Manual for Rehabilitation Treatment Specification

(Version 6.2)

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Better Rehabilitation Through Better Characterization of Treatments: Development of the Manual for Rehabilitation Treatment Specification

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Contents

REHABILITATION TREATMENT SPECIFICATION SYSTEM MANUAL

I. BACKGROUND CONCEPTS AND KEY TERMS

This manual provides the guidelines for **specifying***[1] rehabilitation treatments according to the scheme developed by the multi-disciplinary **Rehabilitation Treatment Specification System*** (RTSS) group, formerly the Rehabilitation Treatment Taxonomy (RTT) group. Although the manual is intended as a how-to, procedural guide, some background in essential concepts is necessary to understand and follow the material.

The original aim of the RTSS project was to develop a **taxonomy*** of rehabilitation interventions, a system for *classifying* all treatments delivered in rehabilitation. More recently, the work has evolved away from the idea of *grouping* treatments, toward that of developing formal rules for specifying certain of their salient characteristics. Ultimately, a well-developed specification system will support the development of a classification system or taxonomy, by highlighting similarities and differences so that general principles may be extrapolated across individual elements—in this case, rehabilitation treatments and treatment approaches.

To date, the RTT/ RTSS has proceeded in 2 phases, the first with funding from the National Institute on Disability, Independent Living, and Rehabilitation Research (2008-2014) and the second with funding from the Patient-Centered Outcomes Research Institute (2015-2018). The focus of the first phase was to clarify the scope of the effort, develop key concepts, and propose the basic elements of a specification scheme; these were explicated in a 2014 Supplement to Volume 95 of *Archives of Physical Medicine and Rehabilitation*. In this second phase, we have modified and refined those concepts, and have set forth procedures intended to be detailed enough to support systematic, consistent specification of rehabilitation treatments by clinicians and researchers.

1.1 The need for a rehabilitation treatment specification system

The field of rehabilitation has made substantial advances in defining and measuring the functional outcomes of the rehabilitation process and the patient characteristics that are associated with those outcomes. However, we lack a rigorous and shared approach to defining, classifying, and measuring the rehabilitation treatments that are hypothesized to improve functional outcomes for patients with a given set of prognostic characteristics. At present, rehabilitation treatments are often described in terms of number of hours or days of service by a particular discipline, without regard to what that service actually entails; or simply by referring to the problems they are intended to address (e.g., “gait training,” “memory remediation”), without specifying the content or process used to address them. In contrast, the RTSS is intended to characterize treatments according to theoretically important elements, particularly the **active ingredients*** that are known *or* hypothesized to account for changes in patient functioning. Such a system will offer many benefits, including:

[1] Terms that may be unfamiliar to the reader or that are used with a particular technical meaning in this manual are **bolded** and marked with an asterisk (*) when first used, and are defined in the Glossary.

- Consistency of language and theoretical concepts within and across disciplines, which will enhance communication throughout the rehabilitation team and among the team, patient, and family;
- More efficient and effective research devoted to developing and comparing treatments and examining the variation in the effects of treatment in specific populations, as well as greater ease of replication and more effective dissemination to the clinic;
- Ultimately *reduced* practice variability, as the RTSS should foster research that enhances the evidence base for rehabilitation, leading to better uptake of proven treatments and more consistency in treatments applied to common problems;
- Improved education, training, and program evaluation;
- More consistent treatment documentation and communication with third party payers, with positive implications for billing and reimbursement.

1.2. Scope of the RTSS project

The RTSS encompasses treatment delivered to individual patients (or other **recipients***, such as caregivers). It does not address environmental changes that affect the public at large

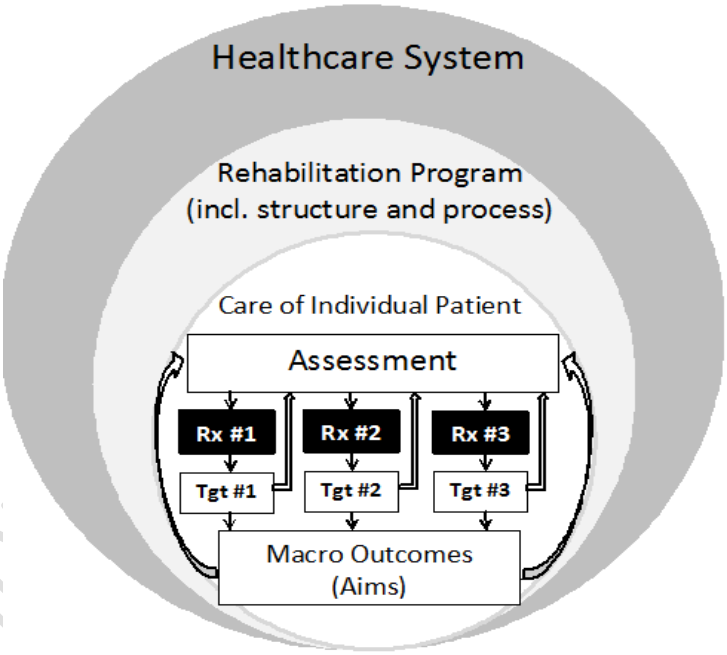


Figure 1. Scope of the RTSS.

(e.g., curb cuts), but does include modifications at home or elsewhere that are intended for one person (e.g., grab bars). It does not include the more or less formal assessment activities that typically precede treatment, although we acknowledge that many rehabilitation interventions are intertwined with "ongoing assessment" as treatment is adjusted. This issue is discussed in more detail later in this document (section 2.13). Figure 1[2] illustrates the focus of the RTSS

[2] Adapted from: Dijkers MP. Rehabilitation treatment taxonomy: establishing common ground. *Arch Phys Med Rehabil*. 2014;95(suppl 1):S1–S5.]

within the larger context of the healthcare delivery system. Although various factors within the larger healthcare system, and in the rehabilitation treatment program, may affect the quality and effectiveness of rehabilitation care, it is ultimately the specific treatments and services delivered to patients (the black boxes labeled "Rx" in the Figure) that account for patient functional changes, and that are the domain of the RTSS. Other elements in the Figure are explained later in this document.

1.3. Potential uses of the RTSS specification framework

Within the proposed scheme for treatment specification, the level of detail that is both useful and feasible depends on the purpose of the specification. Consider the following uses of a specification system:

- *To describe or prescribe a treatment for all patients with a particular problem* (impairment, activity limitation or participation restriction). No information is available about the individual patients who will receive the treatment, other than that they share a need to improve the same aspect of functioning. Examples: Listing **ingredients*** in a dressing treatment for patients with hemispatial neglect, or a word-finding treatment for patients with aphasia.
- *To describe or prescribe a treatment prospectively for a single patient with a particular problem or set of problems*. In the context of specifying treatment for a known, individual patient (e.g., in "handing off" treatment to a substitute clinician), one might specify additional active ingredients that are thought to be important for that patient, but not for others. Example: Letting the next treating therapist know that a particular patient needs to be involved in goal setting to increase his motivation to practice.
- *To describe how treatment WAS delivered for a single patient with a particular problem.* No matter how well specified a treatment may be in advance, the clinician may respond to patient performance with modifications in the treatment ingredients. Thus, complete specification of all treatment ingredients may need to be done in retrospect, to capture those ingredients that are added "on the fly." Example: When the patient started performing an activity incorrectly, the clinician added more instructions to correct that performance.

→ The above examples emphasize an important point, which is that the RTSS is *descriptive, not prescriptive*. The RTSS seeks to specify *all* rehabilitation treatments, whether they are "good" or "bad" (effective or ineffective). Only by establishing a consistent way to define and describe treatments will we be able to compare the effects of their ingredients on specific **targets***, and evaluate their impact on different types of patients with similar target problems.

1.4. What do we mean by "treatment?"

In Fig. 1 we showed that the focus of the RTSS is on treatments administered to individual patients. But "treatment" can be defined in different ways, as illustrated in Figure 2: it can mean a course of treatment, a series of treatments addressing a particular problem, or a set of ingredients directed to a specific aspect of a problem. The RTSS is concerned with specifying

treatments according to the last of these (#3 in the Figure). We use the term **treatment component*** to distinguish the focus of the RTSS from the more common clinical uses of the term.

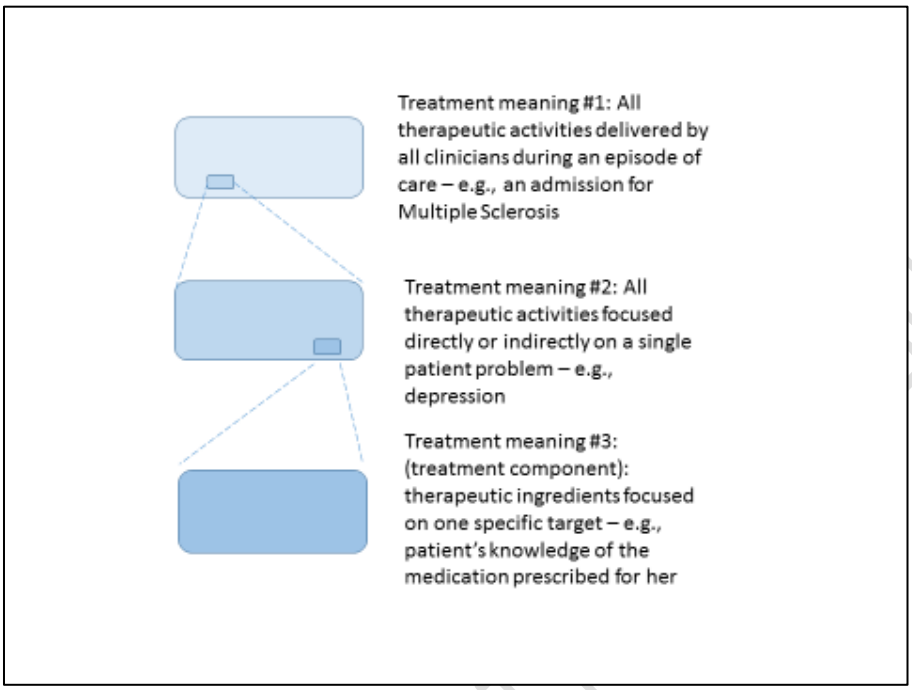


Figure 2. Relationship between treatment components and the broader "treatments" in which they are situated.

1.5. Theoretical basis of the RTSS

The RTSS is a "top-down" scheme that emphasizes the use of theory to describe and organize treatments. At a global level, we distinguish **treatment theories*** from **enablement theories*:** a treatment theory explains what clinicians do to bring about functional change; it is the foundation for the RTSS and explains how and why a treatment works. Enablement theory explains how different impairments, activity limitations, and participation restrictions may be causally related to one another, but *not* how to directly change a patient's status in any of those domains.

We have elaborated treatment theory into what we call a **tripartite structure***, which is depicted in Figure 3. Any rehabilitation treatment may be composed of one or more treatment components; the three elements of a *single* treatment component are depicted in the Figure. A treatment component has one target, which is the proximal, functional change that is intended to be brought about by the treatment.

When we refer to targets as *functions*, *functional change,* or *functioning*, we mean the processes, actions and activities essential or proper to a human's existence as a physical, psychological and social entity. In terms of the International Classification of Functioning, Disability and Health (ICF), this includes:

- Body Functions, which are physiological functions of body systems (including psychological functions);

- Activity, which is the execution of a task or action by an individual;
- Participation, defined as involvement in a life situation; and
- Selected personal factors, which are the particular background of an individual's life and living, and comprise features of the individual that are not part of a health condition or health status.

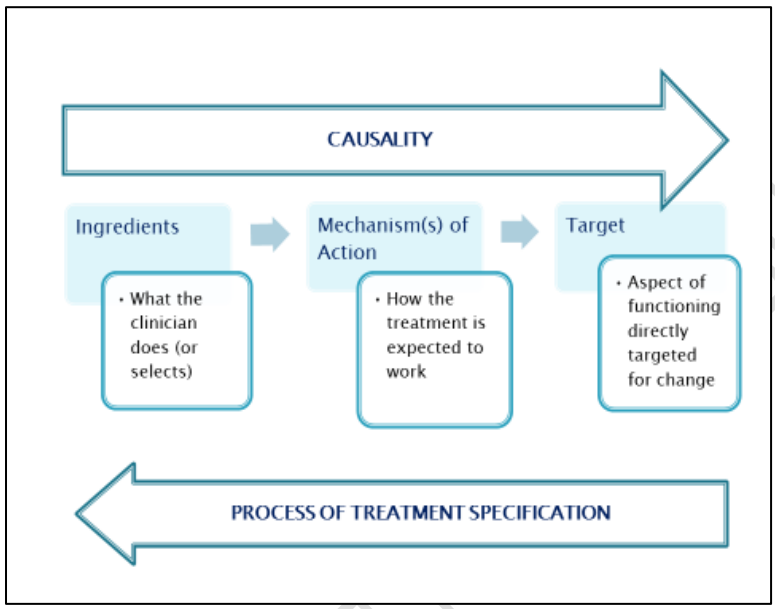


Figure 3. Tripartite structure of a treatment component, based on treatment theory

The description of the ICF issued by the World Health Organization (WHO)[3] indicates that personal factors include such characteristics as gender, race, age, fitness, coping style, social background, **habits***, education, past and current experience, character, psychological assets, and other features that influence how disability is experienced by the individual. The WHO also states that personal factors may have an impact on the outcomes of rehabilitation interventions. While most rehabilitation professionals are likely to state that they provide treatments to improve body functions, minimize activity limitations, and reduce or eliminate participation restrictions, in doing so they often aim to change elements of personal factors: e.g., coping style, lifestyle, and psychological assets such as attitudes and values. In fact, it is often difficult to draw the boundaries between body functions, activities, limitations, and personal factors. Is judgment (ICF b1645) a "body" function, or an aspect of a person's character? In the RTSS, judgment is a valid target of treatment when a rehabilitation clinician develops a treatment theory as to how certain ingredients might bring about a change in some aspect of judgment, and there is no need for this clinician to worry whether judgment is classified as a personal factor or as a "body" function.

The reader might wonder: why are the ICF's Body *structures* (anatomical parts of the body such as organs, limbs and their components) not listed as valid targets? In general,

[3] *International classification of functioning, disability and health (ICF)*. 2001, Geneva: World Health Organization.

changes in body structure are of clinical interest for rehabilitation only to the extent that they translate into changes in body function; hence we identify their targets as the corresponding functional changes. For example, changing the length of a tendon via prolonged stretch (change in body *structure*) would be identified as having a target of improved joint range of motion (change in body *function*). Note also that targets in the RTSS are conceptualized to reflect desired *change* in body function, activity and participation, and/ or personal factors, and that such changes are most likely to be *improvements*. However, rehabilitation targets may also involve preventing deterioration in functioning, i.e., maintaining optimal functioning when a disease process, lifestyle or health-related behavior, or external influence threatens to lead to decline. For the sake of simplicity, this manual uses the concept of *functional change* to discuss targets and the methods used to attain them, but we do not exclude prevention of deterioration in the level of functioning.

A target of any type must be measurable and observable, at least in principle: for example, "improved independence in dressing" might be measured by the number of therapist cues required to complete the task correctly; "improved accuracy of knowledge about effects of disability" could be measured by the accuracy of answers to questions about the effects of disability; "increased range of motion at X joint" could be measured as degrees of movement in a given direction. As a corollary of our focus on the tripartite structure, what we consider "a treatment" in clinical jargon will often have more than one treatment component, each with a separate target (see Fig. 2).

As illustrated in Fig. 3, a clinician administers one or more ingredients to effect change in the target. "Administer" here refers to providing chemicals (e.g., medications), forms of energy (e.g., functional electric stimulation), **devices*** (e.g., splints), common objects (e.g., shoes for dressing training), words (e.g., instructions, feedback, encouragement) and hands-on manipulation (e.g., massage, physical assistance) to the treatment recipient. Ingredients also include tangible aspects of the "therapeutic alliance" such as expressions of warmth and empathy from the clinician. These types of ingredients are also included in the so-called "common factors" of psychotherapy: elements of the relationship between patient and therapist that are thought to promote positive change irrespective of the "specific factors," or theoretically motivated therapeutic techniques, applied by the therapist. Ingredients are active if they are hypothesized or known to affect the target, **inactive*** if they do not. Ingredients can vary categorically (i.e., you use goal setting, or you do not; you use a certain *type* of feedback or you use none) or quantitatively (e.g., schedules of practice; numbers of repetitions). Ingredients, like targets, are always measurable/ observable in principle: e.g., one can see or count the type/ amount of cueing provided, the materials selected for the treatment activity, the type/ amount of error feedback the clinician gives to the treatment recipient. Ingredients change the target via **mechanisms of action*,** which may or may not be observable, but are at least hypothesized, based on observed or expected relationships between ingredients and changes in targets.

In the current state of rehabilitation science, theories about mechanisms of action for therapeutic change vary from precisely specified to extremely crude. Development of scientific theories often proceeds from a mere claim of an association ("A predictably leads to B"), to a much more nuanced theory ("A leads to B by initiating a chain of events involving C, D, E, and F

if not interrupted by X, Y or Z"). There is substantial knowledge about *how* heat affects tissue elasticity, or *how* analgesic medications modulate pain. In contrast, it is not currently possible to theorize at this same level of precision as to how, for example, the delivery of information leads to changes in emotional states. However, it is still possible to predict that receiving certain kinds of information will lead to certain kinds of affective change.

One of the potential benefits of building treatment specification on the basis of treatment theory is that this framework will promote research on mechanisms of change that cut across specific treatment domains. For example, many treatments focus on improving skills through guided practice. By formulating overarching treatment theories about how practice enhances skill, one may accelerate treatment research, instead of considering, e.g., "dressing training", "gait training", and "social skills training" each as a unique treatment to be studied on its own. Given the state of the science, for the current purposes of treatment specification, even rather crude theories about mechanism of action will suffice. It is sufficient for a clinician or researcher to hypothesize that a particular set of ingredients will lead to specific changes in a target, without yet understanding the sequence of mechanistic events that cause this to happen. Indeed, later in this document we assert that what serves as the mechanism of action in some treatment areas is currently as vague as "learning by doing" (i.e., repeated performance leads to improved skill).

Treatment theory predicts why and how a target will change, but it cannot predict the accomplishment of treatment **aims***. Aims are downstream, typically more "macro" effects of treatment that may or may not ensue from the achievement of a more proximal target. For example, achieving a target of getting dressed in a reasonable time with no assistance may contribute to the aim of living independently. But to achieve that aim, the clinician may need to address many additional targets having to do with other activities of daily living, safety, financial management, etc. As well, aims may be affected by factors outside the purview of rehabilitation, such as (in this example) the availability of low-cost or supported housing. The distinction between targets and aims is critical because the act of specifying treatments depends on selecting a target or targets that are specific and achievable with the ingredients that the clinician will provide.

The distinction between targets and aims (and between treatment theory and enablement theory) is illustrated in Figure 4. Note that according to enablement theory, a range of body functions (bottom row) may contribute to the performance of a range of activities and skills (arrows pointing to middle row). Multiple activities and skills may, in turn, contribute to successful participation at the level of societal roles (arrows pointing to top row). Correspondingly, individual impairments or combinations of impairments may limit activities and skills, and individual activity limitations or combinations of such limitations may interfere with participation. The numbers next to the thin black arrows connecting these boxes illustrate hypothetical "weights" by which variables at a "lower" level influence variables at a "higher" level. Thus, for example, an impairment in an individual's ability to convert a pattern of letters into a meaningful word might have much greater impact on reading than on conversing; but no activity depends only on a single body function. Enablement theory attempts to specify the relations among the contents of the various boxes, whereas treatment theory addresses how the treatments illustrated by the thicker red arrows change the targets to which they point.

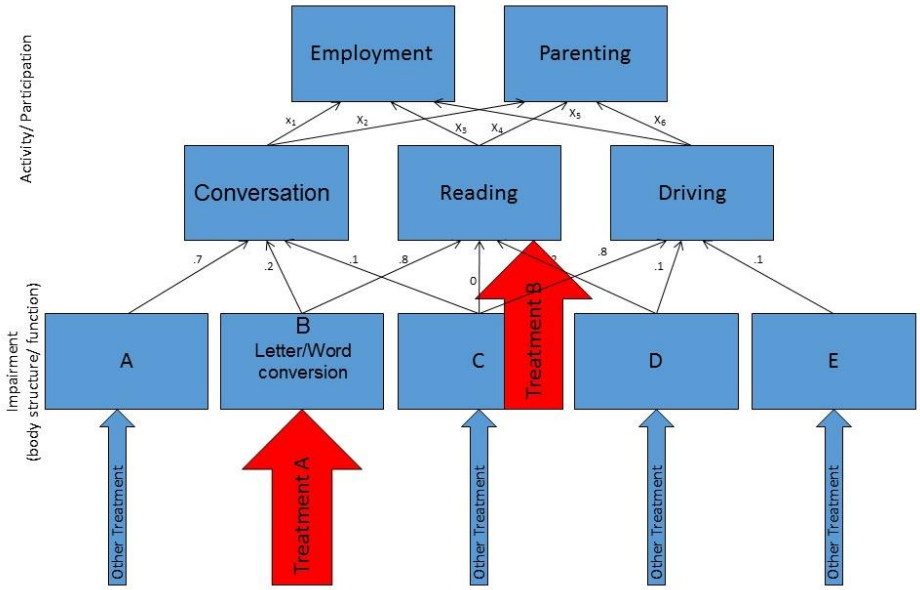


Figure 4. Enablement theory as contrasted with treatment theory.

Figure 4 serves to illustrate several key points about the relationship between treatment theory and enablement theory. First, while Treatment A may reliably improve letter/ word conversion, whether it will improve reading depends also on the status of body function D in an individual patient. Thus, for Treatment A, "improved letter/ word conversion" may be a target, but "improved reading" would be an aim. Importantly, though, these functional areas are only targets or aims *with respect to a specific treatment*. Imagine another Treatment B – providing the client with a device that scans printed text and produces auditory output. This treatment has a mechanism of action that leads directly to reading and, thus, has a *target* of improved reading, although how this will affect employment remains less clear because enhanced employment is, for this treatment, an aim.

It is also important to note that the distinction between target and aim *is not* necessarily the same as the distinction between a short-term goal and long-term goal. It may be the case that an aim takes longer to achieve because multiple different targets must be treated (sometimes sequentially) to have a meaningful impact on that aim (e.g., treating body functions B, C, and D in order to improve reading). But there are targets that may take a long time to achieve. For example, a program of progressive resistance exercises in a very weak patient may take weeks to achieve a clinically adequate increase in strength, even though this is the target of the treatment. Conversely, there are aims that might be achieved quickly. For example, if the risk of skin breakdown while sitting is the primary factor that limits community mobility for a patient with spinal cord injury, it might be the case that a rapid treatment that provides better prevention of skin breakdown – the target – might quickly translate into the aim of greater community participation.

II. TREATMENTS, TARGETS, AND INGREDIENTS

2.1. Treatment groups

We have described in the Archives of Physical Medicine and Rehabilitation supplement mentioned previously the characteristics of three[4] groups of treatment components that are mutually exclusive with respect to their targets, mechanisms of action, and many types of ingredients. These 3 **treatment groups***, which could represent the first level of division of a treatment taxonomy, are summarized in Table 1 below.

Table 1. Treatment groups in the Rehabilitation Treatment Specification System

Name of Group	Typical Targets	Typical Ingredients	Mechanisms of Action	Clinical Examples
Organ Functions	Changed or replaced organ functions	Varies by organ system: e.g., 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 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 & 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, ADL training, training in use of a compensatory memory device, training in habit formation
Representations	Enhanced knowledge, modified attitudes/ emotional responses; changed probability of specific behaviors	Didactic instruction, prompts to process new or previously acquired information; persuasion, motivational techniques; prompts for action	Cognitive/ affective information processing	Patient education, adjustment counseling, instruction on how to perform an activity, motivational interviewing

→ ***The Organ Functions*** **group*** treatments are concerned with effecting changes in the function of organs or organ systems. (Certain changes in body structure with direct effects on

[4] In the original scheme in the Archives of Physical Medicine and Rehabilitation supplement mentioned previously there were 4 groups; a group addressing structural targets (e.g., size/ shape of tissue) was collapsed into the group addressing organ functions, due to the difficulty in separating structural from functional changes at the level of treatment theory.

function are also included, as in the example of prosthetic limbs, which replace a body structure and *some* of its functions, without technically being part of an 'organ system.') Any organ system may be targeted, including the brain/ central nervous system. Changes in function may be achieved by changing the input/ output dynamics of the system, as when aerobic exercise is prescribed for improving the efficiency of the cardiopulmonary system. Or it may be accomplished by replacing the organ altogether, e.g., with a prosthetic limb or a cochlear implant. The brain may be passively targeted in Organ Functions treatments that use habituation or classical conditioning (forms of involuntary learning), treatments that involve systematically administering stimulation in defined patterns (deep brain stimulation, TMS/ tDCS), or those that change neurotransmitter levels (e.g., antidepressant or anti-psychotic medications). The musculoskeletal system is commonly addressed with strengthening exercises, massage, tendon lengthening treatments, etc.

Table 2. Examples of Organ Functions Treatments

Ingredient		Mechanism of Action		Target
Apply force to a tight muscle	→	Increased sarcomere length	→	Increased joint range of motion
Provide a hearing aid	→	Amplification	→	Improved hearing acuity
Provide repeated exposure to stimulus	→	Passive learning (habituation)	→	Reduced sensitivity to stimulus

One thing that is sometimes confusing about the Organ Functions group is that it includes both passive (**non-volitional**) **treatments***, and those requiring voluntary action, such as exercise (**volitional treatments***). The other 2 groups (described below) are made up only of volitional treatments—those requiring active participation and effort on the part of the recipient. Why not include exercise in one of those groups and reserve Organ Functions for passive treatments? The answer is that *exercises targeting the musculoskeletal or cardiopulmonary systems do not depend on information processing/ learning mechanisms to exert their effects on the target; but all other volitional treatments do involve active learning or processing of information.* Thus these types of active treatments fit into the Organ Functions group because their treatment theories stipulate changes to muscle strength or changes in cardiopulmonary efficiency, without reference to learning. As emphasized in later text, all volitional treatments (including those volitional treatments that are in the Organ Functions group) require additional ingredients to ensure that the patient performs the specified exercises or activities that lead to changes in the target. And in some cases, executing the volitional behavior that permits the desired changes in a **direct target*** becomes a target of its own (which we refer to as a **volition target***), with ingredients that are intended to affect voluntary behavior (see Section 2.5).

The Organ Functions treatments are quite disparate from one another, reflecting the differences among the various organ systems and the manner in which they function. The

ingredients and mechanisms of action vary by the specific organ system, as detailed later in this document.

- There is often, but not always, a dimension of **progression*** in the demands on the organ system to achieve improvements; for example, both aerobic and muscle strengthening exercises must be progressively more demanding for the targeted functions to continue changing. (Progression is discussed in more detail in Section 2.14.)
- In other instances, ingredients (such as medications) are titrated up, because: (e.g.) the nature of the reaction of the system to even a small dose is unpredictable; the ingredients need to be introduced a bit at the time; or the effective dose has to be identified.
- However, Organ Functions treatments that *replace* some of the functions of an organ (e.g., fitting a prosthetic limb) act immediately, without any need for progression.
    - Note that learning may be required to make optimal use of an organ replacement such as a prosthesis, but this would be considered a different treatment component reflecting skilled use, and would be classified in the Skills & Habits group.

→ The ***Skills & Habits* group*** treatments include a large variety of treatments that have in common the mechanism of "learning by doing," where learning is accomplished via repetitive practice, and results in increased skillfulness and greater automaticity of the behavioral routine. Familiar clinical examples include the many therapies labeled "training"—gait training, ADL training, social skills training, training in the use of cognitive compensations, etc. This group includes training to address either body functions or activities (in ICF terminology). For example, the patient might practice responding to balance perturbations to improve "involuntary movement reaction functions" (dynamic balance), and a dressing routine may be practiced to improve the activity of "putting on clothes." Other examples are shown in Table 3.

Table 3. Examples of Skills & Habits Treatments

Ingredient		Mechanism of Action		Target
Provide opportunities to **practice** steps from printed list	→	Learning by doing	→	Correct sequence of hemi dressing
Provide opportunities for repeated **practice** handling small objects of **varied sizes**	→		→	Improved fine-motor coordination for grasp
Provide opportunities for repeated practice with guidance in setting watch for appointments	→		→	Increased independence in setting watch for daily appointments

These different types of Skills & Habits targets are discussed in more detail in Section III.

- The Skills & Habits group includes both repetitive practice to attain a time-limited target (e.g., one may engage in a dexterity exercise only until a certain level of dexterity – "coordination of voluntary movements" – is achieved), or to establish a long-term habitual behavior (e.g., the target may be the routine use of a memory compensation in certain situations that should trigger its use).
- As noted above, Skills & Habits group treatments have in common the mechanism of "learning by doing" with the implication that, although some learning takes place in a single episode of practice, structured practice and repetition—sometimes with gradually increased demands on performance, and sometimes with repeated performance in the presence of specific cues—are key ingredients.

→The ***Representations* group*** contains a wide variety of treatments intended to change cognitive and affective representations (e.g., thoughts and feelings; semantic knowledge) as well as **volition***: the mental/ emotional representations—choices or decisions—that may remain internal representations, *or* may be linked to action. Example treatments are shown in Table 4.

Table 4. Examples of Representation Group Treatments

Ingredient		Mechanism of Action		Target
Explain meaning of terms related to aphasia (e.g., anomia, paraphasia)	→	Cognitive / affective information processing	→	Increased knowledge about aphasia
Show video of typical speakers to normalize use of gestures in communication	→		→	Increased willingness to use gestures in communication
Explain importance of home practice	→		→	Increased motivation to practice at home

The central mechanism of action for the Representations group is cognitive/ affective information processing. However, the range of targets in this group reflects the fact that there is a continuum between information that is unconnected to action (e.g., "knowledge for the sake of knowledge," or reassurance to reduce anxiety) and information that is intended to lead directly to a specific behavior (e.g., a firm instruction or exhortation to do something, either now or later.) At one end of this continuum might be "patient education" treatments where the target is simply increased knowledge of one's condition. At the other end might be a "how-to" instruction followed by a direct request to perform the behavior, or even a simple instruction to perform a behavior that already is within the client's repertoire – e.g. "Call vocational rehab

services and set up an appointment." Somewhere in between might be Representation group interventions used to change attitudes, which are considered *propensities* to act. For example, a clinician might use persuasion or the provision of various rationales to alter a patient's attitude toward engaging in less preferred treatment activities.

- In specifying a Representations group intervention, the clinician must indicate where on the continuum of knowledge to action his/ her target lies, by specifying whether the target directly involves behavior change, versus change in internal constructs such as knowledge, belief, emotional valence, awareness, or attitude.
- Bear in mind that the action-related targets in the Representations group *do not* include repeated actions that are intended to develop skills or habits; if a clinician provides instruction/ motivational ingredients for those types of actions, the target is in the Skills & Habits group.

2.2. The role of the brain in the different treatment groups

Users of the RTSS are sometimes confused by the fact that *brain function* is considered a target only for passive treatments contained in the Organ Functions group—for example, TMS/ tDCS, deep brain stimulation, or medications that alter neurotransmitters. Why isn't brain function a legitimate target in the groups containing volitional treatment components, since the brain is necessary to develop skills and habits or to form new mental representations?

The answer is that targets are always expressed as *functionally relevant* changes in the recipient. In the case of Skills & Habits or Representations treatments, the functionally relevant change is not in brain function but in the observed skill, habit, knowledge, affect, etc. We know that changes in the brain must underlie these measurable changes in thought or behavior, but we would consider the changes in the brain as part of the mechanism of action—the "learning by doing" or "information processing" that lead to changed skills or representations, respectively.

2.3. Treatments and treatment components: an illustration

We have noted (Section 1.4) that many episodes that would be labeled "treatments" in the terminology of the clinic are considered in the RTSS to be composed of multiple treatment components, each with its own target, ingredients, and associated mechanisms of action. Consider the following example:

The patient is an elderly man who goes to see his nurse practitioner because he feels depressed. The patient was recently diagnosed with mild cognitive impairment that is gradually worsening. The nurse practitioner prescribes sertraline hydrochloride (Zoloft®), an antidepressant. The patient's spouse, who is with the patient at the visit, reports that the patient already takes several medications and is beginning to have trouble organizing them and taking them in a timely fashion. The nurse practitioner works with the patient and his spouse to accomplish different targets related to this medication, as shown in Table 5.

Table 5. Example of treatment components related to medication management.			
Treatment Component Group	**Ingredients**	**Mechanism of Action**	**Target (recipient)**
Organ Functions	Sertraline hydrochloride	Inhibition of serotonin reuptake	Improved mood (patient)
Representations	Spoken information about medication and possible side effects; printed pamphlet	Information processing	Increased knowledge about sertraline (patient)
			Increased knowledge about sertraline (spouse)
Skills & Habits	Large compartmentalized pillbox with timer attached; training and practice in how to set timer and how to place pills in proper compartments	Learning by doing	Improved abiity to take correct medications at correct times
Representations	Instruction on how to check patient's performance in pill taking and retrain or remind patient as needed	Information processing (leading to voluntary action)	Performance of monitoring/ reminding patient, as directed by clinician (spouse)

Note in this example that although both the patient and the caregiver receive the same information about the medication, this is shown as 2 separate knowledge targets in the Table. Each recipient of a treatment must have his/ her own target identified, even if the ingredients delivered to each are exactly the same.

2.4. The concept of volition

We have concluded that whether or not a treatment component requires *volitional behavior* on the part of a patient/ recipient provides a useful and central distinction, especially for organizing the different types of ingredients to be specified. Volition may be roughly equated with *effort* expended by the treatment recipient.

- Note that effort expended in a task does *not* necessarily equate to awareness of the purpose or aim of the effort. For example, an amnestic patient may be repeatedly talked through the steps of a wheelchair transfer and have no awareness of learning the transfer. Nonetheless, if learning takes place, it has been because of volitional behavior (following the instructions to perform the transfer, which requires effort).
- Also note that many passive treatment components may be paired with effort-requiring components. For instance, in the example in Table 5, a clinician had to teach the patient strategies to remember to take medication (itself a passive treatment) in a timely

fashion. This treatment component requires patient effort, whereas the effects of the medication itself do not.

- Treatment components that do not require *any* recipient effort and are considered *passive* or *non-volitional* include medications, surgeries, and passive range of motion exercises; treatment components based on primitive learning mechanisms such as habituation are also passive, because the learning happens involuntarily.
    - *All* non-volitional treatments are in the Organ Functions group and involve passive treatments intended to change the function of organ systems.
    - However, the Organ Functions group also includes volitional treatments, a prime example being *exercises* to modify the musculoskeletal, cardiovascular, or other organ systems. In these cases, the patient must engage in voluntary behavior in order for the mechanism of action to have an effect on the organ system.
    - Many non-volitional treatments in this group can also be *self-administered* (e.g., range of motion exercises). In this case, effort on the part of the patient is required for an otherwise passive treatment.
- In contrast to the Organ Functions group, *all* Skills & Habits and Representation treatments do require volition. By definition, skills and habits must be actively practiced to be improved. And volition is part and parcel of Representation treatments; even if no overt action is required, the patient must actively attend, listen, think, etc. to process the information supplied by the clinician.

→ *Why is volition so important?* In rehabilitation treatments that depend on the patient's voluntary action, there are two potential sources of treatment success (or failure). Consider the case where a volitional treatment doesn't have the predicted effect on the target. This failure (or partial failure) may be due to the fact that the direct target ingredients contained in the treatment activity are ineffective, even when that activity is performed properly. But a second possible reason for failure is that *the patient did not perform the volitional activity as directed*. That is, the ingredients selected by the clinician didn't even get a chance to work, because the patient did not do a prescribed activity at all; did it with insufficient frequency/ duration/ intensity; or did it incorrectly.

- For example, a patient may fail to progress at the expected rate after practicing walking with a cane in a certain sequence during successive sessions of Physical Therapy. This may be because her therapist has selected a schedule of practice that is inadequate for learning and automatizing the gait sequence. Or, it could be that the training does not have the expected effect because the patient is so distracted by external events that she is unable to apply the required *effort* to learning the task. (Of course, these problems may also coexist!)

Thus, when a volitional treatment fails to work at all, or works less effectively than expected, it can be useful to think about these potential causes separately: Did I choose the wrong mix of ingredients for the direct target? Or did I not ensure that the patient would perform as directed, so that those ingredients could take their full effect?

As illustrated in Figure 5 below, volitional treatment components can be thought of as having a temporally "longer" causal chain than non-volitional treatments, in that the clinician *first* delivers informational and motivational ingredients (A), which *then* result in the patient performing the treatment activities (B) that are, in turn, necessary to induce changes in organs, skills, or representations (C). (There may be other ingredients (D, E) added to achieve the direct target as well.) By "first" we refer to a causal sequence, not exclusively a temporal sequence. In practice, volition-directed ingredients (feedback, encouragement, etc.) may be administered before *or during* performance of the treatment activity.

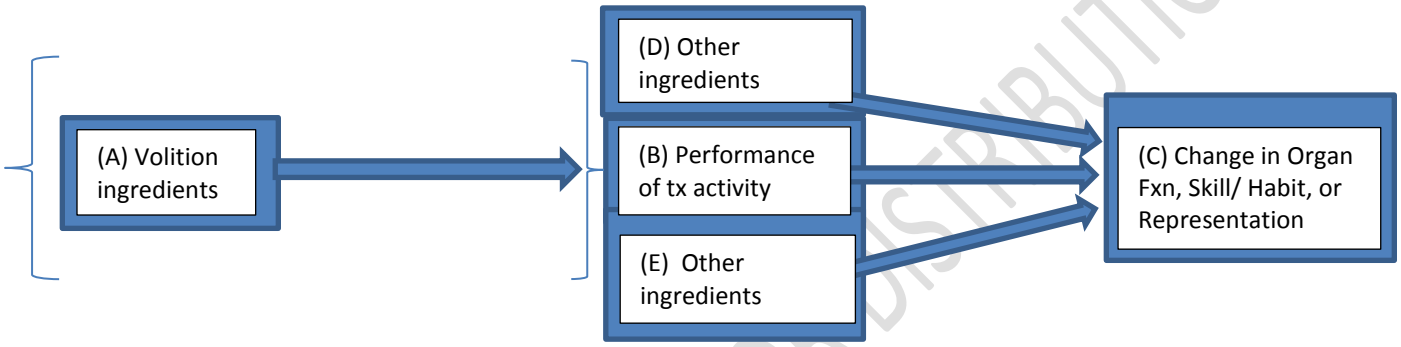


Figure 5. Relationship of volition ingredients to direct changes in target.

For treatments that are administered under the clinician's direct supervision, it is relatively easy to evaluate the success or failure of treatment and the contributions of these two potential sources of failure, and to adjust the mix of ingredients accordingly. In the previous example of the distracted patient, the clinician would likely take note of the patient's distractibility during treatment, and would take steps to reduce its impact on her effort (e.g., by treating her in a quiet environment where she could focus her attention on the task).

But what about the case where the clinician is unable to supervise the patient's performance in person, and/ or in real time? Consider the common example of a home program of strengthening exercises, assigned to supplement the work done in face-to-face treatment sessions. If the patient's strength fails to improve as expected between sessions, the clinician has no *direct* way of knowing whether this is due to the inadequacy of the prescribed exercises themselves (their type, intensity, etc.) or to the failure of (B) the patient to perform them *as prescribed*. Nor does she have the ability to "tweak" ingredients as needed to improve the performance of the volitional behavior. This scenario is also very familiar in medication treatments, as noted above. If the medication fails to have the desired effect, it could be because the prescriber chose the wrong drug or dose to address the target effectively. Or the patient may fail to buy or take the prescribed medication, or may take it incorrectly—all problems of volitional behavior that reduce treatment adherence.

Whether or not the treatment is supervised, success requires that the volitional behavior in the "middle" of the chain occurs. However, when a treatment is supervised, there is less need to decide in advance precisely what instructional and motivational ingredients (A) will be provided, since the clinician can modify these ingredients until he is satisfied that the required volitional behavior is achieved. In Figure 5, the first part of the chain (A→B) is

bracketed to acknowledge that it can receive less formal attention *as long as accurate performance of the treatment activity is assured.* In contrast, when the clinician will not be able to directly verify the performance nor to modify ingredients as needed, it is important to pre-specify the ingredients that will be used to achieve volitional activity and to assess whether the prescribed behavior has, indeed, been performed.

2.5. Volition in treatment specification

These two clinical situations—one where the outcome of the patient's volition can be directly evaluated and modified as needed, and one in which it cannot—are different enough so that we have different specification rules for them. Although the causal sequence is the same for all volitional treatment components, the specification rules require more explicit focus on ensuring volition in less supervised contexts.

2.5a. Volition targets

The RTSS stipulates that when volitional treatments are carried out by the treatment recipient remotely, i.e., away from the clinician's supervision, at least one target must be specified as a volition target (at point B in Figure 5), along with the direct target (C). That is, in unsupervised contexts, we treat volitional treatments as having at least 2 components, one of which has a volition target and the other(s) having direct target(s), with different sets of ingredients directed to each target (in Figure 5, A are the volition target ingredients and D-E are ingredients addressed to the direct target). In contrast, in supervised volitional treatments, we specify a single (direct) target and add the volition ingredients to those used to achieve the direct target. The direct target is the primary change that is the desired outcome of the treatment; volition targets are concerned with the voluntary activity that allows for the delivery of active ingredients to bring about the direct target. In the example of exercise to improve cardiovascular endurance, the change in dynamics of the organ system underlying improved endurance is the direct target. The patient's "exercise behavior"—actually doing the exercises as prescribed—is the volition target. Similar examples exist in each of the treatment groups: greater independence in dressing could be a Skills & Habits direct target, with the volition target being the repeated practice of the patient in the prescribed manner of dressing. In the Representations group, a direct target might entail the acquisition of particular knowledge, with the volition target being the patient behavior (reading, listening) that permits that knowledge to be gained. In general, volition targets are achieved through ingredients such as instructions, motivational messages, and negotiation between clinician and patient or joint planning as to how therapy activities will be accomplished remotely from the clinician. (Volition ingredients are discussed in more detail in succeeding sections, and in Part III of this document.)

It may be noted that ingredients used to achieve the volition target are the same kinds of ingredients used to achieve Representation group direct targets, which involve instilling knowledge, changing motivation or attitudes, and promoting prescribed actions via cognitive/ affective information processing. In fact, *volition targets are a special kind of Representations group target*, falling at the "action" end of the continuum. A Representations treatment component may have a target of increased knowledge, motivation, or future propensity to act,

but it may also have a target of *specific action***,** possibly at a defined time and place (e.g., an "assignment"), in which case it is a volition target.

What are the clinical situations that require a volition target? The most straightforward examples are the ones mentioned above: medications to be taken on a certain schedule, home exercise programs, or indeed any "homework" assignments given to an outpatient. These may be assignments to do one thing ("talk with your mother about X;" "call and make an appointment with Vocational Services;"), to complete a series of tasks at home or in the community, or to perform a selected behavior in the presence of specific cues, in order to form a habit. However, in clinical practice there may be gradations along a continuum of "remoteness" from a supervising clinician. For example, a patient may be given an assignment to complete independently within a session, with the clinician deliberately refraining from supervising or coaching the activity. Or a patient may be told to do 12 sets of 3 repetitions, while the clinician goes to check on another patient. Telerehabilitation treatments may also lie along this continuum, in cases where the clinician is directing the patient remotely but is unable to verify the accuracy, timeliness, or completeness of the desired volitional behavior. The rule in the RTSS is to specify a volition target in any circumstance in which the clinician is unable to evaluate and modify *directly* the performance and outcome of the desired volitional behavior; that is, evaluation through personal verification and not, for example, only through the self-report of the patient.

Why do we raise volitional behavior to the level of a separate target in these cases, rather than simply require the specifier to use "extra ingredients" to ensure that the desired behavior takes place? Mostly, it is to acknowledge and emphasize that volition ingredients and those addressed to the direct target typically have *different mechanisms of action*. A home muscle strengthening program has ingredients that act upon the direct target such as the amount of resistance applied to the muscle, the number of repetitions and sets prescribed, and so on. The ingredients for the volition target, in contrast, are for motivating the patient to exercise, ensuring that he or she has enough time and space to do so, and perhaps helping him or her to set up a reminder system for cueing the activity. None of these latter ingredients has any action on the strength of the patient's muscles; rather, their mechanisms of action have to do with the internal representations that will enhance the probability of engaging in the volitional activity and doing it correctly. Emphasizing these two targets, each associated with different mechanisms of action, increases the likelihood that issues of volition will be addressed in treatment design and delivery, and provides an opportunity to measure the impact of both sets of ingredients, separately, when assessing treatment outcomes.

2.5b. Volition ingredients

We have said that separate volition targets need to be specified for volitional treatments that are designed for the patient to complete remotely, i.e., away from the direct observation of the clinician. What about the common clinical scenario in which the clinician is present during the performance of a volitional treatment? In these cases, we assume that the ingredients addressing volitional behavior are present, but that they are different from those in the "remote" situation in two important ways. First, they typically need to be *less detailed* because adequate time, space, equipment, and scheduling reminders are implicit in the clinic

situation. That is, the patient in a scheduled session under the guidance of a clinician simply has less need for such ingredients to be "added on." Second, because the clinician is present and supervising the volitional activity, volition-related ingredients may be *adjusted as needed during treatment*, rather than fully planned (i.e., specified) in advance. That is, the clinician overseeing an exercise routine directly is in a position to provide more (or less) motivational messages, explanations, instructions, corrections, etc. as needed to maximize the volitional performance. Because the ingredients addressing volition are typically *less detailed and more fluid* in the clinic compared to the remote treatment situation, the RTSS stipulates that volitional treatments performed under the direct supervision of the prescribing clinician do not require the specification of a separate volition target. Rather, volition ingredients are added to those selected to achieve the direct target, which stands alone as the intended change. This is not intended to minimize the importance of volition: ingredients addressed to the volition aspect of the therapeutic activity *must* be specified for every volitional treatment. These ingredients may be specified in brief or "pro forma" fashion (e.g., "oral instructions for use of dumbbells;" "instruction to continue working on task begun in previous session") as appropriate.

Not *every* directly supervised treatment can succeed with *pro forma* volition ingredients, however. The clinician must be alert to situations that require extra thought, attention, and possibly pre-specification with regard to these ingredients. These are situations when even in the clinic setting with direct supervision, *it is more difficult to ensure the performance of the desired volitional behavior*. For example, extra attention needs to be paid to ingredients addressing volition when:

- The activity is tedious, unpleasant or painful;
- The patient is known to have negative attitudes toward, and/ or lack of motivation for, doing the activity;
- The patient has impairments in learning and memory, comprehension, drive, initiation, or persistence, any of which can weaken the causal chain between the clinician's instructions and the patient's action.

→ It is important to acknowledge that the ingredients which address the direct functional target and those which addresss volition may overlap to some degree. Some ingredients may have effects both on the target of treatment *and* the probability that the patient will perform the treatment activity. Feedback is a good example of such an ingredient. When a clinician provides evaluative feedback on the performance of a therapeutic activity, the patient may then perform the activity more accurately, with beneficial effects on the direct target. However, the same feedback may indicate progress, thus providing encouragement for the patient to continue to perform the activity in the clinic or practice it at home (i.e., beneficial effects on volition). Even though it is not possible to "parse" these different effects, the distinction is useful to ensure that we consider all ingredients that are relevant to the effectiveness of treatment when planning, specifying, and assessing the effects of treatments. In unsupervised treatments, it is likely to be easier to sort ingredients into those used to achieve the volition target vs. those used to achieve the direct target. Instructions and motivational messages given in advance are less likely to have effects on the learning that takes place outside of supervision, but are clearly intended to ensure that the required learning experiences take place.

2.6. Volition ingredients and the COM-B framework

To help conceptualize and organize the concepts and ingredients involved in volition, we can refer to a framework developed by Susan Michie and colleagues in the field of Health Psychology. According to the **COM-B framework***, voluntary behavior (B) is a function of 3 elements: Capability, Opportunity, and Motivation.[5] Capability refers to the patient's mental and physical ability to perform the behavior; opportunity to the social and physical resources required; and motivation to the drive state (either triggered automatically, or achieved with reflection) necessary to initiate and complete the action. We find this framework useful in that the clinician may indeed need to alter the recipient's capability, motivation, and/or opportunity to perform the treatment activity that will produce changes in the target. For example, when a therapist explains the importance of exercise (for motivation), instructs in the correct performance of the exercise (for capability), and discusses where and when the patient will exercise (opportunity), she is using ingredients from all 3 COM-B categories. The COM-B scheme supplies a mental or actual checklist for the clinician to ensure that s/he has thought of each aspect important to promoting volitional behavior—Does my patient know what to do, and have the skill to do it as prescribed? (Capability); Does my patient have the time, space, and physical/ social environment that affords his engaging in this activity? (Opportunity); Is my patient sufficiently motivated to follow through? (Motivation).

→ Although it is useful to consider capability, opportunity, and motivation separately, they are NOT intended to be clear-cut, orthogonal categories. Thus it is not necessary (and probably not useful) to specify what specific ingredients belong to which of the three elements underlying volitional behavior. This is because many of the ingredients that affect volitional behavior can work in multiple ways. For example, using task materials that are familiar to the patient or related to the patient's personal goals may improve performance because they are motivating to the patient, *and* because the patient already has some capability for using them; providing information to enhance capability may also have the effect of motivating the patient via increased confidence that s/he can perform; and so on.

More details, and a list of ingredients that may be used to address volitional behavior, are found in Part III.

2.7. Volition ingredients or separate targets?

Note that volition-oriented ingredients, by definition, exert effects on *representations* and *skills*, regardless of the treatment group to which the direct target of the treatment belongs. For example, a patient may need instruction (which affects representations) to carry out an Organ Functions-group muscle strengthening exercise correctly. Or, the patient's technique may need to be corrected and practiced several times to acquire the proper (skilled) form of the exercise. Does this mean that (in a supervised treatment) the clinician must specify a separate Representations target for the instructions, or a separate Skills & Habits target for the repeated practice? Largely for the sake of parsimony, the answer is no. Ingredients may be added without specifying a separate target as long as they are satisfying a *means to an end,* as

[5] Michie, S., van Stralen, M. M., & West, R. (2011). The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implement Sci, 6*, 42.

opposed to a functional goal in their own right. In the examples above, the correct performance is simply the means toward the end of having the patient doing a specific exercise to improve some aspect of organ functioning. A separate target would be specified if there is an entirely different "end." For example, if the clinician delivers a lengthy explanation about how the patient's musculoskeletal system has been altered by the disability, and what the exercise will do over time to help correct the condition, then presumably there is a target that involves changing the patient's knowledge base, for reasons (ends) apart from the performance of the exercise. Again, this rule applies to supervised treatments; as noted in a previous section, unsupervised volitional treatment activities *do* call for a separate target addressed to volition.

2.8. Targets of therapeutic devices and environmental modifications

Devices. Patients are commonly provided with therapeutic devices as part of their rehabilitation treatment.

- Some devices can achieve the intended purpose purely passively (e.g., a pressure relief cushion; an ankle foot orthosis to prevent foot drop). In these instances, the device will have a *treatment target of its own*, in the Organ Functions group.
- More commonly, however, a patient must develop the skill of using the device and/or applying it appropriately during relevant tasks (e.g., learning to use a memory notebook). In these instances, the device's therapeutic attributes are defined as *ingredients* directed toward a Skills & Habits or Representations target.
- Whether a device has its own target (Organ Functions group, passively achieved), or is an ingredient toward a Representation or Skills & Habits target, the ingredients should be defined in terms of the *relevant attributes of the device* rather than as the device itself. For example, the ability of a memory notebook to support appointment-keeping depends on the *organizational structure* of the notebook, not simply the fact that there is a binder with paper.

Environmental modifications. Some targets are met by modifying the recipient's physical environment. In these cases, we express the target as the *functional ability that is normalized or compensated*.

- In most instances, the extent of compensation is narrower than the range of functional problems resulting from the impairment itself. For example, installing a stair glide compensates for the impaired ability to ascend and descend stairs, but only in one's home, not in other environments; installing grab bars allows independent toileting in the home bathroom but not in other bathrooms.
- As in the case of devices, there may be instances where the environmental modification achieves the target passively (e.g., a person newly in a wheelchair can begin to cook independently again as soon as the kitchen cabinets are lowered within reach), and others where the patient must learn to interact with the altered environment (e.g., to practice using grab bars for transfers). Just as with devices, in the former case the environmental modification will have its own target, while in the latter, the relevant attributes of the environmental modification are ingredients directed toward a skilled performance target.

2.9. Target or aim?

It is difficult to determine whether some important rehabilitation goals can be targets or must always be considered aims. Recall the previous statement that no functional entity is, by definition, a target or aim, but that it *becomes* a target if there is a treatment with a mechanism of action capable of changing it directly, as stated in the clinician's treatment theory; otherwise it is an aim. Below we consider two areas that present challenges in this regard.

2.9a. Societal participation

Societal participation is a key concept in the ICF and the ultimate goal of many rehabilitation endeavors. Many participation[6] goals are so broad that it is very unlikely that a single treatment component could address them as a target. For example, a treatment program directed at the goal of "employment" would likely provide treatment components directed at many specific factors that might limit or enhance employment. The patient might receive skill training in specific areas that would enhance work productivity, training in job interviewing skills, instruction in the use of adaptive transportation to get to work, and many more interventions. This participation goal would therefore be an aim, addressed via multiple relevant targets.

However, the ICF authors themselves have found it difficult to draw a clear line between activity and participation, and among rehabilitation researchers there certainly is no agreement as to which ones of the hundreds of functions the ICF lists under the heading "Activities and Participation" (the d codes) fit the ICF definition of Activities, and which ones the definition of Participation. We might conceptualize a continuum from participating in very specific activities related to a societal role such as d4454 Catching, to participating in broader roles that involve many different activities, such as d9201 Sports. Accordingly, we do not rule out that some focused or specific aspects of participation might be targeted with a single treatment component. However, we maintain that broader aspects of participation are almost always approached indirectly as aims.

2.9b. Pleasure/fulfillment

In most of our discussion of rehabilitation targets, we emphasize improvements in performance, whether it be of an organ system, a skilled activity, or the learning or processing of salient information. But human beings do not exclusively seek to "get better," "do better," or "know more," but also to derive pleasure, meaning, and fulfillment from many of the activities in which they engage. Rehabilitation may legitimately be involved in helping people engage in such activities and pursuits. Does this mean that enhanced pleasure, or increased sense of fulfillment, may be specified as treatment targets? We assert that pleasure and meaning (as well as related positive effects such as increased self-confidence and feelings of mastery) should generally be considered *aims* rather than *targets*. Even when the goal of the treatment

[6] In this discussion we are referring to Participation as defined by the ICF as engagement in life roles (working, parenting, being a citizen, etc.), and NOT to "participation in therapy activities," a more generic use of the term that is covered in the Manual sections on volition targets and ingredients.

is to restore competence in an activity that previously brought much pleasure to the individual, there will be intermediate targets that need to be addressed before that pleasure is regained.

Consider the example of a patient whose "passion" is gardening. A Recreational Therapist or horticultural therapy specialist will typically not simply expose such a patient to "gardening" with the goal of inducing pleasure; this would imply that the activity is *diversional* rather than *therapeutic*. In contrast, a therapeutic approach would begin with a careful assessment as to how the patient's disability limits her preferred gardening activities, and proceed with function- or activity-oriented targets geared toward reducing or circumventing those limits, and/ or exposing the patient to new but related activities that might also provide pleasure. The same principle would hold true for the common therapeutic practices related to adapted sports. The targets refer to the learning of new athletic skills (and perhaps to the attitudes toward engaging in sports in a different way compared to pre-disability), with the hope or expectation that as mastery increases, pleasure and meaning will ensue.

A similar example concerns sexual pleasure. Rehabilitation clinicians not uncommonly counsel or train patients and/ or their partners about ways to (re-)experience pleasure through changes in positioning or technique, or use of devices. Although pleasure in this case may seem to be a more proximal outcome of treatment (hence, possibly a target), the principle is the same: the target of counseling is the *knowledge* about how to experience pleasure and the target of skill training is the improved *skills* related to attaining pleasure, rather than the pleasure itself (which, in most clinical settings, is experienced outside of the therapy session!).

2.10. Articulating the target(s) of treatment

The rules for articulating targets vary across the 3 treatment groups and are explained in more detail in Part III; some general guidelines are in order here:

→ Regardless of treatment group, the difference between targets and aims is critical to avoid inadvertently trying to specify an aim.

- A useful rule of thumb is that *targets are achievable (in principle) with one (direct) treatment component, whereas aims typically require more than one*, administered either sequentially or simultaneously.
    - For example, if achieving safe toilet transfers will involve both training the patient and a caregiver, then "safe toilet transfers" would be an aim because it requires 2 targets by definition: one articulating the change desired for the patient, the other the change desired for the caregiver. For another patient who is being trained to transfer independently, "safe toilet transfers" may be a target.

→ Also regardless of the group, consider two parts when specifying a target:

1. WHAT about patient (recipient) functioning is desired to change? This is the "subject matter" of the target, somewhat akin to identifying the functional problem—for example, "knee extensor strength," "dressing," or "understanding of the importance of exercise."

2. IN WHAT WAY should this aspect of functioning change? This characterizes the nature of the change – e.g., *increased* knee extensor strength; *faster* dressing, *more accurate* understanding of the importance of exercise.

There will be a finite list of targets for Organ Functions treatments and for Skills & Habits treatments in which 'functions' are practiced (as explained below), so that the clinician may choose them from a menu. These lists will be created with input from experts in the treatments within each group. (As yet, this "menu" has not been developed, and anyone creating a specification needs to write out the target.) However, for the Skills & Habits treatments addressed to 'activities' and for all Representation targets, the list of targets is potentially infinite (i.e., one can practice any activity, or learn about any topic). Thus the clinician must generate these targets when specifying such treatments, according to the guidelines in Part III.

2.11. Articulating treatment ingredients

Ingredients are very broadly defined as anything selected and administered, or said or done, by a clinician[7] to effect change in a treatment target. Although clinicians cannot themselves be ingredients, a very wide variety of their actions, and the results of their decisions, may be considered as such. Thus, ingredients include forms of energy, tangible objects (materials, equipment, devices) as well as verbal, written, or visual instructions, all kinds of cues and feedback, and aspects of the environment chosen or arranged to help achieve a target.

A future version of the RTSS may include structured menus of ingredients from which clinicians/ researchers may select, depending on the treatment group, the specific organ system targeted for change in the case of Organ Functions, etc. These menus have not been developed as of this writing, so the specifier must select and articulate *all* of the ingredients that are known or hypothesized to have an effect on each target, according to the treatment theory. Such ingredients may include a wide variety of tangible objects, or their attributes; chemicals, as in medications, as well as routes of administration; types and sources of energy and modalities for administering it to specific tissues; and, of course, the ingredients used to support learning and volitional behavior (via capability, opportunity, and motivation), including any *actions* selected by the clinician for the patient to practice. Further guidance as to the types of ingredients to consider for each treatment group is provided in Part III. Below, we discuss some important considerations that cut across treatment groups.

2.11a. Dosing parameters

Many ingredients are simply present or absent, or may vary by type. For example, one may choose to administer feedback, or not to do so; and if feedback is used, one may select a modality by which it will be delivered, e.g., visual or verbal. However, other ingredients vary *quantitatively;* we call these **dosing parameters***. These quantitative ingredients must be expressed in ways that reflect the amounts, frequencies, or other theoretically important quantities that are intended to effect changes in the target. The metrics used and the degree of

[7] If a clinician orders or suggests to another clinician to do something for or with the patient, only the activities of the second clinician need be considered, as the behavior of the first clinician does not affect the patient *directly*.

precision will necessarily vary from one ingredient to another. For example, the speed and incline of a treadmill can be measured on an interval scale, but a cast may need to be described with reference to an ordinal scale – e.g., "moderate tension." It might also be necessary to specify dosing parameters with respect to the "settings" on an identified delivery vehicle for (e.g.) administering heat or electrical energy. Future research can help clarify the amounts of active ingredients delivered by these different vehicles and parameter settings by measuring variations in treatment progress.

In general, *duration* should be avoided as a dosage parameter except where the length of time the patient is exposed to the ingredient is directly relevant to the treatment theory. For example, when applying heat energy to increase tissue elasticity, a certain amount of time may be required to allow sufficient heating. In contrast, duration should not be used as a surrogate for a more informative description of the amount of exposure. For example, one might choose a longer or a shorter counseling session, depending on the patient or the complexity of the issue being discussed. But in literal terms, specifying a longer counseling session without specifying any other differences in the ingredients could mean that the therapist spoke more slowly or allowed longer pauses. It is more likely that the relevant ingredients in the longer session would be the additional topics covered, or perhaps the repetition of topics.

Dosing parameters may be static, or may specify a pattern of changing dose over time. These changes could include varying schedules of practice/ reinforcement or numeric criteria for progressing the demands of treatment (and by what quantity those demands should be increased; see section 2.14). Sometimes, dosing parameters may vary according to patient performance, e.g., the number of cues delivered may depend on the number required in a given session. Although one cannot specify *a priori* the exact amount of those ingredients to be provided during each episode of treatment, or each repetition of a skill, one can specify the *rules* that determine the frequency or schedule of their delivery. For example, one's treatment theory might predict that intermittent error feedback would lead to the fastest progress in an activity and therefore, the clinician might specify delivery of error feedback after every 3 – 5 trials.

It should be noted that some ingredients, although they are technically not considered dosing parameters, contain features that could vary in a quantitative fashion. Goal setting is an example of such an ingredient. Most of the decisions surrounding goal setting are categorical ones: whether or not to use it at all, what type of goal should be introduced, whether it should be self-set, clinician-set, or negotiated, etc. However, there may also be theoretically important distinctions between, for example, challenging a patient to *meet* versus *increase by half* versus *double* her performance on a measurable activity. Although we have not created a separate category for such "hybrid" ingredients, complete specification of ingredients requires that the clinician consider whether there are relevant quantities embedded in categorical ingredients, and define these to the extent possible.

2.11b. "Common factors" as ingredients present in clinical environments

"Common factors" is a term used in clinical psychology to refer to ingredients of interpersonal therapies that are thought to help effect changes in emotional states and behavior, regardless of the "specific factors" included in a clinician's theoretical orientation

(e.g., psychodynamic versus behavioral). In the practice of rehabilitation, the majority of treatments are interpersonal in nature; thus, common factors may be important in effecting change in patient functioning. Common factors include the warmth and empathy of the clinician, as well as other personal qualities that promote trust and liking. Such qualities may enhance patient change by making the patient more willing to discuss uncomfortable topics or try potentially difficult activities. A patient may pay closer attention to, or simply "work harder" to please a clinician who is liked and trusted. Common factors have been advocated for universal use as "therapeutic best practices." That is, we don't typically ask whether we should be warm and understanding in this treatment session or with this patient. Rather, we think we should be warm and understanding all the time, unless there is a good reason not to be.

Similar considerations apply to the treatment environment in rehabilitation. We think that in general, the environment should be clean and well organized, sufficiently quiet that the patient can hear our directions and pay attention to them, and brightly enough lit so that the patient can see the necessary task materials.

The universal acceptance of these personal and environmental factors as "positive" has implications for treatment specification. It would be clerically onerous to list them all as individual ingredients for every treatment. We propose that these ingredients should be specified *when they will be administered at either a greater or lesser extent than in common clinical practice, according to a specific treatment theory.* Although this will be relatively rare, some examples of this might include specifying that:

- Certain clinician behaviors expressive of warmth or affection might need to be avoided when treating victims of sexual abuse;
- Certain social conventions such as eye contact or maintenance of personal space might need to be altered to enhance the comfort of patients from certain cultural backgrounds;
- Individuals with photophobia might need to receive treatment (either passive or volitional) in a dim environment.
- An unusually distracting environment might be desired for a patient who needs to practice strategies for "tuning out" such distractions.

→ Aside from the above considerations about deliberate deviations from "optimal" environments for treatment, there are times when the treatment theory holds that better results will be forthcoming if treatment takes place in a specific environment, which makes the use of that environment an *ingredient*. For instance, patients who are very distractible often are treated in a quiet room; it is hard to teach cooking skills outside of a kitchen; a patient who is to perform cognition-based exercises at home may be instructed to turn off the radio, television and other sources of distraction. When some aspect of the environment is important to the treatment theory, it should be specified as an ingredient.

Specification of the environment as an ingredient is also important for *generalization* of certain treatment effects across physical, cognitive, or social variations: for example, walking on even, then uneven surfaces or working in a quiet, then more distracting milieu (i.e., *progression* in the demands imposed by the environment).

2.12. Can one ingredient have different mechanisms of action, depending on its use?

There are instances where one ingredient may have different mechanisms of action, as is sometimes the case with medications. For example, aspirin has both analgesic effects and anti-clotting effects, and these effects occur via different mechanisms. It remains to be seen, however, whether the same can hold true for ingredients other than pre-formulated and non-adaptable substances such as medications. In most rehabilitation treatments, when ingredients appear to have multiple mechanisms of action, they may turn out not to be ingredients at all but rather devices or other vehicles that may be used to deliver different ingredients or quantities thereof. Consider these examples:

→ A suspension harness might be used for partial body weight supported gait training, and also as a security precaution during balance training with dynamic balance challenges. Although it is "the same" harness, for the former use it would likely be set to deliver a specific amount of off-loading of weight. In the latter instance, it might be set with some slack so that it provided support only if the patient started to fall. Thus the amount of upward tension (the ingredient delivered by the harness) would differ in these two uses, making it two different ingredients.

→ Similarly, we might provide "the same" memory notebook to help ensure that appointments are kept and to allow review of homework assignments from school. Although the notebook may be physically the same, the organization of the appointment section and note-taking section would likely differ, along with the behaviors that the patient is taught to associate with them (i.e., reviewing upcoming appointments for the day in the morning, vs. reviewing homework assignments from the day in the evening). For the purposes of treatment specification, it is the ingredients themselves, rather than the delivery vehicle, that should be specified.

2.13. Can assessment be an ingredient?

We have noted that the RTSS excludes clinical assessment, focusing exclusively on specification of the interventions used in rehabilitation. Yet there are at least two ways in which assessment overlaps with the selection and administration of treatment ingredients:

1. In rehabilitation, ongoing assessment is almost always part of intervention, in that clinicians constantly evaluate the effects of their interventions and make adjustments in dose or treatment approach based on those assessments. It is helpful, however, to consider the different kinds of assessments and adjustments made during the course of treatment:

   a. In treatments involving progression (see section 2.14), assessment of the factors that will determine progression (e.g., how many weight lifting repetitions the patient could perform today) is built into the treatment specification in advance.

   b. A closely related form of assessment monitors performance success and might lead the clinician to adjust the level of demand upward or downward to achieve "just the right level" of challenge.

   In both of these instances, however, the clinician can state in advance how she would modify the treatment intensity or demand based on the assessment results. In other cases, however, the clinician selects a treatment approach but is prepared to

change it if it doesn't produce the desired result or if the patient objects. In these instances, reassessment leads to a new decision about a new treatment. In summary,

→ Where modifications in ingredients or dose of ingredients in response to patient performance can be predicted in advance, these should be included in the specification. However, clinicians need not specify *all* the possible alternative treatments they might employ if the current treatment is not working, nor all of the kinds of observations that might lead them to change treatments. We recognize that not all treatments are successful and that even treatments that are well specified in advance may need to be changed.

→ Specification of how ingredients will be tailored to patient performance should be articulated in a rule-based manner even though the exact amount and timing of those ingredients may not be known in advance. For example, how to handle errors in task performance may constitute an important ingredient defining errorless learning vs. discovery learning; the general response to error may be specified even if the specific quantity or quality of errors cannot be. Similarly, the rules for progressing resistance exercises can be stated even though one may not know how many sessions it will take until the patient is ready to be progressed.

2. Treatment episodes sometimes include discussions in which the clinician wishes to gather information that may not have been obtained during a formal pre-treatment assessment. For example, as noted earlier, the clinician may ask about preferred activities or details of home responsibilities in order to select or design tasks that are meaningful to the patient, or conduct an interview to ascertain a patient's prior experience with and attitudes toward compensatory memory strategies before recommending one.

→Whether or not one needs to specify ingredients for this type of assessment activity depends on the clinician's treatment theory. Would any source of this information (e.g., asking the patient's spouse) do the trick? Or is it hypothesized to be therapeutically important for this patient or for patients in general to participate in this kind of assessment, e.g., to help them establish a "big picture" of their experience and select activities of most importance to them? If so, then the 'assessment' component should be specified as a part of the treatment, with ingredients (and a separate target, if warranted) reflecting some aspect of motivation for treatment or understanding of deficits.

2.14. Progression

The term *progression* has several meanings. In a clinical sense, it can refer simply to a patient's functional improvement or progress in treatment; this improvement may be due to treatment, spontaneous healing/ recovery, or both. In the RTSS, we use *progression* to refer to situations in which ingredients are changed *systematically* over time *in response to patient improvement*, so as to facilitate further improvement by increasing the cognitive or physical demands of the activity. For example, the angle of a cast may be changed at each application as the soft tissues elongate; or the amount of weight to be lifted may be increased as the patient is able to perform more repetitions of the prior weight; or the speed of incoming stimuli may be

increased at a predetermined rate as accuracy of responses to speeded stimuli improves. In these instances, the exact timing of the progression will not be known in advance, but it is still possible to specify *a priori* the rules of progression that guide treatment. In the RTSS, this is the crucial distinction between changes in treatment ingredients simply due to patient improvement—for example, a therapist may administer fewer cues as patients improve and need fewer cues—and progression of treatment, which uses pre-specified criteria for advancing the demands of treatment consequent to patient improvement. In supervising practice opportunities, clinicians often provide "only the necessary assistance" to complete a task. However, without planned progression in task difficulty, the patient's reduced need for assistance may be the result of recovery rather than the dosing parameters used in treatment.

In the above examples, the progression rules may be specified as quantifiable changes in ingredients, i.e., dosing parameters. In other cases progression is not strictly quantitative, but "ordinal": the clinician may require the patient to show competence in preparing a simple cold meal before proceeding to a hot meal consisting of several dishes, or demonstrate mastery of basic information prior to learning more complicated material. In the paragraphs below are some notes on how progression should be specified in the different treatment groups.

Organ Functions group progression. Many treatments in this group include progression of ingredients as a *necessary part of the mechanism of action*. That is, the only way for muscles to become stronger is to be confronted with gradually more resistance to contraction; the only way to improve endurance is to gradually increase the demands on the cardiovascular system. With systematic progression, which is typically a specified change in quantifiable ingredients, the level of challenge to the organ system remains roughly the same as its function improves, which helps to invoke further improvement in function.

Skills & Habits group progression. Progression in this group tends to vary according to whether the skill is **'function-like'*** or **'activity-like.'*** The former are more likely to resemble Organ Functions in their response to quantifiable changes along a single dimension. For example, to address a target involving improvement in finger dexterity, i.e., *"control of voluntary manual movements (fine)"* through repeated practice, one might have the patient begin by practicing picking up large objects and progress to smaller and smaller ones over time. On the 'activity-like' side, performance may be shaped by increasing the demands of the activity in various ways, but this progression may need to be specified in ordinal rather than interval terms.

Representations group progression. Progression in this group may span a continuum from simple / basic to complex / detailed/ specialized information; or from emotionally neutral content to more sensitive content. Specification of progression is most likely to be ordinal in nature.

→ Regardless of the treatment group involved, and whether progression occurs within a treatment session or across multiple treatment sessions, progression should be specified by (a) the criterion that determines the starting level of demand, (b) the criterion that determines when the challenge should be increased in response to improvement in performance, and (c) the amount by which the demand should change when that criterion is reached.

→ Progression need be specified only when it is relevant to improvement in patient functioning. As noted above, progression is a necessary component of the treatment theory for

certain Organ Functions treatments. In contrast, it is not necessary (for example) for a patient to master the preparation of toast before making spaghetti and meatballs. But if the treatment theory includes a hypothesis about the effects of the order with which meals at various levels of complexity are prepared, then it should be specified as a progression rule.

III. SPECIFYING TREATMENTS

Specifying a treatment component is a multi-step process, with each step involving a question(s) to be answered and key decision(s) to be made. Below we itemize the steps in the general order in which they should be followed.

Since this sequence must be followed for each treatment component, an important preliminary step is determining the number of different treatment components you wish to specify. In making this decision, consider the following questions:

- Is there an unsupervised component to the treatment, i.e., is the treating clinician unable to verify directly that a treatment activity has been performed accurately? If yes, there must be a volition target in addition to a direct target.

For the direct target,

- Is the function of an organ or organ system being changed or replaced? If so, there must be at least one treatment component with an Organ Functions target.
- Is a skill being improved or made less effortful or more habitual? If so, there must be at least one treatment component with a Skills & Habits target.
- Is information being processed in order to change knowledge, attitudes, motivation, or propensity to act? If so, there will be at least one treatment component with a Representations target.
- Might there be more than one Organ Functions treatment component, more than one Skills & Habits treatment component, or more than one Representations treatment component? Consider whether there is more than one treatment recipient involved; whether more than one organ function is being changed or replaced; whether specific subskills need to be specified separately, or whether distinct changes in knowledge or attitudes should be separately specified.

→ It's important to note that the stepwise procedure described below does *not* always follow in a simple sequence. For example, the text below proceeds from identifying targets, to specifying the ingredients that are hypothesized to be active for each. However, thinking about ingredients may prompt the specifier to realize that, e.g., additional targets may be needed for some of the planned ingredients. Thus, it is more realistic to think of specification as an iterative process rather than a linear one.

→ *The steps of treatment specification are summarized graphically in a flow chart contained in Appendix A. Appendix B includes treatment vignettes with sample specifications of their targets and ingredients, as well as explanations for why the target and ingredients were specified as they are.*

Step 1: SPECIFYING THE RECIPIENT OF TREATMENT

- In most cases, the treatment recipient is the patient.
    - Patients may be administered treatment components from any of the groups (Organ Functions, Skills & Habits, Representations).
- The treatment recipient may be a family member, caregiver, employer, or any other lay person, if the focus is on functional changes within those people (e.g., changes in knowledge, attitudes, skills, or behaviors) that may support the patient. *[Note that in this case, improved functioning of the patient/client is not the target, but an aim.]*
    - Treatment components administered to recipients other than the patient are *always* within Skills & Habits and/ or Representations. For example, recipients other than the patient may require new skills to care for the patient; or improved knowledge/ changed attitudes to accommodate the patient in workplaces or other settings.
- If there is more than one treatment recipient, each recipient must still have (at least) one separate treatment target. For example, if a group of patients is engaged in the same activity, there is at least one separate treatment target for each; if a patient and her caregiver are receiving the same educational material at the same time, there is at least one separate target for each recipient.
- A clinician *cannot* be a recipient of treatment, even in the case, for example, where one clinician advises or trains another on how to treat a specific patient. Although there is a formal similarity between this situation and the one in which a family member is trained on how to interact with a patient, we adhere to this rule because:
    - There are many sources of a treating clinician's behavior aside from the advice or training of another clinician, leading to lack of clarity as to precisely what parts of any "treatment" would arise from a specific training episode; and
    - We could fall into an infinite regress if we tried to track back to the source of treatment advice, given that an advising clinician herself has had prior advice from others, who have had prior training from others, etc., etc.
- The environment is never a treatment recipient. As noted earlier, changes to the environment may be specified as ingredients for functional changes expected in a human recipient that are made possible by those environmental changes.
- Similarly, an animal (e.g., a service dog) is never a treatment recipient. Training an animal (prior to providing it to the patient) is not treatment. Training the patient to care for and give commands to the animal is treatment, which would fall into the Skills & Habits group.

Step 2: DECIDING ON THE DIRECT TARGET

- Decide *what specific, direct change in the recipient's functioning you want to make* in this treatment component.

- Make sure your treatment theory allows for you to expect this change as a target (measurable in principle, and achievable with this treatment) as opposed to an aim (a more distal or downstream effect that may result from the change in a target).
- If the target will not be *directly* affected by the ingredients you plan to use, you should look for a more proximal target that is directly changed by the planned treatment ingredients.
- This distinction is particularly important in the case where your intervention involves instructing, motivating, etc. for a *later* behavioral change, as with Representation treatment components through which patients are encouraged to adopt various attitudinal changes. Unless you hypothesize that those behavioral changes will ensue as a direct consequence of the ingredients provided, a more proximal target (e.g., in knowledge or attitude) may be necessary.
- In the case of specifying Skills & Habits targets, decide how general the hypothesized change will be. For example, if the patient repeatedly practices dressing in loose sweat clothes, the target might be framed as "independent dressing in sweat clothes", whereas if practice involves many different kinds of clothing, the target might be framed as "independent dressing in chosen clothing."

Step 3: DETERMINING WHAT TREATMENT GROUP THE DIRECT TARGET IS IN

Ask: IS VOLITION (ON THE PART OF THE RECIPIENT) ALWAYS NECESSARY FOR THE CHANGE TO OCCUR?

NO→ Your direct target is a passive treatment target (which includes passive device targets), from the Organ Functions group. *Skip to Step 5.*

YES→ Your direct target could be in Organ Functions, Skills & Habits, or Representations. Determine whether your desired change involves:

- Changing the function of an organ/ organ system via volitional activity
- Changing the performance of a skill, at either the level of function (e.g., *"involuntary movement reaction functions"* (dynamic balance) or at the level of activity (e.g., *"putting on clothes"*), or developing or altering habits (e.g., *"routine use of memory notebook in appropriate settings"*)
- Changing internal representations to affect knowledge, attitudes, beliefs, motivation, or propensity to act, or to elicit performance of specified, time-limited actions[8]

Example treatment targets and groups are shown in Table 6.

[8] The term "time-limited" is used simply to draw a distinction between actions that can result from the transmission of instructional or motivational messages alone (Representation interventions) and those requiring practice for increased skill or automaticity (Skills & Habits interventions).

Table 6. Determining the appropriate treatment group for a target.			
Treatment Scenario	**Desired Change**	**Change involves:**	**Group**
Patient performs triceps extensions with cuff weight	Increase in force production capacity of elbow extensor muscles	Change in function of organ system (musculoskeletal)	Organ Functions
Patient practices performing transfer from wheelchair to bed without assistance from a caregiver	Increased independence in performance of transfer board transfers	Change in performance of a skill	Skills & Habits
Patient, who uses wheelchair exclusively, and clinician discuss implications of not shifting weight regularly	Increased propensity to conduct weight-shifting activities as recommended	Change in mental representations underlying volition	Representations

Step 4: DETERMINING WHETHER A VOLITION TARGET IS ALSO REQUIRED

ASK: If the treatment is volitional, is the treatment activity that carries the active ingredients for the direct target being performed away from the supervision of the clinician? In other words, is there no way for the clinician to verify directly that the activity has been performed as prescribed?

YES→ Then a volition target must be specified, addressing the volitional behavior required for achieving the direct target.

NO→ Only the direct target needs to be specified.

Step 5: ARTICULATING THE DIRECT TARGET

ORGAN FUNCTIONS TARGETS

Ingredients directed at changing organ functions typically launch a sequence of causal events that constitute an underlying mechanism of action and end in a change in output dynamics or function of the organ system. In this sequence of events, it can be challenging to decide where the mechanism of action ends and the target begins. For example, a cochlear prosthesis (ingredient) can stimulate the cochlear nerve and neurons in the auditory cortex, upon which the patient hears sound. Is the target the neuronal firing, or the perception of sound? Similarly, lifting weights (ingredient) leads to calcium release, leading in turn to increased muscle torque around a joint. Is calcium release the target? Or is this calcium release part of the mechanism of action for the target of increased torque?

To help identify the target when there is such a tightly linked sequence of events from the application of ingredients to changes in the target,

1. Consider the sequence of causal events hypothesized (in your treatment theory) to be launched by the treatment ingredients (e.g., repeated lifting of a weight)
2. Identify the *first* (most proximal) function that is a link in the chain; this may be the target (e.g., increased muscle torque around a joint – "muscle power functions" – rather than increased calcium release; perception of sound – "sound detection" – rather than neuronal firing).
3. Test this potential target:
    a. Does the treatment include ingredients with a mechanism of action that acts on this target?
        i. YES→ proceed with this target.
        ii. NO→ the potential target is probably an aim; search for a more proximal target.
    b. Are the treatment ingredients you plan to use hypothesized to be *sufficient* to improve this aspect of functioning *in most patients/ under ordinary circumstances?*
        i. YES→ proceed with that target.
        ii. NO→ are there other targets that in all/many patients will also need to be achieved in order to improve this aspect of functioning? The potential target is probably an aim; search for a more proximal target.

Organ Functions targets. "What" is intended for change in this treatment group will be selected from a finite menu derived from the ICF Body Functions classification. At the present time, this menu has not been compiled but, in the long term, we envision a process in which researchers and clinicians familiar with specific treatment domains develop standard target menus through a process of examining known treatments and reaching consensus on the functional entity that they target. In the current manual draft, we provide only illustrative examples of such menu entries (e.g., muscle strength, joint ROM, arousal level), and individuals wishing to specify Organ Functions treatments in the interim will need to select content from among the sometimes closely related available ICF codes or formulate their own category.

"In what way" Organ Functions targets may change include the following:

- Increased or up-regulated output of organ/ organ system
- Decreased or down-regulated output of organ/ organ system
- Reduced variability in output of organ/ organ system
- Substitution or replacement of organ/ organ system (we include here anatomical entities, such as an arm, that anatomists do not call a "system")
- Prevention of deterioration in normal or optimal output/ function of organ/ organ system (in cases where pathology or outside circumstances threaten to reduce function)

→ Note that many, if not all, organ function *replacement* treatments are imperfect or incomplete. For example,

- Most below knee prostheses restore weight bearing, dependent on "*stability of several joints*" and "*gait pattern functions*" on level ground, but may not allow heel raising or jumping, which is dependent on *"power of isolated muscles and muscle groups of the leg (plantar flexors)."*
- Where this is a matter of degree, it poses no specific challenge since in the case where there is no replacement, Organ Functions targets are written as "increased" or "decreased", not as "normalized." For example, a cochlear implant may have a target of "increased speech discrimination," even though it may not allow normal discrimination.
- However, in other cases, an organ system may normally perform qualitatively different functions (as in the lower limb example above), which creates greater challenges for how the replacement target should be named. Moreover, in some instances the empirical efficacy of such a treatment will depend on the specific functions that are chosen as outcomes.
- We propose that the specifics of how to name organ function replacement targets be determined through a consensus process involving treatment experts in particular domains, as described above. In the interim, depending on the specific replacement strategy, it may be more parsimonious in some cases to say, "replaced functions of X organ except for Y function(s)," whereas in other cases, where the number of replaced functions is less complete, "replaced Y function(s) of X organ" may be more appropriate.

SKILLS & HABITS TARGETS

Skills & Habits group treatments are roughly divided into 2 types: 'function-like' and 'activity-like.' We do not separate these into 2 *distinct* groups because the mechanism of action is the same: *learning by doing*. However, specifying targets is a different process for the two types because there is a finite list of contents for 'function-like' Skills & Habits targets whereas the contents of 'activity-like' Skills & Habits targets are potentially infinite.

- 'Function-like' skills are those such as *"involuntary movement reaction functions"* (dynamic balance), *"coordination of voluntary movements (fine)"* (dexterity), *"shifting attention (spatial)"* (spatial attention), *"memory functions, other specified (working memory)"* (working memory), etc., in which the treatment theory predicts implicit learning through repetition, typically with progression to maintain a consistent level of challenge as performance improves.
    - Conceptualizing these skills as 'function-like' implies that the treatment theory predicts general improvement with practice, which improvement will extend to a number of different activities where that function is deployed. That is, a set of exercises that is claimed to target *"involuntary movement reaction functions"* (dynamic balance), would be predicted to improve many activities requiring that function, whereas a treatment that is claimed to "improve the ability to stand while preparing a meal" (an activity), need not improve balance in other activities. Similarly, if attention or working memory exercises are administered

under the theory that such exercises will improve those mental functions in a general way, then the target should be specified as such.

- 'Activity-like' skills are those such as ADLs (dressing, bathing, grooming, cooking), job-related skills, walking with devices, etc., in which the treatment theory typically predicts a need for explicit learning in addition to any implicit learning that may promote automaticity through practice. These skills also include the instances in which a Skills & Habits target is added to an Organ Functions target to ensure the proper (skillful) performance of an action sequence, such as an exercise that has been prescribed to improve the function of an organ system and which the recipient needs to learn how to do.
    - Training in these skills often involves incorporation of internal and/ or external strategies / devices to enhance performance.
    - In contrast to many therapeutic tasks chosen for practicing 'function-like' skills, most treatments for training 'activity-like skills' make use of practice in the actual activities the patient must perform in daily life, and the typical treatment theory predicts task-specific improvements. For example, increased speed of dressing will ordinarily not be expected to generalize to speed of performing a work task, as the speed-enhancing strategies might be quite different for the 2 activities.
    - The clinician training 'activity-like' skills should specify the breadth of generalization claimed by the treatment theory and the ingredients selected to achieve it, as described in more detail below.

Skills & Habits targets. The "what will change," for function-like skills, may be selected from the menu of ICF Body Functions. As with the Organ Functions target contents, we envision treatment experts defining a finite set of such functions that are addressed through repetitive practice (although we do not have this menu compiled).

For activity-like skills, "what will change" must be specified per case, using the following considerations to articulate the type and scope of change expected in the target skill:

1. If there are *steps or components of the trained activity that play out over time*, consider whether improvement in the *entire* activity is a single treatment target, or whether there are *sub-skills* that should be identified as individual targets.
    a. In general, the target should be framed as the largest "chunk" of the skill that is practiced together on the same schedule.
        i. Thus, if the skilled activity is practiced in toto, the target will typically refer to the entire skill.
        ii. If a sub-skill of a routine requires intensive practice (e.g., learning how to write in and retrieve information from a memory notebook and subsequently learning to use it to allow more independent shopping), that sub-skill should be identified as a separate target.
        iii. Similarly, if mastering a skilled activity requires a significantly different practice schedule addressed to a single element *within* the activity (e.g., if a patient has repeated difficulty buttoning during dressing and the

therapist interrupts "dressing" training to do multiple trials of "buttoning practice"), this also should prompt specification of a separate target.

iv. Note that subskill targets may be identified either in advance (e.g., if the clinician anticipates that some element of the routine will require intensive practice) or post-hoc, as when a patient demonstrates difficulty with some element of the task that then needs to be trained separately.

2. Also consider the *breadth of target generalization* the treatment is hypothesized to achieve. In contrast to treatments for 'function-like' skills, which typically have treatment theories that predict generalization, the treatment theories underlying treatments to improve *activities* with repeated practice tend to predict *task specificity*. Therefore, the target should specify whether the hypothesized improvement encompasses a narrow scope ("more independent donning of sweat pants") or a broader one ("more independent donning of a variety of pants with different closures."). Any generalization described in specifying the contents of the target is likely to be matched by ingredients that promote generalization, e.g.:
    a. Practicing the skill in varied social/ physical environments (e.g., using anger management techniques in the clinic and in a crowded store; ambulating on different surfaces)
    b. Using a variety of task-specific ingredients (e.g., dressing with various types of clothing, preparing hot and cold meals)
    c. Practicing under conditions with varied cognitive and/ or physical demands such as distraction, time pressure, etc.
    d. Any target that involves changing the patient's/ client's performance in the "real world" (e.g., home or community) must have associated ingredients that are hypothesized to act on performance in that setting. These ingredients may involve clinician-supervised training in the outside setting; assigning "homework" practice in that setting; mocking up attributes of that setting within the clinic; etc.

"In what way" Skills & Habits targets may change should be selected from the following menu:

- Improved accuracy of performance:
    - Fewer errors
    - Maintenance of accuracy while requiring less help (= greater independence)
    - Performing in correct sequence
    - Performing in keeping with social/ physical/ temporal context
    - Improved aesthetics/ appearance
- Changed speed of performance
    - Increased or decreased speed
- Increased automaticity of performance
    - Decreased effort/ increased ability to combine with other tasks
    - Formation of habit
- Prevention of deterioration in normal or optimal performance of skills or habits (in cases where pathology or outside circumstances threaten to impair performance)

REPRESENTATION TARGETS

As with the 'activity-like' Skills & Habits targets, the "what will change" of Representation targets is nearly infinite and must therefore be specified by the clinician, using similar considerations as to the scope of the predicted change.

- *Knowledge-focused* Representation targets should be specified by the *domain* of the knowledge imparted (e.g., "knowledge of diagnosis and its near- and long-term effects;" "knowledge of risk factors associated with x"), but need not enumerate the details of that knowledge.
    - The success of a treatment intended to improve amount or accuracy of knowledge could be measured, in principle, using a written quiz, verbal questioning, or demonstration of "how-to" knowledge. However, the statement of the target does not need to specify *how* it will be measured.
- *Attitude-focused* Representation targets may be specified by describing briefly the topic about which one desires the change (e.g., "attitude toward smoking.").
- *Action-focused* Representations targets are volition targets, which are specified with a brief description of the assigned action.
    - In some cases, these targets are paired with a direct target. For example, the target of "performance of object naming exercises as directed" would accompany a direct target such as "improved accuracy of object naming."
    - In other cases, there is no associated direct target. For example, an assignment to "Set up a baby-changing station on your first floor" might have an *aim* of improved energy conservation or reduced fatigue, but stands alone as a volition target addressed simply to completing the assignment.

The *"in what way"* Representation targets may be changed should be selected from the following menu:

- Enhanced knowledge
    - Increased amount
    - Improved accuracy
- Modified internal representations or drive states that affect propensity to act
    - Modified beliefs and values
    - Enhanced motivation
    - Modified attitudes:
        - Increased positive attitude toward (…)
        - Decreased negative attitude toward (…)

→ Note that beliefs and attitudes may refer to external or factual material and/ or emotionally salient material, such as modified beliefs/ attitudes about self.

- Performance as directed (for assigned actions)
- Prevention of deterioration in normal or optimal quality or quantity of internal representations (in cases where pathology or outside circumstances threaten to degrade representations)

Step 6: ARTICULATING THE VOLITION TARGET (IF NEEDED)

The "what will change" for a volition target is that the treatment recipient will *enact a behavior that sets in motion the mechanism(s) of action of ingredients addressing the direct target*. Thus, *"in what way"* volition targets may be met is simply "performance as directed." Of course, each volition target will have different details (e.g., schedule, intensity, etc.) defining what is meant by "as directed." Those details will be found in the list of ingredients specified for the direct target.

Step 7: SPECIFYING THE INGREDIENTS

Regardless of the target/ treatment group for which one is specifying ingredients,

→ remember to specify even "obvious" ingredients that are active according to the treatment theory;

→ remember to specify aspects of the *environment* that are active according to the treatment theory;

→ remember to specify any relevant changes or deviations with regard to the "common factors" typical of good clinical practice.

ORGAN FUNCTIONS INGREDIENTS

The predominant ingredients in Organ Functions treatments are biologically active chemicals and forms of energy delivered to different tissues. These range from mechanical forces used to stretch tissues, break up adhesions, and strengthen muscles, to chemical interactions with cellular receptors, to electrical stimulation to nerves and brain tissue, to thermal energy delivered superficially or deep. Organ systems differ in terms of the kinds of physical and chemical stimuli they respond to, so treatment ingredients tend to be associated with specific organ systems. We propose to engage groups of treatment experts, as discussed previously, to standardize the ways in which particular physical agents are described. In principle, however, each can be described by:

- Ingredients such as heat added to mechanical stretch, padding added to a cast to prevent skin breakdown, etc.
- Ingredients that define how the necessary agent or form of energy will be delivered, if important to the treatment theory: e.g., serial casting, dynamic splinting, or prolonged manual stretch as delivery vehicles for prolonged tension on soft tissues around the joint
- AT/ devices/ implants / orthotics/ prosthetics
- For volitional treatments, VOLITION INGREDIENTS must be specified
- DOSING PARAMETERS, if any

SKILLS & HABITS INGREDIENTS

- These ingredients should include the action or activity the patient is to perform during practice or habit development, the schedule of performance, as well as other theoretically important objects and materials selected for the treatment, e.g., personally relevant materials, or systematic variations in objects/ contexts/ environments to promote generalization.
- VOLITION INGREDIENTS selected from the list below (see Representations ingredients), as all treatments in this group are volitional.
- DOSING PARAMETERS should be specified for all ingredients with a quantitative component (e.g., number of practice trials; % correct criterion for advancement/ progression; etc.), in either interval or ordinal terms.

REPRESENTATIONS INGREDIENTS

- The essential informational content of the treatment should be specified to the extent possible. However, the precision with which this can be done will depend both on the manner of delivery of the treatment and on how much is known about the treatment recipient. Primarily "one-way" forms of information delivery, as in traditional in-person or written education, can be precisely specified as the key "bullet points" contained within the material, much like the learning objectives required for continuing education. However, more interactive forms of education and counseling may have key topics pre-specified, but clinicians will go into more or less detail on each topic depending on the patient's apparent understanding.
    - As in the Skills and Habits group, ingredients may also be materials selected because they are preferred by or relevant to specific patients.
- Ingredients in this group also include a variety of clinician-administered methods to enhance both the acquisition and processing of information and the effects of information on volitional action.
    - We call these VOLITION INGREDIENTS; note that these ingredients may apply to *any* volitional treatment in any of the 3 groups. Volition ingredients are presented below in an outlined list. The organization of this list is subject to change as we discover ways of making the specification of such ingredients more user-friendly. There are many potential ways to group these ingredients, and we acknowledge that the subdivisions in the outline below are by no means mutually exclusive. (For example, feedback may be reinforcing, i.e., effort-enhancing, in addition to serving the function of correcting the performance of an action.)
- DOSING PARAMETERS are often N/A in Representation treatments because the specific pieces of information to be transmitted are already specified, and/or because the variations in manner of presentation (e.g. didactic, Socratic) are categorical in nature.

Where there are plans for repetition, this should be specified and if repetition will continue until comprehension is achieved, one may specify delivery "as needed."

INGREDIENTS TO PREVENT ADVERSE EVENTS

The guidelines above focus on treatment ingredients intended to change the selected treatment target. However, many treatments bring with them the possibility of adverse events. These risks of adverse events may be present for most or all patients (e.g., the risk of skin break down during casting), or may be specific to a known risk in an individual patient (e.g., a particular risk of skin breakdown around an anatomical deformity). Where a clinician plans to include ingredients to minimize the risk of some adverse events either routinely or for a specific patient, these should be included in the list of specified treatment ingredients (e.g., padding substances and where they should be placed during casting). However, it is not necessary to specify a separate treatment target for every potential adverse event being prevented. An inevitable consequence of this rule is that one may find ingredients listed for a treatment that do not have a mechanism of action related to the treatment target (i.e., padding materials do not increase range of motion). For the sake of practicality, however, we view this as preferable to listing all the possible things that could go wrong as separate "prevention targets."

VOLITION INGREDIENTS

For non-volitional (passive) treatments, the clinician must add volition ingredients where volitional behavior is needed to permit administration of active ingredients addressing the target, such that the mechanism of action can be effective. These ingredients may be planned or post-hoc:

- For example, passive ranging of a joint may be impeded by the patient's tensing of the muscles involved, due to pain or anxiety. In this case, the clinician may need to add ingredients that provide reassurance or facilitate muscle relaxation.
- Similarly, overt non-cooperation with any passive treatment may need to be addressed using ingredients relevant to motivation or knowledge of the need for treatment.

For volitional treatments, volition ingredients must be added to the direct target (in *pro forma* or more elaborated fashion) OR used to address a separate volition target in cases where this is required (see section 2.5).

Volition ingredients include but are not limited to the following:

1. Knowledge/ performance-enhancing methods
    a. Provision of instructions or guidance (cues) using:
        i. Single or combination modalities (verbal, visual, hand-over-hand, physical assist)
        ii. Specialized sequence training methods, e.g., forward/ backward chaining; whether training sequence is invariant
        iii. Provision vs. deliberate withholding of cues

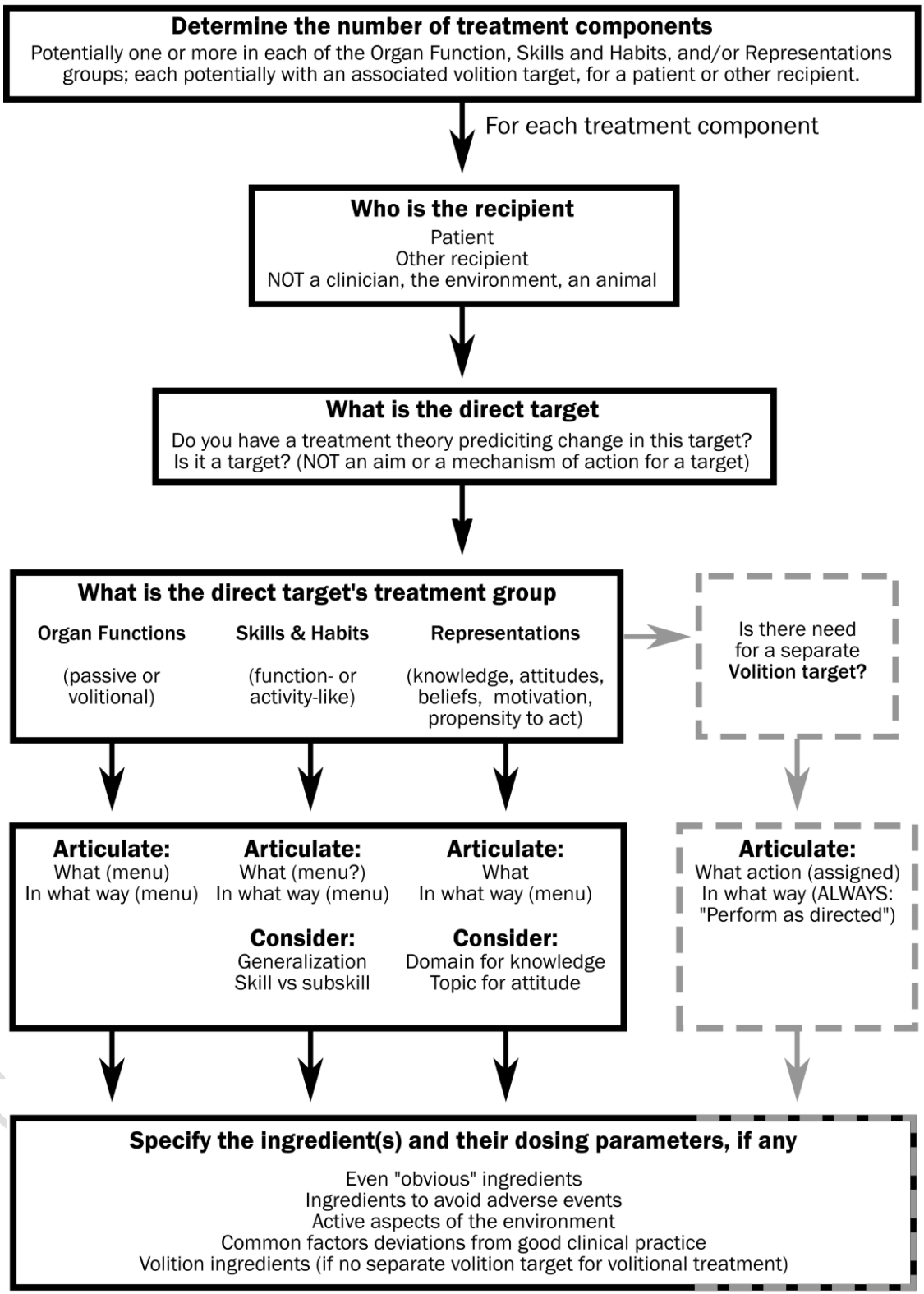
iv. Deliberate change in frequency or directiveness of cues; for example, providing gradually more responsibility to patient over time

b. Provision of semantic information using:
   i. Single or combination modalities (auditory, written, pictorial, interactive, video, web)
   ii. Organizational methods, e.g., chunking, outlining, scaffolding
   iii. Prompting rehearsal/ rephrasing/ spaced retrieval
   iv. Links to prior knowledge
   v. Socratic question-answer
c. Provision of aids and strategies, e.g.:
   i. Mnemonics, internal or external
   ii. Assistive devices
   iii. Degree to which clinician provides strategies or encourages patient problem-solving
d. Deliberate selection/ placement of materials to affect learning/ performance

2. Engagement/ motivational methods
   a. Provision of rationale for specific treatment (activity)
   b. Persuasion→ coercion
   c. Bargaining, contracting
   d. Scheduling of training activities (e.g., morning routine) in naturally occurring contexts/ times
   e. Methods to instill trust in clinician (e.g., rapport, perceived credibility)
   f. Use of materials that convey affective information, to enhance motivation to perform (e.g., preferred foods to increase motivation to eat)
   g. Methods to enhance effort:
      i. Goal setting (types of goals, self-set vs. clinician-set vs. negotiated, optimal level of challenge, proximity/ time frame)
3. Feedback, reinforcement, and response to error
   a. Self- vs. clinician-delivered evaluation vs. comparison of the two
   b. Feedback
      i. Positive vs. negative/ corrective
      ii. Timing (Knowledge of Performance vs. Knowledge of Results) and schedule
      iii. Progress tracking methods
      iv. Use of augmented internal feedback (e.g., biofeedback)
   c. Reinforcement:
      i. Valence (reward or punishment, positive or negative)
      ii. Type (social, tangible)
      iii. Schedule of reinforcement
   d. Error management
      i. Prevent/ minimize (as in errorless learning)
      ii. Ignore
      iii. Correct on the spot

   iv. Prompt self-correction
   v. De-brief or “process” error
4. Affective/ attitudinal change methods
   a. Norm-based appeals
   b. Appeals to fear
   c. Appeals to values
   d. Reassurance
   e. Promotion of alternative interpretations
   f. Elicitation of change talk
5. Generalization via explicit instruction on when/ how to perform skills in different contexts
6. Prompting of problem-solving to promote opportunity(ies) to learn/ practice, e.g., how to remove barriers, how to ensure time/ space/ resources/ social support

Appendix A – Flow Chart of Specification



Appendix B – Specification Examples

In the following pages, we provide example specifications for several treatments. Each begins with a short clinical vignette, followed by the specification that the project team agreed on, along with some notes about the rationale for each specification. Note that when a treatment is being specified by a clinician or researcher, they have full access to the implicit or explicit treatment theories that led to the treatment choices. In these examples, one must infer the clinician's treatment theories from the vignettes, which leaves some room for ambiguity. Keep in mind that any difficulties encountered in specification may pertain to inherent difficulties in applying the RTSS rules themselves, or to ambiguity about the treatment rationales provided in the vignettes.

Ace wrapping a residual limb

Ms. X is a 68-year-old woman with a recent below knee amputation due to diabetes. The nurse plans to apply an ace wrap to the residual limb to reduce edema and help desensitize the limb. The nurse will use 4" ace wrap and will begin with the end of the bandage on the medial side of the thigh. After circling the thigh, the nurse will cross down to the corners of the residual limb in "figure of 8" fashion, taking care to leave no open windows in the bandage and to regulate the compression to be greatest at the distal end. She will ensure that the bandage is changed and re-wrapped at the start of the next shift.

Group = O (Organ), S (Skills and Habits), R (Representations)
Type = NV (direct target for non-volitional or passive); D (direct target for volitional); V (separate volition target as needed)

TARGETS			INGREDIENTS	
What/In What Way	**Group**	**Type**	**Ingredients**	**Dosing Parameters**
Edema/Decrease	O	NV	• 4" Ace bandage • Wrapping of bandage around the stump in a "figure of 8" fashion (repeatedly) with no opening areas (window) and application of strongest force (compression) at the distal end of the stump	• N/A • Once per shift
Sensory reception of organ (limb) surface/ Decrease	O	NV	• Same as above	• Same as above

Notes:

- Ace wrapping of the residual limb by a nurse is a non-volitional (passive) Organ Functions treatment. Although the ingredients are identical, there are 2 different treatment components because in this clinician's apparent treatment theory, the same ace wrapping ingredients affect distinct functional targets (edema reduction vs. desensitization).
- In this vignette, *reducing edema* is a target because that is the functional change the clinician identified. If the only reason for reducing edema was to *shape the limb to fit a prosthesis*, then limb shaping would be the target and *reducing edema* could be a mechanism of action. This example illustrates the clinical dilemma of a "tightly linked chain", i.e., when the active ingredients (in this case pressure) launch a series of linked changes, such that a functional change may be a means to an end or the end itself. In the case of a tightly linked chain, decisions about mechanisms vs. targets could be made via consensus of treatment experts. In our less expert discussion, it was felt that edema reduction would likely be pursued even in an amputee without plans for a prosthesis.

Tracheo-Esophageal Prosthesis (TEP)

Mr. Smith recently had a total laryngectomy and placement of an indwelling trachea-esophageal puncture (connecting the trachea and esophagus). The TEP has a plastic prosthesis that keeps the puncture open and directs airflow. He has just woken up from anesthesia and this is the first time he will be using the TEP. Mr. Smith will be sent home with the TEP in a few hours, so he needs to learn how to use it and maintain it.

The SLP first teaches Mr. Smith how the TEP works. She gives him a mirror and then occludes (covers) his stoma with her finger when he is exhaling, which redirects air from the trachea into the esophagus and produces a sound Mr. Smith can use for voicing. Then the SLP asks Mr. Smith to occlude the stoma himself and make a voiced sound. Mr. Smith practices occluding his own stoma, with verbal feedback from the therapist, until he consistently achieves voicing with the prosthesis.

Next the SLP teaches Mr. Smith about routine maintenance of the TEP prosthesis, such as cleaning the prosthesis with a brush 3-4 times per day. For Mr. Smith's first attempts, the SLP manually helps him insert and rotate the brush in the prosthesis. In the subsequent attempts, the SLP gives Mr. Smith a mirror and he brushes the prosthesis independently with the help of that mirror. Mr. Smith practices 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.

Last, the SLP gives Mr. Smith a written educational handout and reads 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. The handout also tells him what to do if the prosthesis become dislodged or falls out. The SLP gives Mr. Smith a log to track when he cleans the prosthesis.

Group = O (Organ), S (Skills and Habits), R (Representations)
Type = NV (direct target for non-volitional or passive); D (direct target for volitional); V (separate volition target as needed)

TARGETS			INGREDIENTS	
What/In What Way	**Group**	**Type**	**Ingredient**	**Dosing Parameter**
Ability to use TEP for voicing/ Independent	S	D	• TEP prosthesis • mirror • opportunities to perform voicing with TEP • information about how TEP works • verbal instruction • demonstration with mirror • corrective verbal feedback until consistent voicing	• N/A • N/A • repeated trials until independent • N/A • N/A • N/A • feedback on each trial
Ability to clean and maintain TEP/ Independent	S	D	• TEP prosthesis • mirror • brush • opportunities to perform TEP cleaning • physical assistance • verbal guidance • corrective verbal feedback until accurate	• N/A • N/A • N/A • repeated trials until independent • N/A • N/A • feedback on each trial
Regular cleaning of TEP at home/ Perform accurately	R	V	• factual information about risks of not cleaning TEP • written educational handout • verbal delivery with patient reading along • log sheet for tracking TEP cleaning	• N/A • N/A • N/A • N/A
Knowledge of what to do if TEP becomes dislodged/ Increased	R	D	• factual information about what to do if TEP becomes dislodged • written educational handout • reading handout aloud and asking patient to read along	• N/A • N/A • N/A

Notes:

- Although the TEP addresses an organ function problem (lack of functioning vocal cords), note that the TEP does not have a target of its own, because the patient must learn how to use it. Thus, the TEP itself is a key ingredient (along with practice and feedback) in acquiring the skill of using it.
- The skill of using the TEP and the skill of cleaning it are viewed as distinct skill targets because they differ in several of their ingredients and their outcomes would be measured differently.
- Acquiring each of these skills is a volitional treatment but because the practice is directly supervised, no separate volition target is needed. Rather, volition ingredients (e.g., verbal information, demonstration, feedback) have been added to the direct treatment components. In contrast, "Regular cleaning of TEP at home" requires a separate volition target; the ingredients provided in the session must be planned to prompt unsupervised performance of the behavioral routine at home.
- The last component, knowledge of what to do if the TEP becomes dislodged, is at an intermediate position between "knowledge for knowledge sake" and "action directed". The information will only become relevant if and when the TEP becomes dislodged. Therefore, this clinician has chosen to frame is as "useful knowledge" for the future – a direct representation target which, again, includes volition ingredients.
- Note that the informational content of these treatment components is clearly an active ingredient. Whether the modes of delivery of this information (verbal vs. written, read aloud) need to be specified, depends on the clinician's view of the theoretical importance of these choices.

Standing Balance Training

A patient with TBI is receiving physical therapy to improve his ability to perform a variety of tasks while standing, without loss of balance. The patient is easily distracted and has difficulty following multi-step commands. His upper and lower extremity strength is within functional limits but he shows increased postural sway when standing still, and loses balance (requiring minimal assistance to recover) when reaching for objects beyond his base of support.

The therapist explains to the patient that they are going to play ball together to improve his ability to stand better during everyday tasks, and stand without help. (The therapist has selected this activity because it is likely to be intuitive to the patient and because the patient enjoyed playing sports with balls before injury.) The therapist stands next to the patient to be able to physically assist him during the ball tossing activity in case he loses his balance. A volunteer will assist by catching the ball and tossing it back to the patient, and will deliver approximately 30 throws in each treatment session before moving on to another activity. The therapist will initially ask the volunteer to throw the ball directly to the patient so it is easy to catch. When the patient shows he can do this without losing his balance, the therapist will instruct the volunteer to throw the ball off-center (low, then to the side, then to the other side, then high), to add variability to the task. If the patient loses balance, the therapist will provide only as much assistance as needed to prevent a fall, but will allow the patient to feel the loss of balance and try to recover. If falls are frequent, the therapist will instruct the volunteer to throw the ball more to the center. Once the patient has demonstrated that he can catch and throw the ball without losing balance, the volunteer will be cued to throw the ball more off-center (the therapist will motion behind the patient to indicate where she would like the ball thrown, trying to mix up the directions) to increase the level of challenge to one where the patient is able to catch the ball without loss of balance at least 80% of the time. This process will continue in subsequent sessions until the patient demonstrates the ability to reach far out of his base of support for the ball without requiring assistance to avoid a loss of balance, or until no further progress is made for three consecutive sessions.

Group = O (Organ), S (Skills and Habits), R (Representations)
Type = NV (direct target for non-volitional or passive); D (direct target for volitional); V (separate volition target as needed)

TARGETS			INGREDIENTS	
What/In What Way	**Group**	**Type**	**Ingredient**	**Dosing Parameter**
Degree of reach out of standing base of support possible without loss of balance (LOB)/ Increased	S	D	• assist only to prevent fall • opportunities to catch ball • distance and direction of ball placement from base of support • use of familiar and motivating activity • verbal description of task	• N/A • 30 trials/session • increase gradually to maintain ~80% success, until no further increase X 3 sessions • N/A • N/A

Notes:

- This treatment has one component, which addresses a skill target. Note, however, that this is a "function-like" skill in the view of the treating clinician. The target is expressed as a general improvement in ability to reach out of base of support in standing without a loss of balance, rather than an increased ability to "play catch without falling."
- Volition ingredients ("verbal description of task") have been added to this treatment component rather than creating a separate volition target, because the clinician is able to adjust volition ingredients as needed to ensure performance of the therapeutic activity.
- The ingredients are specified in ways that highlight attention to generalization of the skill (throwing the ball in varied directions so that balance in all directions is challenged), and progression (throwing the ball farther from the center of balance as the patient's dynamic balance improves).
- Note that assisting the patient (if and when he is about to fall), is not an active ingredient promoting the development of dynamic balance skill. Rather, it is an ingredient added to prevent an adverse event (falling and injury) that might result from the treatment.
- The dose of practice will be determined by either reaching a desired performance criterion, or by failure to show continued gains. The dose of distance from base of support will be adjusted crudely (from closer to farther) as a form of progression, to maintain adequate balance challenge.

Self-feeding

Mr. Williams, age 77 years, had a left-hemisphere stroke and has oral motor weakness, as well as impaired temperature sense, impaired proprioception, and weakness in his dominant hand. Mr. Williams is easily frustrated by his oral and limb motor problems but will try harder for food he likes. The therapist wants to help him to feed himself independently.

At onset of a meal, the OT will ask Mr. Williams to select only one item for self-feeding with a utensil. Feeding will be practiced with an adapted spoon strapped to the hand to ease ability to hold the utensil. The OT will provide physical assistance to load the spoon and orient the spoon appropriately. The patient will be encouraged to use visual information to guide the hand between the plate and his mouth. Mr. Williams' wife will bring in his favorite foods and the OT will use them for the session.

Group = O (Organ), S (Skills and Habits), R (Representations)
Type = NV (direct target for non-volitional or passive); D (direct target for volitional); V (separate volition target as needed)

TARGETS			INGREDIENTS	
What/In What Way	**Group**	**Type**	**Ingredient**	**Dosing Parameter**
Self-feeding with utensil/ Increased independence	S	D	• Spoon with strap to allow attachment to the hand	• N/A
			• favorite meals from home	• N/A
			• opportunities to perform self-feeding	• repeated practice until independent
			• physical assistance to load & orient spoon	• as needed
			• verbal cues to use visual information as guidance	• as needed

Notes:

- This treatment component has an "activity-like" Skills target (self-feeding with adaptive equipment), since it involves increasing the skill of self-feeding through repeated practice. The task-related materials of food and spoon are required, and the therapist has chosen to incorporate an assistive device into the task. The spoon strapped to the hand has no passive effect (the patient must practice the activity while incorporating its use), so it is an ingredient toward self-feeding rather than having its own treatment component. Just as the patient should practice self-feeding using the adapted spoon, he should also practice directing his vision to the task as he performs it. The key ingredient is the repeated performance itself.

- As the practice will be performed with direct supervision, no separate volition target is required. However, volition ingredients such as the motivating food and verbal cues are added to the treatment.

Smoking Cessation:

Mr. F is a 58-year-old man with a recent stroke. He has smoked more than a pack of cigarettes per day but has not smoked in the 2 weeks that he's been in the hospital after his stroke. The nurse plans to meet with him to discuss his smoking and encourage him to remain abstinent during and after his hospitalization. She will start by interviewing Mr. F to find out what he knows about the health hazards of smoking. She will ask him open-ended questions, including what he knows about the health consequences of smoking, whether he understands its role in his recent stroke, and what he understands about the effects of stopping smoking on his long-term risks for heart disease, a second stroke, and cancer. She will correct any factual errors in how Mr. F answers these questions and will fill in information when he says he doesn't know. After assessing and correcting Mr. F's knowledge of smoking, the nurse will conduct motivational interviewing by asking him, on a scale of 1 to 10 (where 1 is not motivated at all), how motivated he is to remain smoke-free after leaving the hospital. If he does not say, "1", the nurse will ask him why not less motivated (e.g., if he says "4", she will say, "why not 2 or 3?"), and encourage him to name reasons that it is important for him to remain abstinent. She will ask him whether he has ever quit before and, if so, what techniques seemed the most helpful. She will describe and provide him with written materials, about nicotine patches and gum and about oral medications that may make abstinence easier, and she will encourage him to see his physician for one of these medications if he feels strong cravings during abstinence. She will also leave him with written material about two different smoking cessation support groups.

Group = O (Organ), S (Skills and Habits), R (Representations)
Type = NV (direct target for non-volitional or passive); D (direct target for volitional); V (separate volition target as needed)

TARGETS			INGREDIENTS	
What/In What Way Aspect	**Group**	**Type**	**Ingredient**	**Dosing Parameter**
Knowledge of the health hazards of smoking*/More accurate	R	D	• description of the risks of smoking • verbally querying knowledge (of risks) and fill in/correct gaps	• N/A • N/A
Knowledge of the health benefits of stopping smoking*/More accurate	R	D	• description of the benefits of abstinence • verbally querying knowledge (of benefits) and fill in/correct gaps	• N/A • N/A
Motivation to remain abstinent from smoking/Increased	R	D	• discuss patient's attitudes about smoking, desire to stop, strategies from the past • motivational interviewing with numerical rating and probe of reasons for score	• N/A • N/A

Knowledge about pharmacologic aids for smoking abstinence/More accurate	R	D	• description of the available meds and their effects
			  ○ Verbal description
			  ○ Written pamphlets
				• N/A

Motivation to see physician if craving is strong/Increased	R	D	• recommendation to see physician for strong cravings ○ Verbal recommendation	• N/A
Knowledge about smoking cessation support groups/More accurate	R	D	• group contact information and purpose ○ Written information	• N/A

Notes:

- This treatment includes multiple components, all of which are within the R treatment group (no performance or practice is involved and the only ingredients are informational in nature). Thus, division into separate treatment components hinges on clearly different targets (e.g., distinct knowledge, attitude, or action targets), and/or different and/or ingredients used to achieve them.

- Separating the first 2 components (indicated with asterisks) is a judgment call, since they use the same ingredients and are “subtopics” under a single “umbrella topic”.
- The remaining components are distinguished because they vary in their “information” vs. “motivation” balance, and also because the ingredients differ (e.g., motivational interviewing technique vs. a more traditional “educational” approach; verbal information vs. written information.
- All are taking place with direct contact from the clinician (i.e., the patient is not asked to review materials outside of the session or do “homework”), so no separate volition target is required.

GLOSSARY

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

Activity-like (target)
A target within the Skills and Habits group that shares characteristics with Activities in the *International Classification of Disability, Functioning and Health* sense. Performance is typically improved via opportunities for repeated practice with other active ingredients such as instruction, cueing, and feedback; for example, activities of daily living, work tasks, wheelchair mobility, use of memory notebook. Training is usually specific to the activity, i.e., not expected to generalize to others.

Aim(s) (of treatment)
Aspect(s) of the patient's or other recipient's functioning or modifiable personal factors that may or may not change indirectly (via mechanisms specified in enablement theory) as a result of the treatment-induced change in the treatment target or in multiple treatment targets. See *enablement theory*. A single treatment may have multiple aims, and there may be a chain of treatment aims - e.g., increased strength (target) leading to improved ambulation (aim 1) leading to greater community participation (aim 2). In the case of treatments delivered to other recipients, at least one aim is some aspect of the patient's functioning. Although relevant to the ultimate clinical value of a treatment, treatment aims are not relevant to the specification of the treatment, and are therefore not specified in the RTSS.

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 (e.g., at the level of an *International Classification of Disability, Functioning and Health* 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).

Function-like (target)
A target within the Skills and Habits group that derives from the *International Classification of Disability, Functioning and Health's* Body Functions, e.g., balance (*involuntary movement reaction functions*), dexterity (*coordination of fine voluntary movements)*, spatial attention (*shifting spatial attention)*, working memory (*memory functions, other specified)*. Performance is typically improved via implicit learning gained through opportunities for repeated practice of activities that challenge the skill, often with progression of task demands to maintain a consistent level of challenge. In contrast to activity-like Skills and Habits targets, training is typically expected to generalize across tasks requiring the trained skill.

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.

Non-volitional treatments
Treatments whose ingredients and hypothesized mechanisms of action require no effort on the part of the recipient (other than cooperation/nonresistance). Unlike volitional treatments, the recipient of non-volitional treatment is always the patient/client undergoing rehabilitation, not a third party (e.g., a caregiver). Non-volitional or passive treatments include medications, surgeries, and passive range of motion exercises; treatments based on primitive learning mechanisms such as habituation are also passive, because the learning happens involuntarily.

Organ Functions treatment group
Treatments in which the functions of organs or organ systems are modified, often by systematic stimulation in order to increase or decrease system output, or to bring function to a desired level through natural adaptive processes. The latter may include up- or down-regulation, and habituation to repetitive stimuli. Treatments in this group may also (partially) replace the functions of some part of an organ system, as in cochlear implants and prosthetic limbs.

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.

Recipient (of treatment)

Individual whose function/behavior is intended to be changed directly as a result of treatment. In most cases this is the person with a disability (patient/client), but in some instances another person (caregiver, employer) may be the recipient who is changed by the intervention (e.g., taught to provide care or to create a more supportive environment for the patient/client). Enablement theory may be used to postulate distal effects (aims) that improve the patient's/client's functioning.

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.

Representations treatment group
Treatments aimed at changing internal (i.e., central nervous system) representations related to cognitions, affect, motivation, and intentions to perform volitional behaviors. Cognitions are referred to here as thoughts and ideas, whereas affect is used as a shorthand term to encompass both automatic and more reflective aspects of emotional experience and response. Motivation involves the propensity to act, and intentions represent plans to act. Since mental representations underlie intentions to act, volition targets are a sub-group of Representations group targets.

Skills and Habits treatment group
Treatments that have in common learning or improving performance of a skill via practicing that skill, or reducing the effort required/ increasing the habitual nature of a behavioral routine. The target may be a Body Function from the *International Classification of Disability, Functioning and Health,* an activity, or a habit.

Specifying/ specification (of a treatment)
Articulation of the specific ingredients/ dosing parameters delivered by a clinician to achieve a specific target via associated mechanism(s) of action, according to a treatment theory explaining or hypothesizing the links from ingredients to target, i.e., how the desired change will take place. Specification may be performed for:

- All patients (or other recipients) with a particular condition that needs modifying
- All patients (or other recipients) with a particular condition that needs modifying, who have additional impairments which require the amplification and/or modification of ingredients
- One particular patient (or other recipient)

Specification of the last type may be performed prospectively or retrospectively with regard to the treatment episode.

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: e.g., 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.