note that for many skills, *increased* independence (rather than complete independence) may be the target chosen. But in this instance, the clinician determines that training must continue until complete independence is reached. The practice schedule and total number of trials (dosing parameters) are not specified quantitatively because the trials will be closely clustered within a single session; rather than specifying the number of trials, training will be to criterion since the number of trials necessary is not known in advance. Note also that the precise feedback and physical assistance to be given are not stated, since these are dependent on the nature of the patient's difficulties and errors. Both skills and habits targets are volitional treatment components, but because treatment will be closely supervised, volition ingredients (eg, physical assistance, feedback to increase "capability") are specified but no separate volition target is provided.

The third treatment component involves a representations target. Representations targets exist on a continuum from knowledge to action. The patient has already acquired the skill of cleaning the device. The clinician has chosen a target at the action end of the continuum, since she wants the patient not simply to know what he should do at home but to actually do it. Thus, target achievement could be measured (in principle) by the frequency and consistency of TEP prosthesis cleaning at home, which might be approximated by self-report, inspection of the condition of the TEP prosthesis at his next visit, etc. As expected for a representations target, we do not see ingredients involving repeated performance; rather, we see informational ingredients intended to alter capability, opportunity, and motivation (eg, instructions, the log sheet, information on the risks of not cleaning the device regularly). The last treatment component also involves a representations target, albeit further toward the knowledge end of the knowledge–action continuum. The clinician has made the judgment that repeatedly

dislodging the device to allow practice of the skill of dealing with this problem is not feasible and, therefore, has settled for the probability that the knowledge alone will increase the patient's propensity to act as instructed if and when the time comes. Accordingly, she would measure the target through knowledge probes rather than performance assessment. The ingredients for these 2 targets do not have dosing parameters because they are specified as either present or absent (eg, log sheet, written handout) or as the key "bits" of information.

Table 4. Example of How a Treatment Session Could Be Specified Using the RTSS

Context: Mr. Smith recently had a total laryngectomy and placement of a tracheoesophageal puncture (TEP), which connects the trachea and esophagus. Inside the TEP is a surgically placed prosthesis that keeps the puncture open and contains a one-way valve that directs airflow through the esophageal-pharyngeal segment for "voicing" while keeping liquids/saliva from spilling into the airway. He has just woken up from anesthesia, and this is the first time he will be using the TEP prosthesis. Mr. Smith will be sent home with the TEP prosthesis in a few hours, so he needs to learn how to use it and maintain it.

DESCRIPTION OF CLINICAL INTERACTION	TREATMENT COMPONENT		
	Treatment Group	Target	Ingredients
The speech-language pathologist (SLP) will teach Mr. Smith how the TEP prosthesis works. She will give him a mirror and then occlude (cover) his stoma with her finger when he is exhaling, which redirects air from the trachea into the esophagus and will produce a sound Mr. Smith can use for voicing. Then the SLP will ask Mr. Smith to occlude the stoma himself and make a voiced sound. She will ask Mr. Smith to practice occluding his own stoma, with verbal feedback from the therapist, until he consistently achieves voicing with the prosthesis.	Skills and habits	Ability to use TEP prosthesis for voicing/ independent	• TEP prosthesis • Mirror • Information about how TEP prosthesis works • Verbal instruction • Demonstration with mirror • Opportunities to perform voicing with TEP prosthesis, provided until independent performance is demonstrated • Corrective verbal feedback until consistent voicing is observed

DESCRIPTION OF CLINICAL INTERACTION	TREATMENT COMPONENT		
	Treatment Group	Target	Ingredients
The SLP will teach Mr. Smith how to manually clean his TEP prosthesis. She will begin by explaining the benefits of keeping the TEP prosthesis clean (reduced risk of pneumonia, avoidance of leaking during eating, increased life of the prosthesis, etc). For Mr. Smith's first attempts at cleaning the prosthesis, the SLP will manually help him insert and rotate the brush. In the subsequent attempts, the SLP will give Mr. Smith a mirror and ask him to brush the prosthesis independently with the help of that mirror. She will ask Mr. Smith to practice cleaning his prosthesis with the brush and mirror (with verbal feedback from the therapist) until he consistently inserts/rotates the brush into his prosthesis without difficulty.	Skills and habits	Ability to clean and maintain TEP prosthesis/ independent	• TEP prosthesis • Mirror • Brush • Verbal presentation of information about benefits of learning to clean TEP prosthesis • Opportunities to perform cleaning of TEP prosthesis, provided until independent performance is demonstrated • Corrective verbal feedback until accurate technique is performed independently • Physical assistance (decreased over time as patient is able to perform more of the task himself)

DESCRIPTION OF CLINICAL INTERACTION	TREATMENT COMPONENT		
	Treatment Group	**Target**	**Ingredients**
The SLP will educate Mr. Smith about routine maintenance of the prosthesis—specifically, that he should clean the prosthesis with a brush 3 to 4 times per day—and provide a log sheet for him to track when he cleans his prosthesis. The SLP will give Mr. Smith a written educational handout and read it aloud, with him following along. Topics on the handout include risks of not cleaning the prosthesis regularly, such as leaking during eating; risk of pneumonia from aspiration of bacteria; and decreased life of the prosthesis.	Representations	Performance of TEP prosthesis maintenance at home/ as directed	• Verbal delivery of instructions on frequency of cleaning • Log sheet for tracking TEP prosthesis cleaning • Factual information about risks of not cleaning prosthesis • Written educational handout • Reading handout aloud and asking patient to read along

DESCRIPTION OF CLINICAL INTERACTION	TREATMENT COMPONENT		
	Treatment Group	**Target**	**Ingredients**
The SLP will provide the patient with a handout that tells him what to do if the prosthesis becomes dislodged or falls out. She will encourage Mr. Smith to read along with her as she reviews the content of the handout.	Representations	Knowledge of what to do if TEP prosthesis becomes dislodged/ increased	• Factual information about what to do if TEP prosthesis becomes dislodged • Written educational handout • Reading handout aloud and asking patient to read along

Returning to some of the potential impacts of RTSS specification, we believe that a published treatment protocol of the type illustrated in this example would provide the key details needed for other clinicians to implement the treatment, delivering the same active ingredients. Adherence to the treatment protocol (either in a research or a clinical context) could be assessed by observing whether the specified materials are provided, whether initial demonstration and subsequent corrective feedback are provided, whether practice is continued to criterion, etc. The protocol would not require the use of exactly the same words for conveying instructional information, on the assumption that the key points rather than the specific words are theoretically relevant. However, the clinician's treatment theory assumes that reading the written handout aloud while the patient reads along will enhance retention. The specification also sharpens clinical reasoning. It requires the clinician to consider in which contexts information alone will achieve the necessary outcomes and which ones will require practice.

This type of specification offers additional potential benefits for research. A researcher developing such a treatment would not select outcomes such as increased speech intelligibility or increased verbal interaction as targets, because these would be more distal aims that cannot be guaranteed with the ingredients shown or achievement of the targets listed. However, other researchers might provide treatments that facilitate patients' use of their TEP-based voicing in social interaction (eg, supervised practice in social settings) and legitimately choose measures of verbal performance or interaction as outcome measures. Availability of RTSS specifications would prevent attempts at evidence synthesis across these very different types of treatment, even if they were all retrieved while searching for "TEP/voice rehabilitation."

This specification also suggests next steps for the individual clinician if treatment fails and more potential questions for the researcher. If the patient acquires the first 2 skills but does not maintain the device at home, this would contradict the clinician's hypothesis that the ingredients addressing capability, opportunity, and motivation would be sufficient to achieve regular performance at home and would suggest several potential courses of action. The clinician could consider whether more supervised cleaning practice prior to discharge might make the skill less effortful and the patient more likely to perform it at home (ie, that these COM-B ingredients would be sufficient to drive a less effortful skill); whether "stronger" COM-B ingredients (eg, more detailed discussions of risks, goal-setting maneuvers, discussing the most feasible times and contexts for cleaning) might drive the current level of skill at home; or whether enlisting a friend or caregiver to prompt scheduled practice and habit formation at home might be necessary. A clinician treating a similar patient who also had significantly impaired declarative memory could still consider pursuing the 2 skills and habits targets, since such skills can be acquired implicitly with practice by amnestic patients, but he or she would need to recruit caregivers or develop some reliable cuing system to ensure regular cleaning and response to dislodgement. A researcher could ask whether, given the relative simplicity of these skills, a standardized instructional videotape might provide sufficient information for the patient to perform the procedures without repeated practice. Thus, protocols involving instruction alone vs instruction plus practice could be compared. Moreover, teaching other manual skills of a similar nature, pursued by members of other disciplines, could be structured

in a parallel fashion, such that a collection of very similarly structured treatments could be developed and shared and additional questions asked, such as “How is the amount of assistance required on the first trial related to the number of trials required to reach independence?” or “Would supervised ‘overlearning’ toward the development of a minimally effortful habit increase the chance of consistent performance at home?” Thus, the RTSS’s focus on the ingredients that drive skill, habit, and attitude changes may help researchers see the ingredients that could or should be compared in CER, with the specific skill, habit, or attitude that currently receives the most attention taking a secondary place in research.

We are not prepared to discuss in detail the possible ways that an RTSS-based system could be feasibly incorporated into documentation and billing systems to enrich their values as sources of observational evidence. Clearly, asking each clinician to document treatment sessions at this level of detail would be onerous. One possibility would be to standardize and name such a treatment protocol (most likely, in this example, in 4 parts, since clinicians may choose to address different numbers of treatment components for different patients). Once completed, the name(s) (unlike disciplines or goals of treatment) would meaningfully represent the treatment components’ active ingredients. Periodic adherence assessment might be required to prevent drift from the original specification. Alternatively, meaningful ingredient “chunks” might be documented with dosing parameters as appropriate. For example, one could have checkboxes in an electronic medical record that list “risks of not cleaning discussed” and “visual demonstration with mirror provided” for informational items related to representations targets as well as checkboxes for “voicing practice trials (specify number: __)” and “cleaning practice trials (specify number: ___)” for skills and habits targets.

Potential impacts of RTSS specification cannot be illustrated completely with a single treatment. However, it is worth noting that advisory board members—who include clinicians, clinical educators, researchers, and evidence synthesizers and who have had the opportunity to work through multiple treatment specifications in multiple functional domains—perceive that the benefits in these areas could be substantial.

Development of the *Manual for Rehabilitation Treatment Specification* and Submission of Project Manuscripts

The manual was developed during the course of the project, used by core team members in their attempted specifications, and revised iteratively in response to those attempts. We assembled it into 3 full drafts as the project progressed in order to solicit stakeholder feedback. We distributed the first complete version to the advisory board in advance of the January 2017 meeting and asked board members to review it and then to use it for a set of practice specifications at the meeting. We revised the manual in response to the board's feedback and used this next version for the RTSS clinician training cycle. We used feedback from the clinician training cycle to create the version used in the final advisory board meeting in November 2017. The feedback from this meeting resulted in only minor changes, which we implemented in a final draft in the last days of the project. As noted in the Conclusions, we are developing plans for hosting the manual on a publicly available website and disseminating invitations for rehabilitation professionals to engage in beta-testing it.

Publications and Dissemination Activities

In the proposal, we had planned to submit 2 to 3 manuscripts describing the outcomes of the project. By the end of the project period, we had revised the plan to include 4 interrelated manuscripts and an overarching introduction and had arranged with the *Archives of Physical Medicine and Rehabilitation*, the publisher of the 2014 set of RTT manuscripts, to simultaneously publish these in the journal, subject to peer review. We circulated outlines for the 4 planned articles prior to the November 2017 advisory board meeting, and the group discussed each outline at the meeting, with the primary authors noting feedback. One article provides an overall update on the concepts and procedural implementation of the RTT/RTSS since the 2014 set of publications. One focuses specifically on the importance of volitional behavior in rehabilitation and in defining rehabilitation treatment. The two other articles focus on the particular impacts that may be anticipated from the RTSS on clinical practice and on research reporting and evidence synthesis. We also were invited by the *Archives* to write a

commentary on a systematic review article concerning the poor state of treatment description in stroke rehabilitation.

Upon return from the advisory board meeting, the primary authors for each of the articles began working on initial drafts, informed by the board's feedback. These articles, which involved most or all of the core team members, were circulated for collaborator comments and edits and submitted to the *Archives* by March 9, 2018. Revisions based on initial peer review were due to the journal on August 31, 2018, and all have now been accepted. The invited commentary, which illustrates the contribution that the RTSS could make to some of the information gaps cited in the article on which it comments, has been published (see Publications for list of articles).

Next Steps in Dissemination and Implementation

Prior to the final advisory board meeting, we synthesized the multiple forms of feedback received from previous meetings with the advisory board, from the clinician training cycle, and from our various presentations at professional society meetings, to present for discussion with advisory board members. Taken as a whole, the feedback from rehabilitation researchers, clinicians, and educators was consistent: There was strong support for the value of the concepts developed during this project and a clear sense of their potential impact in both clinical and research realms. There was also consistent feedback that the concepts addressed by the RTSS are complex and challenging and require considerable discussion and practice to master. Our work with the advisory board and RTSS clinician training cycle demonstrated that accurate specification is a skill that requires practice and feedback, not the presentation of a simple set of factual knowledge. Indeed, even within our core team, which was immersed in this topic, we often arrived at stable treatment specifications only through discussion.

Though the procedures and rules of the RTSS are somewhat complex, there is consensus that the bulk of the complexity lies in the nature of the treatment domain that we are attempting to specify and in the fact that RTSS specification requires the clinician or researcher to make explicit certain behaviors or approaches that he or she may not have otherwise

considered explicitly. In this context, it became clear that implementing the RTSS would require considerable additional work. To be successfully implemented, the RTSS concepts would need to be introduced into curricula and through training courses over time rather than in brief 1-shot workshops. Providing such exposure and training, in turn, requires curricular materials and a cadre of faculty sufficiently familiar with the system and sufficiently motivated to teach it. In the research realm, journal editors and funding agencies would need to exert pressure on researchers to use the RTSS in defining study treatments, and researchers and peer reviewers, too, would need exposure and training in the RTSS to comply. There also is a need to convene expert consensus groups to develop menus of treatment targets and ingredients used in various treatment areas, as discussed previously, in order to lessen the burden on individual specifiers and reduce variability in the words used in specification.

The final advisory board meeting was substantially devoted to analyzing how we could foster continued development and implementation of the RTSS and who might lead the various relevant efforts. We agreed that a number of different implementation projects should be considered in parallel as next steps, in order to build evidence for the positive impact of local implementation efforts and to identify and address additional obstacles to implementation as it is scaled up. There was considerable enthusiasm among members of the current project team, as well as members of the advisory board, to lead such projects. We hope that the combination of published articles characterizing the work, publicizing the availability of the manual for use in beta-testing, and the design of multiple specific implementation projects will continue to build evidence showing that this method of specification is both useful and feasible.

DISCUSSION

Our project addresses a critical deficit in the specification and measurement of rehabilitation interventions that must be resolved in order to fill the many specific gaps in the evidence base within this branch of health care. Rehabilitation clinicians, educators, and researchers perceive concepts contained in the RTSS as valuable. However, stakeholders also have emphasized that use of the RTSS is a skill that will require ongoing exposure, practice, and active discussion. As a result, potential users of the system must be convinced of its value in order to motivate the various implementation efforts required to generate widespread adoption. The manual is a freestanding product amenable to beta-testing by these various stakeholders. We expect that the 4 manuscripts recently accepted for publication will help researchers and clinicians understand the potential value of the RTSS, leading them to use the manual and to provide feedback for its further development and implementation.

The current strengths of the RTSS include its comprehensiveness (ie, all treatments delivered by all rehabilitation disciplines may be specified by the same system) and its basis in treatment theory. This latter feature of the system forces attention to the proximal outcomes (targets) of precisely defined interventions, rather than macro, downstream effects that may require additional clinical efforts to achieve (aims). Importantly, the system also demands specification of active ingredients (eg, clinician actions, materials, modalities) that are expected to cause the changes in functional targets. The sorting of rehabilitation targets into 3 mutually exclusive (though large) groups is intuitive and helps align the abstract concepts of the RTSS with clinical thinking. The stipulation that both targets and ingredients must be measurable, at least in principle, serves to demystify the actions performed during the "art" of rehabilitation and to encourage measurement of treatment effects not only in the laboratory but also in the clinic. Moreover, the explicit separation of targets and ingredients addressing the *direct* effects of a treatment, and the patient's *volitional behavior* that must occur for those direct effects to be achieved, highlights an important distinction for both clinical practice and research advancement. Clinicians can use this distinction to adjust the ingredients needed to boost one or the other source of the treatment's overall effect; researchers can systematically vary

volition-directed ingredients to determine their separate effects under different conditions and with different patient populations.

The RTSS in its current state of development also has limitations, some of which we described in earlier sections. We have received feedback (and have observed in our own research team process) that the concepts are complex and require much repetition and many clinical examples to be fully understood. As noted earlier, the selection of certain items for target and ingredient specification will need to be driven by selection menus and language conventions, which have yet to be developed. Thus, as it stands, the RTSS is limited in its capacity to produce *identical* treatment specifications from any 2 users, although those specifications might share significant overlap in the most theoretically important treatment elements. Partly for this reason, one anticipated impact of the RTSS—streamlined descriptions of treatment suitable for electronic medical record documentation and third-party reimbursement—awaits a future iteration, in which menus and other language constraints will have been fully implemented.

Despite these limitations, the RTSS represents a forward step in the ongoing effort to solve the problem of the black box of rehabilitation. It simultaneously offers more granularity and, by virtue of being theory driven, more opportunity for standardization across disciplines, settings, and populations compared with alternative systems. For example, the practice-based evidence studies conducted as multicenter observational investigations addressing stroke, joint replacement, spinal cord injury, and TBI rehabilitation[38-41] have used discipline- and study-specific, clinician-generated classifications of treatments to describe each clinical encounter. The resulting codes, naming functional domains, devices, and modalities, tend to emphasize the problems to which interventions are directed (eg, balance, strength, cognition) rather than the process or ingredients of treatment. Moreover, potentially superficial differences among disciplines and specialties have been reinforced by creating separate systems for each study of a different rehabilitation population and for each discipline. Another, more global system, the World Health Organization's emerging ICHI,[42] thus far provides treatment classifications too

broad (eg, practical support with walking and moving, emotional support with walking and moving) to illuminate the actual treatment activities and their mechanisms of change.

The same holds true for an even more recent proposal for classifying aspects of rehabilitation, the International Classification of Service Organization in Health-related Rehabilitation (ICSO-R). The authors, a working group of the International Society of Physical and Rehabilitation Medicine, distinguish classification of (medical) rehabilitation at 3 levels: macro (health system and health policy), meso (service provision and organization), and micro (health condition and function), and they explicitly state that the ICSO-R is aimed at the meso level, ceding the micro level to ICHI.[43] ICSO-R has 2 levels (a third one, consisting of value sets, is planned) and is not a classification or taxonomy per se but a listing of dimensions (9 under *rehabilitation service provider*, 3 under *funding of the service*, and 8 under *service delivery*) that are to be used to characterize organizations/programs delivering rehabilitation services. An operationalization of those 20 dimensions has not yet been provided, making application of the ICSO-R problematic in many aspects, as was made clear in 3 efforts to use the scheme.[44-46]

Yet another source of treatment specification might be found in such efforts as the Consolidated Standards of Reporting Trials for Non-Pharmacologic Treatment[47] and the Template for Intervention Description and Replication,[48] both of which offer journal article reporting guidelines for researchers engaged in nonpharmacologic treatment studies. However, these systems leave it up to the researcher to decide which procedures and other aspects of treatment are critical for reporting. By identifying the tripartite structure of treatment theory as the basis for treatment specification, in contrast to prior systems, the RTSS could potentially standardize both the concepts and the language used to define rehabilitation treatments so that they may be accurately researched, taught, administered, and replicated. Ultimately, a completed RTSS might be useful not only for medical rehabilitation but for other branches of rehabilitation (eg, psychiatric, vocational, drug and alcohol) and health care (eg, behavioral medicine) that rely on both behavioral and pharmacologic treatments.

Further research would be valuable to assess and further refine the reliability of the RTSS. However, a meaningful assessment of reliability will need to wait for the development of

standardized menus of targets in certain areas and categories of ingredients so that minor wording differences do not confound assessments of reliability. Additional work also is needed to develop and test RTSS training curricula for clinician, clinician educator, and researcher stakeholders and to examine the effects of RTSS training and use on clinical reasoning and, ultimately, on treatment outcomes. At our summative advisory board meeting in November 2017, we devoted considerable time to brainstorming and then detailing, to the extent possible, additional beta-test research and clinical implementation projects that might advance the RTSS. For example, Dr. Lyn Turkstra, who is deeply involved in graduate-level training of speech-language pathologists at McMaster University, suggested combining training in the RTSS with existing training programs and formally measuring students' perceptions of the system's contributions to treatment planning. Other suggestions included using the RTSS to develop and test *volition training* programs for difficult problems in rehabilitation (eg, long-term prevention of pressure injuries through self-management in spinal cord injury) and using the RTSS to improve carryover of treatment targets and ingredients in the transition from inpatient to outpatient care.

Of course, executing these plans will require additional time and funding that has not yet been secured. However, one recent NIH R21 (Exploratory/Developmental Research Grant Award)-funded project led by an RTSS core team member (Dr. Jarrad Van Stan, another speech-language pathologist) will incorporate RTSS concepts into the development of a specification system for voice therapies. Another funded pilot project (developed by core team member Andrew Packel, a physical therapist) will examine the effects of in-depth RTSS training on improving the consistency of treatment during the many inevitable episodes of coverage by other clinicians. A third funding application is under review by the Department of Defense to apply the RTSS to specifying a cognitive rehabilitation program for individuals with mild TBI.

Further development of the RTSS will depend not only on projects of this nature but on wider dissemination and uptake by the rehabilitation community. Toward this end, a central location is needed where the manual can be maintained and where decisions about its ongoing use and further elaboration can be managed. The core team decided not to provide the manual

as supplemental content to the published journal articles since this would place its copyright control in the hands of the journal. Rather, the core team has copyrighted the manual and given revocable authority to grant permission for its use to John Whyte, the project principal investigator. Discussions are ongoing with the American Congress of Rehabilitation Medicine to post the manual in a limited-access fashion and to serve as the organizing point for an interest group that would manage requests to use the manual; synthesize feedback resulting from its use; oversee the consensus modifications required by such feedback; and serve as an organizing forum for continued efforts to implement and disseminate the RTSS, the *Manual for Rehabilitation Treatment Specification*, and related training materials and supports.

CONCLUSIONS

Comparative effectiveness research cannot be conducted on rehabilitation interventions until those interventions are described and defined using a common language and systematic framework for specifying their functional targets and known or hypothesized active ingredients. A framework such as the RTSS, when further developed and tested, will enable patient and clinician consumers to examine and compare the strengths, limitations, indications, and outcomes of specific rehabilitation interventions and to customize those interventions for the ultimate goal of maximizing function for people with disabilities.

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APPENDIX

Table A: Presentations by Core Team Members

Speaker(s)	Title	Venue	Date
T. Hart	Toward a theory-driven method for defining and measuring complex interventions	European Health Psychology Society, Limassol, Cyprus	9/15
T. Hart, M.P. Dijkers, J. Whyte, C.C. Chen, M. Ferraro, A. Packel, J. Van Stan, J.M. Zanca	Better Rehabilitation through Better Specification of Rehabilitation Treatments: Progress and aims of the Rehabilitation Treatment Taxonomy project.	American Congress of Rehabilitation Medicine, Dallas TX	10/15
T. Hart	The Rehabilitation Treatment Taxonomy: Toward a theory-driven classification of rehabilitation treatments	Regional Rehabilitation Conference, Sunnaas Rehabilitation Hospital, Oslo, Norway	10/15
J. Whyte	Toward a Rehabilitation Treatment Taxonomy: Defining the Active Ingredients of Rehabilitation.	MossRehab Neurorehabilitation Conference, Philadelphia, PA	11/15
J. Whyte	Development of a Taxonomy for Rehabilitation Interventions.	CHARM International Seminar, Oslo Norway	11/15
J.M. Zanca, M.P. Dijkers, T. Hart, J. Whyte, A. Packel, M. Ferraro	Understanding what we do: Improving spinal cord injury research, clinical education, and practice through better specification of treatments. Presentation	American Spinal Injury Association Annual Meeting, Philadelphia PA	4/16
J. Whyte, T. Hart, M. Dijkers, J. Zanca	You Can Only Treat What You Can Define: Specifying Rehabilitation Treatment Targets	American Congress of Rehabilitation Medicine, Chicago, IL	11/16
J. Whyte	Defining Rehabilitation Treatments: Do We Know What We're Doing and Can We Tell Others?	Toronto ABI Network Conference, Toronto Canada	11/16
J. Whyte, T. Hart, M. Dijkers	You Can't Assess Treatment Efficacy if You can't Define the Treatment: Challenges and Solutions in Specifying Non-Pharmacologic Treatments.	International Brain Injury Association Annual Meeting, New Orleans LA	3/17
M. Dijkers	The RTT and specification of treatments: work to date and relevance to multiple sclerosis treatment	Rehabilitation in Multiple Sclerosis, Barcelona, Spain	5/17
T. Hart	What are we doing when we treat our patients? A scheme-in-progress for analyzing the active ingredients of rehabilitation.	Australasian Society for the Study of Brain Impairment, Melbourne, Australia	5/17
T. Hart	The Rehabilitation Treatment Taxonomy (RTT): A framework-in-progress for specifying rehabilitation interventions according to treatment theory	World Health Organization Meeting to Develop a Framework of Rehabilitation Services, Geneva, Switzerland	6/17
C.C. Chen	Rehabilitation Treatment Taxonomy Specification: Applications and Implications to OT	New Mexico State Occupational Therapy Conference, Albuquerque,	8/17

		NM	
L. S. Turkstra	Rehabilitation Treatment Taxonomy	Rehabilitation Sciences Colloquium Series, McMaster University, Toronto, Canada	9/17
J. Van Stan	What are we really doing in voice therapy?	New England Symposium for Speech-Language Pathologists (NESSLP), Worcester MA	10/17
L.S. Turkstra	What are you actually doing in communication therapy?	New England Symposium for Speech-Language Pathologists (NESSLP), Worcester MA	10/17
J. Whyte, T. Hart, M. Dijkers	Defining Rehabilitation Treatments: Implications for Clinical Education, Supervision, and Treatment Planning.	American Congress of Rehabilitation Medicine, Atlanta, GA	10/17
J. Whyte, L. S. Turkstra, A. Packel, A. Heinemann, M. Dijkers	Specifying Rehabilitation Treatments: Implementing a Common System for Clinical Education and Research Reporting.	American Congress of Rehabilitation Medicine, Atlanta, GA	10/17
C. C. Chen	Treatment taxonomy specification helps OT clinical reasoning	2017 Mountain Central Occupational Therapy Conference, Austin TX	11/17
J. Van Stan, L. S. Turkstra	How to Describe Speech-Language Pathology Treatments Using the Interdisciplinary Rehabilitation Treatment Taxonomy	American Speech-Language-Hearing Association Annual Conference, Los Angeles, CA	11/17

GLOSSARY

Active ingredients

Attributes of a treatment, selected/delivered by the clinician, that are hypothesized to exert the treatment's effects on the target.

COM-B framework

Framework borrowed from Susan Michie and colleagues, working in the field of health psychology. These researchers model voluntary behavior as a function of Capability, Opportunity, and Motivation, with further subdivisions within these 3 elements. This scheme has been particularly useful to the RTSS to create categories that help to prompt specification of ingredients needed for voluntary behavior, especially behavior enacted at a remove from the clinician (e.g., home programs or assignments between sessions).

Devices

Devices are a subcategory of ingredients that include prostheses, orthoses, and assistive devices, either devised in therapy or off-the-shelf, such as cell phones. Some devices (e.g., positioning aids) can achieve their purpose passively, in which instances the device is considered to have a *treatment target of its own*, in the organ functions group. More commonly, however, a patient must develop the skill of using a device during relevant tasks; in these instances, the device's therapeutic attributes are defined to be *ingredients* directed toward a skills and habits or representations target. In either case, the ingredients should be defined in terms of the *theoretically relevant attributes of the device* rather than the device itself.

Direct target

Change in the specific aspect of functioning which is predicted to result from performance of the treatment activity by the clinician (non-volitional treatments) or the treatment recipient (volitional treatments). The direct target for volitional treatments may be accompanied by a separately specified volition target (see entry) in cases where clinicians are

unable to verify directly the performance of the behavior needed to convey the active ingredients for the direct target.

Dosing parameters

Quantitative variations in ingredients, such as numbers of repetitions, intensity of practice, setting on device that delivers energy to tissues, criterion for success for progression and slope of progression in treatment, schedules of practice or reinforcement.

Enablement theory

A formal theory or conceptual system that specifies how change in one aspect of a patient's functioning (eg, at the level of an International Classification of Functioning, Disability and Health [ICF] component: body structure, body functioning, activity/activity limitation, participation/participation restriction, personal factor, or environment) will translate into changes in another aspect, specifically a characteristic classified elsewhere in the framework being used. The RTSS makes a distinction between a treatment theory (which specifies the ingredients that achieve a selected target by means of a mechanism of action) and an enablement theory (which sets out how a change in one or more targets may result in various "downstream" aims).

Habit

A behavioral routine that is repeated regularly and, after acquisition, tends to occur automatically in the presence of certain stimuli. Habits are important considerations for rehabilitation because the long-term goals of rehabilitation often entail patients' acting habitually in new, adaptive ways to sustain or continue improvements in functioning. Habits are included as targets in the skills and habits group because habit formation responds to many of the same active ingredients as skill learning.

Inactive ingredients

Attributes of a treatment that do not define or moderate the impact of the treatment on the target. Ingredients may be presumed to be inactive when they are not addressed by the

treatment theory (e.g., the color of the walls in which the treatment is conducted) or have been empirically determined to be inactive.

Ingredients

Observable (and, therefore, in principle, measurable) actions, words, hands-on manipulation, common objects, chemicals, devices, or forms of energy that are selected/delivered by the clinician to a treatment recipient. See also active ingredients and inactive ingredients.

Mechanism of action

Process by which a treatment's active ingredients induce change in the target of treatment. A treatment theory should specify/hypothesize how the active ingredients engage mechanisms of action to bring about desired treatment effects. That is, specification of the mechanism of action explains *how* the active ingredients alter the treatment target within the framework of the treatment theory. Unlike ingredients and targets, mechanisms of action are frequently not observable and must be inferred by the effects of ingredients on targets.

Progression

The clinician's deliberate, systematic alteration of treatment ingredient(s) to maintain, over time, the degree of challenge to the body system/behavior(s) selected for change. The next highest level in a progression is often triggered by improvements in the target of treatment; therefore, the pace of progression (within a single treatment contact or over a course of treatment) typically depends on the pace of change in the treatment target. The form that treatment progression takes (and hence the nature of the challenge that is being maintained) is often specified by the treatment theory.

Rehabilitation Treatment Specification System (RTSS)

Conceptual framework that can be used to specify any rehabilitation treatment, by connecting the actions of the clinician (ingredients) with the changes produced in the patient or other recipient of treatment.

Target (of treatment)

Specific, measurable (in principle) aspect of the recipient's functioning or personal factor that is predicted in the treatment theory to be directly changed by the treatment's mechanism of action. A single target plus the treatment ingredients hypothesized to achieve it constitute a treatment component. Change in a target causally precedes any aims that may be achieved as a result.

Taxonomy

System of classification or categorization based on common/distinct characteristics of the elements within the group to be classified. The resulting classification may have pragmatic, theoretical, and/or heuristic utility.

Treatment component

Portion of a clinical treatment that includes one target, selected active ingredients, and associated known or hypothesized mechanism(s) of action, as defined by an underlying treatment theory. Treatment components are often, though not necessarily, administered in combinations in an effort to produce the desired changes in functioning faster or more completely.

Treatment group

Broad class of treatments that are mutually exclusive with respect to treatment targets and mechanisms of action. See organ functions treatment group, skills and habits treatment group, representations treatment group.

Treatment theory

Conceptual system that predicts the effects of the ingredients used in specific forms of treatment on their targets, specifying the law(s) of the relationship between active ingredients and changes in treatment targets. Because all treatment theories contain ingredients, mechanisms of action, and targets, they are described as having a tripartite structure.

Tripartite structure (of treatment theory)

See **Treatment theory**

Volition

Volition may be roughly equated with *effort* expended by the treatment recipient. Some organ functions treatments—physical exercise being a prime example—and *all* skills and habits and representations treatments require volition.

Volition target

A target in the representations group that is expressed as a specific volitional behavior assigned by a clinician. Volition targets may stand alone or be paired with direct targets, in cases where the clinician cannot directly verify the occurrence/accuracy of the recipient's action: eg, in the case of a home program, homework assignment, certain forms of telerehabilitation. In such cases, a volition target must be enacted by the treatment recipient in order for the ingredients for the direct target to be implemented.

Volitional treatments

Treatments where a (hypothesized) mechanism of action requires some effort, either mental or physical, on the part of the treatment recipient. They can be contrasted with non-volitional (passive) treatments where such effort is not required for the mechanism of action to unfold.

Better Rehabilitation through Better Specification of Rehabilitation Treatments: Development of the *Manual for Rehabilitation Treatment Specification*

Participant Homework Directions

Homework 1: Manual Review Quiz (Homework due by **Sunday June 4, 2017**)

Please read the manual, which has 3 main sections: conceptual overview, how-to directions for specification, and a glossary of technical terms. Please note things that you find confusing or unclear. As we discuss the material over the next several weeks, if you discover that there are concepts or directions that you thought you understood when you read the manual, but had difficulties with once you started to apply them, please go back and mark those sections of the manual as well, for later discussion.

Once you have read the manual, please complete the following short-answer questions. Save your answers as a Word document in the format "FIRSTINITIAL_LASTNAME_MRQ.DOCX" and return it to mferraro@einstein.edu by Sunday June 4, 2017.

1. Briefly describe the difference between treatment theory and enablement theory
2. Which of the following *are not* included within the RTT's treatment specification system (list all that apply): 1) Counseling a patient to increase motivation to participate in treatment; 2) Standardized testing (e.g., Neuropsychological assessment; FIM scoring); 3) Team meeting to plan treatment; 4) Provision of an assistive device; 5) Social worker completing application for benefits
3. What is the key feature of a treatment *component* (as opposed to a treatment)?
4. What are the three parts of a treatment theory?
5. What are the main treatment groups?
6. A patient with stroke in a comprehensive rehabilitation program receives exercises to strengthen her hemiparetic leg, dynamic balance training (practicing recovering from increasingly large challenges), and manual stretch of the knee extensors to combat extensor tone, all in the hope of facilitating independent ambulation. Name 1 possible treatment target and 1 possible treatment aim.
7. What is meant by a "volitional treatment component"?

Better Rehabilitation through Better Specification of Rehabilitation Treatments: Development of the *Manual for Rehabilitation Treatment Specification*

Participant Homework Directions

Name:

Homework 2 (Targets) (Homework due by **Sunday June 11**)

Please read the two treatment vignettes below (*Strength Training* and *Teaching to use an Electronic Organizer as a Memory Aid*). For each vignette, complete a separate specification grid. Before you start, you may want to reread Section III of the manual, as well as the note on treatment theories and vignettes on page 41. A review of Appendix A and the rest of Appendix B may also be helpful.

- Start by determining how many treatment components the vignette describes. In the grid, use one row for each treatment component.
- Write the target content and aspect for each treatment component in the first 2 columns.
- Under "Group" put the letter O, S, or R to indicate which of the 3 treatment groups each component belongs to.
- Under "Type", indicate whether each treatment component is non-volitional ("NV"), or volitional. If the component is volitional, indicate whether it is a direct treatment component (code – "V-D"); or, whether it is a stand-alone volition target (e.g., it will be challenging to get the patient to perform the treatment activity so you need to focus on ensuring that will happen – code "V-S").
- Leave the shaded ingredients columns blank this time. We will come back to those in our next assignment.
- Please save your completed grid as a Word document in the format "FIRSTINITIAL_LASTNAME_TGT.DOCX" and send it to mferraro@einstein.edu by Sunday June 11th.

Strength Training

Ms. L has a PT assessment 4 weeks following a total knee replacement. At this point, pain has mostly resolved and range of motion is improving, but the PT identifies deficits in knee extensor strength as a limiting factor in maximizing Ms. L's functioning, and decides to recommend a home exercise program.

The therapist has Ms. L sit in a chair with her knee bent to 90 degrees, and tries different colors of resistive band (colors code different amounts of resistance). He finds that Ms. L is able to perform 8 repetitions with the blue band, with good form, so he selects that one. The PT instructs Ms. L in making sure she starts with her knee at 90 degrees each time, and then goes through her full range of motion, to having her knee completely straight. The PT also instructs Ms. L to try to move slowly, and to count to 3 each time she straightens her knee in order to provide a controlled speed of movement.

The therapist instructs Ms. L to try to perform as many repetitions as she is able to do with good form and through the full ROM, and then to take a break, and do a second set, and then a third.

The PT then instructs Ms. L to perform the exercise at home each day, telling her how to attach the band, and providing her with both a blue and a black band, which has increased resistance. Ms. L is instructed that she should use the black band when she is able to perform in each set, 15 repetitions in a row with good form with the blue band.

Group = O (Organ), S (Skills and Habits), R (Representations)
Target Type = NV (Non-volition), V-D (Direct target is a volitional treatment component), V-S (Volition is added as a separate target)

TARGETS				INGREDIENTS	
Content	**Aspect**	**Group**	**Type**	**Ingredients**	**Dosing Parameters**

Teaching to Use an Electronic Organizer as a Memory Aid

The patient is a mid-30's woman with severe anterograde memory deficits due to encephalitis. Other cognitive abilities are largely intact and she is fully aware of her memory problems and motivated to address them. The psychologist will first discuss with the patient the various kinds of compensatory devices that are available and, depending on patient experiences and preferences, they will jointly select a device to try. In this case, the patient is young enough to have extensive experience with using a smartphone and still owns one and is able to use it, so they decide to install one or more apps for memory compensation.

As a next step, the psychologist will interview the patient in depth to ascertain the types of materials that the patient wants to use her phone to remember, and to increase the patient's investment in the process. In this case, remembering intentions (appointments, errands, things to do) and remembering what people have told her are the biggest problems.

Next, the psychologist will review the apps that fit the patient's needs and her phone's operating system. She has bookmarked several clearinghouses containing app reviews and she will read these in detail before selecting one or two. When she has selected them, she will download them onto the patient's phone. She will then create a detailed step-by-step training sequence covering how to use the app to enter an appointment/ errand/ item to do or to make a note about what has been said, as well as the steps required to retrieve the information at set times when prompted by alarms.

The psychologist will use Systematic Instruction to train the patient how to use the apps. This means that (1) the patient will learn the use of one app to complete mastery, defined as 100% performance on 3 consecutive practice runs, before starting another one; and (2) the training will follow an invariant sequence with errors prevented to the extent possible, and corrected immediately if they occur.

Once this level of mastery has been achieved for each app function during clinic practice, the psychologist will give a homework assignment to promote generalization to real-world activities. She will ask the patient to use the appropriate app each time a situation calls for one of them, during the week before their next session, and to use the Notepad function (which she has learned to use to record the contents of conversations) to record brief notes about successful use and problems encountered. These notes will be reviewed in the next session.

Group = O (Organ), S (Skills and Habits), R (Representations)

Target Type = NV (Non-volition), V-D (Direct target is a volitional treatment component), V-S (Volition is added as a separate target)

TARGETS				INGREDIENTS	
Content	**Aspect**	**Group**	**Type**	**Ingredients**	**Dosing Parameters**

Better Rehabilitation through Better Specification of Rehabilitation Treatments: Development of the *Manual for Rehabilitation Treatment Specification*

Participant Homework Directions

Name:

Homework 3 (Ingredients) (Homework due by Sunday June 25th)

Please review the attached vignettes, which are the same as the ones we discussed in relation to treatment targets. The attached grid already includes the targets for the vignettes as were presented last week (as we think is the most accurate specification), and your assignment this week is to specify the ingredients. Before you start, you may want to reread Section III of the manual, as well as the note on treatment theories and vignettes on page 42. A review of Appendix A and the rest of Appendix B may also be helpful.

1. For each treatment component, consider the ingredients that are therapeutically important. Consult the list of ingredient categories in the manual to help you consider all the possible kinds of ingredients that might be relevant to the treatment's action.
2. Put all the ingredients for a single treatment component on one row, under "Ingredients", using bullets to separate different ingredients.
3. Some of the ingredients will have meaningful dosing parameters associated with them, while others will not. In the last column, describe the dosing parameter where applicable, and put "N/A" where the concept of dosing parameter doesn't apply. If you think the ingredient **should** have had a dosing parameter attached but none was given in the vignette, indicate this with a question mark. Please keep the dosing bullets lined up with the corresponding ingredient bullets, so the reader can tell what doses correspond to what ingredients.
4. Do not "invent" ingredients that are not described in the vignettes. Even if you think that the treatment as described is bad, or incomplete, do not add anything. The RTT can be used even for specifying bad treatment, and we must assume that according to the treatment theory of the clinician described in the vignette, the ingredients listed are adequate for achieving the target(s) that we/you have distinguished.

Please save your completed grid as a Word document in the format "FIRSTINITIAL_LASTNAME_ING.DOCX" and send it to mferraro@einstein.edu by Sunday June 25th.

Strength Training

Ms. L has a PT assessment 4 weeks following a total knee replacement. At this point, pain has mostly resolved and range of motion is improving, but the PT identifies deficits in knee extensor strength as a limiting factor in maximizing Ms. L's functioning, and decides to recommend a home exercise program.

The therapist has Ms. L sit in a chair with her knee bent to 90 degrees, and tries different colors of resistive band (colors code different amounts of resistance). He finds that Ms. L is able to perform 8 repetitions with the blue band, with good form, so he selects that one. The PT instructs Ms. L in making sure she starts with her knee at 90 degrees each time, and then goes through her full range of motion,

to having her knee completely straight. The PT also instructs Ms. L to try to move slowly, and to count to 3 each time she straightens her knee in order to provide a controlled speed of movement.

The therapist instructs Ms. L to try to perform as many repetitions as she is able to do with good form and through the full ROM, and then to take a break, and do a second set, and then a third.

The PT then instructs Ms. L to perform the exercise at home each day, telling her how to attach the band, and providing her with both a blue and a black band, which has increased resistance. Ms. L is instructed that she should use the black band when she is able to perform in each set, 15 repetitions in a row with good form with the blue band.

Group = O (Organ), S (Skills and Habits), R (Representations)
Target Type = NV (Non-volition), V-D (Direct target is a volitional treatment component), V-S (Volition is added as a separate target)

TARGETS				**INGREDIENTS**	
Content	**Aspect**	**Group**	**Type**	**Ingredients**	**Dosing Parameters**
Knee extensor strength	Increase	O	V-D	•	•
Performance of knee exercises at home	As directed	R	V-S	•	•

Teaching to Use an Electronic Organizer as a Memory Aid

The patient is a mid-30's woman with severe anterograde memory deficits due to encephalitis. Other cognitive abilities are largely intact and she is fully aware of her memory problems and motivated to address them. The psychologist will first discuss with the patient the various kinds of compensatory devices that are available and, depending on patient experiences and preferences, they will jointly select a device to try. In this case, the patient is young enough to have extensive experience with using a smartphone and still owns one and is able to use it, so they decide to install one or more apps for memory compensation.

As a next step, the psychologist will interview the patient in depth to ascertain the types of materials that the patient wants to use her phone to remember, and to increase the patient's investment in the process. In this case, remembering intentions (appointments, errands, things to do) and remembering what people have told her are the biggest problems.

Next, the psychologist will review the apps that fit the patient's needs and her phone's operating system. She has bookmarked several clearinghouses containing app reviews and she will read these in detail before selecting one or two. When she has selected them, she will download them onto the patient's phone. She will then create a detailed step-by-step training sequence covering how to use the app to enter an appointment/ errand/ item to do or to make a note about what has been said, as well as the steps required to retrieve the information at set times when prompted by alarms.

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Once this level of mastery has been achieved for each app function during clinic practice, the psychologist will give a homework assignment to promote generalization to real-world activities. She will ask the patient to use the appropriate app each time a situation calls for one of them, during the week before their next session, and to use the Notepad function (which she has learned to use to record the contents of conversations) to record brief notes about successful use and problems encountered. These notes will be reviewed in the next session.

Group = O (Organ), S (Skills and Habits), R (Representations)
Target Type = NV (Non-volition), V-D (Direct target is a volitional treatment component), V-S (Volition is added as a separate target)

TARGETS				**INGREDIENTS**	
Content	**Aspect**	**Group**	**Type**	**Ingredients**	**Dosing Parameters**
Knowledge about available compensatory memory devices	Increase	R	V-D	•	•
Accuracy in using smartphone apps to perform	Improve	S	V-D	•	•

intended actions and record notes on conversations, in clinic setting					
Practice using app at home in appropriate contexts and noting challenges encountered	Perform-ance as directed	R	V-S	•	•
Automaticity of use of correct apps at appropriate times to record and retrieve information/ complete intended tasks in real-world settings	Increase	S	V-D	•	•

Welcome to Group A Discussion on "Specifying Targets"

- We'll start at 7 pm Eastern
- Reminder:
  - Please keep phone muted until ready to speak
  - Please do not use a "hold" button at any time
- We DO want you to speak during this session!– it will be a discussion, not a lecture
- Thank you again for doing the homework– we have built the discussion around the materials you turned in

Introductions: Name & Discipline

- From the RTT Core Team
  - Tessa Hart (Neuropsychologist)
  - Andy Packel (Physical Therapist)
  - Lyn Turkstra (Speech/ Language Pathologist)
- Other participants (roll call)
- When you chime in to the discussion, please start by identifying yourself

Overview

- We will review each homework vignette separately (knee strengthening home program, use of smartphone as strategy to remember appointments and conversations)
- We'll ask what was challenging in each vignette
- We will show you what we think the most 'accurate' target specifications look like
- Then show & discuss some common areas where your responses differed from ours
- MOST IMPORTANTLY we want to know about your thought process– what was confusing? What was hard about the various steps?
  - This will help us to improve the manual and training materials
- Finally, we'll ask– is it ultimately helpful to specify targets in this fashion? Why/ why not?

What challenges did you encounter…

- For the vignette on knee strengthening:
  - Deciding how many targets?
  - Deciding what group each belonged to?
  - Deciding whether volitional or non-volitional?
  - Deciding whether direct or (separate) volition target?
- Do you think it's useful to think about these distinctions relative to treatment targets?
- Which are useful and which are not?

Strength Training: Targets

Content	Aspect	Group	Type
Knee extensor strength	Increase	O	V-D
Performance of knee exercises at home	As directed	R	V-S

Main differences seen in the homework...→

Targets placed in ‘wrong’ treatment groups

- What is the main change in patient functioning desired by the therapist? (That’s the direct target.)

- “Increased knee extensor strength” refers to change in an organ system (musculoskeletal system) = Organ Functions group
  - *Some of you focused on the home program without mentioning the knee strengthening target*

- Many of you thought there was at least 1 Skills & Habits target in this vignette. Let’s discuss why that was… volunteers?

- Some thought “better understanding of home exercise” was a Skills target. But “better understanding” would always go in the Representations group (understanding is “in your head”– not a skill you perform.)

- Some put “practice exercise as directed” (a correct target) in the O group instead of the R group. “Activity as directed” is ALWAYS a Representations target (information in your head that leads to action)

Volitional vs non-volitional treatment components (targets)

- The knee extensors cannot become stronger without active (volitional) participation on the part of the patient
  - = Volitional treatment component

- Let’s discuss why that was sometimes called a non-volitional treatment in the homework; what was confusing?

- What about the separate volition target, ‘performance of exercises at home as directed.’ Why should this be a separate target (or would you argue that it should not?)?

Designating ingredients as targets

- Therapist instructions (“Start with knee at 90 degrees…”) identified as targets
- Targets are aspects of patient functioning intended to change when ingredients are applied
- Ingredients are anything said/ done / delivered by the clinician (including instructions) to try to make the change

Contents vs. aspects

- This was confusing to many of you…
- Content is WHAT is intended to change about the patient's functioning (knee extensor strength)
- Aspect is HOW it should change (increase)
- The tendency was to make this more complicated than it needs to be
- What's incorrect about the following examples?

Content	Aspect
Band resistance	Increase
Understanding of utilization of blue and black bands and when to use black bands for increased resistance…	Increase amount of knowledge
Gains in strength to progress to black band	Increase in knee extensor strength
The patient understanding how to complete each exercise	Better understanding
Training in how to perform exercises	Greater independence

Including elements that might be present in clinical practice, but not in vignette

- Knee replacement (was done before this scenario takes place– and isn’t a target…)
- Explanation of importance of home practice (not in vignette– and not a target)
- Take care to stick to the vignette (which we know is artificial) when practicing specification

Lumping vs splitting

- Some of you listed many different knowledge targets (Representations group), e.g.:
  - How to complete each exercise; how to attach the band; when to use the blue vs. black band; knowledge of proper form; understanding of how to progress exercise; etc.
- For parsimony, OK to just say “Performance of knee exercises as directed” as Representations target
  - As a practical matter, no 2 people would (or, in your case, did) choose the same set of “details” to list as separate targets
- Discussion?
  - Decisions about lumping/ splitting might depend on purpose of specification (documentation of session vs. hand-off to a covering therapist)

On the positive side,

- NO ONE listed an ‘aim’ (of increased knee extensor strength) as a target!!
- Excellent job!

What challenges did you encounter…

- For the vignette on the smartphone:
  - Deciding how many targets?
  - Deciding what group each belonged to?
  - Deciding whether volitional or non-volitional?
  - Deciding whether direct or (separate) volition target?
- Any further thoughts on:
- Do you think it’s useful to think about these distinctions relative to treatment targets?
- Which are useful and which are not?

Smartphone: Targets

Content	Aspect	Group	Type
Knowledge about available compensatory memory devices	Increase	R	V-D
Accuracy in using smartphone apps to perform intended actions and record notes on conversations, in clinic setting	Improve	S	V-D
Automaticity of use of correct apps at appropriate times to record and retrieve information/ complete intended tasks in real-world settings	Increase	S	V-D
Practice using app at home in appropriate contexts and noting challenges encountered	Performance as directed	R	V-S

Main differences seen in the homework...→

Targets placed in ‘wrong’ treatment groups

- Home practice placed in Organ Functions group; what organ (system) is being changed by home practice?
- All targets in this vignette have to do with:
  - increasing skill & developing habit– in use of apps as memory compensations (Skills & Habits group);
  - increasing knowledge of compensations (Representations group); and
  - completing assigned practice (Representations group)

Designating Ingredients as Targets

- Teach her how to use apps;
- selection of apps by clinician…
- give homework;
- train using systematic instruction…

- these are clinician actions– so are they targets, or ingredients?

Specifying Target Content

- “Improved memory function;” “working memory” – does this treatment improve memory function? – particular caveat with compensatory devices and strategies
- Use of clinical conventions, e.g., “The patient will…” under target content; but the target content is not what the patient will do but WHAT ABOUT THE PATIENT’S FUNCTIONING needs to change?
  - Her KNOWLEDGE of memory strategies
  - Her ACCURACY in using a specific strategy (2 strategies) in clinic
  - Her AUTOMATICITY in using them in real-world setting
  - Her PERFORMANCE OF ASSIGNED HOMEWORK to report back to therapist

Contents vs. aspects

- As in the other vignette, this was confusing to many
- What is incorrect about the following examples…

Content	Aspect
The patient will learn to use the apps	Better understanding
Sequence of steps	Increase mastery of correct sequence
Use of apps in real world routinely	Increased habit formation
Use app on smartphone to enter appt/ errand/ to do item	Accurately on 3 consecutive practice runs
Examination of deficits and selection of apps by clinician	Fewer memory errors
Journal for success and problems	Increase

Lumping vs. splitting

- Similar issues here as in strengthening vignette
- Understandable because there's more to this vignette
- Thoughts about our 4 targets? Should there be more?– and why/ why not?

Smartphone: Targets

Content	Aspect	Group	Type
Knowledge about available compensatory memory devices	Increase	R	V-D
Accuracy in using smartphone apps to perform intended actions and record notes on conversations, in clinic setting	Improve	S	V-D
Automaticity of use of correct apps at appropriate times to record and retrieve information/ complete intended tasks in real-world settings	Increase	S	V-D
Practice using app at home in appropriate contexts and noting challenges encountered	Performance as directed	R	V-S

What do you think, overall?

- Is this way of thinking about/ specifying treatment targets helpful?
  - In what ways?
  - For what purposes?
- How might we change it to make it more helpful?
- Your suggestions for a next wave of training?

Welcome to Group A Discussion on "Specifying Ingredients"

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- Thank you again for doing the homework– we have built the discussion around the materials you turned in

Introductions: Name & Discipline

- From the RTT Core Team
  - Marcel Dijkers (Methodologist)
  - Andy Packel (Physical Therapist)
  - Lyn Turkstra (Speech/ Language Pathologist)
- Other participants (roll call)
- When you chime in to the discussion, please start by identifying yourself

Overview

- We will review each homework vignette separately (knee strengthening home program, use of smartphone as strategy to remember appointments and conversations)
- We'll ask what was challenging about specifying the ingredients in each vignette
- We will show you what we think the most 'accurate' ingredient specifications look like
- Then show & discuss some common areas where your responses differed from ours
- MOST IMPORTANTLY we want to know about your thought process– what was confusing? What was hard about the various steps?
  - This will help us to improve the manual and training materials
- Finally, we'll ask– is it ultimately helpful to specify ingredients in this fashion? Why/ why not?

What challenges did you encounter…

- For the vignette on knee strengthening:
  - Deciding on ingredients for direct targets?
  - Deciding on ingredients for volition targets?
  - Specifying dosing parameters and progression?
- Do you think it's useful to think about these different kinds of ingredients?
- Do you think it's helpful to consider which ingredients are used to affect which targets?
- Which aspects of this process were helpful and relevant and which were not?

A clarification

- The manual (and the earlier lectures) emphasized that ingredients are **only** the things that the clinician says/does/gives/delivers
- The answers for the two homework vignettes assigned made it clear that such is a limited (or limiting) viewpoint:
  - The clinician doesn't deliver the knee extensions that will strengthen the knee; the patient "delivers" them
    - But the extensions are the crucial ingredient for the direct target of knee extensor strength
  - The clinician does not use the phone apps for a full week to create automaticity; the patient does
    - But the use whenever indicated is the crucial ingredient for the direct target of creating a new habit (automaticity of app use to help remember things). The therapist doesn't "hand" the patient a new habit

A clarification

- Trying to be in line with the manual, some of you may have gotten to become desperate: “WHAT am I expected to put here?”
- Trying to come up with SOMETHING to enter may have resulted in some weird entries
- We clearly need to think through more where a line needs to be drawn between what patients/clients do and what clinicians do when it comes to designating ingredients

Strength Training: Ingredients

Targets				Ingredients	
Content	**Aspect**	**Group**	**Type**	**Ingredients**	**Dosing Parameters**
Knee extensor strength	Increase	O	V-D	• Blue, black therabands • Full extension of knee against resistance	• N/A • 3 sets/day of as many reps as able with good form; switch to black when able to do 15 reps X 3.
Perform-ance of knee exercises at home	As directed	R	V-S	• (Spoken) instruction on correct position, form, pacing, schedule, progression	• N/A

Common problems noted in homework

- Specifying ingredients or doses that are not in evidence in the vignette
  - Error correction during therapy session
  - Motivation
  - Handout
  - Etc.
- The instructions made clear that the RTT concepts and rules can be used to describe even poor treatment – no need to improve the work the therapist was described as doing

Common problems noted in homework

- Failure to specify: “instruction to do exercise at home” for the as-directed V-S target
  - Often, the components were given (good form, switch to black band, etc.), but not the fact that they were part of an order
- “Instruction to do exercise at home” as an ingredient for the V-D target of strengthening
  - The clinicians words do not make the knee stronger!
- Blue and/or black bands as ingredients for the exercising at home ‘as directed’ target

Common problems noted in homework

- Lack of (sufficient) specificity in describing the nature of the exercise ingredient
  - No ‘extension’, no ‘good form’, etc.
- Specifying range of motion or some other thing potentially related to the target as an ingredient

Common problems noted in homework

- Listing the homework instructions as the dose for the exercise
- Placing dosing parameters for the ingredients for the ‘strength’ direct target behind ingredients for the ‘homework as directed’ target
  - The clinician did not repeat her instructions 8-15 times; that’s the dose for the exercise
- Lack of specificity in giving doses
  - ‘number of sets’ is not a dose; ‘3 sets’ is
  - Not including ‘blue to black’ switch (progression!) in the dose parameters

Common problems noted in homework

- Turning into an ingredient for the strength target
  - The therapist selecting blue and black as suitable material

What challenges did you encounter…

- For the vignette on electronic organizer use:
  - Deciding on ingredients for direct targets?
  - Deciding on ingredients for volition targets?
  - Specifying dosing parameters?
- Do you think it's useful to think about these different kinds of ingredients?
- Do you think it's helpful to consider which ingredients are used to affect which targets?
- Which aspects of this process were helpful and relevant and which were not?

Teaching Electronic Organizer Use for Memory Compensation: Ingredients

Targets				Ingredients	
Content	**Aspect**	**Group**	**Type**	**Ingredient**	**Dosing Parameter**
Knowledge about available compensatory memory devices	Increase	R	V-D	• Information about memory compensation devices (delivered orally)	• N/A

Teaching Electronic Organizer Use for Memory Compensation: Ingredients (cont.)

Targets				Ingredients	
Content	**Aspect**	**Group**	**Type**	**Ingredient**	**Dosing Parameter**
Accuracy in using smartphone apps to perform intended actions and record notes on conversations, in clinic setting	Improve	S	V-D	• Prompting patient to discuss experiences and preferences re: strategies and content she wants to remember • Apps with appropriate features, downloaded to patient's smartphone • Systematic Instruction process which includes ingredients of: ○ Training and prompting practice in using 1 app to mastery before training another ○ Training in an invariant sequence of steps with error minimization/ immediate correction	• N/A • N/A • Sufficient # of practice runs on each app to achieve 100% accuracy on 3 consecutive runs • N/A

Teaching Electronic Organizer Use for Memory Compensation: Ingredients (cont.)

Targets				Ingredients	
Content	**Aspect**	**Group**	**Type**	**Ingredient**	**Dosing Parameter**
Practice using app at home in appropriate contexts and noting challenges encountered	Perform-ance as directed	R	V-S	• Instruction to use each app in the coming week when relevant situation arises • Instruction to use notepad function to record successes and problems in use of apps, for discussion at next session • Review of notes on successes and failures in using apps in prior week	• N/A • N/A • N/A

Teaching Electronic Organizer Use for Memory Compensation: Ingredients (cont.)

Targets				Ingredients	
Content	**Aspect**	**Group**	**Type**	**Ingredient**	**Dosing Parameter**
Automaticity of use of correct apps at appropriate times to record and retrieve information/ complete intended tasks in real-world settings	Increase	S	V-D	• Apps with appropriate features on patient's smartphone • Repeated use of apps in real life • Recording of successes and failures in app use	• N/A • N/A • N/A

Common problems noted in homework

- Specifying ingredients that are not in evidence in the vignette
  - Written list of steps to be taken in using an app
  - Handout
  - Etc.
- The instructions made clear that the RTT concepts and rules can be used to describe even poor treatment – no need to improve the work the therapist was described as doing

Common problems noted in homework

- Specifying the phone and/or the app(s) as an ingredient toward the knowledge target
- Specifying about anything mentioned in the vignette (aside from the ‘oral information on available memory compensation devices’) as an ingredient

Common problems noted in homework

- Turning into an ingredient (for any target) any of the following:
  - the clinician questioning the patient about WHAT she wants to remember
    - This may help focus the treatment, but IS NOT treatment
  - the clinician deciding which app is the best
  - the clinician creating a training sequence
- The RTT's stance is that anything not handed to or put onto/into the patient is not an ingredient (yet)
  - Patients are not mindreaders
  - Protocols and lists have no effect until they are used by or on clients

Common problems noted in homework

- Making an ingredient for the accuracy of use-target out of
  - Client's notes review
- Making an ingredient for the automaticity of use target out of
  - Accurate use of apps
  - Set goal of automatic use

Common problems noted in homework

- Non-specific ingredients
  - ‘education’ for the knowledge target
  - ‘practice’ for the accuracy of use target
  - ‘homework assignment’ for the ‘practice as assigned’ target
- Failure to list as an ingredient (for both the accuracy and automaticity targets) the phone and the apps

Common problems noted in homework

- Specifying as the dose for the accuracy of use target
  - “100% mastery on 3 consecutive trials”,
  - rather than:
  - “sufficient practice to see 100% mastery on 3 consecutive trials”
- Making “each time use of the app is appropriate” a dosing parameter for the ingredients for the
  - V-S target (home use as directed)

  OR
  - V-D target of automaticity of use

Questions:

- For ingredients for the knowledge and the automaticity target, is dose parameter ‘as needed’ more appropriate than ‘N/A’?
- Where is ‘generalization’ for this vignette, mentioned by many. Is ‘automatic use whenever appropriate’ an implicit statement of generalization ingredients?

Welcome to Group A: Discussion of the *Manual for Rehabilitation Treatment Specification*, and the Associated Training

- We'll start at 7:00 pm Eastern
- Reminder:
  - Please keep phone muted until ready to speak
  - Please do not use a "hold" button at any time
- Please have your homework and manual at hand
- We DO want you to speak during this session!– it will be a discussion, not a lecture
- Thank you again for doing the homework– we have built the discussion around the materials you turned in

Introductions: Name & Discipline

- From the RTT Core Team
  - John Whyte (Physiatrist, Cognitive Psychologist)
  - Andy Packel (Physical Therapist)
  - Mary Ferraro (Occupational Therapist)
- Other participants (roll call)
- When you chime in to the discussion, please start by identifying yourself

Your Role

- To help us evaluate the concepts we have developed, particularly in terms of their contributions to:
  - Clinical reasoning and treatment planning
  - Interprofessional communication
  - Clinical training supervision
- To suggest ways that the manual could present these concepts in a clearer or more useful manner
- To suggest ways that the associated training could aid in mastering the concepts contained in the manual
  - For their conceptual value in clinical reasoning and communication
  - To provide the skill to specify treatments from scratch
  - …And points in between

Venues for Feedback

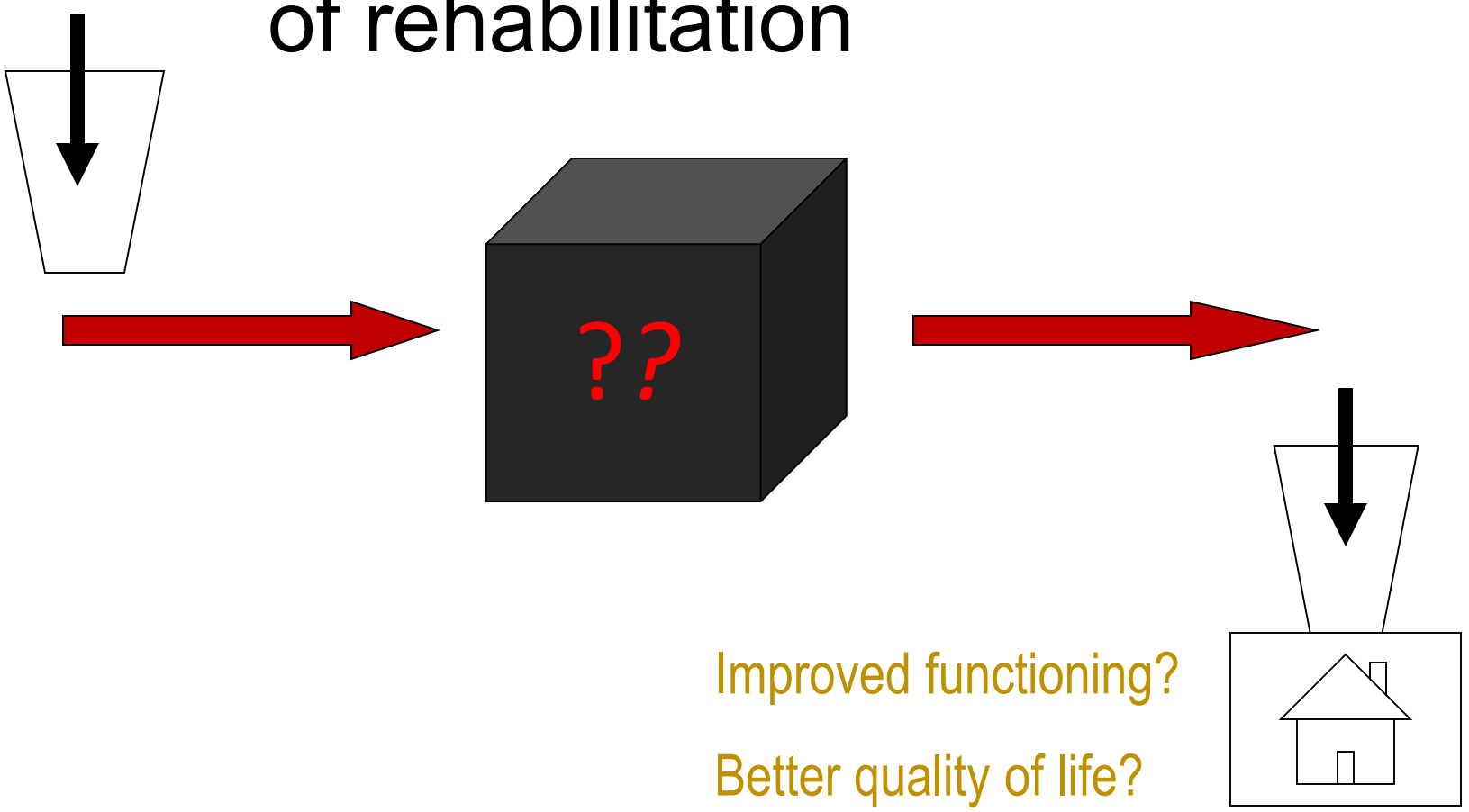
- Tonight's discussion
  - In contrast to prior discussion sessions, we are not presenting new content this time.
  - We want YOU to do most of the talking
- Word copy of manual to be distributed shortly; add comments/suggested edits directly in "track changes" and return
- Post-training survey with numerical ratings and room for prose comments

As a Reminder…

Impairments

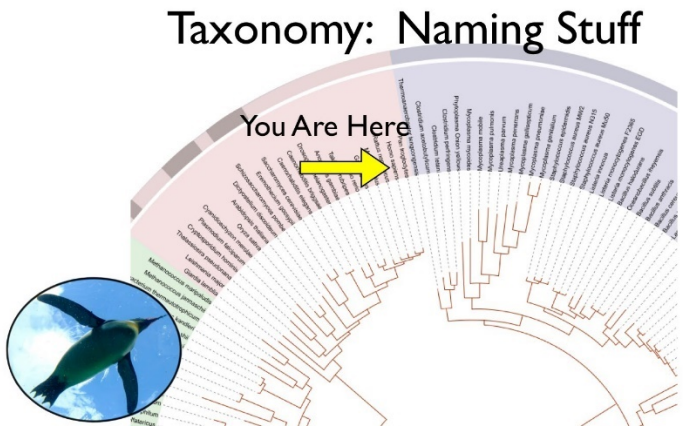
Activity limitations

The black box of rehabilitation



What we need: a system for

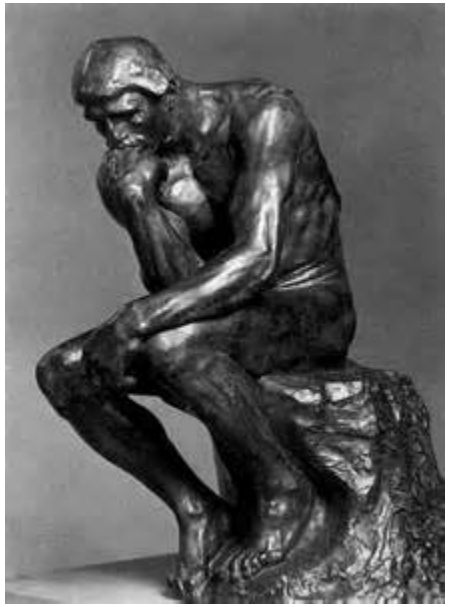
- Identifying treatments, services, procedures
- Based on those characteristics of interventions that are relevant both theoretically and practically
- Which would allow quantification of the dosage of treatment administered
- (A Rehabilitation Treatment Taxonomy: RTT)



PCORI project aims:

- Develop a reliable and effective *Manual for Rehabilitation Treatment Specification* and associated training materials describing a standardized set of steps that will guide researchers, clinical educators, and clinicians in applying the tripartite structure of treatment theory to:
  - Determine whether a “treatment” needs to be decomposed into distinct **treatment components**;
  - Specify the **treatment target** for a particular treatment component, and distinguish it from (“downstream”) **clinical aims**;
  - Specify in observable/measurable form the **ingredients** required to initiate the (known or hypothesized) **mechanism of action** of the treatment component.

All this will help us to:



- **THINK** more cogently/ incisively about what we do in rehabilitation, by making us pay attention to our choices in selecting treatments
- Better **COMMUNICATE** what we do in rehabilitation, to colleagues, trainees, and the people we serve
- More precisely and effectively **STUDY** relationships between what we do and the outcomes we achieve, so that we can figure out *WHAT* works and *WHY* it works
- **IMPROVE** the quality and effectiveness of rehabilitation

Treatment Components

- Dividing a “treatment” into separate treatment components, each with its own target
  - Does this make sense to you? (Suggestions for change/clarification?)
  - Is the separation of treatment components useful for practice?
    - In what ways?
    - What would make it more useful?

Targets

- 3 Groups (Organ functions; Skills & Habits; Representations)
  - Does this division make sense to you? (Suggestions for change/clarification?)
  - Is this distinction useful for practice?
    - In what ways?
    - What would make it more useful?

Targets (cont.)

- The separation of direct and volition targets
  - Is this distinction clearly presented? (Suggestions for change/clarification?)
  - Is this distinction useful for practice?
    - In what ways?
    - What would make it more useful?
- What are your thoughts about the optional specification of a separate volition target? (Suggestions for change/clarification)

Targets (cont.)

- Content and Aspect
  - Is this distinction clearly described? (Suggestions for change/clarification?)
  - Is this distinction useful for helping people to specify targets?
    - If yes, how/ why/ for what purpose do you think it is useful?
    - If no, suggestions for changing?

Ingredients

- Definition
  - Is it clear what we mean by “ingredients?” Is it clear what are and are not ingredients? (Suggestions for change/clarification)
  - Is this way of thinking about ingredients useful for practice?
    - In what ways?
    - What would make it more useful?

Ingredients (cont.)

- Qualitative vs. quantitative ingredients (with dosing parameters)
  - Is this distinction clearly described? (Suggestions for change/clarification)
  - Is this a useful distinction?
    - If yes, how/ why/ for what purpose do you think it is useful?
    - If no, suggestions for changing?
  - Thoughts on “N/A” vs. “as needed” as ways of addressing dosing?

Ingredients (cont.)

- The distinction between “what” and “how” kinds of ingredients
  - Is this distinction clearly presented? (Suggestions for change/clarification)
  - Is this distinction helpful in generating relevant ingredients useful for practice?
    - If yes, how/ why/ for what purpose do you think it is useful?
    - If no, suggestions for changing?

Ingredients (cont.)

- Assigning ingredients to treatment components
  - Are the rules that guide assignment of ingredients to specific treatment components clearly presented? (Suggestions for change/clarification)
  - Is the sorting of ingredients into different treatment components useful for practice?
    - If yes, how/ why/ for what purpose do you think it is useful?
    - If no, suggestions for changing?

The Training

- Big picture
  - These concepts can be used conceptually, to sharpen thinking and improve communication about treatments and treatment components that have been pre-specified
  - The concepts and associated rules can also be used to guide independent specification
  - For practicing clinicians, does the training change a “Representations” target (knowledge and understanding of the RTT) or a “Skills and Habits” target (independent skill in accurately specifying treatments)
    - How important is the specification skill for clinicians vs. the underlying concepts?
    - If more skill development is desirable, how could that be achieved?

The Training (cont.)

- Treatment vignettes
  - How helpful were the vignettes and their sample specifications in illustrating the concepts and procedures? (Suggestions for making them more useful)
- Practice specifications – what would be most instructive?
  - Specifying targets as one step, and ingredients associated with those targets as another (as we did)
  - Go through discussion of more pre-specified examples and underlying rationale
  - Specifying targets and ingredients of a “simple” treatment followed by specification of more complex treatments.

Closing

- Thanks for your participation in this training cycle, including tonight's feedback discussion
- Look for the Word version of the manual and our on-line survey to provide additional feedback
- Thanks!

Disclaimer:

The [views, statements, opinions] presented in this report are solely the responsibility of the author(s) and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute® (PCORI®), its Board of Governors or Methodology Committee.

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https://www.pcori.org/research-results/2014/creating-manual-better-define-rehabilitation-treatments