Translating Assessments into Practice Using Principles of Patient-Centered Measurement: An Exemplar Using the Coma Recovery Scale-Revised

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Translating Assessments into Practice Using Principles of Patient-Centered Measurement:
An Exemplar Using the Coma Recovery Scale-Revised

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April 26, 2021

Translating Assessments into Practice Using Principles of Patient-Centered Measurement: An Exemplar Using the Coma Recovery Scale-Revised

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Abstract

Translating Assessments into Practice Using Principles of Patient-Centered Measurement: An Exemplar Using the Coma Recovery Scale-Revised

Background: Disorders of consciousness (DoC) include different states (e.g., comatose, vegetative state/unresponsive wakefulness syndrome, minimally conscious state (MCS), and emerging minimally conscious state (eMCS)) following a severe brain injury. Yet, effective communication about treatment of patients with DoC is often inhibited because family caregivers and rehabilitation practitioners do not interpret recovery of consciousness in the same way (Epstein & Street, 2007; Weaver et al., 2018). Because a person may remain in a disordered state of consciousness for as long as two decades and receive multiple episodes of rehabilitation during that time, ensuring clear communication among family caregivers and rehabilitation practitioners about treatment decisions is important (Beaumont & Kenealy, 2005). Incorporating person-centered measurement principles (American Institutes for Research, 2017) into how assessment results are shared between and within key stakeholders’, rehabilitation practitioners’ and family caregivers’, may facilitate shared treatment decision-making (SDM). SDM is the process in which both family caregivers and rehabilitation practitioners share clinical data and personal values to arrive at a mutual treatment decision (Elwyn et al., 2016; Papadimitriou et al., 2020).

Objective: The long-term objective of this research is to facilitate shared decision making in treatment planning between rehabilitation practitioners and the family caregivers of individuals with DoC following a severe brain injury. The purpose of this research is to create a recovery ruler that facilitates effective communication about assessment results
between caregivers and rehabilitation practitioners as a preliminary step in advancing shared treatment decision making.

**Methods:** Using a mixed methods design, a shared decision making tool was developed with the purpose of facilitating communication between family caregivers and rehabilitation practitioners when treatment planning. A scoping review evaluated and characterized treatments for patients with DoC, particularly ones that could be tailored to patient-specific contextual factors, and which would be enhanced with family caregivers and rehabilitation practitioner’s collaboration. Next, the qualitative phase explored family caregivers’ and rehabilitation practitioners’ (key stakeholders) decision making process when treatment planning for the patient. The quantitative phase, conducted mostly simultaneously with the qualitative phase, examined one of the most widely used neurobehavioral assessments, the Coma Recovery Scale – Revised (CRS-R) for its psychometric properties. Neurobehavioral assessments play an important role in evaluating recovery of function that is a key indicator of treatment effectiveness for patients in DoC. A co-calibration, performed using Rasch Analysis, aligned states of consciousness to CRS-R items, rating scale steps and total score, to create a Keyform prototype (Linacre, 1995, 1997). A participatory design with family caregivers, rehabilitation practitioners, and an instructional designer, facilitated the co-creation of a shared decision making tool based on the Keyform prototype to ensure comprehensibility, timeliness, transparency, and a relationship focus. Design groups with key stakeholders transformed the initial Keyform prototype from quantitative data output to a final prototype that could be evaluated for supports and barriers to implementation.
**Results:** In the scoping review, four studies meeting the Scottish Intercollegiate Guideline Network criteria for acceptable to high levels of evidence were identified for targeting body functions that incorporated contextual factors (e.g., personal preferences and interests) and demonstrated positive findings; three of these studies demonstrated medium to large effect sizes. Ultimately, the scoping review findings provide preliminary evidence supporting the tailoring of treatments to patient-specific contextual factors. During the ethnographic study, two types of shared treatment decision making, integrative and declarative, were identified from the qualitative analyses. Both types served to foster a partnership between the family caregiver and rehabilitation practitioner. Integrative shared decision making was observed when the family caregiver was included in the delivery of the rehabilitation treatment and contributed to decision-making as the treatment unfolded. Declarative shared decision making was observed when the rehabilitation practitioner and family member agreed upon treatment at a prior time that was then subsequently delivered by the rehabilitation practitioner.

Based on Rasch Analysis in the quantitative phase, the six items on the CRS-R were found to demonstrate good structural validity, reproducibility, and strong external validity with states of disordered consciousness. All items had monotonic rating scale structures, demonstrated sufficient unidimensionality, excellent measurement precision (Wright’s person separation reliability 0.95) and the item hierarchy reflected a continuum of neurobehavioral function that aligned with clinical expectations and prior literature. Co-calibration aligned CRS-R items and rating scale steps with consensus-based states of disordered consciousness, known as the Aspen criteria. This analysis identified additional rating scale steps which are of equal challenge to those in the consensus criteria and may help better distinguish between MCS and eMCS.
A participatory method to co-create a shared decision making tool facilitated the identification of content that could be added, removed, or changed, to create a ‘recovery ruler’. Key features that were added to the recovery ruler included descriptions of the states of disordered consciousness and a box where the family can share information about the patient’s preferences, values, and interests. Participants reported improved usability, acceptability, adaptability, and feasibility of the recovery ruler after incorporating recommended changes from the design groups. In addition, supports and barriers to implementing the recovery ruler in practice were identified which informed the creation of an implementation strategy, including developing practitioner training for the recovery ruler and laminating the tool to keep at the patient’s bedside.

**Conclusions:** Findings suggested the value of tailoring treatments for patients with disorders of consciousness, which requires rehabilitation practitioners collaborate in shared decision making with family caregivers to identify personal preferences, values, and interests. Understanding how shared decision-making occurs in choosing and implementing evidence-based rehabilitation treatment can inform education approaches for rehabilitation practitioners so they develop specific skills related to engaging family caregivers in treatment planning. Determining that the CRS-R had good psychometric properties on a large sample size provides substantive evidence that it was valid and appropriate for use in designing a recovery ruler. Integrating person-centered measurement principles based on feedback from design group participants resulted in a prototype that can provide instantaneous assessment results to family caregivers and rehabilitation practitioners. To our knowledge, this is the first study that has incorporated person-centered measurement principles to develop a shared decision making tool for an existing assessment about neurobehavioral function. Future
evaluation of the recovery ruler in a real-world setting will determine if it improves communication between family caregivers and rehabilitation practitioners. Addressing the supports and barriers to implementation identified in this study, such as using the ruler at the patient’s bedside and developing training, will be critical to the design and approach for future studies.
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Chapter 1: Introduction, Purpose, and Theoretical Framework

Background

With medical and technological advancements, patients with disorders of consciousness (DoC) resulting from a severe brain injury may remain in this state for 17 years or more (Beaumont & Kenealy, 2005). DoC include a range of states from comatose (no sleep wake cycles), vegetative state/unresponsive wakefulness syndrome (VS/UWS, presence of wakefulness), minimally conscious state (MCS, inconsistent volitional behavior), and emerging MCS (eMCS, consistent functional behavior) (Giacino et al., 2020). Medical and rehabilitation practitioners are challenged to correctly identify the correct state of consciousness and the misdiagnosis rate may be as high as 40% (Giacino et al., 2020). Misdiagnosis often ascribes a lower state of consciousness to the patient than they may be which, in the US, may limit access to more intensive rehabilitation services. With high levels of ambiguity around patient diagnosis and prognosis, effective information exchange is crucial for the family members who must often make difficult treatment decisions on the patient’s behalf.

Many individuals with DoC following a severe brain injury have potential to recover beyond a vegetative state but will still require significant daily assistance (Fins, 2009a). Approximately 30-40% of patients that receive inpatient rehabilitation go on to recover functionally important skills such as communication and command following (Giacino et al., 2020). About 20% of patients with DoC go on to achieve independence in the community within five years (Giacino et al., 2020; Katz et al., 2009; Whyte et al., 2013). Recovery for patients with DoC has been reported to occur ten years post injury (Hammond et al., 2018). As a result, family caregivers’ shoulder much of the
responsibility for transitioning their person home and for the multiple future treatment
decisions that must be made during these long periods of recovery (Fins, 2009a, 2013;
Hauber & Jones, 2002).

Family caregivers often report dissatisfaction with the process of transitioning
home particularly with regards to unnecessary hospitalizations and missed opportunities
for rehabilitation (Hauber & Jones, 2002; Piccenna et al., 2017). Family caregivers who
plan to provide most of the care for their loved one require the most preparation for a
successful transition home. Family caregivers report feeling forgotten during clinical
practice due to the focus of care being on the patient (Kreutzer, Livingston, et al., 2009;
Kreutzer, Rapport, et al., 2009).

Family caregivers’ opinions are often divergent from those of rehabilitation
practitioners (Moretta et al., 2016; Moretta et al., 2017). Family caregivers report not
feeling listened to by rehabilitation practitioners when they see a new behavior or
response from their loved one (Weaver et al., 2019). Interviews with families of loved
ones in DoC describes the importance of incorporating the family’s beliefs about the
patient’s behaviors into a clinical assessment because it validates the family’s
observations, provides additional information to practitioners, and mitigates under-
interpretation of patient behaviors by practitioners (Phipps et al., 1997). In addition,
because of their shared history with the patient in DoC, family caregivers have ‘insider’
knowledge about the patient’s preferences providing greater context from which to
ascribe interpretations of the patient’s behavior.

At all phases of recovery, from acute hospital care through post-acute
rehabilitation to care at home, the family caregiver takes the primary role in making
decisions for the patient. To date, literature has primarily focused on how families make
decisions related to life sustaining treatments (Fins, 2009a, 2013; Jox et al., 2015;
Kuehlmeyer et al., 2012) or novel treatments (Smart & Giacino, 2015). By contrast, much
of the treatment that patients in DoC receive during rehabilitation are neither of these.
Instead, many rehabilitation treatment decisions represent smaller moments that may
impact the patient’s recovery such as initiating medication or whether to practice oral
care sitting on the edge of the bed. Most of this type of decision-making occurs in
situations in which there is more than one option, for which there is limited evidence, and
for which the outcome(s) may be unknown. Such decision-making events have been
referred to as micro-decisions (Karlsen et al., 2020), which occur during encounters and
involve in-the-moment decisions with immediate action or follow through. Family
caregivers and rehabilitation practitioners of patients with DoC must make many micro-
decisions each day yet, to date there has been no systematic study of caregiver decision-
making.

Rehabilitation practitioners make treatment decisions using their clinical
reasoning skills (Higgs, 2008; Mattingly, 1998; Mattingly & Fleming, 1994) and
information from standardized assessments. Currently, best practice is to serially assess
the patients using the Coma Recovery-Scale revised (CRS-R) (Giacino et al., 2009;
Schnakers et al., 2009; Seel et al., 2010). Yet, misdiagnosis rates are high, and detection
of recovery is challenging. Consequently, rehabilitation practitioners working with
patients in DoC do so with a high level of uncertainty (J. Giacino, & Whyte, J., 2005;
Giacino et al., 2016). Rehabilitation practitioners often strive to improve the patient’s
functional performance, arousal, and awareness using limited evidence to support
The CRS-R is currently the most widely used assessment of neurobehavioral function which clinicians use to evaluate states of consciousness. The CRS-R has 23 items that align to six sensory domains addressing auditory, visual, motor, oromotor, communication, and arousal functions (Giacino et al., 2004). Items within each domain reflect cortical processes of increasing neurobehavioral complexity. For example, the lowest item in the motor domain reflects a reflexive activity while the hardest item requires the person to produce a behavior that requires integration across cortical regions. The CRS-R has been recommended to assess patients in DoC with minor reservations because it demonstrates good reliability and validity, but to date criterion validity remains unproven (American Congress of Rehabilitation Medicine et al., 2010). The CRS-R has standardized administration and scoring procedures resulting in good inter-rater reliability and excellent content validity (American Congress of Rehabilitation Medicine et al., 2010). One study has analyzed the CRS-R using a partial credit Rasch model to evaluate the internal validity and measurement precision (La Porta et al., 2013). In the visual sensory domain, Rasch analysis indicated differential item functioning among patients with traumatic and anoxic brain injuries suggesting that neurobehavioral function in the sensory domains may differ for these two clinical populations. The study demonstrated that the CRS-R has a high person separation reliability ($r=.897$) indicating that measures obtained are sufficiently precise for individual level decision-making (La Porta et al., 2013). The approach of the assessment’s procedures, with regards to sensory stimuli, reflects the era in which it was developed. Specifically, with a focus on standardizing and decontextualizing the stimuli used during a CRS-R assessment to
maintain consistency and comparability across patients and measurement periods. However, contemporary research is demonstrating personally-relevant stimuli is critical for eliciting behavioral responses from the patient (Jonas Stenberg et al., 2018). This also comports with more recent literature indicating that connections between brain regions is an indicator of neurobehavioral recovery (Bender Pape et al., 2020). Novel neuroscience findings supports the notion that rehabilitation practitioners could provide salient sensory treatment interventions that do not require overt task participation from the patient but may facilitate recovery in multiple neural networks (Bender Pape et al., 2020). This aligns with other research that advocates for a person-centered approach to assessment (American Institutes for Research, 2017; Jonas Stenberg et al., 2018).

The principles of person-centered measurement (PCM) promote assessments that are: 1) comprehensible and timely, 2) transparent, 3) patient-driven, 4) co-created, and 5) holistic (American Institutes for Research, 2017) (Fig 1.1). Assessments are comprehensible and timely when practitioners and family caregivers can obtain information that is easy to understand and timely. When caregivers have the same access to data as rehabilitation practitioners,
assessments are transparent. Assessments that are patient-driven (e.g., relationship focused) promote the inclusion of the patient’s and family’s preferences, values, and priorities when treatment planning. Assessment results are co-created when caregivers and rehabilitation practitioners both influence results are displayed. Holistic assessment processes recognize the importance of considering the whole person when making treatment decisions. These PCM principles contrast with the most current rehabilitation assessment practices and support the need to build a foundation for information exchange between stakeholders that promotes shared decision-making.

The recent practice guidelines for DoC have eight recommendations related to communication between practitioners and family caregivers with a specific emphasis on incorporating families in the decision-making process (Giacino et al., 2018b; Peterson et al., 2019) but, there is no study describing how practitioners and family members make decisions together. Most assessments for DoC, including the CRS-R, were not developed using person-centered measurement principles, thus it is likely that assessment results are not communicated to family members in ways that the information is transparent and co-created when treatment planning and making micro-decisions.

Advancement in contemporary measurement approaches, such as Rasch Measurement Theory, identifies the assessments hierarchy of items and rating scale steps which starts to stage the underlying construct (Woodbury et al., 2013). For example, the CRS-R’s underlying construct is neurobehavioral function and patients with DoC progress through stages (e.g., comatose, VS/UWS, MCS, and eMCS) that reflect a continuum of progression throughout neurobehavioral function. These stages can become distinct with cutoff scores that are derived from assessment items and rating scale steps
that correspond to behaviors that differentiate patients from each category (Woodbury et al., 2013). Patients with the same ability levels can be categorized to each stage. These illustrations and associations can be visualized on paper by using a keyform to display measurement principles for scoring assessments (Grattan et al., 2018; Kielhofner et al., 2005; Linacre, 1995, 1997; Velozo & Woodbury, 2011). The pen and paper Keyform method overcomes the barrier of translating assessments into practice because it quickly transforms ordinal raw scores into equal interval Rasch measures (Kielhofner et al., 2005). Furthermore, the Keyform can be expanded to include complex relationships from Rasch co-calibration methods (Hoffman et al., 2012; Perkins et al., 2008; Wright et al., 2000).

The Keyform continues to rely on output from Rasch Analysis computer software, however it offers an opportunity to incorporate person-centered measurement principles in the way in which assessment results are displayed (American Institutes for Research, 2017). Person-centered measurement requires consideration of key stakeholders’ when deciding how to report and use assessment information (American Institutes for Research, 2017). A person centered Recovery Ruler that visualizes CRS-R assessment data aligns with the National Action Plan to Advance Patient Safety by engaging family to share meaningful decisions (National Steering Committee for Patient Safety, 2020). Without this critical step of engaging stakeholders to co-produce a Recovery Ruler for the CRS-R, the assessment risks providing information that is not useful to the family caregiver. Aligning person-centered measurement principles to a Recovery Ruler that aligns with the stakeholders’ needs creates an opportunity to communicate better information for making treatment decisions in partnership to ultimately provide better
care to the patient.

**Statement of the Problem**

This research addresses a knowledge gap in communication between the rehabilitation practitioners, family caregivers, and patients with DoC. Despite the Centers for Medicaid and Medicare Services (CMS) (Centers for Medicare & Medicaid (CMS), 2018) and Practice Guidelines for Disorders of Consciousness (Giacino et al., 2018b) recommending that practitioners engage families in their clinical encounters, family caregivers’ perspectives about treatment decisions are frequently not sought out by practitioners (Jolles et al., 2018; Krishnan et al., 2019; Ronis et al., 2019). Yet, because patients in DoC cannot advocate for themselves, and because family caregivers may be in this decision-making role for nearly two decades, highlighting the need for family caregivers to receive transparent clinical assessment information early on and partner with rehabilitation practitioners for treatment decisions (Beaumont & Kenealy, 2005; Coronado et al., 2011).

Communicating assessment results that are comprehensible and timely, transparent, and relationship-focused are hallmarks of person-centered measurement (American Institutes for Research, 2017; Epstein & Street, 2007). Yet, family caregivers of individuals with DoC report being rarely, if ever, told about assessment results or their implications and report feeling dismissed when they provide observations of the patient’s recovery (Peterson et al., 2019; Tam et al., 2015; Weaver et al., 2018; Weaver et al., 2019). Prior work shows rehabilitation practitioners (occupational therapists, physical therapists, and speech-language pathologists) use caution when communicating about assessment results because the patient’s behavior fluctuates and they do not want the family to assign too much meaning to a patient’s behavior (Guernon et al., 2018; Weaver et al., 2018).
Practitioners rely on assessment data when making treatment decisions but, the treatments are rarely collaboratively deliberated with caregivers. Shared decision making encourages rehabilitation practitioners and family caregivers to partner when planning treatments. When family caregivers are provided with good information, they can ask well-informed questions and then provide personally-relevant information to the rehabilitation practitioner. In turn, the rehabilitation practitioner can provide information about treatments that can incorporate the patient’s preferences and values. Ultimately, this partnership in decision-making can impact the quality of treatments, communication, and satisfaction (Agency for Healthcare Research and Quality, 2017).

**Purpose and Research Questions**

The purpose of this research is to create a Recovery Ruler that facilitates effective communication about assessment results between caregivers and rehabilitation practitioners as a preliminary step in advancing shared treatment decision-making.

Aim 1. Describe the decision-making process for family caregivers and rehabilitation practitioners when treatment planning for a person with disorders of consciousness.

Research Question 1: How do family caregivers and rehabilitation practitioners make decisions when treatment planning for a person with disorders of consciousness?

Aim 2. Examine the extent to which the CRS-R displays psychometric properties that make it useful for communicating about assessment results when making treatment decisions.

Research Question 2: What are the underlying psychometric properties of the Coma Recovery Scale-Revised, including step and item calibrations, measurement precision (e.g., reliability), and hierarchical item order?
Aim 3. Identify salient features of the Recovery Ruler that facilitate effective communication between family caregivers and rehabilitation practitioners about treatment goals and options.

Research Question 3: How should assessment result information be displayed to facilitate effective communication about treatment decisions?

Significance of the Study

The proposed study seeks to incorporate PCM principles (comprehensible, timely, transparent, and relationship-focused) into a visual representation of assessment results (e.g., a Recovery Ruler) to facilitate effective communication between family caregivers and rehabilitation practitioners and a prerequisite step to enhancing shared decision-making. Ultimately, the long-term goal of this research is to improve caregiver satisfaction, bi-directional communication, and the quality of care for patients in disorders of consciousness (DoC) (Figure 1.1) (American Institutes for Research, 2017). Available research has focused on family caregivers making life-changing decisions such as withdrawing artificial nutrition and hydration rather than on less “critical” but equally important micro-decisions such as when to start a swallowing program or sitting the person up, which occur during daily rehabilitation encounters (Fins, 2009a, 2009b; Fins, 2011; Fins, 2013; Fins & Shapiro, 2007; Karlsen et al., 2020). Routine clinical assessments of neurobehavioral function should inform these communications, yet family caregivers and practitioners both routinely report struggling to communicate about the results of assessments that inform these types of treatment choices (Weaver et al., 2018). The long-term goal of this research is to promote effective shared decision-making (SDM) and person-centered care. This study is based on the understanding that patient outcomes and quality of care are enhanced when caregivers are directly involved in the treatment
decision-making process (Epstein & Street, 2007). Effectively communicating assessment information to family caregivers of patients in DoC is a critical first step in this direction (Figure 1.1).

**Better Information**

In rehabilitation of adults in DoC, assessments are the primary way rehabilitation practitioners document and interpret recovery of consciousness (American Congress of Rehabilitation Medicine et al., 2010; Giacino et al., 2018a; Giacino et al., 2018b). Yet, rehabilitation practitioners often report the challenge of communicating quantitative results in real time that are comprehensible. Most assessments are written in clinical language and are not comprehensible to family caregivers, which inhibits practitioners from sharing assessment results. Unpublished data from a small qualitative study found that 75% of caregivers (n=12) do not recall seeing an assessment being administered or being told assessment results when discussing their loved one’s progress. Sharing comprehensible, real-time assessment results will prepare caregivers to discuss the recovery process and treatment options.

**Better Person-Centered Care**

Family caregivers need an opportunity to receive better assessment information, but they also need an opportunity to share their knowledge about the patient’s preferences and values. Using a Recovery Ruler assist the practitioner to engage the caregiver in a bi-directional information exchange. Further, it may foster a greater sense of partnership, where both parties can discuss treatment options together with integrated, transparent
information. Further a person-centered approach in which assessment information is reciprocally shared may facilitate relationship focused decisions throughout the care continuum (Armstrong, 2019).

**Better Care Quality & Outcomes**

Quality of care could be improved for patients in DoC when family are engaged in the decision-making process. Caregivers are also more likely to be satisfied with treatment decisions when they are included from the beginning. Caregivers are more likely to have a better experience with the care when they can contribute to the patient’s recovery by enabling treatment that is personally relevant. Improved communication between rehabilitation practitioners and family caregivers about treatment decisions should lead to more person-centered, evidence-informed, quality rehabilitation for patients who cannot speak for themselves (American Institutes for Research, 2017; Epstein & Street, 2007).

**Conceptual Framework**

Effective communication of assessment results and a shared understanding of recovery of consciousness between the family caregivers and rehabilitation providers is fundamental for better patient outcomes (Figure 1.1) (Epstein & Street, 2007). Figure 1.2 displays the conceptual framework guiding this work, which delineates between current

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**Figure 1.2**

*Conceptual Framework Delineating the Gap in Current Practice and How Effective Communication of Assessment Data Changes the Rehabilitation Landscape*
practice using the CRS-R and a hypothetical practice in which the sharing assessment results incorporates PCM principles. In order to bridge the divide between the two practices depicted in Figure 1.2, this study will apply the Knowledge to Action Framework (KTA) (Graham et al., 2006), which guides implementation endeavors through a creation funnel and action cycle (Nilsen, 2015; S. E. Straus et al., 2013; Sudsawad, 2007) (Figure 1.3). The action cycle’s phases can occur sequentially or concurrently, whereas the creation funnel’s phases often occur more sequentially to distill information into usable products and tools (Graham et al., 2006). Phases from the action cycle can occur at each step of the knowledge creation funnel.

In this study, the KTA framework guides the research about the identified problem & knowledge needed (action cycle) by focusing on the three phases from the creation funnel (knowledge inquiry, knowledge synthesis, and knowledge tools/products. During the creation funnel, there are feedback loops with three phases from the action cycle (adapt knowledge to local context, assess barriers to knowledge use, and select, tailor, implement interventions) for this dissertation study (Figure 1.3). The knowledge inquiry phase (creation funnel) begins by exploring how treatment decisions are made in clinical practice and to what extent family caregivers are...
included in treatment planning for patients with disorders of consciousness. Knowledge inquiry continues with examination of the CRS-R psychometric properties particularly measurement precision, critical for detecting change in neurobehavioral function, and an item hierarchy that comports with current neuroscience regarding recovery of consciousness. Knowledge synthesis, in the form of a scoping review examines what is currently known about the types of treatments the rehabilitation practitioners and family caregivers might discuss when treatment planning. The information from these two phases (knowledge inquiry and knowledge synthesis) will be synthesized to produce the recovery ruler, a visual tool to represent assessment outcomes and promote collaborative conversations about treatment planning. During the development of the recovery ruler, there will be a feedback loop to gather the insights from stakeholders by examining three phases of the action cycle. These feedback loops to the phases in the action cycle will 1). inform the Recovery Ruler’s adaptations to fit the local context, 2). describe potential barriers to use in specific clinical settings, and 3). identify implementation strategies for the recovery ruler. The Knowledge to Action framework was selected for this dissertation because it provides guidance to inform the development of a strategy for implementing and testing the recovery ruler for future feasibility and pilot testing studies.

**Translational Nature of the Study**

This study is underpinned by the Knowledge to Action Framework as it guides the iterative manner to better translate the evidence into practice (Figure 1.3) (Graham et al., 2006; S. Straus et al., 2013; S. E. Straus et al., 2013). Feedback loops, a key feature of translational research, are facilitated by stakeholder involvement throughout multiple stages of the project. Feedback loops allow for a bi-directional flow of information between the research team and stakeholders to ensure the knowledge generated is tailored
to the specific needs of end users. The research project begins by exploring how family caregivers and rehabilitation practitioners make decisions and then incorporates their feedback and perspectives in the design and creation of the Recovery Ruler (Brownson et al., 2012; Seel et al., 2010). The exploratory aim to understand how decision-making about treatment interventions occurs is a critical pre-implementation phase. A scoping review evaluated and characterized rehabilitation interventions that might be discussed between family caregivers and rehabilitation practitioners. The scoping review is also a critical pre-implementation phase to understand what types of treatments family caregivers and rehabilitation practitioners might discuss as options when sharing decisions. The initial prototype of the Recovery Ruler is derived from Rasch analysis of the CRS-R and then uses a participatory study design to engage stakeholders in informing changes to the Recovery Ruler. This study examines the translational chasm of bringing proven clinical applications, in this case the Coma Recovery Scale-Revised assessment and the principles of PCM, into clinical practice.

**Summary of the Methodology**

To improve communication about assessment results, the Recovery Ruler must be empirically grounded in recovery of consciousness data from the most widely used neurobehavioral function assessment and include information that is beneficial to family caregivers and rehabilitation practitioners when treatment planning. To address this complex phenomenon a mixed methods study was designed. Exploratory, qualitative inquiry describes whether and how rehabilitation practitioners and family caregivers make treatment decisions. A scoping review examined possible treatment interventions that a family caregiver and rehabilitation practitioner might discuss. For the Recovery Ruler to be meaningful, it must provide accurate and precise, but also intuitive
assessment result information that is useful for decision-making (Linacre, 1997; Papadimitriou et al., 2017; Powers et al., 2017). Rasch Analysis informs the CRS-R’s reliability, item hierarchy, and alignment with the states of consciousness (Bond, 2007; Velozo & Woodbury, 2011; Wright et al., 2000). Design groups with stakeholders including rehabilitation practitioners and family caregivers used a prototype to explore whether the assessment results can be shared in a way that is comprehensible, timely, transparent, and relationship-focused. During the design groups, the recovery ruler product, will be evaluated for necessary adaptations to facilitate person-centeredness and also to identify barriers to uptake into clinical practice (Graham et al., 2006). Barriers to uptake in clinical practice identified during the design groups as well as the evaluation of pre-implementation factors will identify implementation strategies that will ultimately facilitate the uptake of the recovery ruler in clinical practice.

Limitations

This study as designed has limitations that impact the interpretation and generalizability of the findings. The first study aim explores family caregivers and rehabilitation experiences making treatment decisions in an urban, level I trauma center and may not reflect how care is provided in other clinical settings. Findings from the interviews with rehabilitation practitioners and family caregivers reflects the study sample’s experiences and may not be generalizable to other populations. The second aim examining the CRS-Ruses secondary datasets, which did not have uniform variables describing the participants. Differential item functioning was not examined for significant differences in item functioning across population subgroups (e.g., anoxic brain injury and traumatic brain injury). The item functioning from this study should be interpreted for the etiology of traumatic brain injury (92% of sample). Perspectives of both family
caregivers and rehabilitation practitioners were included in the design groups to ensure the Recovery Ruler reflects PCM principles during the third aim. The Recovery Ruler will be developed and tailored based on the feedback from the study participants. The rehabilitation practitioners mostly provided care in acute care hospitals or inpatient rehabilitation facilities and therefore, the Recovery Ruler may not be tailored to the needs of practitioners and family caregivers making treatment decisions in a long-term acute care setting.

**Definitions of Key Terms**

Disorders of consciousness: When a person’s consciousness (e.g., arousal and awareness) has been impaired. This includes individuals who are comatose, in the vegetative state/unresponsive wakefulness syndrome, or in the minimally conscious state.

Micro-decision: Small-scale decisions that occur numerous times each day at the patient’s bedside (Karlsen et al., 2020).

Rasch Model: The Rasch model represents the mathematical equation for the relationship between the probability of “being observed in a particular category and the difference between the individual’s ability and an item’s difficulty” (Wright & Linacre, 2001).

Shared Decision-Making: Practitioners and [patients and/or family caregivers] work together to understand the patient’s situation and how to best address it (Montori et al., 2017).
Chapter 2: Scoping Review

Foreword

This chapter presents the results of a five-year review of studies examining the outcomes of rehabilitation interventions for patients with disorders of consciousness. This review is pertinent to the broader goal of this dissertation project which is focused on understanding how family caregivers and rehabilitation practitioners make decisions when treatment planning. This review provides a needed understanding of the landscape of evidence-based treatment options available for practitioners and caregivers to consider when treatment planning. This literature review is in the format of a scoping review because it allowed for a broader research question and inclusion of a broad range of study designs that were not limited due to quality and methodological rigor (Arksey & O'Malley, 2005). This scoping review follows the format of Arksey & O’Malley’s (2005) methodological framework and PRISMA scoping review reporting guidelines which ensure quality in the conduct of the scoping review (Arksey & O'Malley, 2005; Tricco et al., 2018).

This manuscript focuses on identifying whether, and to what extent, the interventions being studied were tailored to the participant’s preferences, values, and priorities. A growing body of literature is highlighting the benefits to patients of including personally relevant stimuli for activating the neuronal network and stimulating a behavioral response (Pape et al., 2012; J. Stenberg et al., 2018) The study was informed by the structure of the World Health Organization International Classification of Functioning, Disability, and Health (WHO ICF) model in which tailoring of the intervention is
considered as a contextual factor influencing daily activity and participation (World Health Organization, 2001; World Health Organization, 2013).

Around the same time as this scoping review was being conducted, a systematic review was reported by Thibaut and colleagues on interventions for patients with prolonged disorders of consciousness. While this study overlaps with that study in that rehabilitation interventions were examined for patients with DoC, this study was unique in that it included patients in the acute phase of their recovery and extracted information about how the intervention was tailored to the participant.

This manuscript was submitted for consideration to the Journal of Head Trauma and Rehabilitation on November 16, 2020. The manuscript was reviewed as having strengths but needed revisions before it could be considered again for publication. Specifically, the main considerations for revision included 1) rationale for a scoping review when a systematic review was published within the past two years, 2) defining and operationalizing contextualization of treatments, and 3) using the WHO ICF to classify treatments rather than outcomes. These issues are discussed in the afterword that appears at the end of this chapter.
Rehabilitation Interventions for Adults With Disorders of Consciousness Following a Traumatic Brain Injury: A Scoping Review

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Abstract

Objective: Evaluate and characterize rehabilitation interventions for persons with disorders of consciousness following a traumatic brain injury.

Design: Scoping review using multiple databases from 2015 to 2019. Ten reviewers contributed to the review of the articles and data extraction. Two reviewers evaluated each article to confirm inclusion and data extraction. The World Health Organization International Classification of Functioning, Disability and Health served as a framework for analysis of the data.

Results: 20 studies met inclusion criteria. Twelve studies evaluated interventions targeting body structures while the remaining eight studies evaluated interventions targeting body functions. Fourteen studies were evaluated to be of acceptable or high quality, including nine randomized controlled trials (RCTs). Eight of these nine acceptable to high quality RCTs indicated positive results with participants receiving rehabilitation interventions trending towards more recovery of consciousness compared to usual care, withdrawal of the intervention, or a placebo. Seven studies contextualized interventions for participants: of these, 6 targeted body functions. The most frequent contextualization was the use of a familiar voice followed by preferred music.

Conclusions: Rehabilitation interventions for disorders of consciousness targeting body structures have been studied more frequently but those targeting body functions are more likely to incorporate contextual factors. Contextual factors have been shown to evoke brain activity and this review provides preliminary evidence supporting further study of personalization of interventions.
**Introduction**

Patients with disorders of consciousness (DoC) following a traumatic brain injury (TBI) require specialty rehabilitation services addressing various states of consciousness ranging from comatose, vegetative state (VS), minimally conscious state (MCS), and emergence from MCS (American Congress of Rehabilitation Medicine et al., 2010; Giacino et al., 2018b; Schnakers et al., 2009). Considerable work has examined the accuracy of categorizing patients into each of these states because individuals who are in an MCS are more likely to continue receiving rehabilitation treatment (Giacino et al., 2018b; Giacino et al., 2020). Misdiagnosis of patients with DoC occurs frequently and limits reimbursement for services, evaluation of treatment effectiveness, and access to rehabilitation treatment services (American Congress of Rehabilitation Medicine et al., 2010; Giacino et al., 2018a; Giacino et al., 2020; Merbitz et al., 1989; Schnakers et al., 2009).

Practice guidelines recommend patients with DoC receive rehabilitation services from a multidisciplinary team inclusive of occupational, physical, and speech therapy to optimize functioning and neurologic recovery (Giacino et al., 2018b). However, there is a paucity of evidence for rehabilitation therapists to use when designing rehabilitation intervention strategies for patients with DoC. Rehabilitation therapists are often hindered in their ability to tailor specific and effective interventions for patients at different levels of DoC due to limited empirical evidence; as a result, they may resort to simply ‘trying things’ to elicit any response from the patient (Papadimitriou, unpublished data).

One systematic review focused on therapeutic interventions for patients with prolonged DoC (>28 days) and found patients may benefit from rehabilitation interventions years after injury (A. Thibaut et al., 2019). Additionally, studies focusing
on neuromodulation techniques such as transcranial direct current stimulation (tDCS) and repetitive transcranial magnetic stimulation (rTMS) show promise, but none have shown significant group level improvement in a randomized control trial (Lefaucheur et al., 2017; Pape et al., 2006; A. Thibaut et al., 2019). These neuromodulation treatments are hypothesized to induce neural plasticity by producing a neuromodulatory effect or by enhancing synaptic connections, respectively. By contrast, sensory stimulation treatments aim to engage neural-specific circuits facilitating neuroplasticity and prevention of sensory deprivation (Bender Pape et al., 2012; Bender Pape et al., 2015a). A systematic review on sensory stimulation intervention studies found that multi-modal sensory stimulation was efficacious in improving recovery if used frequently (three to five times a day for seven to 20 minutes) for a duration of six to 14 days, especially when the stimulation used contextualized stimuli (Padilla & Domina, 2016). Collectively, these systematic reviews suggest rehabilitation interventions such as sensory stimulation and neuromodulation stimulation have promise for the field, but intervention parameters such as stimulation intensity and duration are inconsistent across studies.

To date, no review has categorized the contextual factors of interventions facilitating recovery of consciousness. Contextualization of a treatment describes the inclusion of a meaningful real-life component (e.g., personal preference, inclusion of family or peers) to the intervention (Bogner, Dijkers, et al., 2019; Bogner, Hade, et al., 2019; Hade et al., 2019). Contextualized interventions are characterized as function-focused (e.g. grooming) rather than impairment-focused (e.g. initiating movement) tasks. Evidence suggests that contextualized treatment has a positive impact on clinical outcomes for individuals with TBI (Hade et al., 2019) and stroke (Bode et al., 2004).
Consequently, contextual factors were examined for whether and how they were included in intervention research.

A scoping review was conducted to examine the literature reporting rehabilitation interventions for individuals with DoC following a traumatic brain injury. Rehabilitation interventions and contextualization of treatment stimuli were categorized with the goal of helping rehabilitation therapists maximize treatment session effectiveness. Scoping review research questions are broad in order to examine the extent and nature of the literature to provide a summary of the findings that highlight gaps in the field and to inform future practice and research (Arksey & O'Malley, 2005; Brien et al., 2010; Tricco et al., 2018).

Methods

This scoping review drew studies from a larger systematic review exploring outcome measures used to evaluate interventions for people with DoC following TBI [PROSPERO CRD42017058383] (Weaver et al., 2017). For the current study, Arksey & O’Malley’s (2005) methodological framework and PRISMA scoping review reporting guidelines were followed (Arksey & O'Malley, 2005; Tricco et al., 2018). Scottish Intercollegiate Guideline Network (SIGN) criteria were used to evaluate study design and quality (Scottish Intercollegiate Guideline Network, 2001). The research process included: 1) identifying the research question(s), 2) establishing definitions 3) identifying relevant studies, 4) selecting studies, 5) charting the data, and 6) collating, summarizing, and reporting results (Arksey & O'Malley, 2005).

Two research questions were addressed.

1. What are the rehabilitation interventions utilized for individuals with DoC following a TBI?
2. What types of contextual factors are included in rehabilitation interventions?

**Defining and Explicating Rehabilitation Interventions**

Rehabilitation interventions were defined as treatments that are delivered external to the body to facilitate recovery of body structures, body functions, daily activities, and participation (World Health Organization, 2001). The World Health Organization (WHO) International Classification of Functioning, Disability and Health (ICF) served as a framework to categorize the target of the interventions (e.g., body structures or body functions) (World Health Organization, 2001). Treatments targeting body structures include those that aim to change structures in the nervous system (e.g. neuronal activity) while treatments targeting body functions aim to facilitate changes in the physiological functions of the body system (e.g. consciousness, orientation, perception). The definition of rehabilitation interventions used for this review excludes fully implanted therapies such as spinal cord and deep brain stimulators. How interventions were tailored to participants needs were characterized by contextual factors (i.e., environmental or personal factors) (World Health Organization, 2001). Environmental factors are external influences on functioning (Geyh et al., 2018) and can provide opportunities and demands on an individual’s participation (Svensson et al., 2018). Personal factors include the person’s lifestyle, habits, social background, and behavior patterns (Geyh et al., 2011).

**Search Strategy**

A research librarian with expertise in scoping and systematic reviews collaborated with the first and senior authors to develop a comprehensive search strategy (Weaver et al., 2017). Search terms were related to TBI, disorders of consciousness, recovery of function, and treatment outcomes (Table 2.1). Cochrane,
Embase, PsycINFO, PubMed, and Scopus databases were searched.

**Table 2.1**

*Search Strategy for the Scoping Review*

<table>
<thead>
<tr>
<th>Database</th>
<th>Search Terms</th>
<th>Customization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embase</td>
<td>((exp traumatic brain injury/ OR traumatic brain injury*.ti,ab.) OR (exp coma/ OR coma*.ti,ab.) OR (exp persistent vegetative state/ OR persistent vegetative state*.ti,ab.) OR (exp minimally conscious state/ OR minimally conscious state*.ti,ab.) OR (exp consciousness disorder/ OR consciousness disorder*.ti,ab. OR disorder* of consciousness.ti,ab.)) AND ((exp convalescence/ OR convalescence.ti,ab. OR recover*.ti,ab.) OR (exp daily life activity/ OR daily life activity*.ti,ab. OR activit* of daily living.ti,ab.) OR (exp awareness/ OR awareness.ti,ab.) OR (exp wakefulness/ OR wakefulness.ti,ab.)) AND ((exp critical care outcome/ OR critical care outcome*.ti,ab.) OR (exp treatment outcome/ OR treatment outcome*.ti,ab.) OR (evaluation*.ti,ab.) OR (exp outcome assessment/ OR assessment*.ti,ab.))</td>
<td>English, 2015-current</td>
</tr>
<tr>
<td>Scopus</td>
<td>(TITLE-ABS-KEY (&quot;traumatic brain injur*&quot;)) OR TITLE-ABS-KEY (com<em>a</em>) OR TITLE-ABS-KEY (&quot;persistent vegetative state*&quot;) OR TITLE-ABS-KEY (&quot;minimally conscious state*&quot;) OR TITLE-ABS-KEY (&quot;consciousness disorder*&quot;) OR TITLE-ABS-KEY (&quot;disorder* of consciousness&quot;) AND (TITLE-ABS-KEY (recover*) OR TITLE-ABS-KEY (&quot;activit* of daily living&quot;) OR TITLE-ABS-KEY (awareness) OR TITLE-ABS-KEY (wakefulness)) AND (TITLE-ABS-KEY (</td>
<td>English</td>
</tr>
</tbody>
</table>
Selection Process

To be included in the parent systematic review, studies had to (1) be published in peer-reviewed journals, (2) include at least one adult (≥ 18 years) with a primary diagnosis of severe TBI resulting in a state of disordered consciousness (Glasgow Coma Scale≤8 at injury), (3) report on an intervention aimed at recovery of consciousness, and (4) be published in English (Weaver et al., 2017). The exclusion criteria were: (1) published abstracts, (2) non-traumatic cause of brain injury, or (3) participants were documented with history of psychiatric illness and/or organic brain syndrome, (4) were fully conscious, or (5) all were <18 years of age.

The parent study search history covers 33 years (i.e., 1986-2019) (Weaver et al., 2017). This scoping review analyzed articles from the parent study between 2015-2019 in which rehabilitation interventions were the primary intervention. Two reviewers confirmed article inclusion, data extraction, and quality evaluation. Disagreements during the review process were resolved with consensus discussion.

Data Extraction

Data extracted from the included studies were: 1) sample size, 2) etiology, 3) level of consciousness, 4) time since injury, 5) location of intervention, 6) type of intervention, 7) description of intervention, 8) contextual factors, 9) study findings, and 10) study type.
Quality Evaluation

Included studies were evaluated for their quality using SIGN criteria (Scottish Intercollegiate Guideline Network, 2001). Consistent with the SIGN protocol, case study designs were not evaluated for quality; other studies’ methodological quality was rated as high, acceptable, low, or unacceptable-reject (Scottish Intercollegiate Guideline Network (SIGN)).

Data Summarizing and Analysis

Descriptive analyses were used to report frequency of study designs, time since injury (acute and chronic) of the study sample, proportion of rehabilitation interventions targeting body structures and functions, and the frequency of using contextual factors during interventions. Last, a narrative synthesis was conducted to summarize the studies nested within body structures and body functions (Patton, 2015).

Results

Of the 54 studies included in the parent systematic review from 2015-2019, 20 met inclusion criteria for this study (Figure 2.1). Of these, 12 were randomized control trials (Bender Pape et al., 2015b; Cavinato et al., 2019; Cincotta et al., 2015; Estraneo, Pascarella, et al., 2017; Frazzitta et al., 2016; He et al., 2018; Krewer et al., 2015; Martens et al., 2018; Moattari et al., 2016; Nekkanti et al., 2016; Thibaut et al., 2017; Zhang et al., 2017), six were non-randomized control trials (Bai et al., 2018; Binzer et al., 2016; Legostaeva et al., 2019; Lei et al., 2015; Park & Davis, 2016; Xia et al., 2017), one was a case control study (Cheng et al., 2018), and one was a case series (Sullivan et al., 2017) (Table 2.2). According to SIGN criteria, two studies were high quality, 12 studies
were acceptable, three studies were low quality, and two studies were of unacceptable quality; the case series was not rated.

**Figure 2.1**

**PRISMA Flow Diagram**

[Diagram showing the flow of studies through screening, eligibility, and inclusion stages with specific numbers and reasons for exclusion.]
Table 2.2

Description of the 20 Included Studies

<table>
<thead>
<tr>
<th>Reference</th>
<th>Sample Size</th>
<th>Location of Intervention</th>
<th>Intervention</th>
<th>Description of Intervention Delivery</th>
<th>Contextual Factor</th>
<th>Study Findings</th>
<th>Study Design</th>
<th>SIGN Quality Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legostaeva, et al.</td>
<td>38</td>
<td>Research center</td>
<td>rTMS</td>
<td>Active rTMS for 10 sessions over two weeks, five days per week. rTMS administered over left angular gyrus, 20 Hz, intensity 80% of RMT for 3200 stimuli. Each train 4s with 26s intertrain pause for 20 minutes.</td>
<td>No</td>
<td>Patient in MCS, not VS, demonstrated a significant increase on the CRS-R total score after stimulation (P=0.0001).</td>
<td>Non-randomized control trial</td>
<td>Acceptable</td>
</tr>
<tr>
<td>He, et al.</td>
<td>6</td>
<td>Rehabilitation</td>
<td>rTMS</td>
<td>Active and sham rTMS for one week with a one-week washout period. Stimulation administered between 8-10am, Monday-Friday. rTMS administered over left M1, 20 Hz, intensity 100% of RMT for 1000 pulses, delivered in 20 trains. Each</td>
<td>No</td>
<td>Longitudinal change of CRS-R scores shows slight improvement during both real and sham sessions. Changes were not significantly different on repeated measures ANOVA</td>
<td>Randomized Control Trial</td>
<td>Low Quality</td>
</tr>
<tr>
<td>Study Authors</td>
<td>Sample Size</td>
<td>Setting</td>
<td>Intervention</td>
<td>Outcome Measure</td>
<td>Randomization</td>
<td>Volume</td>
<td>Acceptability</td>
<td></td>
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<td>---------------</td>
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<td></td>
</tr>
<tr>
<td>Xia, et al. (2017)</td>
<td>16</td>
<td>Inpatient acute care</td>
<td>rTMS</td>
<td>Train 2.5s with 28s intertrain pause. Active rTMS for 1 session per day for 20 consecutive days. rTMS administered over left DLPFC, 10 Hz, intensity 90% of RMT for 1000 pulses. 10Hz trains for 10s; repeated 10 times, inter-train interval of 60 s; 11min and 40s for total sessions.</td>
<td>Analysis (p=0.376). After the treatment, patients demonstrated significant increase in CRSR scores compared to baseline (p=0.007). When analyzing patients separately based on baseline diagnosis (MCS and VS), significant improvement was found on the CRSR in MCS patients (p=0.042) but not in VS patients (p=0.066).</td>
<td>Non-randomized control trial</td>
<td>Acceptable</td>
<td></td>
</tr>
<tr>
<td>Cincotta, et al. (2015)</td>
<td>11</td>
<td>Not reported</td>
<td>rTMS</td>
<td>Active rTMS for 10 minutes each session for 5 days and sham stimulation for 5 days with a one-month washout period.</td>
<td>No significant change between real or sham stimulation in CRS-R total (p=0.564, p=0.129, p=0.334,</td>
<td>Randomized Control Trial</td>
<td>Acceptable</td>
<td></td>
</tr>
</tbody>
</table>
rTMS delivered to left M1, stimulation of 1-sec 20 Hz trains repeated five times with an inter-train interval of 5 sec and a 30-sec pause for a total of 1000 pulses at an intensity of 90% RMT.

p=0.705) or subscale scores (p=0.414, p=0.109, p=0.109, p=0.197) at the four time points. No significant differences in classification of patients by the Clinical Global Impression-Improvement scale for rTMS (p=0.670) and sham (p=0.198).

| Transcranial Direct Current Stimulation (tDCS) | Cavinato, et al. (2019) | 26 *2 lost to acute medical complications | Neurorehabilitation tDCS | Two weeks of active and two weeks of sham tDCS (5 days/week) with a washout period of 10 days. tDCS was provided to the left DLPFC centered at F3 for an intensity of 2mA for 20 minutes. | No | MCS patients exhibited significantly higher total scores on the Western Neuro Sensory Stimulation Profile after real stimulation (p=0.004). No clinical changes were observed in unresponsive patients or after sham. | Randomized Control Trial | Acceptable |


Bai, et al. (2018) 17 Not reported tDCS One real and one sham session of tDCS with a three-day washout. tDCS was provided to the left DLPFC centered at F3 for an intensity of 2mA for 20 minutes with a 15 second fade in/fade out period. No Significant positive correlation between theta coherence variation and CRSR total scores ($r=0.60$, $p=0.009$). Gamma band coherence variation demonstrated a significant negative correlation with CRSR total scores ($r=-0.48$, $p=0.025$).

Martens, et al. (2018) 27 At home, in nursing homes or in rehabilitation facilities tDCS 20 sessions of active and 20 sessions of sham tDCS for 4 weeks each with a washout period of 8 weeks. tDCS was provided to the left DLPFC centered at F3 for an intensity of 2mA for 20 minutes. Yes: Environmental Factor included treatment in the participant’s home and personal factor includes family administering treatment. Randomized control trial CRS-R total score with moderate effect sizes of 0.47 ($p=0.053$) for modified intention to treat and 0.53 ($p=0.043$) per protocol analysis at end of 4 weeks of tDCS favoring active treatment.

Estraneo, et al. (2017) 15 Inpatients admitted to Unit for DoC tDCS Random assignment to either three-week Randomized Control Trial No Small changes of patients’ conditions after
*2 lost to acute medical complications

protocol: active-rest-sham or sham-rest-active. Five active stimulation sessions occurred Monday-Friday, rest had no stimulation, five sham stimulations occurred Monday-Friday. Active tDCS delivered at 2mA intensity over the left DLPFC centered at F3 for 20 minutes. The first tDCS session and immediately after the 5 active stimulations. Clinical and EEG changes observed in 5/13 patients (3 in MCS and 2 in VS) starting after study protocol and further progressing during following months. No tDCS is safe for persons with chronic MCS. Treatment effect observed in active tDCS sessions at end of treatment (p=0.013; effect size: 0.43) and at 1 week follow-up (p=0.002; effect size: 0.57). Increase found in total CRS-R scores for active tDCS.

<p>| Thibaut, et al. (2017) | 21 | Not reported | tDCS | Random assignment to either protocol: active-washout-sham or sham-washout-active. Five consecutive, active tDCS sessions, washout for 1 week, five consecutive sham tDCS sessions. Active tDCS delivered at 2mA intensity over the left DLPFC for 20 minutes. | No | Randomized Control Trial | Acceptable |</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>Intervention</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zhang, et al. (2017)</td>
<td>26</td>
<td>Department of Rehabilitation at a Hospital tDCS</td>
<td>Participants were randomized to either the real tDCS or sham stimulation. Twenty 20-minute sessions were administered over 10 consecutive working days (Monday-Friday). Active tDCS delivered at 2mA intensity over the left DLPFC centered at F3. No change occurred in the sham condition (p=0.64). Patients with MCS who received real stimulation demonstrated a significant improvement on the CRSR total score (F(1,22)=72.54, p&lt;0.0005), but no significant difference in patients with VS in either the real or sham stimulation groups (F&lt;1) or the patients with MCS in the sham stimulation group (F(1,22)=4.21, p=0.052).</td>
</tr>
<tr>
<td>Nekkanti, et al. (2016)</td>
<td>20</td>
<td>Inpatient RMNS</td>
<td>Subjects randomized to 1)RMNS with medication or 2)RMNS without medication. No significant improvement on GCS score in both the experimental and control groups. Significant improvement in the RMNS with medication group. Randomized control trial acceptable.</td>
</tr>
<tr>
<td>Study, Year</td>
<td>Number</td>
<td>Lost at Follow-Up</td>
<td>Interventions</td>
</tr>
<tr>
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<td>------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Lei, et al. (2015)</td>
<td>437</td>
<td>*51 lost at follow-up</td>
<td>Neurological Intensive Care Unit, RMNS</td>
</tr>
</tbody>
</table>
Interventions Targeting Body Functions
Multi-component sensory stimulation

<table>
<thead>
<tr>
<th>Study Authors</th>
<th>Sample Size</th>
<th>Setting</th>
<th>Intervention Details</th>
<th>Design</th>
<th>Case Control Study</th>
<th>Acceptability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cheng, et al. (2018)</td>
<td>29</td>
<td>Inpatient Rehabilitation</td>
<td>Sensory stimulation program (SSP) - An ABAB withdrawal design had each phase last 4 weeks. During baseline (A phase), no SSP occurred, and patients received 15 hours of comprehensive rehabilitation. During treatment (B phase), the SSP was administered 3 times a week, twice a day. SSP included: visual stimulation, auditory stimulation, tactile stimulation, olfactory stimulation, and gustatory stimulation. Each stimulation was applied three times on both sides of the patient lasting around 20 minutes each session.</td>
<td>Yes: Personal Factors included visual (picture of family member), auditory (patient’s favorite music), olfactory (preferred smell).</td>
<td>A medium effect size ($n_p^2=0.12$) of phase (ABAB) ($F(3)=3.17$, $p=0.03$) was found. Diagnosis also had a main effect ($F(1)=39.78$, $p&lt;0.001$). There was a significant difference between treatment phases and no treatment phases ($F(1)=6.98$, $p=0.01$). CRSR total scores were significantly higher for patients with MCS during treatment ($F(1)=7.18$, $p=0.01$).</td>
<td>Low Quality</td>
</tr>
<tr>
<td>Moattari, et al. (2016)</td>
<td>60</td>
<td>Intensive Care Unit</td>
<td>Sensory stimulation program (SSP) - 20 patients were randomly assigned</td>
<td>Yes: Personal Factors</td>
<td>Randomized control Trial</td>
<td>Low Quality</td>
</tr>
</tbody>
</table>
to one of three groups. Group 1 and 2 received SSP twice a day for 30 minutes over 7 days. Group 1: SSP administered by family members. Group 2: SSP administered by a nurse. Group 3: Usual Care SSP had five parts: 1) awakening for 5 minutes, 2) auditory stimulation for 10 minutes (favorite music or taped recordings of family members), 3) visual stimulation for 10 minutes (familiar object, family photograph, film, etc.), 4) tactile stimulation for 5 minutes, and 5) olfactory stimulation for 10 seconds (favorite aromas).

included stimulations familiar to the patient based on the patient’s priorities or favorites. Family was encouraged to bring perfumes, objects, and tapes from home.

groups improved however, SSP administered by family demonstrated significantly higher scores on the GCS (p=0.001), RLA (p=0.001), WNSSP (p=0.001) after seven days compared to the other two groups.

<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>Setting</th>
<th>Interventions</th>
<th>Randomization</th>
<th>Control</th>
<th>Outcome</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frazzitta, et al. (2016)</td>
<td>40</td>
<td>Neurological Intensive Care Unit</td>
<td>Verticalization with stepping</td>
<td>Randomized to either a) conventional</td>
<td>No</td>
<td>Both groups with significant improvements</td>
<td>Randomized Control Trial</td>
</tr>
</tbody>
</table>
| Krewer, et al. (2015) | 50 | *6 lost to follow up. | Intensive care or early rehabilitation unit of neurological rehabilitation hospital | Verticalization with stepping | No | Both groups were statistically significant demonstrating improvement on CRSR scores at the 3-week and 6-week intervention period compared to baseline (Erigo group: \( p=0.29 \) and \( p=0.28 \); Tilt Table group: \( p<0.001 \) and \( p<0.001 \)). The
| | | | Randomized Control Trial | | | Randomized Control Trial | High Quality |
rate of recovery when looking at intra-individual changes was statistically better in the tilt table only group (p=.021).

<table>
<thead>
<tr>
<th></th>
<th>Outcome</th>
<th>Study Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Auditory Stimulation</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>Music</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Binzer, et al. (2016)</td>
<td>7</td>
<td>Hospital Inpatient Individual dialogic music therapy</td>
</tr>
<tr>
<td>Park &amp; Davis. (2016)</td>
<td>9</td>
<td>Neurological and trauma intensive care units Auditory stimulation</td>
</tr>
</tbody>
</table>
stimulation in a randomized order. Stimulations were provided between 8-5pm, five to eight sessions per day for 3-5 days with 1 hour between each session for a washout. Each stimulation session was 15 minutes.

Direct auditory stimulation requires interpersonal interaction between the patient and stimuli. It includes voices of family members, orientation by a family member or nurse, and familiar music. Non-direct auditory stimulation is less interactive and consists of music and television sounds.

<table>
<thead>
<tr>
<th>Study-telling</th>
<th>Long-Term Care facility</th>
<th>Auditory Stimulation</th>
<th>The patient had a 4-week baseline observation, 6 weeks of FAST intervention</th>
<th>Yes: Personal Factors included familiar voices telling</th>
<th>Improvement on the DOCS after FAST occurred during active treatment</th>
<th>Case Study</th>
<th>Not applicable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sullivan, et al. (2017)</td>
<td>1</td>
<td>Auditory Stimulation</td>
<td>The patient had a 4-week baseline observation, 6 weeks of FAST intervention</td>
<td>Yes: Personal Factors included familiar voices telling</td>
<td>Improvement on the DOCS after FAST occurred during active treatment</td>
<td>Case Study</td>
<td>Not applicable.</td>
</tr>
</tbody>
</table>
Acute inpatient Auditory stimulation

Subjects randomized to 1) Familiar Auditory Sensory Training or 2) Placebo of Silence. FAST and placebo were provided using compact discs or speakers. Each protocol was for 10 weeks. FAST comprised of eight 5-minute stories developed and recorded by the participant's friend and mother. Stories included emotional (happy or sad) content. All events occurred at least one year before the TBI.

Both groups showed neurobehavioral improvement on the Disorders of Consciousness Scale. Only FAST participants had statistically significant improvement over placebo. BAEP findings also improved and were sustained following sham stimulation.

Pape, et al. (2015)

16 subjects included familiar voices telling familiar stories. Which was not maintained during the sham stimulation.
minutes, 4 times per day, with at least 2 hours in between, for 6 weeks. FAST provides customized recordings of stories told by people well known to the participant. Stories represent specific events experience by both the participant and the storyteller. Placebo is silence.

significant (p=0.049) improvement on the Coma Near Coma scale with a large treatment effect (d=1.88, 95% CI= 0.77, 3.0).
Eleven studies (55%) included participants in both MCS and VS states, five studies did not report state of consciousness at time of injury (25%), two studies included participants in MCS (10%), and two studies included participants in VS (10%) (Table 2.3). Participants were most often in a chronic state of DoC (>3 months) (n=9, 45%) compared to acute (<3 months) (n=4, 20%) or a mix of acute and chronic (n=6, 30%) (Table 2.3). One study did not report the acuity of the participants.

Table 2.3

**Descriptions of the Participants From Each Study**

<table>
<thead>
<tr>
<th>Reference</th>
<th>Etiology</th>
<th>State of Consciousness</th>
<th>Acute and/or Chronic (time since injury at enrollment)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Interventions Targeting Body Structures</strong></td>
<td></td>
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<tr>
<td>Repetitive Transcranial Magnetic Stimulation (rTMS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Legostaeva, et al. (2019)</td>
<td>12 TBI</td>
<td>16 VS</td>
<td>Chronic (3-39 months)</td>
</tr>
<tr>
<td></td>
<td>26 NTBI</td>
<td>22 MCS</td>
<td></td>
</tr>
<tr>
<td>He, et al. (2018)</td>
<td>4 TBI</td>
<td>3 VS</td>
<td>Acute and chronic (1-28 months)</td>
</tr>
<tr>
<td></td>
<td>2 NTBI</td>
<td>3 MCS</td>
<td></td>
</tr>
<tr>
<td>Xia, et al. (2017)</td>
<td>2 TBI</td>
<td>11 VS</td>
<td>Chronic (3-35 months)</td>
</tr>
<tr>
<td></td>
<td>14 NTBI</td>
<td>5 MCS</td>
<td></td>
</tr>
<tr>
<td>Cincotta, et al. (2015)</td>
<td>2 TBI</td>
<td>11 VS</td>
<td>Chronic (9-85 months)</td>
</tr>
<tr>
<td></td>
<td>9 NTBI</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Transcranial Direct Current Stimulation (tDCS)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cavinato, et al. (2019)</td>
<td>9 TBI</td>
<td>12 VS</td>
<td>Chronic (4 months-7 years)</td>
</tr>
<tr>
<td></td>
<td>17 NTBI</td>
<td>14 MCS</td>
<td></td>
</tr>
<tr>
<td>Bai, et al. (2018)</td>
<td>7 TBI</td>
<td>9 VS</td>
<td>Chronic (6-35 months)</td>
</tr>
<tr>
<td></td>
<td>10 NTBI</td>
<td>8 MCS</td>
<td></td>
</tr>
<tr>
<td>Martens, et al. (2018)</td>
<td>12 TBI</td>
<td>27 MCS</td>
<td>Chronic (10 months-33 years)</td>
</tr>
<tr>
<td></td>
<td>15 NTBI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estraneo, et al. (2017)</td>
<td>1 TBI</td>
<td>7 VS</td>
<td>Chronic (3-84 months)</td>
</tr>
<tr>
<td></td>
<td>12 NTBI</td>
<td>6 MCS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>*2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>exxcluded</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thibaut, et al. (2017)</td>
<td>11 TBI</td>
<td>16 MCS</td>
<td>Chronic (5-365 months)</td>
</tr>
<tr>
<td></td>
<td>5 NTBI</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Interventions</strong></td>
<td><strong>Number</strong></td>
<td><strong>outcome</strong></td>
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<tr>
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<td></td>
</tr>
<tr>
<td><strong>Right Median Nerve Electrical Stimulation (RMNS)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nekkanti, et al. (2016)</td>
<td>20 TBI</td>
<td>Not reported.</td>
<td></td>
</tr>
<tr>
<td>Lei, et al. (2015)</td>
<td>437 TBI</td>
<td>Not reported.</td>
<td></td>
</tr>
<tr>
<td><strong>Interventions Targeting Body Functions</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multi-component sensory stimulation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cheng, et al. (2018)</td>
<td>15 TBI</td>
<td>11 VS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>14 NTBI</td>
<td>18 MCS</td>
<td></td>
</tr>
<tr>
<td>Moattari, et al. (2016)</td>
<td>58 TBI</td>
<td>Not reported.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 NTBI</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Motor Stimulation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frazzitta, et al. (2016)</td>
<td>12 TBI</td>
<td>Not reported.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>19 NTBI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*9 unknown (died)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Krewer, et al. (2015)</td>
<td>10 TBI</td>
<td>14 VS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>34 NTBI</td>
<td>30 MCS</td>
<td></td>
</tr>
<tr>
<td>*6 unknown (lost to follow up, did not receive intervention)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Auditory Stimulation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Music</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Binzer, et al. (2016)</td>
<td>1 TBI</td>
<td>4 VS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6 NTBI</td>
<td>3 MCS</td>
<td></td>
</tr>
<tr>
<td>Park &amp; Davis. (2016)</td>
<td>9 TBI</td>
<td>Not reported.</td>
<td></td>
</tr>
<tr>
<td><strong>Story-telling</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sullivan, et al. (2017)</td>
<td>1 TBI</td>
<td>1 VS</td>
<td></td>
</tr>
<tr>
<td>Pape, et al. (2015)</td>
<td>16 TBI</td>
<td>5 VS</td>
<td></td>
</tr>
<tr>
<td>*1 excluded.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 Healthy Controls</td>
<td></td>
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</tr>
</tbody>
</table>

*Chronic >3 months; traumatic brain injury (TBI); non-traumatic brain injury (NTBI)
Twelve studies (60%) reported interventions targeting body structures and eight (40%) targeted body functions. Interventions targeting body structures included rTMS (n=4) (Cincotta et al., 2015; He et al., 2018; Legostaeva et al., 2019; Xia et al., 2017), tDCS (n=6) (Bai et al., 2018; Cavinato et al., 2019; Estraneo, Fiorenza, et al., 2017; Martens et al., 2018; Thibaut et al., 2017; Zhang et al., 2017), and right median nerve electrical stimulation (RMNS, n=2) (Lei et al., 2015; Nekkanti et al., 2016).

Interventions targeting body functions included multi-component sensory interventions (n=2) (Cheng et al., 2018; Moattari et al., 2016), motor stimulation (n=2) (Frazzitta et al., 2016; Krewer et al., 2015), and auditory stimulation (n=4) (Bender Pape et al., 2015b; Binzer et al., 2016; Park & Davis, 2016; Sullivan et al., 2017).

**Interventions Targeting Body Structures**

**Repetitive Transcranial Magnetic Stimulation.** Four studies used rTMS as the primary intervention. rTMS uses a stimulating coil applied to the surface of the scalp to generate a magnetic field, which triggers an action potential in the targeted cortical neurons (Pape et al., 2006). rTMS has the potential to alter the excitability of neurons in the brain via repetitive delivery of single-pulse magnetic stimuli that subsequently evoke electrical currents in neuronal networks (Xia et al., 2017). Due to the relatively focal nature of the rTMS stimulation, it is hypothesized the stimulation up- or down-regulates neuronal activity (Pape et al., 2006). Studies varied in the treatment duration, stimulation frequency (20 Hz (Cincotta et al., 2015; He et al., 2018; Legostaeva et al., 2019) and 10 Hz (Xia et al., 2017)), stimulation intensity with respect to the resting motor threshold (RMT) (e.g. 80% (Legostaeva et al., 2019), 90% (Cincotta et al., 2015; Xia et al., 2017), and 100% (He et al., 2018)), and target site (left angular gyrus (Legostaeva et al., 2019),
left dorsolateral prefrontal cortex (Xia et al., 2017), and the primary motor cortex (Cincotta et al., 2015; He et al., 2018)) (Table 2.2).

The four studies all used different rTMS treatment administration procedures (Table 2.2). While all of the studies included patients with mixed DoC etiology, three studies also included patients in different states of consciousness (He et al., 2018; Legostaeva et al., 2019; Xia et al., 2017), one study enrolled only participants in VS (Cincotta et al., 2015), and three of the four studies included participants with chronic DoC (Table 2.3) (Cincotta et al., 2015; Legostaeva et al., 2019; Xia et al., 2017). One of the studies was deemed to be of low quality; while participants in this study demonstrated slight improvement on the CRS-R, none of the changes were statistically significant (He et al., 2018). Two of the studies found improvement in total CRS-R scores for participants in MCS (Legostaeva et al., 2019; Xia et al., 2017). Participants with chronic VS demonstrated mixed findings; one study found significant changes on total CRS-R score after 20 rTMS sessions (Xia et al., 2017) but another study providing 5 rTMS sessions to participants in chronic VS did not find significant changes (Cincotta et al., 2015).

**Transcranial Direct Current Stimulation.** Six studies used tDCS as the primary intervention. tDCS uses anode and cathode electrodes applied to the scalp surface to deliver low level direct electrical current between them to the brain (Thibaut et al., 2017). It is hypothesized that anodal tDCS enhances synaptic connections and decreases firing thresholds, while cathodal tDCS weakens connections and increases firing thresholds (Thibaut et al., 2017).
While all six studies provided tDCS to the left DLPFC at an intensity of 2mA for 20 minutes, the protocols varied in duration and participant inclusion criteria (DoC state and time since injury) (Table 2.2) (Bai et al., 2018; Cavinato et al., 2019; Estraneo, Fiorenza, et al., 2017; Martens et al., 2018; Thibaut et al., 2017; Zhang et al., 2017). All of the studies included participants of mixed etiology. Four studies included participants in any state of consciousness, two studies included participants in MCS (Martens et al., 2018; Thibaut et al., 2017). One study included participants with mixed acuity (Zhang et al., 2017) and the remaining five studies included participants with chronic DoC (Table 2.3). One of the studies was deemed as being of low quality (Bai et al., 2018). Overall, the findings across all studies demonstrated positive changes for the participants (e.g., higher scores on neurobehavioral function assessments or EEG changes) and tDCS was found to be safe to administer (Table 2.2).

**Right Median Nerve Electrical Stimulation.** Two studies used RMNS as an intervention. Electrical stimulation of the right median nerve is hypothesized to improve consciousness based on the theorized role of this peripheral nerve as a gateway to the central nervous system (Lei et al., 2015). Both studies used similar protocols (pulse width of 300 microseconds, 40 Hz frequency for 20 seconds on, 40 seconds off, but varied in stimulation intensity and treatment session duration (Lei et al., 2015; Nekkanti et al., 2016).

One study provided RMNS for 8 hours per day for two weeks (Lei et al., 2015) while the other study administered RMNS for 30 minutes per day for one month (Table 2.2) (Nekkanti et al., 2016). Both studies only included participants who presented initially with a severe TBI (GCS<8); baseline state of consciousness was not reported.
One study did not report the time elapsed since injury (Nekkanti et al., 2016) while the other study enrolled participants two weeks after injury (Lei et al., 2015) (Table 2.3). One of the studies was deemed to be of unacceptable quality (Nekkanti et al., 2016) while the other was deemed acceptable (Lei et al., 2015). Overall, the findings in both studies reported improvement scores on the Glasgow Coma Scale from baseline to follow-up post-treatment (Table 2.2).

**Interventions Targeting Body Functions**

**Multi-Component Sensory Stimulation.** Two studies investigated the effect of multi-component sensory stimulation, (e.g., addressing more than one sensory modality with the intervention). Sensory stimulation enriches the patient’s environment, facilitates brain plasticity (Cheng et al., 2018), and prevents sensory deprivation (Moattari et al., 2016). Both studies utilized a combination of visual, auditory, tactile, and olfactory stimuli (Cheng et al., 2018; Moattari et al., 2016). The sensory stimulation differed in that one study described an awakening protocol as part of the sensory stimulation program (SSP) being administered in the intensive care unit (Moattari et al., 2016) and the other study included gustatory stimuli in a protocol administered during inpatient rehabilitation (Table 2.2) (Cheng et al., 2018).

Both studies included participants with DoC of mixed etiology and only one study reported the state of consciousness at the time of the study (Table 2.3) (Cheng et al., 2018). Both studies compared the treatment to usual care using either a control group (Moattari et al., 2016) or a withdrawal design (Table 2.2) (Cheng et al., 2018). The one randomized control trial, although noted to be of low quality, found that participants who received SSP from family members achieved statistically significant improvement in
scores on the Glasgow Coma Scale, Western Neuro Sensory Stimulation Profile, and Rancho Los Amigos Scale compared to the two other intervention groups (usual care and SSP delivered by a nurse) (Moattari et al., 2016). The case control study found that patients in MCS receiving multi-component sensory stimulation demonstrated a medium effect size on total CRS-R scores when treatment occurred as compared to when no treatment occurred (Cheng et al., 2018). Overall, both studies found positive changes for the participants as a result of the multimodality sensory stimulation administration (Table 2.2).

**Motor Stimulation.** Two studies utilized motor stimulation via verticalization and mobilization of the participant using an Erigo tilt table that includes a stepping device (Frazzitta et al., 2016; Krewer et al., 2015). It is hypothesized that verticality influences arousal and alertness of the participant (Frazzitta et al., 2016; Krewer et al., 2015) and also reduces physical deconditioning and risk of secondary complications (Frazzitta et al., 2016).

Both studies were considered high quality randomized control trials and used the same intervention but under different administration protocols (Table 2.2). Both studies enrolled participants with DoC of mixed etiology (Table 2.3). One study delineated the states of consciousness of the participants (Krewer et al., 2015) and one did not. Both studies included participants in the intensive care unit with acute DoC (Frazzitta et al., 2016; Krewer et al., 2015). Frazzitta, et al., (2016) found that the experimental group statistically significantly improved their CRS-R scores compared to the conventional physiotherapy group. Krewer, et al., (2015) found that both the tilt table group and tilt table with stepping demonstrated statistically significant improvement on the CRS-R
during the intervention phase (baseline to three-week follow-up) and that the tilt table group was superior at the six-week follow-up. Krewer, et al., (2015) did not have a usual care group for comparison and Frazzita, et al., (2016) did not include a tilt table only group. Both studies found participants in both groups (experimental and comparator) demonstrated statistically significant improvement on the CRS-R from baseline to follow-up.

**Auditory Stimulation.** Four studies used auditory stimulation as an intervention. Auditory stimulation is thought to enrich the environment to improve arousal and awareness through the auditory cortex.

**Music.** Two studies used a music intervention (Binzer et al., 2016; Park & Davis, 2016). Using music stimuli, an experimental awakening approach (Wu et al., 2018) has been shown to have beneficial effects on cognitive processes (Castro et al., 2015). Both studies use music based on the concept that emotionally salient, meaningful stimuli involve more interpersonal interaction and potentially increase the likelihood of observing a response (Binzer et al., 2016; Park & Davis, 2016).

The studies did not use the same procedures (Table 2.2). Binzer, et al (2016) included participants with mixed etiology, acuity, and states of consciousness (Table 2.3) (Binzer et al., 2016). Park and Davis (2016) only included participants with acute DoC following a TBI (Table 2.3), but the study was considered to be of unacceptable quality. Both studies found positive outcomes for the participants in the treatment groups.

**Story-telling.** Two studies used the same story telling intervention, the Familiar Auditory Sensory Training (FAST) protocol (Bender Pape et al., 2015b; Sullivan et al., 2017). The FAST protocol involves family members recording stories that include
emotional content familiar to the patient. These are then played for participants via headphones (Bender Pape et al., 2015b). It is hypothesized that telling familiar stories with emotional content will increase neural activation in cortical association areas (Bender Pape et al., 2015b).

While these studies used the same protocol, one study was a case study of an individual in a chronic VS following a TBI and one study was a randomized control trial that included individuals in VS or MCS following TBI in acute and chronic phases of recovery. In the RCT, FAST participants showed statistically significant improvements on the Coma Near Coma scale resulting in a large treatment effect (Bender Pape et al., 2015b). For the case study, the individual made improvements but did not sustain these positive changes on a neurobehavioral outcome measure at follow-up (Sullivan et al., 2017). Both studies found participants improved when receiving the FAST intervention.

**Contextualization of Study Interventions**

Six of the eight studies targeting body functions (75%) and one of the 12 studies targeting body structures (8%) contextualized the intervention. Of these, one included an environmental factor and six included personal factors.

**Environmental Factors.** An intervention targeting body structures, tDCS, was administered in the participant’s home environment after training the family member in the administration procedures (Table 2.2) (Martens et al., 2018).

**Personal Factors.** Factors included familiar pictures (Cheng et al., 2018; Moattari et al., 2016), family movies (Moattari et al., 2016), scents (Cheng et al., 2018; Moattari et al., 2016), tastes (Cheng et al., 2018), music (Binzer et al., 2016; Cheng et al., 2018; Moattari et al., 2016; Park & Davis, 2016), stories (Bender Pape et al., 2015b;
Sullivan et al., 2017), and voices (Bender Pape et al., 2015b; Moattari et al., 2016; Park & Davis, 2016; Sullivan et al., 2017). One study matched the participant’s actions (e.g. breath pattern) with music matching the participant’s body rhythm and was continuously adapted to the participant’s reactions (Binzer et al., 2016). Familiar stories followed a protocol including story length, volume, and inclusion of sensory details (Pape et al., 2012).

Discussion

This review describes two types of rehabilitation treatments—those targeting body structures and those targeting body functions. In general, rehabilitation interventions targeting body structures, such as rTMS, tDCS, and RMNS did not include contextual factors that personalized the intervention to the individual with DoC and their family. Only one such study, using tDCS, contextualized the intervention by delivering it in the participant’s home. Rehabilitation interventions targeting body functions including multi-component stimulation, motor stimulation, and auditory stimulation were more likely to include contextual factors.

Contextual factors typically addressed personal factors (e.g., inclusion of the participant’s preferred activities, values, preferences, and experiences) more often than environmental factors (e.g., delivering treatment in the participant’s home). Contextualization of auditory stimulation was the most intensive with study participants receiving interventions tailored with familiar voices, stories, family movies, and music. Familiar voices have been shown to demonstrate increased cerebral activation on EEG, particularly in the temporal lobe (Wu et al., 2018). Contextualized interventions may have an influence on the individual’s response by providing saliency (Pape et al., 2012).
Many of the interventions including contextual factors showed medium to large effect sizes (Bender Pape et al., 2015b; Cheng et al., 2018; Martens et al., 2018) or statistically significant improvement on the primary outcome measure (Binzer et al., 2016; Moattari et al., 2016; Park & Davis, 2016). Due to cultural considerations, the ICF does not have a robust taxonomy for personal factors (World Health Organization, 2001). However, western rehabilitation approaches have described the role of personal motivation, habits, life stories, and environmental press (de las Heras et al., 2019; Svensson et al., 2018; Taylor, 2017). Further development of the ICF contextual factors will enable researchers to systematically describe and categorize intervention strategies.

Acceptable and high-level quality studies (n=14, 70%), according to SIGN criteria, often yielded favorable results with study participants’ demonstrating progress on primary outcome measures. Participants in a MCS were more likely to demonstrate improvement on the primary outcome measure compared to individuals in a VS. Only one of fourteen studies did not demonstrate a difference between real or sham intervention for participants in a chronic VS (Cincotta et al., 2015).

This scoping review has implications for how researchers may consider designing future trials. To date, no published study has paired interventions targeting both body structures and body functions for persons with DoC. Contextualizing interventions may maximize neural activation, integration, and patients’ responses to stimuli. While not completely analogous to interventions aimed at restoring neurobehavioral function in patients with DoC, functional electrical stimulation combined with voluntary movement has been shown to elicit greater cortical excitability compared to passive neuromuscular stimulation (Eraifej et al., 2017). Rehabilitation researchers could consider designing
studies in which a treatment targeting neural pathways primes physiological aspects of the brain in combination with a treatment facilitating neurobehavioral function, such as visually tracking a familiar picture.

More and better-quality studies are needed to improve the effectiveness of rehabilitation interventions for patients in DoC. In particular, greater coherence in categorizing interventions may facilitate enhanced comparability across large multi-center studies.

Limitations

This study incorporated a quality rating using SIGN for included studies, but low quality studies were not excluded. Additionally, many studies did not have a control group. Results should be interpreted with caution. Additionally, participants’ wide variation in acuity of injury, (e.g., some participants were 3 days post injury while other studies included participants many years post injury) makes it difficult to evaluate at what point in recovery interventions have most effect. This range in acuity may contribute to the heterogeneity in findings. Additionally, there is a possibility this study missed relevant publications; this risk was mitigated by searching multiple databases and manually searching references of relevant systematic reviews.

Conclusions

Currently, rehabilitation interventions for individuals with DoC target body structures or body functions. Interventions targeting body structures have been studied more frequently but minimally incorporate contextual factors. Four acceptable to high level studies incorporated contextual factors and all demonstrated positive findings; three of
these studies demonstrated medium to large effect sizes. This review provides preliminary evidence supporting further study of personalizing interventions.
Afterword

The scoping review provides a knowledge synthesis (KTA Framework, Creation Cycle – Figure 1.3) of treatment options for patients with DoC. Knowledge synthesis refers to second generation of knowledge, where there are multiple first generation studies about treatments for recovery of consciousness and they can be aggregated, appraised, and synthesized (Graham et al., 2006). As mentioned in the forward, a systematic review of interventions for individuals with prolonged DoC was published in 2018 (A. Thibaut et al., 2019). However, the review describes interventions to be administered by physicians and surgeons (e.g., medication and implantable devices) rather than those that rehabilitation therapists can use in practice. Therefore, this review is important for rehabilitation therapists because it focuses on treatments that they can deliver and also, the ways in which the treatment can be tailored to the patient.

The secondary research question in the scoping reviews explored the ways in which interventions were contextualized, meaning that the interventions include meaningful real-life components (e.g., personal preference, inclusion of family or peers) to the intervention (Bogner, Dijkers, et al., 2019; Bogner, Hade, et al., 2019; Hade et al., 2019). Rehabilitation practitioners often tailor interventions to the patient’s interests and preferences, yet this is particularly challenging with patients in DoC who cannot advocate for or describe their own needs and preferences. The exploration of which ingredients of interventions can be tailored in terms of patients’ personal or environmental factors may help engage patients who are not demonstrating behavioral responses to de-contextualized stimulation. This review provides rehabilitation practitioners with relevant knowledge about treatments so that when they engage in conversation about treatment planning with family caregivers the
practitioner brings forward ideas that are evidence-informed while being able to tailor the approach to the patient’s preferences.

Reviewers of this manuscript noted the need to address the following issues: 1) rationale for a scoping review when a systematic review was published within the past two years, 2) defining and operationalizing contextualization of treatments, and 3) using the WHO ICF to classify treatments rather than outcomes. These issues are briefly discussed below and either present a rationale for the way in which The forward described the rationale for the scoping review as it allowed the research question to remain broad and include: 1) all rehabilitation treatments, 2) patients with disorders of consciousness from acute to chronic stages, and 3) exploration of whether and how rehabilitation treatments were contextualized to the participant’s preferences. Whereas a systematic review question is often far more focused and narrow to a particular intervention or outcome (Arksey & O'Malley, 2005). The scoping review defined contextual factors using the WHO ICF to include environmental and personal factors. The contextualization of treatments was described in relation to Bogner et al.’s (2019) work that provides a definition of “interventions that are provided in the context of a real-life activity (Bogner, Dijkers, et al., 2019, p. 1811).” However, contextual factors according to the WHO ICF consider providing treatment in the participant’s home to be contextualized because the change in location for the administration of the treatment is an environmental factor. Therefore, a future revision to the scoping review will include a change from identifying the contextual factors to the active ingredients of the intervention that were tailored to the participant’s preferences and interests. The WHO ICF was utilized as a framework to classify treatments. One reviewer found the use of the framework to be novel and another found
this to be confusing. Therefore, a future revision will include revising the paragraph in the introduction describing contextual factors to ensure it reflects the WHO ICF framework and not the relationship to contextualizing treatments as it relates to previous work by Bogner et al. (2019). Contextualized treatments will refer to active ingredients of the intervention that were tailored to the participant’s preferences, needs, and/or priorities.
Chapter 3: Methodology

Introduction

Informed by the Knowledge to Action framework for implementation of new and evolving clinical approaches, this mixed methods research project was divided into exploratory and design phases. Throughout, the project used a pragmatic approach to ensure the recovery ruler is feasible for future adoption into clinical practice. Each research phase had unique considerations for data management procedures to assure quality, integrity, confidentiality, and accuracy.

Phase one involved exploration of the kinds of treatments available in the literature for practitioners and family caregivers to choose among, the process by which practitioners and caregivers currently discuss treatments and conduct micro-decision-making, and the examination of the most widely used neurobehavioral functional assessment, the CRS-R, for its accuracy and precision. A scoping review analyzed studies that included rehabilitation-focused interventions to understand the evidence available for treatment decision-making in patients in DoC. The qualitative study used observations in the field and semi-structured interviews to provide insight into how rehabilitation practitioners and caregivers plan and execute treatments. The quantitative study analyzed the CRS-R for its psychometric properties and item hierarchy that could inform development of the recovery ruler.

Phase two involved the design of a shared decision-making tool prototype using a pragmatic, experimental mixed methods approach to incorporate the perspectives of the rehabilitation practitioners and family caregivers. The goal of this second phase was to develop a tool that provided intuitive CRS-R assessment results that aligned to states of
consciousness. This phase involved iterations of data gathering via design groups and interviews, design, further interviews, and redesign to ensure that the tool meets the end user’s needs ultimately, facilitating communication and decision-making about treatment planning on a day-to-day basis to promote recovery of consciousness. Overall, the experimental mixed method design employed in Phase two allowed for the creation of a communication tool, the recovery ruler, with refinement prior to a future feasibility study and pilot testing study (Biesta, 2010; Creswell & Plano Clark, 2010, 2018; Fetters et al., 2013). The information collected in this study will inform the development of a strategy for implementing and testing the recovery ruler in clinical practice.

**Restatement of Research Questions & Aims**

**Phase 1**

**Aim 1.** Describe the decision-making process for family caregivers and rehabilitation practitioners when treatment planning for a person with disorders of consciousness.

Research Question 1: How do family caregivers and rehabilitation practitioners make decisions when treatment planning for a person with disorders of consciousness?

**Aim 2.** Examine the extent to which the CRS-R displays psychometric properties that make it useful for communicating about assessment results when making treatment decisions.

Research Question 2: What are the underlying psychometric properties of the Coma Recovery Scale-Revised, including step and item calibrations, measurement precision (e.g., reliability), and hierarchical item order?
**Phase 2**

**Aim 3.** Identify salient features of the Recovery Ruler that facilitate effective communication between family caregivers and rehabilitation practitioners about treatment goals and options.

Research Question 3: How should assessment result information be displayed to facilitate effective communication about treatment decisions?

**Research Design**

As described, the research problem requires a series of studies, which build upon each other and that are connected at each iteration. A mixed methods study was employed with a pragmatic approach (Creswell & Plano Clark, 2018) since this design provided an appropriate methodology to develop a shared decision-making tool in which qualitative studies complemented and supported the quantitative results. Phase one explored evidence for treatments available for practitioners and family caregivers to choose among, the process by which practitioners and caregivers currently make daily treatment decisions at the patient’s bedside, and the examination of the most widely used neurobehavioral functional assessment, the CRS-R, for its accuracy and precision. The scoping review describes rehabilitation interventions found in 20 manuscripts. The ethnographic, qualitative study explores 14 rehabilitation encounters and interviews with seven rehabilitation practitioners and 17 family caregivers. The quantitative study involved Rasch analysis of a retrospective dataset of 262 individuals with DoC following brain injury assessed by the CRS-R. Phase two created a recovery ruler using an explanatory, sequential mixed methods approach. A key aspect of the Rasch co-calibration was the generation of cut-points delineating states of consciousness.
Generating cut-points was considered important because treatment decision-making is often connected to the patient’s state of consciousness. The Rasch co-calibration and prior CRS-R analyses informed the content for a shared decision-making tool. The qualitative, participatory study involving key stakeholders iteratively integrated person-centered measurement principles, content and re-designed the tool. Family caregivers and rehabilitation practitioners participated in design groups and interviews using cognitive interview methods to inform the development and refinement of the recovery ruler.

**Setting of the Study**

**Phase one** involved observation of rehabilitation practitioners and family caregivers in Washington, D.C., United States of America. Phase one also involved interviewing rehabilitation practitioners and family caregivers, however, these participants were geographically dispersed throughout the United States, participating via teleconferencing software. Rasch Analysis used CRS-R data collected at the Shirley Ryan Ability Lab in Chicago, IL, the Texas Institute for Rehabilitation Research (TIRR) in Houston, TX, Edward J. Hines Veterans Administration Hospital in Hines, IL, and from the multi-center study referred to as the Amantadine trial (Giacino et al., 2012).

**Phase 2** allowed for both national and international recruitment as participation occurred using video-conferencing software for the cognitive interviews and design groups.

**Participants**

**Rehabilitation Practitioners.** The rehabilitation practitioners were recruited based on convenience and criterion sampling. Rehabilitation practitioners were required to have experience working with patients with disorders of consciousness as well as use
of the CRS-R. Variation in practice setting (e.g., intensive care unit and inpatient rehabilitation facility) was important for understanding how communication may occur differently across rehabilitation settings.

**Family Caregivers.** Caregivers were family members who made decisions about their loved one’s care. Thus, the family caregiver did not need to live with their loved one, who may have resided at a facility, but needed to be primarily responsible for decision-making. Family caregivers were recruited using a snowball sampling strategy. The researcher’s network provided initial contacts and those contacts were asked for one to three more potential caregivers. All caregivers were 18 years or older.

**Patients With Disorders of Consciousness.** Patients were observed during their treatment sessions with rehabilitation practitioners, and when possible, family caregivers. All patients were in a state of disordered consciousness according to the practitioner and above the age of 18 years old.

**Instruments**

- **Caregiver Semi-Structured Interview Guide.** See Appendix A.

- **Rehabilitation Practitioner Semi-Structured Interview Guide.** See Appendix B.

- **Rehabilitation Practitioner Observation Log.** See Appendix C. The observation log was completed during each field observation.

- **Control Preferences Scale.** See Appendix D. The control preferences scale was completed by rehabilitation practitioners and family caregivers recruited for field observations.

- **Design Group Guide.** See Appendix E.
Data Collection and Analyses

Data collection and analyses began following approval by the researcher’s institutional Internal Review Board (IRB).


Data Collection. Data for the scoping review came from a larger systematic review. Volunteers from the larger systematic review effort extracted data from included studies using a data extraction form and also completed a SIGN form with a quality rating, when applicable. Manuscripts included in the larger systematic review were reviewed at the title, abstract, and full text level to confirm the manuscripts relevancy to this study’s research question. Data extraction forms were confirmed by two members of the research team. Additional data about the intervention’s contextualization was extracted by JW and a volunteer research intern. Additional details can be found in Chapter 2.

Data Analysis. The interventions described in the 20 included studies were categorized using the WHO ICF. Descriptive analyses were used to report frequency of study designs, time since injury of the study sample, proportion of rehabilitation interventions targeting body structures and functions, and the frequency of using contextual factors during interventions. A narrative synthesis summarized the studies nested within the WHO ICF domains (Patton, 2015).
Data Management. All data extraction forms were received via email from contributors and stored on Box. Extraction forms were checked for accuracy and completeness.

Aim 1. Describe How Family Caregivers and Rehabilitation Practitioners Make Treatment Decisions

Data Collection. Data collection, which occurred with family caregivers and rehabilitation practitioners involved both clinical observations and interviews.

Clinical Observations. IRB approval was received from GWU on May 22, 2019. A convenience sampling strategy was employed in the Washington, D.C. area to recruit rehabilitation practitioners. Rehabilitation practitioners were consented to participate in observations exploring how and what they communicate with caregivers and other team members and how they make sense of assessment data related to recovery of consciousness. Observations provided insight into how practitioners make treatment decisions. Once a rehabilitation practitioner had a patient on their caseload that met inclusion criteria, the researcher met first with the family member to discuss the research study. The family member provided consent for themselves and the patient with disorders of consciousness.

During the clinical observation, the researcher observed the treatment encounter. The treatment encounter was audio-recorded and transcribed. Field notes, and an observation log (Appendix C), were completed for each treatment encounter. The Control Preferences Scale was completed at the first encounter by the rehabilitation practitioners and family caregiver (Appendix D).

Interviews: Family Caregivers. IRB approval was received on March 15th, 2019. Caregivers were being recruited using snowball technique from the researcher’s personal
network. Once caregivers were consented and agreed to participate, they were asked about how they communicate with rehabilitation practitioners and what they would like to communicate with rehabilitation practitioners following a semi-structured interview guide (Appendix A). Caregivers were also asked if they received information about assessment tools or if assessment results had been described to them in the past. All caregivers who completed an interview also completed a demographic survey using RedCap. These family caregivers are not the same family members from the observational data collection.

**Interviews: Rehabilitation Practitioners.** IRB approval was received from GWU on May 22, 2019. Interviews were conducted with practitioners that consented to the clinical observations. Rehabilitation practitioners were consented to participate in a semi-structured interview exploring how and what they communicate with caregivers and other team members and how they make sense of assessment data related to recovery of consciousness for treatment planning (Appendix B).

**Data Analysis.** All transcripts were transcribed verbatim onto a word document from listening to the audio recording. The researcher listened to the audio recording while reading the transcript to check for accuracy. Transcripts were de-identified by removing the names or places and people. Committee members, LD, and CP checked the transcripts and audio-recordings for authenticity. De-identified transcripts were uploaded to NVivo 11 Plus for content and thematic analysis (Fereday & Muir-Cochrane, 2006). Grounded theory principles were employed to generate categories and themes from the data. A constant comparative method was used to compare the interview data between and within the rehabilitation practitioner and caregiver groups. Initial coding used the line by line
‘open coding’ process (Saldana, 2016). These open codes then organized into axial codes. Some axial codes generated sub-categories. During the analytic process, the researcher wrote analytic notes and memos for transparency. Memo writing clarified patterns that were emerging resulting in theory generation. Furthermore, the researcher used bracketing and journaling to capture thoughts and feelings that occurred during data collection and analysis.

Strategies for trustworthiness were used during the research process to address credibility, transferability, dependability, and confirmability (Shenton, 2004). To ensure credibility, JW had prolonged engagement with individuals in the rehabilitation context and multiple sources of data (e.g., observations and interviews) were analyzed to address the strengths and weaknesses of each method. Coding also included negative cases when shared decision making did not occur. To describe transferability, results were provided on the participants and number of treatment activities to describe the context in which the data was collected. Dependability of the data were achieved by using overlapping methods. Additionally, JW asked the practitioners and caregivers clarifying questions after each observation. To support confirmability of the data, JW used a reflexive process throughout the data collection and analyses.

**Data Management.** All consent forms were stored on the GW Box and only authorized members of the research team had access to these forms. All interviews and observations were audio-recorded and stored on the GW Box site. The initial transcription was verbatim from the audio-recording. All transcripts were de-identified, and any names used during the interview were changed to protect the individual’s privacy and confidentiality. A member of the research team performed quality checks to ensure
that the audio-recording was accurately transcribed verbatim. All consent forms, surveys, observation forms, audio-recordings, and analytic files were stored and/or uploaded to the GW box site, while hard copies were stored in a locked cabinet.

Aim 2. Examine the Underlying Psychometric Properties of the Coma Recovery Scale-Revised (CRS-R), Including Step and Item Calibrations, Item Order and Reliability

Data Collection. Retrospective data from 262 participants with DoC following a brain injury were used to examine the CRS-R’s precision, accuracy, and item hierarchy. Participants had at least one CRS-R record and up to 37 re-assessments. Non-disclosure and/or data use agreements (NDA, DUA) were signed, and data variables were provided to the researcher. The data were cleaned using STATA. The sample included individuals ≥14 years of age with disorders of consciousness following a brain injury. The dataset included variables such as: gender, age at time of injury, days post-injury at first assessment, state of disordered consciousness, and veteran/civilian status. These variables were critical to interpreting the generalizability of the results as well as for looking at potential bias in person measurement (Tennant & Pallant, 2007).

Data Analysis. The data were analyzed using the partial credit Rasch model allowing each item’s rating scale steps to take on its own rating scale structure (Bond & Fox, 2015). Each rating scale step was examined to ensure that they 1) each had at least 10 responses to ensure stability in estimation of the Andrich threshold, 2) proceeded monotonically within each item, and 3) average category measures advanced indicating different levels of ability (Bond & Fox, 2015; Eckes, 2011; Linacre, 2002). To ensure the data did not violate the assumption of local independence, Mallinson’s method for repeated measures was used to select each patient from only one timepoint for the initial
calibration (Mallinson, 2011). For the initial calibration, the rating scale structure, item fit, and person fit was assessed. Items and persons were considered to misfit if their infit meansquare is <0.6 or >1.4 (Wright, 1994). Once all items and persons generally fit the model, logits were transformed to a 0-100 scale before generating the item and rating scale step anchor files. The anchor files were used to conduct the validity analyses on a validation subsample. Once the anchors were found to be reproducible for item and person measures, the remaining analysis used the full sample with the anchors from the calibration sample. Analyses for structural validity assessed rating scale structure, item fit, person separation index and reliability, as well as the hierarchical order and unidimensionality. An aspect of structural validity is determining that the CRS-R items identify a unidimensional construct. The apriori construct is neurobehavioral function and therefore, lower rating scale steps such as a 0 will reflect less neurobehavioral function and it will be ‘easier’ for more patients to respond to items and rating scale steps lower on the hierarchy. Whereas items and rating scale steps that are higher on the hierarchy will reflect more neurobehavioral function and will be ‘harder’ for patients to respond to the more complex stimuli.

To connect this analysis to treatment planning, external validity of the CRS-R to states of consciousness were examined. State of consciousness was determined for each participant’s CRS-R record by applying the Aspen criteria, which were first described in 2002 (Giacino et al., 2002). Interdisciplinary perspectives contributed to a document delineating between the different states of consciousness using published articles and consensus-based recommendations during meetings known as the Aspen Workgroup (Giacino et al., 2002) (Table 3.1). The Aspen Criteria have been applied to the CRS-R
assessment to identify which items and rating scale steps align to each state of consciousness (Schnakers et al., 2009)(Table 3.2). The Aspen Criteria were created to improve consistency across practitioner’s diagnosing states of consciousness; however, empirical work is required to evaluate the criteria.

**Table 3.1**

*Descriptions of States of Consciousness Applying the Aspen Criteria*

<table>
<thead>
<tr>
<th></th>
<th>Coma</th>
<th>Unresponsive Wakefulness Syndrome /Vegetative State</th>
<th>Minimally Conscious State</th>
<th>Emerging Minimally Conscious State</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Opening</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Sleep/Wake Cycles</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Visual Tracking</td>
<td>No</td>
<td>No</td>
<td>Often</td>
<td>Often</td>
</tr>
<tr>
<td>Object Recognition</td>
<td>No</td>
<td>No</td>
<td>Inconsistent Object Use (x2)</td>
<td></td>
</tr>
<tr>
<td>Command Following</td>
<td>No</td>
<td>No</td>
<td>Inconsistent</td>
<td>Inconsistent</td>
</tr>
<tr>
<td>Communication</td>
<td>No</td>
<td>No</td>
<td>Inconsistent</td>
<td>Functional</td>
</tr>
<tr>
<td>Contingent Emotion</td>
<td>No</td>
<td>No</td>
<td>Inconsistent</td>
<td>Inconsistent</td>
</tr>
</tbody>
</table>

**Table 3.2**

*Coma Recovery Scale-Revised Items and Rating Scale Steps Are Aligned to the States of Consciousness*

<table>
<thead>
<tr>
<th>CRS-R items</th>
<th>Unresponsive Wakefulness Syndrome /Vegetative State</th>
<th>Minimally Conscious State</th>
<th>Emerging Minimally Conscious State</th>
</tr>
</thead>
</table>
Therefore, a part of this aim was to analyze the external validity of the CRS-R in two ways: 1) Spearman’s correlation between CRS-R person measures and states of consciousness and 2) co-calibration aligning states of consciousness to the CRS-R items and rating scale steps. A Spearman’s correlation between CRS-R person measures and the states of consciousness (Aspen-based) determined the strength of the relationship. A co-calibration used the step and item anchors for the CRS-R data to then layer on top the Aspen-based states of consciousness (Mead, 2009; Perkins et al., 2008; Wright et al., 2000). The half-point rating scale step thresholds were used from the Aspen-based states.
of consciousness to examine the cut-points for VS, MCS, and eMCS. All analyses were completed using Winsteps 4.0.1 (Linacre & Wright, 2017).

**Data Management.** All NDA and DUA forms were stored on the GW box site. Each site sent de-identified data. These data were stored on the GW box site as well as all analytic files. All original files were saved and when changes were made it was saved as a new file. All changes were recorded in an electronic notebook (i.e., do file). All data variables were named and assigned response categories appropriately. Any missing data were appropriately reported. Quality was assured through discussions with the methodological expert on the committee.

**Phase 2: Design Phase.**

**Aim 3: Identify Salient Features of the Recovery Ruler That Facilitate Effective Communication Between Caregivers and Therapists About Treatment Goals and Options.**

The Rasch analysis from Phase 1 produced a Wright Map, which arranges the CRS-R items from less to more neurobehavioral function (NBF) on a linear continuum while transforming the range of scores to 0-100 (Figure 3.1). Conceptually, oral/reflexive movement reflects the easiest item while functional communication and functional object use were harder items for neurobehavioral function as ‘harder items’ reflected indications of emergence into consciousness (La Porta et al., 2013; Lannin et al., 2013; Pape et al., 2014). A Keyform illustrated each rating scale step and the threshold to achieve the next level of functioning on each item (Linacre, 1997; Velozo & Woodbury, 2011). This Keyform represented the initial item and rating scale step hierarchy. An important and unique contribution of this study was the inclusion of threshold ranges for states of
consciousness using co-calibration (Hughes et al., 2003; Perkins et al., 2008). A co-calibration was chosen because it aligns the CRS-R items to the states of consciousness (Wright et al., 2000). The specific benefit of using the Rasch model for the co-calibration is that it places the variables on the same equal-interval scale of measurement, which enables a visual depiction of the alignment between items, rating scale steps, and states of consciousness as well as the ability to detect any deviations from expected patterns of responses (Wright et al., 2000). By knowing which rating scale step for each item aligns with each state of consciousness will enable rehabilitation practitioners to start linking assessment data with important clinical concepts that inform treatment planning. In turn, this is expected to foster more collaborative conversations between rehabilitation practitioners and family caregivers.

A participatory design brings the perspectives of caregivers and practitioners together to participate in design groups or design interviews to refine the initial design of the recovery ruler. During the design groups/interviews, a semi-structured interview guide helped identify features needed to foster information exchange and collaborative deliberation (Krueger, 2000; Patton, 2015). Content analysis and constant comparative methods (Glaser, 1965; Green & Thorogood, 2014; Patton, 2015) were used to classify the participant’s words with similar attributes (e.g., eliciting values, describing treatment preferences and visual design of the recovery ruler) to determine what needs to be added or removed. This collaborative process, between caregivers and practitioners, describes how two PCM principles, comprehensible and timely and patient-driven are incorporated into the recovery ruler design in order to facilitate a third PCM principle of transparency when the two stakeholders exchange information and discuss treatment planning.
A participatory, step-wise process including caregivers and practitioners created a recovery ruler that incorporates PCM principles (Groen-van de Ven et al., 2018; Meiland et al., 2014; Robinson et al., 2009; Span et al., 2018). Rehabilitation practitioners and family caregivers shared their perspectives to ensure the recovery ruler was easy to understand (PCM principle: comprehensible), contextualized to the patient (PCM principle: patient-driven) to facilitate real time assessment results (PCM principle: timely) that were available to all stakeholders who understood how the results were generated and would be used (PCM principle: transparent), ultimately facilitating a discussion between these two stakeholders about the patient’s functional status and treatment plan (American Institutes for Research, 2020).

**Data Collection.** Caregivers and practitioners were invited to a virtual design group. Caregivers and practitioner participated in two one-hour design groups to re-engineer the visual representation of CRS-R items to incorporate meaningful, qualitative content to create the recovery ruler. The purpose of gathering together both of the stakeholders was to co-create elements the recovery ruler prototype.

Practitioners and caregivers were recruited from a convenience sample available from the GW SMHS Advanced Metrics Lab database (Creswell, 2013; Patton, 2015). JW led the design groups using a semi-structured interview guide (Appendix E). If a participant could not attend a design group, a 1:1 semi-structured interview occurred. All design groups/interviews were audio-recorded and transcribed verbatim. After each design group, participants completed a survey in RedCap to provide demographic information, System Usability Scale, Acceptability of Intervention Measure, Intervention Appropriateness Measure, and Feasibility of Intervention Measure.
Design Group 1: The purpose of the first design group was to critique the initial recovery ruler prototype for PCM principles: 1) comprehensible and timely and 2) patient-driven. The initial recovery ruler prototype was based on output from the Rasch analysis aligning the CRS-R items and rating scale steps to the states of disordered consciousness. The caregivers and rehabilitation practitioners focused on how intuitive the hierarchy of the CRS-R is for providing comprehensible and timely assessment data. The participants brainstormed on how to make the hierarchy easier to understand. The researcher used case examples to walk-through a clinical scenario. A case example included data plotted on the prototype recover ruler to initiate conversation about how the participant’s perceived the data (e.g. patient’s progress, strengths, and weaknesses). Participants critically examined the prototype and whether the visual representation of CRS-R items aided (or did not aid) the understanding of the assessment results. Recommendations were made to incorporate qualitative descriptors on the prototype. The goal was to ensure the recovery ruler was patient-driven, assessment data was easy to understand, and that the keyform facilitated timely assessment results being discussed between the practitioners and caregivers. Feedback from this first design group was used by JW and the instructional designer to create three stakeholder-driven prototypes for the second design group.

Design Group 2: The purpose of the second design group was to ensure the first two PCM principles were incorporated in the new prototype and identify ways in which the recovery ruler could be shared with the family caregivers (PCM Principle: transparency). During the second design group, practitioners and caregivers reviewed the content analysis from the first design group as a method of member-checking (Patton,
After member-checking, three stakeholder driven prototypes were examined and discussion occurred as to whether and how the new prototypes reflect suggestions from the first design group. A semi-structured interview guide explored how the new prototypes incorporated PCM principles. Caregivers and practitioners provided additional suggestions to ensure the recovery ruler is easy to understand and interpreted by both stakeholders in the same way. A cognitive walk through of a case scenario was conducted to understand if and in what ways the recovery ruler facilitates communication about assessment results and treatment planning. After the second design group, the recommended changes were made by the instructional designer under the direction of the researcher resulting in the final prototype that is ready for testing in a future feasibility study.

**Data Analysis.** All audio-recordings from the design groups/interviews were transcribed verbatim. Content analysis of each transcript was conducted by two coders, JW and a non-credit research intern (Patton, 2015). The latter was a Bachelor student who has received qualitative research training for a year from JW and CP. Any coding discrepancies were resolved through discussion with the qualitative expert mentor (CP). Content analysis generated codes identifying aspects of the prototype to keep, add, or tailor (Patton, 2015). Constant comparative method was used to compare codes from the practitioners and caregivers to facilitate a balance of perspectives (Glaser, 1965). Final codes were provided to the participants in a presentation creating an opportunity for member-checking and validation (Patton, 2015). Descriptive analyses were conducted on the survey data from each design group.

**Data Management.** All consent forms were stored on the GW Box and only authorized members of the research team had access to these forms. All design
groups/interviews were audio-recorded and stored on the GW Box site. Detailed memos were stored on the GW box site. The research team had access to these files using the GW Box.
Chapter 4: Results

Foreword Paper 4.1

This chapter presents the results from the first of the three primary research objectives of this project that broadly were described to inform shared decision-making, psychometric properties of the Coma Recovery Scale-Revised, and the development of a recovery ruler to facilitate shared decision-making between family caregivers and rehabilitation practitioners when treatment planning. The initial primary objective was to describe the barriers and facilitators of the shared decision-making process for family caregivers and rehabilitation practitioners when treatment planning for a person with disorders of consciousness. As initially conceived, this involved application of a medical model of shared decision-making that included using the OPTION-5 to evaluate to what extent shared decision-making occurred when treatment planning. However, in the course of investigation, it became evident that treatment decisions in rehabilitation were recursive and occurred in-the-moment. Multiple treatment decisions were made within one rehabilitation encounter and the treatments did not always require deliberation about risks and benefits. Therefore, using tools like the OPTION-5, that evaluate shared decision-making with components such as deliberations about the risks and benefits of a treatment (e.g., whether or not to use a CT to diagnose uncertain abdominal pain (Ijaz et al., 2018)), were not feasible for evaluating shared decision-making that occurred at the patient’s bedside in rehabilitation practice.

During this exploratory work that included hours observing rehabilitation encounters and interviewing family caregivers and rehabilitation practitioners, it became clear that addressing the first primary objective required taking a step back to uncover how
shared decision-making occurs in the rehabilitation context. Therefore, the analytic plan changed from a framework analysis using the Theoretical Domains Framework to an initial round of open coding and the use of constant comparative analysis to identify patterns when shared decision-making was and was not occurring. This second paper presents the results of a study of two types of shared decision-making, integrative and declarative, grounded in observational and interview data with family caregivers, rehabilitation practitioners, and patients with disorders of consciousness.
Conceptualizing Treatment Decision Making in Rehabilitation Encounters When Patients Are Without a Voice: A Grounded Theory Analysis

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Acknowledgements: None.

Keywords: shared decision-making; rehabilitation; disorders of consciousness; brain injury; qualitative
Abstract

**Objective:** The purpose of this study is to explore whether micro treatment decisions are shared between practitioners (e.g., rehabilitation therapists and physiatrists) and family caregivers of a patient that is in disorders of consciousness following a brain injury.

**Design:** Ethnographic approach used clinical observations and interviews with caregivers and rehabilitation practitioners. Interviews with family caregivers from a separate study were integrated into this study.

**Setting:** Observations of rehabilitation encounters occurred in a level I trauma hospital. Interviews occurred either virtually or in-person at a location suitable to both the participant and interviewer.

**Participants:** Observations included interactions between rehabilitation practitioners, family caregivers, and patients with disorders of consciousness. Interviews included family caregivers and rehabilitation practitioners.

**Results:** Fourteen clinical observations resulted in 88 treatment decision moments. To triangulate the data, 20 interviews with family caregivers and 8 interviews with rehabilitation practitioners were included. This study found that one rehabilitation encounter has multiple treatment activities and micro-decisions that occur at the patient’s bedside. Treatment decisions were shared by the rehabilitation practitioner(s) and family caregiver or made with a unilateral perspective. Shared treatment decisions occurred in two ways—integrative and declarative. Integrative shared decision-making occurs when family are included in the treatment session and their unsolicited contributions provided new information for in-the-moment decision-making. Declarative decision making occurs
when the therapist elicits the patient’s values, preferences, and/or priorities from the family and then executes these preferences within the session.

**Conclusions:** Partnership between the stakeholders is the hallmark of shared decision-making in rehabilitation treatments for persons with disorders of consciousness. The explication of two types of shared decision-making in the rehabilitation context will inform the field as to how families and patients are engaged as partners when treatment planning.

**Introduction**

Patients with severe acquired brain injury (BI) resulting in disorders of consciousness (DoC) rely on their family caregivers and rehabilitation practitioners to plan treatments that facilitate their arousal and awareness. DoC includes comatose, unresponsive wakefulness syndrome (UWS), minimally conscious state (MCS), and emerging from MCS (Giacino et al., 2020). Patients in DoC can remain in one of these unconscious states for up to two decades (Beaumont & Kenealy, 2005; Giacino et al., 2020). During the acute phase of the injury, rehabilitation practitioners plan treatments to facilitate recovery of consciousness. During the chronic phase of DoC, opportunities arise to revisit treatment planning because patients have demonstrated improvement in function ten years post injury (Hammond et al., 2018).

Available research has focused on caregivers and rehabilitation practitioners making life-changing decisions such as withdrawing artificial nutrition and hydration rather than on less “critical” but equally important decisions such as when to start a swallowing program or sitting the person up (Demertzi et al., 2011; Fins, 2009a, 2013; Jox et al., 2015; Kuehlmeyer et al., 2012; Rodrigue et al., 2013). Due to the paucity of
effective rehabilitation interventions that facilitate recovery of consciousness, one study described how family caregivers navigate decision making around novel diagnostic and treatment procedures (Smart & Giacino, 2015). To date, treatment decisions about daily rehabilitation interventions focusing on improving arousal and awareness has not been explored.

Treatment encounters are initially constructed by either the rehabilitation practitioners (e.g., occupational therapy, physiatry, physical therapy, and speech language pathology) or family caregivers who identify activities that will benefit the patient either in a medical setting or at home. During the day, multiple small scale decisions occur frequently at the patient’s bedside known as micro-decisions (Karlsen et al., 2020). Micro-decisions occur in response to the patient’s behavioral responses initiating the desire to change the treatment plan. Micro-decisions might be about whether to get the patient out of bed or to start a swallowing program. Rehabilitation practitioners and family caregivers make these daily micro-decisions about treatments by observing and interpreting the patient’s behavioral responses or lack thereof.

Decision making models have been described in relationship to DoC, but they are focused on medical decisions (Armstrong, 2019). One model that has growing interest is shared decision-making (Armstrong, 2019). Shared decision-making typically involves choices between two or more evidence-based treatment options (Elwyn et al., 2016). Rehabilitation practitioners have limited evidence-based treatment options to choose from for patients with DoC (A. Thibaut et al., 2019). Practitioners experience uncertainty interpreting patients’ behaviors and must navigate system-level factors such as insurance company rules and their organization’s productivity demand when selecting treatments.
(Rose et al., 2017; Weaver et al., 2018). Shared decision-making in rehabilitation may share similarities with medically focused decision-making, such as including the exchange of information, elicitation of and incorporation of the patient’s preferences into treatment and agreeing on a decision to implement (Armstrong, 2019; Entwistle & Watt, 2006, 2016; Kaizer et al., 2012). However, in a field that lacks multiple effective treatments, the deliberation about treatments with clear risks and benefits will be missing.

Despite multiple recommendations for engaging families and patients in their treatment encounters (Centers for Medicare & Medicaid (CMS), 2018; Josiah Macy Jr. Foundation (JMF), 2014), there is very little research about the process of making treatment decisions (Olding et al., 2016). Treatment decisions can occur using different decision-making models such as: paternalistic, informed, shared, and clinician as best agent for decision making (Armstrong, 2019). Current decision-making models stem from medical decision-making literature (Charles et al., 1999; Seaburg et al., 2014) and not rehabilitation literature. Therefore, this study aims to explore how decision-making occurs within the context of rehabilitation. To address this knowledge gap between the literature and clinical practice, the purpose of this study is to explore whether micro treatment decisions are shared between practitioners (e.g., rehabilitation therapists and physiatrists) and family caregivers of a patient that is in DoC using an ethnographic approach.

**Theoretical Underpinnings**

Mattingly & Fleming’s description of clinical reasoning illustrates how the rehabilitation therapy process differs from the traditional medical decision-making literature (Mattingly & Fleming, p.4). Clinical reasoning is a process that occurs when
rehabilitation practitioners make decisions. Clinical reasoning occurs in different modes: procedural, interactive, and narrative (Mattingly & Fleming, 1994). Each type of reasoning is used to understand a clinical problem and includes both action and meaning that iteratively evolves as new information is known. In this way, and based on clinical and research experiences, it is possible for decision making to be similar to clinical reasoning, in that it can occur in many ways such as, in-the-moment and recursively across multiple treatment encounters.

There is potential for partnership between the triad (patient, family caregiver, and rehabilitation practitioner) when treatment planning. The family caregiver represents the voice of the patient’s and their own preferences, values, and priorities. Each stakeholder brings specific knowledge and responses that collectively can inform shared decisions around treatments that will improve person-centered care (Figure 4.1.1).
Figure 4.1.1

Conceptual Framework for Partnership When Treatment Planning for a Patient in a Disordered State of Consciousness

Treatment and Daily Life Decisions

Family Member
- Pre-injury relationship with patient
- Experience of health care journey
- Daily interactions & observations with patient

Patient in Disordered State of Consciousness Following a Brain Injury
- Pre-injury personality & medical history
- Post-injury co-occurring medical conditions & symptoms
- Post-injury unintelligible vocalizations and non-verbal behaviors

Rehabilitation Practitioner
- Focuses on formal definition of levels of awareness
- Interprets behaviors from “medical” perspective
- Knowledgeable in assessment and interventions
- Time limited interactions with patient
Methods

This exploratory study describes whether and how family caregivers (inclusive of their voice and the patient’s voice) and rehabilitation practitioners share decisions around treatment planning when the patient is in a state of DoC following a BI. The research question is: “How do family caregivers and rehabilitation practitioners make treatment decisions together when the patient is in DoC following a BI?” An ethnographic methodology was used to explore the behaviors and interactions of family caregivers and rehabilitation practitioners caring for a patient in a disordered state of consciousness following a brain injury. Observational data are foundational to an ethnographic approach for understanding how decisions occur in real time as opposed to a narrative approach that would require the practitioner and family caregiver to recall the nuanced details of each decision (Olding et al., 2016). An ethnographic approach also allowed the data to be inclusive of the patient with DoC. This study was approved by the institutional review board at The George Washington University and Oakland University.

Positionality

The first author, JW, has worked clinically with patients in DoC as an occupational therapist for over 10 years. She has also collaborated with the co-authors and caregiver partners on studies exploring the caregivers’ and clinicians’ perspectives of recovery of consciousness (Guernon et al., 2018; Weaver et al., 2018; Weaver et al., 2019). Much like a therapist will use their body as a treatment tool (Mattingly & Fleming, 1994) in clinical practice, the first author brings this experiential knowledge in practice and research when analyzing the data. The first author collected the data and met with co-authors to discuss the data collection process, memos, and coding.
Collectively, the research team brings multiple disciplinary perspectives such as occupational therapy, physical therapy, and speech and language pathology. Co-authors also bring a sociological perspective, expertise in qualitative methodology, and a burgeoning interest in shared decision-making. All team members have been engaged in qualitative work in their past experiences. The first author and AG have extensive training under the mentorship of CP, specifically in qualitative data collection and analysis of topics related to caring for a person in DoC.

**Sources of Data**

The data come from two studies. A prior study, known as *No One Listens to Me*, collected interviews with family caregivers using narrative methods to elicit stories about when the family noticed meaningful change in their loved one with DoC (Weaver et al., 2019). The interview data from the *No One Listens to Me* study describes moments when treatment decisions were made in and out of therapy encounters. The emphasis of the aforementioned interviews was to explore meaningful change from the caregivers’ perspectives of their loved ones with disorders of consciousness. This present study collected additional data to understand how rehabilitation practitioners and family caregivers make rehabilitation treatment decisions together. This study used an ethnographic methodology to include the collection of observational data and interviews with family caregivers and rehabilitation practitioners (Table 4.1.1). Combining these data allow for triangulation of the family caregiver experience across settings (Denzin, 1978).
Table 4.1.1

Data Sources and Collection Methods

<table>
<thead>
<tr>
<th>Data Collection Methods</th>
<th>No One Listens To Me Study</th>
<th>Treatment Decision-Making Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interviews with Family Caregivers</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Interviews with Rehabilitation Practitioners</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Observations of Rehabilitation Encounters</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

**Sampling**

Previously collected interviews with family caregivers were included in this study (Weaver et al., 2019). In the previous study, a convenience sampling strategy was used, and the caregiver partners reached out to their personal networks to facilitate recruitment. The caregiver partners posted the recruitment flyer to their social media pages and groups. The convenience sampling along with a snowball strategy technique enabled the interviews to have a national reach.

To supplement the previously collected interview data, this study conducted observations of rehabilitation encounters by recruiting rehabilitation practitioners, family caregivers, and their loved one (e.g., the patient) from a local urban, level I trauma hospital. For additional data collection, an opportunistic sampling approach was used. The first author gained the confidence of the practitioners at the local trauma hospital. When a patient, potentially meeting inclusion criteria, was admitted to the intensive care unit, a practitioner would notify the first author facilitating access for recruitment. The strength of the opportunistic sampling approach was it allowed for new leads for the collection of observational and interview data (Creswell, 2013). It was important to
supplement existing interview data with the observations because the research question aims to uncover how decisions are made, especially their process thus requiring an in-depth approach. Observations allow the researchers to see decisions occur in real time, how family caregivers and rehabilitation practitioners talk and communicate with one another when making treatment decisions. The first author collected additional interview data to add context to the decision-making process. The interview guide focused on asking rehabilitation practitioners and family caregivers about how they make treatment decisions, what sources of information were considered, and if there were other influencing factors.

**Inclusion/Exclusion Criteria.** Participants included rehabilitation practitioners, patients in a disordered state of consciousness, and family caregivers of the patient. Participants were eligible if they were an adult (≥18 years). Rehabilitation practitioners were eligible if they were treating patients with disorders of consciousness. Patients were eligible if they were in a state of disordered consciousness (comatose, vegetative state, or minimally conscious state) when consented. Family caregivers were eligible if they described their role as a caretaker for their loved one with disorders of consciousness.

**Data Collection**

Data collection approaches included: 1) observations of rehabilitation encounters, 2) interviews with rehabilitation practitioners, and 3) interviews with family caregivers. These approaches were used to uncover the multiple realities that are constructed through lived experiences and interactions with others (Creswell, 2013).

**Observations.** Observational data was collected in order to see and hear the interactions between the practitioner(s), family caregiver, and patient in the hospital
setting. Observations allowed the researcher to uncover how the rehabilitation practitioners and family caregivers interact and talk to one another and make decisions. Once a practitioner notified the first author about a possible participant, the first author consented the family caregiver and patient. Then, the first author reached out to the rehabilitation team and consented treating practitioners. The family caregiver(s) and rehabilitation practitioners completed the Control Preferences Scale (CPS). The CPS describes how a person prefers to make decisions (Degner et al., 1997) and was used to classify the preferred decision-making pattern of each practitioner and family caregiver. The treating practitioners notified the first author of their schedule with the consented patient each day to enable observations of the clinical encounter. Each clinical encounter was audio recorded and transcribed verbatim. Fieldnotes were recorded by the first author and embedded into the transcripts. To create consistency across clinical encounters, the first author completed a structured observation guide during each encounter. The persistent observation in the field was used to build trust and learn the culture (Creswell, 2013). To support triangulation of the observational data, the first author debriefed with the family caregiver and practitioner after the observations to clarify the reasoning behind actions. All observations were audio-recorded and transcribed verbatim. Fieldnotes and debriefing notes were embedded into the final observation transcript.

**Interviews with Rehabilitation Practitioners.** Rehabilitation practitioners were interviewed to uncover how they make treatment decisions when working with a patient and their family in the hospital setting. A semi-structured interview guide was used to ask about assessment use, information that informed treatment decisions, and engagement with family caregivers. The interviews occurred over the phone or in person at a site
mutually agreed upon between the participant and first author. All interviews were audio-recorded and transcribed verbatim.

**Interviews with Family Caregivers.** Interviews with family caregivers from the previous study, *No One Listens to Me*, were used along with newly collected data. Those data from previously collected interviews with family caregivers were included as these interviews explored the family caregiver’s perception of meaningful change in their loved one with disorders of consciousness. The first author re-interviewed some of these family caregivers to further elicit information about how a meaningful change led to making a treatment decision. The previous interviews did not go into detail about ‘how’ caregivers made decisions and what information they considered. All interviews used a semi-structured interview guide and occurred using video-conferencing software to increase the geographical variation of the sample. All interviews were audio-recorded and transcribed verbatim.

**Data Analysis**

Data analysis occurred in four stages using NVivo11 Plus. First, an inductive open coding of the observational data occurred by JW and AG. During the open coding and multiple readings of the observational transcripts, it became apparent that multiple treatment activities occurred during a single therapy encounter. After six observational transcripts were open coded using in-vivo methods, the first author met with AG, LD, and CP to come up with more focused codes. Second, because the observational transcripts had multiple moments when different treatment decisions were present; either explicitly or implicitly, each treatment decision was coded to understand how often decisions were being made in rehabilitation. Treatment decisions could be explicit or
implicit. Explicit decisions were identified when discussions about ‘what to do next’ were articulated out loud, often to another person. Implicit decisions were identified when the action of the therapist changed but the actions were not discussed or articulated aloud. Both explicit and implicit decisions may use tacit knowledge. Prior experience, action, and reflection develops a rehabilitation therapist’s tacit knowledge and this knowledge is not articulated but embedded in how they execute their actions with patients (Mattingly & Fleming, 1994). Third, each treatment decision in the observational transcripts were coded using the focused coding structure. The first author wrote analytic memos and constantly compared the data to establish concepts related to decision-making in rehabilitation. Constant comparisons of the data were used to find similarities and differences as well as patterns (Corbin, 2008; Glaser, 1965). The fourth stage involved analyzing the interview data (both rehabilitation practitioner and family caregiver) both using codes that emerged from the observational coding and additional open coding, allowing for new codes to emerge.

**Reflexivity.** Efforts at reflexivity included: 1) writing memos after each interview were completed; 2) analytic notes to be explicit about data that reminded the research team of content from peer-reviewed publications; and 3) regular meetings with experts in qualitative methodology (CP and LD) during data analysis to discuss the coding scheme and interpretation. These meetings challenged the first author’s assumptions and provided opportunities for discussions about the clinical encounters occurred by creating intersubjectivity in the analytic process (Dowling, 2006).

**Trustworthiness.** Strategies for trustworthiness were used during the research process to address credibility, transferability, dependability, and confirmability (Shenton,
2004). To ensure credibility, JW had prolonged engagement with individuals in the rehabilitation context and multiple sources of data (e.g., observations and interviews) were analyzed to address the strengths and weaknesses of each method. Coding also included negative cases when shared decision making did not occur. To describe transferability, results were provided on the participants and number of treatment activities to describe the context in which the data was collected. Dependability of the data were achieved by using overlapping methods. Additionally, JW asked the practitioners and caregivers clarifying questions after each observation. To support confirmability of the data, JW used a reflexive process throughout the data collection and analyses.

Results

Participants

The study enrolled 17 family caregivers, 8 rehabilitation practitioners, and two family/patient dyads. All names used in the results are pseudonyms. Participants had the opportunity to identify a preferred pseudonym and it was used in the transcripts.

Participants in the Observations. All observations occurred at an urban, level I trauma hospital. Fourteen clinical encounters were observed by the researcher and included two family dyads (Table 4.1.2) and eight rehabilitation practitioners (Table 4.1.3). Eight rehabilitation practitioners were observed during their treatment encounters with the patient. While there were more occupational therapy participants, it is worth mentioning that during a clinical encounter a physical therapist and an occupational therapist would co-treat during most of the observations (71%, Table 4.1.3). According to
the Control Preferences Scale, rehabilitation practitioners preferred to either share responsibility for decisions with the family caregiver or to make the final decision about the treatment after seriously considering the family caregiver’s opinion (Table 4.1.3).

One dyad was observed for 12 of the rehabilitation encounters in the intensive care unit, medical/surgical floor, and rehabilitation unit (Table 4.1.2). The second dyad was observed for two encounters in the intensive care unit (Table 4.1.2). Both patients had recent injuries and the family caregivers were new to their roles of being the primary caregiver.
### Table 4.1.2

Demographics of the Dyad (Family Caregiver and Patient)

<table>
<thead>
<tr>
<th>Family Unit</th>
<th>Age Range (years)</th>
<th>Gender</th>
<th>Do you consider yourself the primary caregiver?</th>
<th>Do you make the medical decisions for your loved one?</th>
<th>Control Preferences</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>56-65</td>
<td>Female</td>
<td>Yes</td>
<td>Yes, I consult other’s opinions when making decisions.</td>
<td>I prefer to make the final decision about my loved one’s treatment after seriously considering my health care provider’s opinion.</td>
</tr>
<tr>
<td>2</td>
<td>46-55</td>
<td>Female</td>
<td>Yes</td>
<td>Yes, I consult other’s opinions when making decisions.</td>
<td>I prefer to leave all decisions regarding treatment for my loved one to the health care provider.</td>
</tr>
</tbody>
</table>

Information About Loved One with Disorders of Consciousness

<table>
<thead>
<tr>
<th>Family Unit</th>
<th>Age Range</th>
<th>Gender</th>
<th>State of Consciousness</th>
<th>Setting of Initial Encounter</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>26-35</td>
<td>Male</td>
<td>Comatose</td>
<td>Intensive Care Unit</td>
</tr>
<tr>
<td>2</td>
<td>26-35</td>
<td>Male</td>
<td>Unresponsive Wakefulness Syndrome/Vegetative State</td>
<td>Intensive Care Unit</td>
</tr>
</tbody>
</table>
Table 4.1.3

Demographics of the Rehabilitation Practitioners

<table>
<thead>
<tr>
<th>Rehabilitation Practitioners</th>
<th>Number of Participants (n=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discipline</td>
<td></td>
</tr>
<tr>
<td>Occupational Therapist</td>
<td>4</td>
</tr>
<tr>
<td>Physical Therapist</td>
<td>1</td>
</tr>
<tr>
<td>Speech and Language Pathologist</td>
<td>1</td>
</tr>
<tr>
<td>Medical Doctor</td>
<td>2</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>7</td>
</tr>
<tr>
<td>Male</td>
<td>1</td>
</tr>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>18-25</td>
<td>1</td>
</tr>
<tr>
<td>26-35</td>
<td>7</td>
</tr>
<tr>
<td>Years Practicing in Profession</td>
<td></td>
</tr>
<tr>
<td>3-5</td>
<td>4</td>
</tr>
<tr>
<td>6-10</td>
<td>2</td>
</tr>
<tr>
<td>More than 10</td>
<td>2</td>
</tr>
<tr>
<td>Years Practicing with Patients in DoC</td>
<td></td>
</tr>
<tr>
<td>&lt;1</td>
<td>2</td>
</tr>
<tr>
<td>1-2</td>
<td>2</td>
</tr>
<tr>
<td>3-5</td>
<td>2</td>
</tr>
<tr>
<td>6-10</td>
<td>2</td>
</tr>
<tr>
<td>Control Preferences Scale</td>
<td></td>
</tr>
<tr>
<td>For this situation, I prefer to leave all decisions regarding treatment to the family member.</td>
<td>3</td>
</tr>
<tr>
<td>For this situation, I prefer that this family member makes the final decision about which treatment will be used but seriously considers the information I provided.</td>
<td>5</td>
</tr>
</tbody>
</table>

Participants in the Interviews With Rehabilitation Practitioners. The rehabilitation practitioners were recruited from the observational study (Table 4.1.3).

Seven rehabilitation practitioners were audio-recorded during a telephone or web-based
interview, which was transcribed verbatim. These interviews focused on the process of making treatment decisions.

**Participants in Interviews With Family Caregivers.** Recruitment for the family caregivers occurred nationally in the United States using social media and snowball technique (Table 4.1.4). Data came from two sources. The first is the study No One Listens to Me. During this study, 15 interviews were conducted with 16 family caregivers. One interview included both the mom and grandmother of the son with disordered consciousness. For this study, four of the family caregivers were re-interviewed as well as one new family caregiver. These 5 new interviews focused on decision-making moments during the recovery process.

Most of the family caregivers were female and have spent less than 5 years caregiving (Table 4.1.4). These caregivers considered themselves to be the primary caregiver for their person that was unconscious and either made decisions on their own or consulted other’s opinions when making decisions (Table 4.1.4). As is common in most qualitative reporting traditions, participant quotes are chosen because they best articulate the categories discovered during analyses.

**Table 4.1.4**

_Demographics of the Family Caregivers Who Participated in an Interview_

<table>
<thead>
<tr>
<th>Demographic Information of Caregiver</th>
<th>Number of participants (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>14 (82%)</td>
</tr>
<tr>
<td>Male</td>
<td>3 (18%)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>18-35</td>
<td>1 (6%)</td>
</tr>
<tr>
<td>36-65</td>
<td>11 (65%)</td>
</tr>
<tr>
<td>&gt;65</td>
<td>5 (29%)</td>
</tr>
<tr>
<td>&lt;5</td>
<td>8 (47%)</td>
</tr>
<tr>
<td>5-10</td>
<td>7 (41%)</td>
</tr>
</tbody>
</table>
### Years Caring for Loved One with Disorders of Consciousness

| Years Caring for Loved One with Disorders of Consciousness | More than 10 | 2 (12%) |

### Do you consider yourself the primary caregiver?

| Do you consider yourself the primary caregiver? | Yes | 13 (76%) |
| | No | 4 (24%) |
| | Yes, I make decisions on my own. | 6 (35%) |

### Do you make the medical decisions for your loved one?

| Do you make the medical decisions for your loved one? | Yes, I consult other’s opinions when making decisions. | 9 (53%) |
| | No, another person makes decisions. | 2 (12%) |

### Information about Loved One with Disorders of Consciousness

| Gender | Female | 3 (18%) |
| | Male | 14 (83%) |
| | 18-25 | 9 (53%) |
| | 26-35 | 5 (29%) |
| | 36-45 | 1 (6%) |
| | 46-55 | 2 (12%) |
| | <2 years | 0 (0%) |
| | 2-5 years | 7 (41%) |
| | 6-10 years | 7 (41%) |
| | >10 years | 3 (18%) |
| | Inpatient rehabilitation | 12 (71%) |
| | Long-term care facility | 2 (12%) |
| | Skilled Nursing facility | 3 (18%) |
| | Home Health services | 7 (41%) |
| | Outpatient services | 7 (41%) |
| | Other | 3 (18%) |
| | Comatose | 0 (0%) |
| | Vegetative State/Unresponsive wakefulness Syndrome | 1 (6%) |

| Time Since Injury | 2 (12%) |
| | 6-10 years | 7 (41%) |
| | >10 years | 3 (18%) |
| | Inpatient rehabilitation | 12 (71%) |
| | Long-term care facility | 2 (12%) |
| | Skilled Nursing facility | 3 (18%) |
| | Home Health services | 7 (41%) |
| | Outpatient services | 7 (41%) |
| | Other | 3 (18%) |
| | Comatose | 0 (0%) |
| | Vegetative State/Unresponsive wakefulness Syndrome | 1 (6%) |

### Current State of Consciousness

| Current State of Consciousness | Minimally conscious state | 4 (24%) |
| | Conscious | 11 (65%) |
| | Unsure | 1 (6%) |

### Micro-Decisions in Observational Data

Each of the 14 observations ranges in length (20 to 120 minutes). During each observation, a range of treatment activities (2-14) with a total of 88 treatment activities in the clinical observation data. On average, one treatment activity occurs for every ten minutes of observational data. Each treatment activity was important to code because in the medical shared decision-making literature one encounter focuses on the deliberation
between two options for one specific decision or action. Whereas, in these rehabilitation treatment encounters multiple treatment activities occur and micro-decisions are nested within each treatment activity.

Theme: Some decision-making processes are collaborative, and some are unilateral when planning treatments for patients with disorders of consciousness.

The one core theme is made up of three underlying categories: 1) integrative treatment decision making, 2) declarative treatment decision making, and 3) unilateral treatment decision making (Table 4.1.5).

Table 4.1.5

Types of Decision-Making Processes When Planning Treatments for Persons With Disorders of Consciousness

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Decision-Maker</th>
</tr>
</thead>
<tbody>
<tr>
<td>Integrative Decision Making</td>
<td>Occurs when family are included in the treatment session and their unsolicited contributions provided new information for in-the-moment decision-making</td>
<td>Partnership between the family member (or patient) and rehabilitation practitioner</td>
</tr>
<tr>
<td>Declarative Decision Making</td>
<td>Occurs when the rehabilitation practitioner elicits treatment preferences from the family and then executes these preferences within the session or future sessions.</td>
<td>Partnership between the family member (or patient) and rehabilitation practitioner</td>
</tr>
<tr>
<td>Unilateral Decision Making</td>
<td>Occurs when either the rehabilitation practitioner or family member makes a treatment decision.</td>
<td>Family member, Patient, or rehabilitation practitioner</td>
</tr>
</tbody>
</table>
The underlying categories were constantly compared based on the patterns of focused codes during micro-decisions. Figure 4.1.2 highlights the codes that were distinct from each category.

**Figure 4.1.2**

*Depiction of Focused Codes That Support and Delineate Each Category*

---

Micro decisions about treatments are made during every encounter. Rehabilitation practitioners make in-the-moment decisions to change treatments based on the patient’s responses (or lack thereof). Data showed that shared decision-making occurred in two ways—integrative and declarative decision making. Both types of decisions had the foundation of creating a partnership between the family caregiver and rehabilitation practitioner and incorporating the patient’s preferences, values, or priorities. The difference is in how the partnership emerges during the micro-decision. Decisions also occur that are not collaborative amongst the triad. Some decisions are made solely by the
family caregiver, patient, or by the rehabilitation practitioner, as described by unilateral decision-making.

In-the-moment treatment decisions are the best way to explicate micro-decisions. For example, RP2 and RP4 were working with patient 1 to hold himself up in a seated position at the edge of the bed. Initially, the treatment activity was looking for the patient to demonstrate protective reactions (e.g., steadying himself on the bed with his hand) when the practitioner perturbated the trunk. The patient sits at the edge of the bed with his hands placed on either side of his body during this activity. Throughout the activity, his hands would fall off the edge of the bed and the rehabilitation practitioners would ask him to bring his hand up onto the bed. The mom enters the room from being outside and is excited to see his hand moving. The mom asks, “Where’s your friend at? Where’s your ball?” The rehabilitation practitioner had moved small stuffed animals and balls from the bed’s medical trapeze. RP4 points to where the ball is and says “Oh, I put it right there.” The mom proceeds to pick up the ball and tell her son to “Look at your orange ball. Look. You have your orange ball.” The rehabilitation practitioners continue to support the patient to sit at the edge of the bed and change the treatment to have the mom hold the orange ball and ask the patient to look at

Figure 4.1.3

*Depiction of Micro-Decisions As They Occur During One Moment of a Treatment Encounter*

<table>
<thead>
<tr>
<th>Overarching Treatment Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Practitioners want the patient to demonstrate protective reactions such as “moving the arm”</td>
</tr>
<tr>
<td>Initial treatment activity: perturbations of trunk</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Micro-decisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rehabilitation practitioners engage with mom to incorporate the patient’s favorite orange ball</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Further decisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rehabilitation practitioners ask mom to move the ball to facilitate visual tracking, patient looks at the ball and moves leg (e.g., goal met)</td>
</tr>
</tbody>
</table>
of the ball. In an earlier observation, the rehabilitation practitioners had learned that the patient liked the color orange and basketball. At the end of this treatment moment, RP2 noticed that the patient’s leg moved, and she stated, “We have protective stuff. Woohoo! We get excited about the little things.” This micro-decision is depicted in Figure 4.1.3 to illustrate how the treatment changed based on the integration of the mom’s insight to use a personally relevant object as stimuli. The rehabilitation practitioners agreed with this decision when they engaged with the mom and started to give the patient verbal cues to look at the ball. Although the treatment strategy changed from the patient bringing his hand up onto the bed to looking at a ball, the patient demonstrated a protective reaction during the new treatment by moving his leg out. Both the rehabilitation practitioners and family caregiver were excited to see this progress.

**Integrative Decision Making.** Integrative shared decision-making occurs when family are included in the treatment session and their unsolicited contributions provided new information for in-the-moment decision-making. Integrative decisions occurred during the very first encounter with family caregiver and patient 1. Three rehabilitation practitioners were working with the patient and evaluating his abilities; they wanted to see if he would respond to anything. The RPs tried using ice under his arm pits and did not notice a behavioral response. RP1 noticed that the patient would track if she held his eyelids open. At the same time, the mom was dancing side to side in the room because she was so happy to see her loved one up.

“RP2: Just one eye. Just see if when you open the eye...Okay Jax take a look around. RP3: just one of your eyelids is open okay. RP2: Take a look around can you find Mom? RP1 [to the mom]: Can you move? There you go. RP2: She moved. Where’d she go? Family1: Hi Jax. Hi! RP1 [to the mom]: Now walk. RP3: Can you find her again? She’s on the move again. Try to find her.”
The RPs included the mom in the treatment, and they tried to get the patient to demonstrate awareness to his surroundings. This same pattern is highlighted again in Figure 4.1.4. In future sessions, the RPs say phrases to the mom like “come play with us” generating collaborative treatment decisions in-the-moment.

**Figure 4.1.4**

*Example of Coding Process for Data Supporting Integrative SDM*

<table>
<thead>
<tr>
<th>Transcript Text</th>
<th>Open Coding</th>
<th>Focused Coding</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>[....using mouthwash as stimulant for taste]</td>
<td>Family brings out patient’s cologne</td>
<td>Family provides information on patient preference/interests</td>
<td></td>
</tr>
<tr>
<td>FMI: Your cologne again.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RP2: Oh, the cologne.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fieldnotes: The cologne has been brought out previously and the family has shared that a friend makes the customary cologne special for the patient.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RP 4: Try the cologne on this side and see if he’ll look at it up there.</td>
<td>Customized cologne</td>
<td>Practitioner integrates family and patient preference into treatment</td>
<td></td>
</tr>
<tr>
<td>Fieldnotes: Family member moves the cologne into view of the patient. Patient looks at the cologne.</td>
<td></td>
<td></td>
<td>Integrative Shared Decision Making</td>
</tr>
<tr>
<td>RP 4: Yeah</td>
<td>Rehabilitation Practitioner integrates cologne into treatment</td>
<td>Patient shows interest in personally relevant stimuli</td>
<td></td>
</tr>
<tr>
<td>RP2: Yeah, cool.</td>
<td>Family integrated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FMI: He liked what he saw?</td>
<td>Patient looks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RP2: Yeah, he was looking at it and his eyes went.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FMI: This is your cologne. I’m sorry but you have a bigger one. I try not to use it.</td>
<td>Family’s perception Rehabilitation practitioner agrees with family</td>
<td>Practitioner and family continue treatment</td>
<td></td>
</tr>
<tr>
<td>RP2: You try again, we’ll see if he’ll do it again. You have to open your eyes back up [Name Patient #1].</td>
<td>Try it again</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Integrative decision making was also seen in family caregivers that had home health therapy being provided to their loved one. When the home health therapist was treating the patient, they were working on answering questions by looking at pairs of cards that were either red and green or said yes and no. The family caregiver would continue to work with her loved one using these cards. The family caregiver would notice her loved one getting bored and she personalized the treatment activity.

“Family Caregiver 3: So, he gets, he’s very very tired, and you know he gets really annoyed with questions. And so, if they’re really really simple, his cue is he will eye roll and [sigh] and drop his head. If he drops his head he’s done, he’s not gonna answer you, he’s checked out. And it’s a challenge using very simple
things so we kinda progressed to letters, uh you know ‘big A’ ‘big B’ and I used to do you know ‘which one’s a C?’ ‘which ones’ an M?’

Interviewer: Mmhmm.

Family Caregiver 3: and then I would ask him or tell him that, you know ‘what does your name start with?’ ‘what does [patient name] start with?’ And he’d get it. Then we progressed to small words. Um, and he was quickly getting very bored with now ‘are you tired?’, or ‘are you this and that?’ So, we kinda went to, [patient name] has really eclectic interest and one of his big things is astrology. Yeah, so, I used the names of the Norse gods and wrote questions because the therapists were like clueless. I was trying to think you know, like I said, he also spoke Latin. So, I also wrote out Latin words.

Interviewer: Nice.

Family Caregiver #: And I was trying to think, I don’t know what his cognitive abilities are and I don’t want to make it so frustrating, but I’m still trying to keep him engaged.

Interviewer: Right, right.

Family Caregiver 3: And so, he also spoke Russian and I’d come up with some Russian words. And you know, and when I first started with the mythology, I would hold them up, and I was doing it without the therapists, because I was like well this might be a little weird for them. But, and then so, he would answer me, and he would very clearly turn his head and look at them. And I was still kind of like well I’m not sure if that’s a coincidence, probably not, eh. So, you know, I left them laying out when the speech therapist came, she picked them up and was like “what is this?” So, I explained it to her, she holds them up and asked him a question and he immediately goes bam and she was like, [Family Caregiver name] did you see that? And I was like, well yeah. And she was like ‘has he been doing this?’ And I was like well yeah. ‘And you didn’t say anything?!!’ [laughter]. And I was like well I really wasn’t sure if you know, was he just turning his head or was he really answering questions.”

This excerpt highlights that the practitioner was willing to integrate the family caregiver’s treatment idea immediately. It also shows how both the family caregiver and practitioner were evaluating the patient’s behavioral response to the personalized cards.

Patterns were identified in the focused coding delineating integrative from declarative shared decision-making. In integrative shared decision-making, focused codes included the rehabilitation practitioner and family administering the treatment and evaluating the patient’s responses (Figure 4.1.4). Often, the family would provide information about the patient’s preferences or interests and the rehabilitation practitioner
would re-direct from their current treatment to integrate the family as well as their suggested treatment stimuli into the subsequent treatment.

**Declarative Decision Making.** Declarative decision making occurs when the therapist elicits the patient’s values, preferences, and/or priorities from the family and then executes these preferences within the session. In these types of decisions, the family shares information and identifies treatment strategies in conjunction with the rehabilitation practitioner. However, a key distinction from *integrative decision-making* is that in declarative decision making the rehabilitation practitioner(s) executes the treatment.

For example, two rehabilitation practitioners are working with Luke (patient 2). As they work with the patient to inhibit his tone, they ask the mom about what type of television shows he likes to watch. “RP2: Does he like to watch tv? Family Caregiver 2: Mmhmm. RP2: What kind of shows does he like? Do you know? Family Caregiver 2: Funny shows.” The rehabilitation practitioner learns that he likes comedy and Pinocchio from his childhood. Once the rehabilitation practitioner finds a YouTube video, they show it to the mom, and then execute the treatment using the video as a visual stimulus for Luke. “RP2: Can you see the video? Try to keep your eyes on it.”

Rehabilitation practitioners also use preferences that they elicit in prior treatment sessions as new behaviors emerge. In Jax’s case, the rehabilitation practitioners had elicited Jax’s preferences of basketball. Prior to this treatment idea, Jax became emotional and was crying. The rehabilitation practitioner offered him tissues and told him to “Feel all the feels.” The rehabilitation practitioner gave him a pep talk and facilitated his use of the tissue with hand over hand actions. RP3 brings a trash can over to the
patient’s right side as he sits on the edge of the bed and she says, “All right basketball star, what you got?” In this moment she is making meaning with the patient and the mom using words that reflect his interests and acknowledges that prior to the accident he would play basketball. RP2 provides encouragement saying, “I see a trash can basketball court in your future.” The patient was able to use his left hand to place the tissue in the trash.

As Jax becomes more aware and starts to inconsistently communicate, the rehabilitation practitioners give him more autonomy with making treatment decisions. For example, the rehabilitation practitioners noticed that his belly was distended and asked him if he needed to go to the bathroom (Figure 4.1.5). RP3 promptly brings a bedside commode next to the bed. Once Jax was on the commode, RP2 wonders if he needs a real toilet. When the patient indicated he does want to use a real toilet by nodding, the rehabilitation practitioners bring him into the bathroom and get him on the regular toilet without a bedside commode.
Declarative shared decision-making is different from integrative in that two treatment options are presented, and a preference is indicated by either the family or patient and the rehabilitation practitioner executes the shared decision.

**Unilateral Decision Making.** Integrative and declarative decision making reflect shared decision making with collaboration and partnership. However, some decisions do not reflect a partnership in the decision-making. Rather, a decision is made without deliberation or agreement. Unilateral decision making occurred by either the rehabilitation practitioner or the family.

**Rehabilitation Practitioner as the Decision Maker.** There are moments when decisions are made out of caution for the patient. For example, the practitioners will

---

**Table: Coding Process for Declarative SDM Excerpt**

<table>
<thead>
<tr>
<th>RP2:</th>
<th>We can totally do it. I'm not, that's not... I'm thinking, I am not opposed to making that happen, I just don't know if enough time will lapse.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Thinking Treatment is Possible</strong></td>
</tr>
<tr>
<td>RP3:</td>
<td>Yeah, I just didn’t know if that would feel more...</td>
</tr>
<tr>
<td></td>
<td><strong>Practitioner Considers Treatment Options</strong></td>
</tr>
<tr>
<td>RP 2:</td>
<td>Hey, [Name of Patient]? Do you want to sit on a real toilet? [Fielding: Patient needs his head yes], Done. Let me just clean it out. Okay, I had this moment like look at him look at that. I mean, how many commodes are in here..</td>
</tr>
<tr>
<td></td>
<td><strong>Asking Patient Preference</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Patient Answers</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Therapist Asking Patient Preference</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Patient Indicates Treatment Preference</strong></td>
</tr>
<tr>
<td>RP3:</td>
<td>Your wish is my command.</td>
</tr>
<tr>
<td></td>
<td><strong>Practitioners Make Treatment Happen</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Therapist Integrates Patient Preference</strong></td>
</tr>
</tbody>
</table>
initiate a rest for the patient when they notice the heart rate increasing or pause treatment
to remove food that was pocketed in the patient’s mouth.

Other examples for unilateral decision-making occur when the treatment is related
to eliciting the patient’s response to painful stimuli (Figure 4.1.6). In a separate instance,
a rehabilitation practitioner relies on other staff members to identify the patient’s
preferences and interests. The rehabilitation practitioner described being unsuccessful at
contacting the family and would make decisions about treatments based on discussions
with colleagues, evidence in the literature, and asking staff members about their
knowledge of the patient’s preferences. Communication between the rehabilitation
practitioner and family did not occur to determine the treatment.

**Figure 4.1.6**

*Coding Process for Unilateral Treatment Decision Made by the Rehabilitation Practitioner*

<table>
<thead>
<tr>
<th>Transcript Text</th>
<th>Open Coding</th>
<th>Focused Coding</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RP2:</strong> I’m going to be mean, but I’ve got to make sure that you’re still with me. I feel like it’s here ... we’ll see if you wake up a little more for me.</td>
<td>Being mean</td>
<td>Rehabilitation practitioner determines treatment activity</td>
<td>Practitioner Makes Unilateral Treatment Decision</td>
</tr>
<tr>
<td><strong>Fieldnotes:</strong> RP2 presses a plastic tube on the left finger, left toe and right toe. When she does this, she is referring to herself as being mean because she is inflicting pain. She is looking for withdrawal from the painful stimuli. She also wants him to wake up more as he is less ‘awake’ or ‘responsive’ than previous sessions.</td>
<td>Wake up a little more</td>
<td>Rehabilitation practitioner selects treatment stimuli</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Practitioner uses plastic tube</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Looking for a response from the patient</td>
<td>Rehabilitation practitioner looks for a behavioral response from the patient</td>
<td></td>
</tr>
</tbody>
</table>

**Family Caregiver as the Decision Maker.** Family caregivers also made unilateral
treatment decisions in both the acute and home care settings. During an interview, a
family caregiver shared a story of engaging her loved one, Andrew, with the church and
music, two of Andy’s favorite past times. Family Caregiver 1 describes, “I just had a
feeling. And so, when the choir started singing, I kept my eyes on her and she started
singing the words and at this point she didn't have a trach and tears were just pouring down my face and I looked around and the whole congregation was staring at her and there were grown men that were crying because she was back.” The family caregiver made the decision to bring Andrew back into the community, specifically attending a church she had been at since the age of three.

Similar to Andrew’s mom, another mom made a unilateral decision to initiate dolphin therapy with her son. Prior to her son’s accident, he had swum with a dolphin and when he did this the dolphin became very protective of him. The family caregiver read a story about how another individual was rehabilitated with dolphin therapy and in that moment, she recognized it was the same dolphin from years ago. Both of the above unilateral decisions came from stories of caregivers providing care in their home.

Unilateral decision making also occurred in the acute care setting. During observations of rehabilitation encounters, the family of patient 1 decided for the patient to go back to bed so he could visit with a friend instead of staying on the commode (Figure 4.1.7). In this moment, the rehabilitation practitioners asked the mom to let the patient stay on the commode because he had selected toileting when asked for his preference between going to bed or staying on the toilet. However, neither the family caregiver or the rehabilitation practitioner thought to ask the patient if he wanted to stay on the toilet or visit with a friend resulting in a missed opportunity to re-consider the patient’s perspective when the treatment options had changed. The mom agreed that toileting was important, and he would have more therapy time to work on this task. In this moment, the
family caregiver felt it was important for the patient to see his friend and was adamant about her decision.

**Figure 4.1.7**

*Coding Process for Unilateral Treatment Decision Made by the Family Caregiver*

<table>
<thead>
<tr>
<th>Transcript Text</th>
<th>Open Coding</th>
<th>Focused Coding</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FMI:</strong> I understand. I understand. But, he's been doing it for about a couple of hours just now, and as people, I'm satisfied with his progress where his progress is for today. He can finish later on, because it's supposed to be an all day thing, so it's not like we want to take the time to let's focus on the toilet today.</td>
<td>Family understands patient’s progress</td>
<td>Family makes treatment decision</td>
<td>Family Makes Unilateral Treatment Decision</td>
</tr>
<tr>
<td><strong>RP2:</strong> But toileting is kind of part one of his big goals in life, so we need-</td>
<td>Toileting is a big goal</td>
<td>Rehabilitation practitioner describes treatment goal</td>
<td></td>
</tr>
<tr>
<td><strong>FMI:</strong> Oh, he’s going to be here for a minute now. He’s going to be down in PT, so he’ll have time to practice.</td>
<td>Time to practice</td>
<td>Family perceives patient will have time to practice</td>
<td></td>
</tr>
<tr>
<td><strong>RP 2:</strong> Okay.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FMI:</strong> He’ll have time. He needs to see... This gentleman works with him, and he needs to see people to be familiar with something better.</td>
<td>Family perceives patient’s need to be with friends</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Discussion**

This study specifically focused on understanding shared decisions that occurred at the patient’s bedside. Shared treatment decisions occurred in two ways—integrative and declarative. These two types of shared decision-making were contrasted with data illustrating unilateral treatment decisions with the primary decision-maker being either the family caregiver or the rehabilitation practitioner to highlight the difference in the patterns of focused codes for each category of decision-making.

Rehabilitation practitioners share decisions with family caregivers in two ways. Integrative decision making engages the family caregiver by having the family administer the treatment and also includes the family’s evaluation of the patient’s behavioral
response to the treatment. Declarative decision-making is when the family caregiver (or patient) and rehabilitation practitioner discuss treatment options. Ultimately, in the declarative model the rehabilitation practitioner enacts the decision by executing the treatment. A key difference in these two types of shared decision-making types is who is doing the action of delivering the treatment and evaluating the patient’s response.

Declarative decision making is more analogous to the medical shared decision-making literature in that treatment options are presented, the caregiver’s (or patient’s) preferences are elicited, and the practitioner integrates the preference into the shared treatment decision. Declarative decision making aligns with the ‘Three Talk model’ of shared decision-making in that it includes the 1) introduction of a choice, 2) description of options, and 3) integration of the patient’s preferences into a decision (Elwyn et al., 2012; Joseph-Williams et al., 2019). This finding is significant because to date, shared decision-making literature has primarily been described in the medical context and this is the first study to observe how decisions occur in a rehabilitation setting. Furthermore, this study analyzes the everyday decisions that occur at the bedside. These micro-decisions are about the process of therapy treatments rather than a deliberation about the potential risks and benefits to achieve a potential outcome. The declarative shared decision-making model in the rehabilitation context does not include the practitioner presenting risks and benefits about treatment options but, may include a discussion about how it relates to goals or education on facilitating the rehabilitation process.

Integrative shared decision-making is strikingly different from declarative in the level of engagement from the family caregiver. Previous work about clinical reasoning in therapy describes interactive reasoning as a method to better understand the patient as a
person (Mattingly & Fleming, 1994). Interactive reasoning is described by illustrating how an occupational therapist will work with the patient to interpret their motives and meanings based on what the patient did and said (Mattingly & Fleming, 1994, p. 180). The observational data support this interactive reasoning process between the rehabilitation practitioners and family caregiver. For example, when the rehabilitation practitioner decides to stop the current treatment (e.g., moving the patient’s arm), and invites the family caregiver to hold the ball and then cues the patient to look for the ball (Figure 4.1.3) interactional reasoning is occurring with the family caregiver. The rehabilitation practitioners interpret what the family caregiver wants from the therapeutic moment (Mattingly & Fleming, 1994). Integrative decision-making is the action that occurs from the interactive reasoning process.

It is worth noting many of the rehabilitation practitioners and family caregivers in this study had more than five years of experience interpreting the behavioral responses of a person that is unable to communicate their needs and preferences due to severe cognitive disabilities. Benner (2004) suggests that individuals with consistent experiential learning, such as being a practitioner in an intensive care unit or a family caregiver providing around the clock care, will reach a level of expertise much quicker than individuals with less consistent practice (Benner, 2004). An expert rehabilitation practitioner makes complex scenarios such as interactive reasoning and integrative shared decision-making appear fluid and natural by flawlessly switching between treatments in-the-moment and engaging the family caregiver in the doing of therapy treatments (Benner, 1982; Mattingly & Fleming, 1994). These actions of the rehabilitation practitioner during the observations looked effortless and it is these moments that would
not have been captured through a narrative description of clinical practice. It is likely that the family caregivers that were observed during the rehabilitation treatment encounters were still novice to the clinical information as the injury to their loved one occurred within the past month. However, the interviews with family caregivers who provided care to a person with a chronic disordered state of consciousness provided descriptions that illustrate their expertise and ability to try new things to personalize their loved one’s treatments. Family caregivers became experts over time and discussed medications, medical procedures, and how they decided to try different treatment activities.

This study is the first to describe how practitioners share decisions with family caregivers and patients in DoC in the rehabilitation context. There is burgeoning literature about shared decision making and it is important to know whether and how shared decision making occurs in rehabilitation. This study uncovered nuanced differences between shared rehabilitation micro-decisions and medical decisions. In rehabilitation, a shared decision may use information that was elicited in previous encounters and may not explicitly deliberate between two treatment options. However, this study’s data demonstrate how the family, patient, and rehabilitation practitioner form a partnership and share a decision. Knowledge of how shared decision-making occurs in rehabilitation will have implications for how the field moves forward to engage families and patients in shared decision-making when treatment planning.

Limitations

The initial research question was not aimed at understanding treatment decisions, but rather the barriers and facilitators of using assessments in clinical practice for treatment planning. Thus, there was an initial element of understanding treatment
planning. These categories and theme emerged from the initial open coding, memo writing, reflexivity, and debriefings with the study team. Reflection of peer reviewed literature illustrated the need to understand how treatment decisions are made prior to explicating how assessments could be used for treatment planning. Another limitation is that it is possible our personal experiences were imposed onto the data and highlighted findings that are meaningful to us.

The observational data involve two patient/family dyads from an urban level 1 trauma center, which provided 88 rehabilitation treatment decision moments which were the unit of analysis for this study. Observational data was primarily collected in the intensive care setting and future work should include data collected in post-acute care rehabilitation settings. Future interviews should maximize the variation of the sample, specifically the interviews with family caregivers because the included participants all had at least two years of caregiving experience.

**Conclusion**

This study’s data demonstrate that multiple shared micro-decisions occur in one rehabilitation treatment encounter. Some of the micro-decisions are shared and collaborative with the family and/or patient, while other decisions are made by only one stakeholder (e.g., family caregiver or rehabilitation practitioner). The data illustrate how family caregivers and rehabilitation practitioners collaborate to share micro-treatment decisions, either using an integrative or declarative approach, at the bedside of the person who is unconscious. Partnership between the stakeholders is the hallmark of shared decision-making in rehabilitation treatments for persons with disorders of consciousness.
The shared decision-making process will inform the rehabilitation field as to how families and patients are engaged as partners when treatment planning.
Afterword Paper 4.1

This exploratory, ethnographic study to describe how treatment decisions occur in rehabilitation began by identifying a gap between how shared decision-making was explained in the literature and how it is applied to rehabilitation treatment decisions. Identifying a gap between the literature and clinical practice led to the identification of a new problem (KTA Framework, Action Cycle, Figure 1.3) because the conceptualization of shared decision making in the literature was not applicable to the context of rehabilitation when making decisions for patients that are unconscious. As a result, this study started with knowledge inquiry regarding how treatment decisions occur in rehabilitation (KTA Framework, Creation Funnel, Figure 1.3).

Knowledge of how shared decision-making occurs in rehabilitation practice is a necessary pre-requisite to training rehabilitation practitioners in how to foster communication about treatment planning with family caregivers and patients. This study specifically focused on exploring shared decision-making with a surrogate decision-maker, the caregiver, because the patient is unable to advocate for themselves. The caregiver is the available expert in providing rehabilitation practitioners with information about the patient’s preferences, priorities, and values as well as their own. This study found that shared decision making occurs in two ways—integrative and declarative. The key difference in these two types of shared decision making is that an integrative approach includes the caregiver in administering the treatment whereas a declarative approach has the rehabilitation practitioner administer the treatment.
Foreword Paper 4.2

This chapter presents the results from the second of the three primary research objectives of this project that broadly were described to inform shared decision-making, psychometric properties of the Coma Recovery Scale-Revised, and the development of a recovery ruler to facilitate shared decision-making between family caregivers and rehabilitation practitioners when treatment planning. The second primary aim of this dissertation project was to examine the extent to which the CRS-R displays psychometric properties that make it useful for communicating about assessment results when making treatment decisions. This study examines the structural validity (rating scale step structure, unidimensionality, and measurement precision), reproducibility (comparability of measurement across individuals and time), and external validity (association between person measures and state of consciousness) of the most widely used assessment of neurobehavioral function, the Coma Recovery Scale-Revised (CRS-R).

The interpretation and usefulness of assessment results relies on the psychometric properties an assessment. For example, when examining measurement precision a person separation reliability that is <0.90 may not be the most appropriate for individual decision-making (Bond & Fox, 2007). Furthermore, knowledge that the assessment’s items measure the same concept of interest (e.g., unidimensionality) such as, neurobehavioral function, is important because it means that the items and responses are evaluating what the intended construct. This third paper presents the results of a study examining psychometric properties of the CRS-R using Rasch Measurement theory.

I am thankful to Katherine O’Brien, Piper Hansen, Joseph Giacino, John Whyte, and Theresa Bender Pape for providing me with data sets. In addition, these individuals
have contributed to the interpretation of the data analyses during poster and oral presentations.
The Coma Recovery Scale-Revised: Examining the Reliability and External Validity

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Abstract

Objective: To empirically examine the association between Coma Recovery Scale-Revised (CRS-R) person measures and Aspen-based states of consciousness for people with disorders of consciousness following a severe traumatic brain injury (TBI).

Design: Rasch analysis of data from four cohorts.

Setting: Rehabilitation facility or clinical trial.

Participants: 262 patients with disorders of consciousness following severe TBI receiving rehabilitation services or participating in a clinical trial.

Interventions: Not applicable.

Main Outcome Measure(s): CRS-R

Results: Six CRS-R items demonstrated good construct validity with no misfitting items, excellent precision (Wright’s person separation reliability 0.95). The item hierarchy reflected a continuum of neurobehavioral function from Communication (hardest to respond to), to Auditory, Visual, Motor, Arousal, and lastly Verbal (easiest to respond to). CRS-R person measures and the Aspen-based state of consciousness showed a statistically significant correlation ($r_s=0.86, p<0.01$).

Conclusions: Rasch analysis supported a unidimensional construct for neurobehavioral function that reflects the current clinical understanding. The high person separation reliability suggests CRS-R is appropriate for making individual-level clinical decisions. The CRS-R person measures and Aspen-based state of consciousness showed a strong correlation further supporting the use of the CRS-R to evaluate state of consciousness.

Keywords: disorders of consciousness, measurement, outcome assessment, brain injury

Abbreviations
Coma Recovery Scale-Revised (CRS-R)
Disorders of Consciousness (DoC)
Emerging Minimally Conscious State (eMCS)
Meansquare (MnSq)
Minimally Conscious State (MCS)
Vegetative State (VS)
Principal Components Analysis of Residuals (PCAR)
Person Separation Reliability (PSR)
Introduction

Correctly identifying a person’s state of consciousness when diagnosed with disorders of consciousness (DoC) following a traumatic brain injury (TBI) is critical because state of consciousness is used to determine access to rehabilitation services in the United States (Giacino et al., 2020). Some inpatient rehabilitation facilities may deny access to care if the individual does not demonstrate behaviors indicative of the minimally conscious state (Giacino et al., 2020). Disorders of consciousness (DoC) includes a range of states from comatose (no sleep wake cycles), vegetative state (VS, presence of wakefulness), MCS (inconsistent volitional behavior), and emerging MCS (eMCS, consistent functional behavior) (Giacino et al., 2020). In 2002, the Aspen Neurobehavioral Conference Workgroup proposed diagnostic criteria for MCS and compared clinical features for each state as it relates to sleep/wake cycles, motor function, auditory function, visual function, communication, and emotion (Giacino et al., 2002). Discerning states of consciousness from one another can be challenging for clinicians due to observed behaviors occurring infrequently and random movements being interpreted as volitional behavior (J. T. Giacino, 2005).

Prior work has estimated that 40-70% (Andrews et al., 1996; Schnakers et al., 2009) of people in a MCS are misdiagnosed as being in a VS (Kalmar & Giacino, 2005; Schnakers et al., 2009). Individuals misdiagnosed in a VS may miss an opportunity to access intensive rehabilitation services and an even more grim consequence is that it may result in conversations about end-of-life care (Schnakers et al., 2009). Up to 40% of individuals with DoC that receive intensive rehabilitation are likely to recover functionally relevant behaviors such as communication and command-following when
accepted into an inpatient rehabilitation program or a specialized DoC program (Giacino et al., 2012; Giacino et al., 2020; Hammond et al., 2019; Whyte et al., 2013). Misdiagnosis of states of disordered consciousness may result from failure to use a standardized behavioral tool to evaluate neurobehavioral function and instead rely on unstructured bedside observations (Schnakers et al., 2009).

To date, the most widely used neurobehavioral function assessment to evaluate individuals with DoC following a brain injury is the Coma Recovery Scale-Revised (CRS-R). The CRS-R covers the domains of auditory, visual, motor, verbal, communication, and arousal and is intended to capture higher levels of neurobehavioral function reflective of the emerging minimally conscious state as described by the Aspen criteria (Giacino et al., 2004). The Aspen criteria reflects best clinical consensus on differences for each state of disordered consciousness. Previous work using three psychometric approaches indicated that the CRS-R is unidimensional and monotonic indicating that the additional rating scale steps occur in order and that all items reflect the concept of neurobehavioral function (Gerrard et al., 2014). Prior evaluation of CRS-R using the Rasch Measurement Model demonstrated the hierarchy of the items is Communication (hardest), Verbal, Auditory, Visual, Motor, and Arousal (easiest); these items are stable within $\pm \frac{1}{2}$ logit with 99% confidence intervals because the sample included 129 persons (La Porta et al., 2013; Linacre, 1994).

The CRS-R items were revised to operationalize the Aspen criteria (Schnakers et al., 2009). But alignment of the CRS-R person measures and Aspen-criteria have not been systematically evaluated. Due to the consequences of misdiagnosis, using the CRS-R for diagnosis can be considered high-stakes testing (Linacre, 1994). Therefore, it is
critical to examine the CRS-R for its relationship with the Aspen-criteria and replicate the findings with a sample size that is recommended for high-stakes testing (Linacre, 1994).

The purpose of this study is to 1) examine and substantiate the prior findings for the psychometric properties of the CRS-R in a larger sample size and 2) examine the association between the CRS-R Rasch person measures and Aspen criteria for states of consciousness. Examination of the rating scale steps will confirm the item hierarchy, describe which rating scale steps are easier or harder, and describe the relationship of the CRS-R total score to state of consciousness. It is hypothesized that the average item order will remain the same as prior analyses, but that presenting the hierarchical order of the rating scale steps will provide more nuanced detail of what behaviors are easier or harder to respond to for patients. This study will use a sample of >250 persons so that the item calibrations can be stable for high stakes testing (Linacre, 1994) purposes as state of consciousness may determine eligibility for inpatient rehabilitation admission and conversations about end-of-life care (Giacino et al., 2020; Schnakers et al., 2009).

Methods

Setting and Participants

Participants were young adults or older (≥ 14 years) who were in states of DoC from a brain injury. Each participant was evaluated by a rehabilitation practitioner or trained research assistant using the CRS-R. Participants had at least one CRS-R assessment and up to 38 re-assessments. CRS-R data came from four cohorts: two clinical trials and two rehabilitation hospitals. One clinical trial administered amantadine and the other administered repetitive transcranial magnetic stimulation (Giacino et al., 2012; Pape, 2015). The two rehabilitation hospitals are located in metropolitan areas in
the Midwest and South of the United States. Data were also collected on age, time from onset to enrollment, etiology of the brain injury.

**Measure**

*Coma Recovery Scale-Revised.* The CRS-R items includes a hierarchical ordering of rating scale steps; a higher score indicates more neurobehavioral function. The assessor begins with the highest rating scale step and if a response is observed, the assessor moves to the next item (O'Dell et al., 1996). If no response is observed, the assessor continues to the next rating scale step for that item. Number of rating scale steps varies by item; for example, communication has three rating scale steps (0, 1, 2) while the motor subscale has six rating scale steps (0, 1, 2, 3, 4, 5, 6). Total raw scores range from 0-23.

**Analytic Procedures**

The partial credit Rasch Model was applied using Winsteps version 4.0.1 (Linacre & Wright, 2017). The partial credit model allows for each item to have its own rating scale structure. First, the structural validity and reproducibility of the CRS-R was examined. Second, the external validity to evaluate how state of consciousness aligns with CRS-R measures was examined.

To reduce local dependency of persons in the full sample, two random subsamples were generated—calibration and validation samples—in which each individual is represented once by either their first or last record (Mallinson, 2011). The calibration sample was used to produce step and item anchors; these were validated with the validation sample. Once the step and item anchors were validated, they were applied to the full sample.
**Structural Validity**

Structural validity includes examination of the rating scale step structure, unidimensionality (item fit, principal components analysis of residuals), and measurement accuracy (person separation reliability, alignment of items and person, person fit).

**Rating Scale Steps**

Rating scale steps for each item were examined to ensure that (1) each had 10 or more observations and (2) the thresholds proceeded monotonically (Linacre, 2018).

**Unidimensionality**

Items with an infit mean square (MnSq) >1.4 or <0.6 were considered misfitting (i.e., may not represent the same trait) (Wright, 1994). The order of average item difficulty and the category measure (each rating scale step) in the hierarchy was evaluated. Principal component analysis of residuals and disattenuated correlations were used to evaluate unidimensionality. Disattenuated correlations above 0.82 indicate that items are likely measuring the same underlying trait (Linacre, n.d.-a). Local item dependence was analyzed by evaluating the inter-item correlations. Inter-item correlations >0.70 indicate local dependence which violates the Rasch measurement model. To confirm item fit and principal component analysis of residuals, a more stringent technique was applied. Simulated data sets were generated that approximated calibration data and fit model assumptions to identify more precise upper and lower bounds for infit mean square, Eigenvalue and percent variance of the first contrast (Smith et al., 1998).
**Score to Measure Conversion**

The Rasch model transforms ordinal scores into equal-interval measures. The raw scores as they relate to Rasch measures were plotted.

**Measurement Accuracy**

To indicate the precision of the assessment and ability to distinguish among persons of different levels of consciousness, the separation index and person separation reliability were reported. Reporting of Wright’s PSR will be provided if the Shapiro Wilks test indicates a non-normal distribution. Person strata identifies how many levels of consciousness the assessment can distinguish (Wright, 1996; Wright & Masters, 2002).

Person and item means were compared and any ceiling or floor effects were reported to describe how well the test aligned with person ability. Person misfit identifies individuals with unexpected patterns of responses. These unexpected patterns can often be clinically useful in identifying people with particular conditions (Smith, 1986).

**Reproducibility**

Reproducibility describes the extent to which the CRS-R results are comparable across individuals and time. Luppescu’s method of crossplotting person measures and item calibrations with 95% confidence intervals were used to evaluate whether there were significant deviations between the calibration and validation sub-samples (Luppescu, 1995). Step and item anchors were validated by evaluating item displacement >.50 logits (Linacre, n.d.-b).
**External Validity of the CRS-R**

The Aspen Criteria were applied to all CRS-R records to determine state of consciousness (Aspen-based) in the full sample using STATA (Schnakers et al., 2009) (Table 4.2.1).

**Table 4.2.1**

*Coma Recovery Scale-Revised Items and Rating Scale Steps Are Aligned to the States of Consciousness*

<table>
<thead>
<tr>
<th>CRS-R items</th>
<th>Unresponsive Wakefulness Syndrome /Vegetative State</th>
<th>Minimally Conscious State</th>
<th>Emerging Minimally Conscious State</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Auditory</td>
<td>0-2</td>
<td>3-4</td>
<td>--</td>
</tr>
<tr>
<td>Visual</td>
<td>0-1</td>
<td>2-5</td>
<td>--</td>
</tr>
<tr>
<td>Motor</td>
<td>0-2</td>
<td>3-5</td>
<td>6</td>
</tr>
<tr>
<td>Arousal</td>
<td>0-2</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Verbal</td>
<td>0-2</td>
<td>3</td>
<td>--</td>
</tr>
</tbody>
</table>

The distribution of the CRS-R person measures was examined for each Aspen-based state of consciousness using descriptive statistics. A Spearman’s correlation evaluated the association between person measures and Aspen-based state of consciousness. To confirm state of consciousness is statistically different, a long one-way ANOVA tested the differences of the person measure means (last record). Reporting of a
Kruskal Wallis was provided if the Bartlett test indicates unequal variance in the full sample.

**Results**

**Participants**

Participants (n=262) were mostly males (70%) in a MCS (Aspen-based) (74%) after sustaining a traumatic brain injury (92%) (Table 4.2.2). Most participants were enrolled in an intensive rehabilitation setting (n=72) or a clinical trial (n=190) within the first 70 days post-injury (58%). The average age of participants was 36.5±15.2 years (range: 14-82 years).

**Table 4.2.2**

**Participant Characteristics**

<table>
<thead>
<tr>
<th>Participant Characteristic</th>
<th>Total n=262</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, Mean years at Injury (SD)</td>
<td>36.5 (15.2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gender, n (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>184 (70)</td>
</tr>
<tr>
<td>Female</td>
<td>78 (30)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time From Onset to Enrollment, n (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 28 Days</td>
<td>3 (1)</td>
</tr>
<tr>
<td>28 to 70 Days</td>
<td>153 (58)</td>
</tr>
<tr>
<td>71 to 112 Days</td>
<td>41 (16)</td>
</tr>
<tr>
<td>113 to 365 Days</td>
<td>3 (2)</td>
</tr>
<tr>
<td>366 to 730 Days</td>
<td>7 (3)</td>
</tr>
<tr>
<td>More than 730 Days</td>
<td>2 (1)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td>-------</td>
</tr>
<tr>
<td>Missing</td>
<td>51 (19)</td>
</tr>
</tbody>
</table>

**Etiology of Brain Injury, n (%)**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Traumatic</td>
<td>240 (92)</td>
<td></td>
</tr>
<tr>
<td>Non-Traumatic</td>
<td>22 (8)</td>
<td></td>
</tr>
</tbody>
</table>

**State of Consciousness (First Record), n (%)**

<p>| | | |</p>
<table>
<thead>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Emerging Minimally Conscious State</td>
<td>21 (8)</td>
<td></td>
</tr>
<tr>
<td>Minimally Conscious State</td>
<td>194 (74)</td>
<td></td>
</tr>
<tr>
<td>Vegetative State</td>
<td>47 (18)</td>
<td></td>
</tr>
</tbody>
</table>

**Sequence of Analytic Decisions**

The calibration and validation sample are represented by 242 participants with either their first or last record. Twenty participants with a single record were randomly assigned to either the calibration (n=252) or validation (n=252) sample (Supplemental Fig S1). Repeated assessments resulted in a dataset of 1142 CRS-R records for analysis (full sample).
Table 4.2.3 presents the sequence of analytic steps. The Shapiro-Wilk test for normality confirmed the calibration sample was not normally distributed (test statistic=0.93, p<0.01). The calibration sub-sample indicated that the six CRS-R items had good precision (Wright’s PSR=.95) and no misfitting items. No local item dependence was found in the data when examining inter-item correlations (Linacre, 2020; Tennant & Conaghan, 2007). Items were slightly more challenging than the persons’ ability to respond (mean person measure (-0.35 ± 1.98 logits). 22 (8.7%) individuals reached the assessment’s ceiling while there was a negligible floor effect (Table 4.2.2). PCAR indicated unidimensionality (Eigenvalue 1.63; percent variance explained by the
first contrast 8.1%). Inspection of the loadings further confirmed unidimensionality (disattenuated correlations >0.82 for all item contrasts). Step and item anchors from the calibration sub-sample were applied to the validation sub-sample; results obtained compared favorably (Supplemental Figures S4.2.2 and S4.2.3) and the step and item calibrations were then applied to the full sample (Table 4.2.3). All results below refer to the full sample unless otherwise specified.

**Supplemental Figure S4.2.2**

Comparison of Person Measures From the Validation Sample Unanchored and Anchored Using a 95% Confidence Interval
Supplemental Figure S4.2.3

Comparison of Item Measures From the Calibration and Validation Samples Using a 95% Confidence Interval
Table 4.2.3

Sequence of Rasch Analyses and Psychometrics Summary

<table>
<thead>
<tr>
<th>Analysis</th>
<th>Items</th>
<th>Rating Scale Steps</th>
<th>Person Mean (SD) logits</th>
<th>RMSE</th>
<th>Adj. SD</th>
<th>SI</th>
<th>PSR</th>
<th>Wright’s PSR</th>
<th>Num. of Misfitting Items</th>
<th>PCAR Eigenv. 1st contrast (%)</th>
<th>Ceiling Effect n (%)</th>
<th>Floor Effect n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calibration Sample, 252</td>
<td>6</td>
<td>29</td>
<td>-0.35 (1.98)</td>
<td>0.75</td>
<td>1.83</td>
<td>2.43</td>
<td>0.86</td>
<td>0.95</td>
<td>0</td>
<td>1.63 (8.1)</td>
<td>22 (8.7)</td>
<td>0</td>
</tr>
<tr>
<td>participants Validation</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample, 252</td>
<td>6</td>
<td>29</td>
<td>-0.15 (1.82)</td>
<td>0.72</td>
<td>1.67</td>
<td>2.33</td>
<td>0.84</td>
<td>0.95</td>
<td>0</td>
<td>1.71 (9.1)</td>
<td>18 (7.1)</td>
<td>0</td>
</tr>
<tr>
<td>Validation Sample, 252</td>
<td></td>
<td></td>
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<tr>
<td>252 participants,</td>
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<tr>
<td>ANCHORED Full Sample,</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1442 Records, ANCHORED</td>
<td>6</td>
<td>29</td>
<td>-0.13 (1.89)</td>
<td>0.74</td>
<td>1.74</td>
<td>2.35</td>
<td>0.85</td>
<td>0.95</td>
<td>0</td>
<td>1.74 (9.5)</td>
<td>18 (7.1)</td>
<td>0</td>
</tr>
<tr>
<td>Standard Deviation (SD); Standard Deviation (SD); Root Mean Square Standard Error (RMSE); Separation Index (SI); Person Separation Reliability (PSR); Principal Components Analysis of Residuals (PCAR)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Structural Validity

Rating Scale Step Structure. All rating scale steps were monotonic and had 10 or more responses for the calibration and full sample. The validation sample had less than 10 responses for rating scale step 0 for two items: motor (n=6) and arousal (n=8). Rating scale steps were monotonic for all items in the calibration, validation, and full sample.

Unidimensionality: Item Fit, Principal Components Analysis, and Item Hierarchy. Items from the calibration, validation, and full sample continued to fit the model with the infit MnSq ranging from 0.80 to 1.36 logits across samples (Table 4.2.4). The simulated data sets identified a more stringent infit MnSq criteria range of 0.78 to 1.22 (Table 4.2.4) (Linacre; Smith et al., 1998). The calibration sample met this stringent infit MnSq criteria with all items between 0.84 and 1.12 logits. Two items misfit for the validation and full samples using the more restrictive criteria: Motor (1.31 and 1.21 logits, respectively) and Verbal (1.36 and 1.27 logits, respectively).

Table 4.2.4

<table>
<thead>
<tr>
<th>Items</th>
<th>Measure (logits)</th>
<th>Std. Error</th>
<th>Infit MnSq</th>
<th>Infit zstd</th>
<th>Outfit MnSq</th>
<th>Outfit zstd</th>
<th>Disp.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication</td>
<td>1.99</td>
<td>0.06</td>
<td>0.90</td>
<td>-2.0</td>
<td>0.68</td>
<td>-3.4</td>
<td>0.05</td>
</tr>
<tr>
<td>Auditory</td>
<td>-0.05</td>
<td>0.04</td>
<td>0.80</td>
<td>-5.5</td>
<td>0.75</td>
<td>-6.9</td>
<td>-0.12</td>
</tr>
<tr>
<td>Visual</td>
<td>-0.08</td>
<td>0.03</td>
<td>0.90</td>
<td>-2.6</td>
<td>0.86</td>
<td>-3.2</td>
<td>0.04</td>
</tr>
<tr>
<td>Motor</td>
<td>-0.48</td>
<td>0.03</td>
<td>1.21</td>
<td>-4.4</td>
<td>1.33</td>
<td>6.0</td>
<td>0.05</td>
</tr>
<tr>
<td>Arousal</td>
<td>-0.66</td>
<td>0.05</td>
<td>0.99</td>
<td>-0.2</td>
<td>1.01</td>
<td>0.4</td>
<td>-0.11</td>
</tr>
<tr>
<td>Verbal</td>
<td>-0.72</td>
<td>0.05</td>
<td>1.27</td>
<td>6.6</td>
<td>1.28</td>
<td>6.4</td>
<td>0.06</td>
</tr>
</tbody>
</table>

MeanSquare (MnSq); Z Standard (zstd); Displacement (Disp.)

*Data from full sample using anchors from calibration sample.

The PCAR Eigenvalue was 1.61 with 8.8% variance of the first contrast which was comparable with average values derived from the 10 simulated data sets with an Eigenvalue
of 1.44 and unexplained percent variance in the 1st contrast of 5.44 (Linacre; Smith et al., 1998). To further substantiate unidimensionality, the disattenuated correlations were all greater than 0.85 indicating the same underlying trait was being measured by the items.

The item order from hardest to easiest to respond to was communication (average item measure 1.99) followed by Auditory, Visual, Motor, Arousal, and then Verbal (average item measure -0.72) (Table 4.2.4). The average category measures provide information on the hierarchy of the rating scale steps; a 0 on Verbal is the easiest and a 6 on Motor is the hardest to achieve (Figure 4.2.1).

**Figure 4.2.1**

*Nomogram & Wright Map for the Coma Recovery Scale-Revised*

![Nomogram & Wright Map for the Coma Recovery Scale-Revised](image)

**Score to Measure Conversion**

Figure 4.2.1 displays a visual ruler for converting the CRS-R total raw scores into Rasch measures. The total raw score of 0 to 23 corresponds to -6.52 to 5.85 logits (Supplemental Table S4.2.1).
## Supplemental Table S4.2.1

*Raw Score to Rasch Measure Conversion Table Using the Full Sample*

<table>
<thead>
<tr>
<th>CRS-R Raw Score</th>
<th>CRS-R Rasch Person Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>-6.52</td>
</tr>
<tr>
<td>1</td>
<td>-5.14</td>
</tr>
<tr>
<td>2</td>
<td>-4.18</td>
</tr>
<tr>
<td>3</td>
<td>-3.5</td>
</tr>
<tr>
<td>4</td>
<td>-2.9</td>
</tr>
<tr>
<td>5</td>
<td>-2.34</td>
</tr>
<tr>
<td>6</td>
<td>-1.81</td>
</tr>
<tr>
<td>7</td>
<td>-1.36</td>
</tr>
<tr>
<td>8</td>
<td>-1.00</td>
</tr>
<tr>
<td>9</td>
<td>-0.69</td>
</tr>
<tr>
<td>10</td>
<td>-0.43</td>
</tr>
<tr>
<td>11</td>
<td>-0.19</td>
</tr>
<tr>
<td>12</td>
<td>0.04</td>
</tr>
<tr>
<td>13</td>
<td>0.28</td>
</tr>
<tr>
<td>14</td>
<td>0.55</td>
</tr>
<tr>
<td>15</td>
<td>0.86</td>
</tr>
<tr>
<td>16</td>
<td>1.22</td>
</tr>
<tr>
<td>17</td>
<td>1.61</td>
</tr>
<tr>
<td>18</td>
<td>2.04</td>
</tr>
<tr>
<td>19</td>
<td>2.50</td>
</tr>
</tbody>
</table>
Measurement Accuracy

Wright’s PSR is 0.95 and equates to a maximum statistically different levels of strata of 4.5 for all samples. The separation index was 2.20 (Table 4.2.3).

The mean of the persons (-0.44±1.75) was less than the mean of the items (0.0) indicating the persons had less neurobehavioral function than the items targeted. There was no appreciable floor effect (0.1%) and a minimal ceiling effect (4.9%) (Table 4.2.3) (Andresen, 2000; Andresen et al., 1998; Portney & Watkins, 2015). Person misfit was consistent across samples at 18%, 20%, and 19% for the calibration, validation, and full samples, respectively.

Reproducibility

The calibration and validation sub-samples indicate reproducibility for person and item measures (Supplemental Figures S4.2.2 and S4.2.3). Item anchors were further validated by evaluating item displacement; no displacement was greater than 0.50 logits when applied to the validation and full samples (Linacre, n.d.-b).

External Validity of the CRS-R

The relationship between the CRS-R person measures and state of consciousness was assessed after applying the Aspen Criteria to all CRS-R records (n=1,442) using STATA.
(Schnakers et al., 2009). Correlation between Aspen-based state of consciousness and CRS-R person measures was statistically significant ($r_s=0.86$, $p<0.01$) (Portney & Watkins, 2015).

The CRS-R person measures were examined for their distribution by Aspen-based state of consciousness (Figure 4.2.3, Supplemental Table S4.2.2).

**Figure 4.2.2**

*Box and Whisker Plot Demonstrating CRS-R Rasch Measures for Each State of Consciousness*

![Box and Whisker Plot Demonstrating CRS-R Rasch Measures for Each State of Consciousness](image)

**Supplemental Table S4.2.2**

*Descriptive Statistics Based on the First and Last Record for Each Participant Using the CRS-R Person Measures (logits)*

<table>
<thead>
<tr>
<th>Record</th>
<th>N</th>
<th>Median</th>
<th>Mean (95% CI)</th>
<th>SE</th>
<th>Variance</th>
</tr>
</thead>
<tbody>
<tr>
<td>eMCS</td>
<td>7</td>
<td>0.85</td>
<td>1.11 (-0.02, 2.24)</td>
<td>0.46</td>
<td>1.49</td>
</tr>
<tr>
<td>Last</td>
<td>93</td>
<td>4.52</td>
<td>4.37 (4.04, 4.69)</td>
<td>0.16</td>
<td>2.46</td>
</tr>
<tr>
<td>All</td>
<td>225</td>
<td>3.63</td>
<td>3.65 (3.40, 3.89)</td>
<td>.12</td>
<td>3.45</td>
</tr>
<tr>
<td>MCS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First</td>
<td>164</td>
<td>-0.19</td>
<td>-0.14 (-0.29, .01)</td>
<td>0.08</td>
<td>0.93</td>
</tr>
<tr>
<td>Last</td>
<td>106</td>
<td>0.16</td>
<td>0.36 (0.14, 0.57)</td>
<td>0.11</td>
<td>1.27</td>
</tr>
</tbody>
</table>
Participants in the VS have a CRS-R Rasch person measure from -5.12 to 1.19 logits (raw score 0 to 16), MCS have CRS-R Rasch person measures from -2.88 to 3.63 logits (raw score 4 to 21), and eMCS have CRS-R Rasch person measures from -0.43 to 5.84 logits (raw score 10-23). The descriptive statistics showed a wide range in variance for each state of consciousness (Supplemental Table S4.2). The Bartlett test from the one-way ANOVA confirmed that the variances of the CRS-R person measures (last record) by each state of consciousness were statistically unequal ($X^2=20.43$, $p<0.001$). The Kruskal-Wallis test showed that the mean ranks of CRS-R person measures (last record) were statistically different across the levels of Aspen-based state of consciousness ($H(2)=194.74$, $p<0.01$).

**Discussion**

The purpose of this study was to 1) examine and substantiate the prior findings for the psychometric properties of the CRS-R in a larger sample size and 2) examine the association between the CRS-R Rasch person measures and Aspen criteria for states of consciousness. Consistent with prior studies, the CRS-R items demonstrated good structural validity, reproducibility, and external validity. Analysis of the six CRS-R items substantiated the initial findings of the CRS-R in a larger sample so that the item calibrations, rating scale category measures, and person measures are stable for high stakes testing. The CRS-R total
person measures demonstrated a good correlation with the Aspen criteria for states of consciousness providing empirical support for the use of the CRS-R for diagnostic purposes.

Conceptually, all CRS-R items underpin the same concept of interest, neurobehavioral function, as indicated by the fit of the items and strong disattenuated correlations supporting unidimensionality. The items representing neurobehavioral function presented in order from hardest to easiest to respond to is Communication, Auditory, Visual, Motor, Arousal, and then Verbal. The easiest item on the CRS-R in this study is Verbal/Oromotor. This finding aligns with neuroscience evidence that a tongue blade would provide pre-swallowing input and requires less complex central nervous systems processing (Pape et al., 2014). Whereas the hardest item, Communication, includes functional communication a highly anticipated task by both caregivers and rehabilitation practitioners as it indicates emergence from MCS. Functional communication requires the complex CNS networks for both comprehension of spoken language and communication (Bara et al., 2001; Aurore Thibaut et al., 2019).

In contrast to the hypothesis, the item hierarchy differs from previously reported Rasch analysis of the CRS-R (La Porta et al., 2013). This sample was predominantly individuals with TBI and therefore, the hierarchy findings are compared to La Porta et al.’s (2013) findings for individuals with TBI. A moderate relationship was found between the average item measures from La Porta’s findings and this study’s findings. This study substantiates that the Communication item remains the most challenging (La Porta et al., 2013). Verbal/Oromotor and Arousal demonstrate the most difference between average item measures across the two studies (Figures 4.2.3a & 4.2.3b). Previous work by LaPorta et al (2013) found Verbal/Oromotor as one of the harder items for neurobehavioral functioning.
whereas this study found it to be the easiest item. Overall, the item hierarchy produced from this study demonstrated somewhat similar average item calibrations to previous work.

The Aspen criteria were applied to the CRS-R records to determine the participant’s state of consciousness for each record. A good relationship was found between the CRS-R person measure and state of consciousness. This relationship is supported by the Kruskal Wallis showing that each state of consciousness (VS, MCS, and eMCS) are distinct from one another (Figure 4.2.3, Supplemental Table S4.2.2). Determining the correct state of consciousness for a patient is critical as it dictates provision of rehabilitation services (Giacino et al., 2018b; Giacino et al., 2020).
Figure 4.2.3a

Comparison of the CRS-R Average Item Measures From This Data Compared to La Porta et al. Average Item Measures for Traumatic Brain Injury

\[ y = 0.6729x + 0.0073 \]

\[ R^2 = 0.7452 \]
Figure 4.2.3b

Comparison of the CRS-R Average Item Measures From This Data Compared to La Porta et al. Average Item Measures for Non-Traumatic Brain Injury

Limitations

This study is a retrospective analysis of CRS-R data from individuals with DoC after brain injury receiving inpatient rehabilitation services or participating in a clinical trial, therefore the data lacks representation of individuals that present as comatose. Future studies should evaluate the influence of rater severity/leniency to remove bias from the person measures (Linacre et al., 1994). Additionally, the Aspen criteria that identifies behaviors indicative of different states of consciousness needs to be further explored empirically due to its influence on service provisions.
Conclusion

The CRS-R is used to evaluate state of consciousness which has implications for patients and their access to rehabilitation services. This is the first study to provide empirical data for the CRS-R with a sample size appropriate for high-stakes testing and establish robust item and step calibrations. This Rasch analysis indicated a different hierarchy of the CRSR items that was unidimensional and underpins neurobehavioral function as a construct. The CRS-R’s high reliability further supports its use for making individual-level decisions. The CRS-R person measures and Aspen state of consciousness showed a strong correlation further supporting the use of the CRS-R to evaluate state of consciousness. The CRS-R should be used in lieu of clinical observations for identification of state of consciousness when critical decisions are being made such as access to rehabilitation.

Afterword Paper 4.2

This study empirically examined the CRS-R for its structural validity, reproducibility, and external validity. This knowledge inquiry (KTA Framework, Creation Funnel—Figure 1.3) about the psychometric properties of the CRS-R is foundational to sharing clinical data with family caregivers and using assessment results to guide treatment planning. Data that is used for making clinical decisions and subsequently shared with decision-makers (e.g., rehabilitation practitioners and family caregivers) needs to measure a concept of interest for recovery of consciousness and demonstrate reliability that is conducive for individual level decision making.

This study found good structural validity for the six CRS-R items were unidimensional, had no misfitting item, excellent measurement precision, and a hierarchy that reflected a continuum of neurobehavioral function. The CRS-R items also demonstrated good reproducibility across the item and person measures. The use of Rasch analysis
converted the ordinal raw scores of the CRS-R into equal-interval measures. Equal interval measures are significant for interpreting treatment effectiveness because the difference between measures can be calculated and used to make inferences, whereas ordinal scores only describe if there is more or less change (Merbitz et al., 1989). Rehabilitation practitioners and family caregivers can use the assessment’s measure to determine if a treatment is making a positive impact on the patient’s progress.

A secondary aim of this study was to examine the correlation between CRS-R person measures and states of consciousness. State of consciousness has implications for the care that patients may receive (Giacino et al., 2020), therefore it was a critical variable to examine. Another common use of the CRS-R is to diagnose states of consciousness. The CRS-R person measures and the Aspen-based state of consciousness showed a strong statistically significant correlation ($r_s=0.86$, $p<0.01$) further supporting the use of the CRS-R to evaluate state of consciousness. This study represents the first step towards examining the psychometric properties of the CRS-R to ensure that they are suitable for individual-level decision making when treatment planning.

**Foreword Paper 4.3**

This section of the chapter presents the results from the last of the three primary research objectives of this project that broadly were described to inform shared decision-making, psychometric properties of the Coma Recovery Scale-Revised, and the development of a recovery ruler to facilitate shared decision-making between family caregivers and rehabilitation practitioners when treatment planning. The third main objective of this dissertation was to identify the salient features of the recovery ruler that facilitate effective communication between family caregivers and rehabilitation practitioners when treatment
planning. This fourth paper focuses on translating Coma Recovery Scale-Revised assessment results in a way that can inform treatment planning. This paper cites results from the third paper that describes the psychometric properties of the Coma Recovery Scale-Revised as this work was foundational to building the recovery ruler.

This paper integrates person-centered measurement principles with a CRS-R keyform. Person-centered measurement principles included 1) comprehensible and timely, 2) transparency, and 3) relationship-focused. The recovery ruler aims to provide real-time assessment results that reduce the need to add up a raw score and review a table to identify the Rasch measure. The recovery ruler should also be comprehensible in that it is easy for both the rehabilitation practitioners and family caregivers to interpret what the results mean. Furthermore, the purpose of the recovery ruler is so that assessment results can be shared (e.g., transparent) with family caregivers. Communication about the assessment results leads to a relationship-focused discussion surrounding treatment planning. This fourth paper focuses on the development of the recovery ruler. An experimental mixed methods study uses Rasch analysis to co-calibrate the CRS-R variables with states of consciousness, design groups to tailor the recovery ruler using person-centered measurement principles, and an evaluation of the recovery ruler’s usability and pre-implementation factors to identify whether the recovery ruler was ready for a feasibility study.
Translating the Coma Recovery Scale-Revised Into Clinical Practice Using Person-Centered Measurement Principles

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Introduction

Bedside neurobehavioral function assessments are the primary way rehabilitation practitioners classify state of consciousness for patients with disorders of consciousness (DoC) following a brain injury (Giacino et al., 2018b). Patients with DoC may be classified as comatose, unresponsive wakefulness syndrome (UWS)/vegetative state (VS), minimally conscious state (MCS), and emerging MCS (eMCS) (Giacino et al., 2002). Neurobehavioral responses that indicate different states of consciousness have largely been determined by expert consensus panels and evidence-based reviews (J. T. Giacino, 2005; Giacino et al., 2002). The most widely used neurobehavioral function assessment is the Coma Recovery Scale-Revised (CRS-R). CRS-R items and response categories have been aligned to the disordered states of consciousness (Giacino et al., 2002; Schnakers et al., 2009).

A patient’s state of consciousness is instrumental for decision-making when treatment planning, especially when making decisions about discharge placement. In the United States, patients must be categorized as MCS to be considered for inpatient rehabilitation services (Giacino et al., 2020). Unfortunately, misdiagnosis rates for states of disordered consciousness can be as high as 40% with patients most often being categorized as VS/UWS when they are most likely MCS (Giacino et al., 2020). Contributing factors to misdiagnosis include relying on unstructured observations and complications that arise when using standardized neurobehavioral assessments (e.g., items not administered due to motor impairment and tracheostomy) (Schnakers et al., 2009). Unstructured observations are likely used more often than standardized assessments because practitioner’s report challenges generating meaningful quantitative results in real time and end up interpreting the qualitative responses to guide their practice (Jette et al., 2009).
As a result, family caregivers are too often asked to make decisions about discharge placement and treatment with limited and inaccurate information about diagnosis and prognosis. Further, family caregivers report not being listened to when they tell rehabilitation practitioners about observations of their loved one responding to stimuli in a new way (Weaver et al., 2019). If family caregivers understand what behaviors reflect the different states of consciousness, then they can provide practitioners with more information about the patient’s neurobehavioral function throughout the day, which will lead to informed treatment and discharge planning.

Standardized assessments, like the CRS-R, document treatment effectiveness and has a critical role in discerning the patient’s state of consciousness (Merbitz et al., 1989; Velozo & Woodbury, 2011). Yet, therapists are challenged in incorporating this assessment into clinical practice and it may be because the perceived benefit of the assessment is not outweighing the challenges to implementation. Rehabilitation practitioners need real-time interpretation of the patient’s status to tailor a treatment plan (Linacre, 1997). Currently, the numerical output from the CRS-R does not directly connect to information about states of consciousness or knowledge about which items and rating scale steps might be achieved in the future.

The Rasch model evaluates item difficulty and person ability, and this information is useful when a rehabilitation practitioner and family caregiver is considering treatments and goal-setting (Bond & Fox, 2015). A Keyform is a visualization of item difficulty and person ability that can provide instantaneous measurement and information to the rehabilitation practitioner and family caregiver (Linacre, 1997). The Keyform arranges the items and rating
scale steps in difficulty order. The items arranged in hierarchical order quickly show the rehabilitation practitioner or family caregiver that the items at the bottom are easier and the items at the top are harder, meaning that patients with less neurobehavioral function will have a harder time responding to the harder items. Rating scale steps on the left side of the Keyform are easier and as the rating scale steps progress to the right side of the scale the person needs to have more neurobehavioral function to achieve a higher score.

Keyforms were first introduced in 1995 and have been expanded to align multiple assessments or variables on one equal-interval ruler (Linacre, 1995). Previous works have used Keyforms to identify cognitive function, upper extremity function post-stroke, and the probability of having Alzheimer’s disease based on three assessment results (Hughes et al., 2003; Linacre, 1997; Velozo & Woodbury, 2011). Keyforms do not have widespread use in clinical practice.

The Keyform needs to be reimagined to include person-centered measurement principles. Person-centered measurement principles include, 1) comprehensible and timely, 2) transparent, and 3) relationship-focused. Comprehensible and timely refers to the information being easy to understand and can be ascertained quickly. Transparency means that all stakeholders will have access to assessment results. Relationship-focused means that the family caregiver’s perceptions of the patient’s preferences, priorities and values will be considered when treatment planning. Applying these person-centered measurement principles to a Keyform will necessitate partnering with the stakeholders that use the assessment information, such as rehabilitation practitioners and family caregivers, to determine how CRS-R assessment results should be reported.
There is a critical need to improve effective communication of assessment results between the family caregivers and rehabilitation practitioners to facilitate shared decision-making when treatment planning (Epstein & Street, 2007). Person-centered measurement principles, including assessment data that are timely and comprehensible, transparent, and relationship-focused, can be applied to improve how assessment results are presented to caregivers (American Institutes for Research, 2017). To improve how the Coma Recovery Scale-Revised assessment results are communicated to caregivers of patients in DoC, a method of visualizing assessment results that is comprehensible, timely, and transparent creating a *noteworthy contribution to providing person-centered care* is proposed (American Institutes for Research, 2017).

This study uses the Knowledge to Action (KTA) framework to guide the implementation process to ensure the recovery ruler developed from a Keyform prototype is ready for clinical practice. Evidence is lacking as to why Keyforms have not been used in clinical practice, therefore an implementation strategy will be critical to future uptake. The KTA framework has an action cycle (applying knowledge) and creation funnel (generating knowledge) that outlines an iterative process for moving research evidence into clinical practice (S. E. Straus et al., 2013). The purpose of this study is to identify salient features of a recovery ruler, based on the CRS-R, that facilitate effective communication between family caregivers and rehabilitation practitioners about treatment goals and options. A long-term goal of this work is to have a recovery ruler prototype that can be evaluated for real-world implementation in a feasibility study.
Methods

Study Design

This study used an experimental mixed methods design (Creswell & Plano Clark, 2018) to create a recovery ruler that demonstrates initial readiness for clinical practice. Both quantitative and qualitative data were used to ensure that the needs of rehabilitation practitioners and family caregivers were met. CRS-R data were analyzed using a co-calibration approach (Bond & Fox, 2015) to align rating scale categories and patient total scores with Aspen-based states of consciousness criteria (Giacino et al., 2002; Schnakers et al., 2009). The Rasch analysis of the CRS-R and Aspen-based states of consciousness produced a Keyform. Design groups were held to inform the development of a visual tool for conveying neurobehavioral assessment and state of DoC results, referred to as a ‘recovery ruler.’ The recovery rule incorporated three person-centered measurement principles, 1) comprehensible and timely, 2) transparent, and 3) relationship-focused (American Institutes for Research, 2017). Development of the recovery ruler involved integration of both qualitative and quantitative data. Pre-implementation factors were evaluated during the design groups and with four surveys to ensure the recovery ruler is usable, acceptable, appropriate, and feasible for clinical practice (Bangor et al., 2009; Weiner et al., 2017). The KTA framework guided the creation of the recovery ruler and informed how this new tool could be implemented into practice by adapting it to the local context and assessing the recovery ruler for its barriers to uptake into clinical practice (Graham et al., 2006).

The first phase addressed a problem in the field which is being able to quickly align CRS-R assessment data to state of consciousness (Giacino et al., 2020). In Rasch co-calibration, a linear combination of CRS-R items was aligned to three of the states of DoC.
This enables the items from the state of consciousness variable (e.g. UWS/VS, MCS, and eMCS) to be expressed in the same units as the CRS-R rating scale steps and items, providing an empirically-based description of patients in each category. Because the estimates obtained in this linear combination of CRS-R items and state of consciousness variable are not influenced by the particular sample of patients scored on these items, the results are applicable to other samples of patients in DoC (Hughes et al., 2003). The Rasch co-calibration analyses produced a Keyform to serve as the first prototype to stimulate conversation and walk-through clinical scenarios.

During the second phase, the initial recovery ruler prototype was revised with input from the two groups of end-users of the information, namely rehabilitation practitioners and family caregivers. Previous work has identified prototyping and engaging stakeholders as being a critical first step to future widespread use (Bonham-Werling et al., 2021). Perceptions of the rehabilitation practitioner are important for initial uptake of the recovery ruler in clinical practice and to identify concerns with how the tool might be adapted to the local context in which it would be used. Because it is the intent that the recovery ruler will be used to convey information about assessment results with caregivers to facilitate shared decision-making when treatment planning, the perspective of family caregivers was also sought. This qualitative phase focused on better understanding the stakeholders’ needs and incorporation of three person-centered measurement principles to ultimately facilitate successful implementation and sustainability (Chambers et al., 2013).

During the third phase, pre-implementation factors were assessed. To ensure future iterations of the recovery ruler were perceived useful and ready for a feasibility study, a usability survey and three implementation surveys were completed after the first and last
design group. It is hypothesized there will be an increase in the scores on each survey indicating that the recovery ruler has improved because the recovery ruler is being re-designed based on feedback from participants.

**Phase One: Aligning States of Consciousness to the CRS-R**

**Data Sources & Participants.** CRS-R data came from four data sources: two clinical trials and two rehabilitation centers. The clinical trial sources included administered amantadine (Giacino et al., 2012) and repetitive transcranial magnetic stimulation (Giacino et al., 2012; Pape, 2015). The rehabilitation centers were in Midwest and South metropolitan areas of the United States. Participants were young adults (≥ 14 years) or older who were in states of DoC from a brain injury. Each participant had at least one CRS-R assessment and reassessments were included. Additional data collection information and procedures can be found in Chapter 4, Section 2, Paper 3.

**Measures.**

**Coma Recovery Scale-Revised.** The CRS-R is the most widely used neurobehavioral function assessment in the United States (Formisano et al., 2019; Giacino et al., 2018b). The hierarchical order of the items reflect least to most challenging neurobehavioral responses includes Communication, Auditory, Visual, Motor, Arousal, and Verbal. Total raw scores range from 0-23. The CRS-R has been found to have excellent measurement precision, good structural validity, reproducibility, and external validity.

**Aspen-Based Categories of States of Disordered Consciousness.** For each record, a categorical state of disordered consciousness was assigned based on clinical consensus and expert literature reviews referred to as Aspen criteria (Giacino et al., 2002). Previously published literature has demonstrated the alignment between these criteria and specific rating
scale steps on the CRS-R (Schnakers et al., 2009) (Figure 4.3.1). For a participant to be evaluated as MCS or eMCS only one of the rating scale steps aligned with that state of consciousness had to be recorded. Whereas, for a participant to be recorded as UWS/VS then all items needed to be recorded to a rating scale step that aligned with UWS/VS. For each record, a DoC category was assigned based on these criteria: 1: UWS/VS, 2: MCS, 3: eMCS.

**Figure 4.3.1**

*Rating Scale Steps From CRS-R Items Were Aligned to VS/UWS (Triangles), MCS (Squares), and eMCS (Circles)*

**Rasch-Derived Categories of States of Disordered Consciousness.** For each record, a categorical state of disordered consciousness was assigned based on the half-point thresholds for the Aspen-based categories. Half-point thresholds define the ends of each category interval (Linacre, 2021). Any rating scale step measure that fell above the half-point threshold for MCS or eMCS was categorized to indicates either MCS or eMCS.

**Analytic Plan.** Following procedures described by Wright et al. (2000) and Hughes et al. (2003) CRS-R step and item anchors (from previous analyses, Chapter 4, Section 2, Paper 3) were applied to the full dataset of CRS-R records. To align the Aspen-based states of consciousness, this variable was allowed to float in the model. Once, the variables
placement was determined as it aligned along the CRS-R step and items, anchors were produced and then applied to the full dataset. The Rasch-derived state of consciousness variable was created by examining the half-point thresholds for each category of the Aspen-based variable. All CRS-R records were categorized as UWS/VS, MCS, and eMCS based on the empiric data. The association between the Aspen-based and Rasch-derived state of consciousness variables were examined using a Fisher’s exact test (Portney & Watkins, 2015).

**Phase Two: Translating a Keyform to a Recovery Ruler for Clinical Practice**

To make the information more interpretable for decision-making in clinical practice, Rasch logits were transformed to a 0-100 range of measures (Bond & Fox, 2015). The Keyform output from Winsteps was re-created in Adobe Illustrator by an instructional designer to improve visual appeal. The Keyform prototype was reviewed by rehabilitation practitioners and family caregivers during a design group to identify ways in which it can be easier to understand and facilitate communication between these two stakeholder groups.

**Participants.** Participants were recruited by emailing individuals in known networks to the research team, including the Advanced Metrics Lab database including caregivers of persons with disorders of consciousness, and social media posts. Recruitment was targeting individuals who had experience being a primary caregiver for a person with disorders of consciousness as well as rehabilitation practitioners that provided services to patients in DoC. There was no minimum amount of experience caring for a person with DoC required to participate. The study was approved by the George Washington University Internal Review Board and all participants consented to be in the study.
Data Collection. Participants were asked questions based on a semi-structured interview guide during each of the two 60-minute design groups. All design groups and interviews occurred using a virtual webconferencing platform and were audio-recorded. The goal of the first design group was to ensure assessment data were *comprehensible and timely* on the recovery ruler by ensuring it is easy to understand and quickly facilitates interpretation of assessment results. The goal of the second design group was to ensure the recovery ruler incorporates the selected PCM principles, specifically *relationship-focused*, in that the patient’s preferences, values, and interests were captured.

The first design group used the recovery ruler prototype of the CRS-R items and state of consciousness variables (Figure 4.3.3). Methods such as brainstorming and cognitive walk-throughs (Krueger, 2000) were utilized to inform revisions needed and suggest how the recovery ruler will be incorporated into clinical practice. Feedback from the first focus group was used to revise and add content to the recovery ruler in collaboration with an instructional designer. The second design group focused on reviewing changes to the recovery ruler to make sure the revisions reflected the previous design discussions (e.g., member-checking) (Patton, 2015). After member-checking, a cognitive walk through of a case scenario was conducted to understand to what extent the recovery ruler facilitates communication about assessment results and treatment planning. Additional recommended changes were made by the instructional designer following the second design group.

Analytic Plan. The audio-recordings were transcribed verbatim. Content analysis of the data was conducted to generate codes identifying aspects of the recovery ruler to keep, add, or tailor by two team members (Patton, 2015; Renz et al., 2018). Content analysis involves searching documents, including interview transcripts, to identify core categories and
meanings (Renz et al., 2018). Constant comparative method compared the data from the practitioners and caregivers to facilitate a balance of perspectives (Glaser, 1965). Final codes from the first design group were provided to the instructional designer to inform future iterations of the recovery ruler. The instructional designer reviewed the codes to determine feasibility of the changes. The new recovery ruler prototypes (n=3) and the final codes from the first design group were provided to the participants in the second design group creating an opportunity for member-checking and validation (Patton, 2015).

**Phase Three: Evaluation of Pre-Implementation Factors for Uptake of the Recovery Ruler in Clinical Practice**

Pre-implementation factors related to the usability, acceptability, appropriateness, and feasibility of the recovery ruler for clinical practice was evaluated simultaneously with participants in the design groups.

**Measures.**

**System Usability Scale.** The System Usability Scale (SUS) consists of 10 items with half of the responses worded positively and the other half worded negatively (Holden et al., 2019; Lewis & Sauro, 2009; Sauro, 2011). SUS items are scored on a five-point Likert scale with response options ranging from strongly disagree (1) to strongly agree (5). To establish a SUS total score, items are rescored to a range of 0-40. Specifically, for positively worded items 1 point was subtracted from each response; for negatively worded items, 5 points were subtracted from each response. The re-scored items were added together and multiplied by 2.5 to convert the total score range to 0-100 (Bangor et al., 2009; Sauro, 2011). SUS scores >70 are considered acceptable and less likely to have concerns around usability (Bangor et al., 2009).
Acceptability of Intervention Measure. The Acceptability of Intervention Measure (AIM) has four items covering approval and appeal of the recovery ruler that are answered with a five-point scale of agreement from completely disagree (1) to completely agree (5). The reliability of the AIM is 0.85 (Cronbach’s alpha) (Weiner et al., 2017).

Intervention Appropriateness Measure. The Intervention Appropriateness Measure (IAM) has four items covering suitability and applicability of the recovery ruler that are answered with a five-point scale of agreement from completely disagree (1) to completely agree (5). The reliability of the IAM is 0.91 (Cronbach’s alpha) (Weiner et al., 2017).

Feasibility of Intervention Measure. The Feasibility of Intervention Measure (FIM) has four items covering the practicality (e.g., doable, possible) of the recovery ruler that are answered with a five-point scale of agreement from completely disagree (1) to completely agree (5). The reliability of the FIM is 0.89 (Cronbach’s alpha) (Weiner et al., 2017).

Data Collection

At the end of each design groups, participants were provided a RedCap website link to complete the self-report assessments evaluating usability (Sauro, 2011) and the pre-implementation factors acceptability, appropriateness, and feasibility (Weiner et al., 2017). All four measures evaluate how well the recovery ruler will fit with clinical practice. If a participant did not complete the surveys, a reminder email was sent after 48 hours. A total of three email reminders were sent to participants. The survey responses were exported from RedCap to an Excel file and transferred into STATA for cleaning and analysis.

Analytic Plan. Descriptive statistics were calculated using STATA version 14. A paired t-test examined the difference in SUS scores between the two design groups. A Wilcoxon signed-rank test examined the difference between the two design groups for the
three implementation measures (AIM, IAM, and FIM). For all analyses of the differences between results from the design groups, a t or z test statistic is reported based on a one-tailed p-value.

The quantitative data from phase three synthesized with the qualitative data from phase two informed the adaptations of the recovery ruler as well as the development of a strategy for implementing the recovery ruler. The integration of the data resulted in three new iterations of the recovery ruler for design group 2 and a final prototype for a future feasibility study. Insights about pre-implementation factors and barriers will guide the development of an implementation strategy.

Results

*Phase One: Aligning States of Consciousness to the CRS-R*

**Participants.** Participants (n=262) were mostly males with a traumatic brain injury. Based on the Aspen-criteria, participant’s state of consciousness for their first CRS-R record was vegetative state/unresponsive wakefulness syndrome (n=47, 18%), minimally conscious state (n=194, 74%), and emerging minimally conscious state (n=21, 8%). The average age of participants was 36.5±15.2 years. There was a total of 1,162 CRS-R records, some participants had up to 38 records.

**Rasch Co-Calibration.** The CRS-R items and rating scale steps ranged from -6.52 to 5.85 logits and were transformed to a 0-100 equal-interval scale to improve interpretability (Figure 4.3.2). After anchoring the CRS-R items and rating scale steps, the positioning of the Aspen-based state of consciousness variable indicated participants were likely in a Vegetative State/Unresponsive Wakefulness Syndrome <41.5, or in 41.5≤MCS<73.4, and eMCS≥73.4 units (Figure 4.3.2). The Aspen-based state of consciousness variable was
anchored in place along with the CRS-R items to allow for the Rasch-derived state of consciousness variable to determine its relative positioning as an outcome variable. The transition zones (‘:’) between the states of consciousness for the Aspen-based state of consciousness variable and the rating scale steps for each CRS-R item were determined using the half-point thresholds (Figure 4.3.2). The half-point thresholds for the Aspen-based consensus criteria indicated rating scale steps 0 for communication and 2 for verbal indicate MCS whereas rating scale steps 4 for auditory, 3 for arousal, and 3 for verbal likely indicate eMCS. The new criteria derived from the Aspen-based co-calibration was applied to the data to generate the Rasch-derived state of consciousness variable. Rasch derived state of consciousness indicated participants were: VS/UWS <26.4, 26.4<MCS<67, and eMCS>67 units (Figure 4.3.2).

**Figure 4.3.2**

*CRS-R Measure on a 0-100 Ruler*

![Ruler Diagram](image)

The Rasch-derived state of consciousness variable re-classified rating scale steps that aligned to states of consciousness based on the results from the Aspen-based analysis. A Fisher’s Exact test examined whether the difference of proportions for each variables’ state
of consciousness was significant. Relative to categorizing participants, Aspen-based and Rasch-derived approaches agree on categorization of participants with eMCS (100% agreement). There was significant disagreement in categorizing participants with MCS and VS between Aspen-based and Rasch-derived variables (p<0.001, Fisher’s Exact Test). Specifically, of the 711 categorized at MCS by Aspen-based criteria 95 (13%) were re-categorized as eMCS on the Rasch-derived variable; of the 506 VS Aspen-based participants, 327 (65%) were re-categorized as MCS on the Rasch-derived variable. The results show that participants are likely to be categorized in a better state of consciousness when using the Rasch-derived variable compared to the Aspen criteria.

**Phase Two: Translating a Keyform to a Recovery Ruler for Clinical Practice**

**Participants.** Participants were mostly white (86%), females (79%) that had an average of approximately six years of experience caring for a person that is unconscious (Table 4.3.1). Of the 14 participants, six were family caregivers and the other eight were rehabilitation practitioners. Participants were able to select all settings in which they have provided care and the majority have experience in inpatient rehabilitation settings (86%). All family caregivers and six of the rehabilitation practitioners were located in the United States. Two rehabilitation practitioners were located outside of the United States (Ireland and United Kingdom).

**Table 4.3.1**

*Participants in Design Groups*

<table>
<thead>
<tr>
<th>Role when caring for a person that is unconscious</th>
<th>Participants (n=14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Role</td>
<td>Count (Percentage)</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>Family Caregiver</td>
<td>6 (43)</td>
</tr>
<tr>
<td>Doctor</td>
<td>1 (7)</td>
</tr>
<tr>
<td>Occupational Therapist</td>
<td>4 (29)</td>
</tr>
<tr>
<td>Physical Therapist</td>
<td>2 (14)</td>
</tr>
<tr>
<td>Speech &amp; Language Pathologist</td>
<td>1 (7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gender</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>11 (79)</td>
</tr>
<tr>
<td>Male</td>
<td>3 (21)</td>
</tr>
</tbody>
</table>

| Months Caring for a Person that is Unconscious (missing=2) | 71.8 (SD 28.2) |

<table>
<thead>
<tr>
<th>Settings Where Care Was Provided*</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Care Facility/Hospital</td>
<td>6 (43)</td>
</tr>
<tr>
<td>Inpatient Rehabilitation Facility</td>
<td>12 (86)</td>
</tr>
<tr>
<td>Long Term Acute Care Hospital</td>
<td>2 (14)</td>
</tr>
<tr>
<td>Outpatient Facility</td>
<td>5 (36)</td>
</tr>
<tr>
<td>Home</td>
<td>6 (43)</td>
</tr>
<tr>
<td>Missing</td>
<td>1 (7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hispanic or Latino Origin</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>13 (93)</td>
</tr>
<tr>
<td>Missing</td>
<td>1 (7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Race</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asian</td>
<td>1 (7)</td>
</tr>
<tr>
<td>White</td>
<td>12 (86)</td>
</tr>
<tr>
<td>Missing</td>
<td>1 (7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Highest Level of Education</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>166</td>
<td></td>
</tr>
</tbody>
</table>
High school degree or GED 2 (14)
Some college, no degree 1 (7)
Associate degree 1 (7)
Bachelor’s degree 1 (7)
Master’s degree 3 (21)
Terminal degree 5 (36)
Missing 1 (7)

*Family caregiver and rehabilitation practitioner may have provided care to person with DoC in more than one setting.

**Design Group 1.** Prior to hosting design group 1, the first author [JW] worked with an instructional designer to transform the Winsteps output (Figure 4.3.2) using Adobe Illustrator; this served as the initial Recovery Ruler prototype for review (Figure 4.3.3).

**Figure 4.3.3**

*Winsteps Keyform Output Transformed to Recovery Ruler Prototype by the Instructional Designer*
Content analysis specifically identified elements that could be added, removed, or changed of the Recovery Ruler. Discussions about the recovery ruler also included how the information might be used differently across practice settings (e.g., inpatient rehabilitation facility or long-term acute care hospital) and across patient populations (e.g., acute versus chronic).

**Added.** Participants wanted to add a qualitative descriptor for the 0-100 Rasch measure, a mechanism to track CRS-R results over time, and space for narrative text for personal preferences to guide treatment decisions. Participants also suggested that the backside of the Recovery Ruler could be used to describe the states of consciousness, state the limitations of the CRS-R, and statements such as ‘fluctuation is the norm’ and ‘we consistently see inconsistency’ to facilitate communication about assessment results. Practitioners wanted a training manual, specifically in the form of a short video, to describe ‘how to’ use the recovery ruler.

**Removed.** The state of consciousness variables that informed the transition zones were helpful for knowing understanding how the zones were made, but overall participants felt they could be removed from the ruler.

**Changed.** Participants identified that Vegetative State should change to Unresponsive Wakefulness Syndrome, specifically because the tool was to facilitate communication between caregivers and rehabilitation practitioners and both stakeholders did not want to use the word vegetative in conversations. One participant from outside of the United States mentioned that the term, ‘unresponsive wakefulness syndrome’ has not yet been adopted in their care system.
Overall, the caregivers and rehabilitation practitioners wanted better communication and better information from assessment results. The recovery ruler was received positively and many suggested that it should be laminated and kept in the patient’s room if in a facility. One participant felt that the type of care setting may implement the recovery ruler differently based on how frequently the CRS-R was conducted. The major hesitation about the recovery ruler came from the practitioners’ perspectives in that they did not want to overwhelm the family with information. One participant stated, “I like the view of a ruler but would not want to overwhelm family members with a lot of information at once. I feel as though this happens a lot at the bedside and it does not allow us to thoroughly explain all findings.” However, one family caregiver felt that leaving the recovery ruler in the room at the bedside would allow the family to review the information again after hearing the information. The family caregiver felt that this would be helpful, especially when relaying information to other family members.

Another finding from the design groups, is that the rehabilitation practitioners felt a brief training would be necessary for uptake into clinical practice. The training could include knowledge about how the CRS-R was aligned to the states of consciousness and information on the transition zones between rating scale steps. One participant mentioned that it would be great to have a short video recorded on how to use the recovery ruler because they felt practitioners are less likely to read a manual.
**Design Group 2.** During Design Group 2, participants were provided with three new designs. The first design was the simplest, in that it provided a table to track progress on the CRS-R below the recovery ruler. The other two designs included options to chart progress on a graph. All designs included a descriptive component about the states of consciousness to go on the backside of the recovery ruler. The recovery ruler was presented as a tool that could be laminated and placed in the patient’s room based on feedback from design group one.

Overall, consensus was reached that the first design that was simpler would work best in practice. Practitioners and caregivers both liked the idea of having a complex version for
individuals that would prefer to have more data. Content analysis specifically identified elements that could be added, removed, or changed based on the simplest design of the recovery ruler.

**Added.** Participants wanted to know more than the date of the highest response because they felt that knowing if the highest response occurred in the morning or afternoon could influence future assessment times and the scheduling of therapy. Additionally, a total score was added at the bottom of the table.

**Removed.** No content was identified for removal.

**Changed.** The initial text box for ‘Patient’s Preferences’ was confusing for the rehabilitation practitioners because they felt it could reflect the preferred stimuli to produce the highest CRS-R response or preferences that could link to treatment activities. It was important that there was a subjective textbox to record the patient’s preferences, priorities, and values as this was felt to include a relationship-focused perspective. Therefore, this text box was split into two differed concepts so that the rehabilitation practitioners had space to write in optimal positioning and testing stimuli for an optimal CRS-R reassessment and also include space to record the ‘Patient’s Preferred Activities/Interests’ to facilitate conversation with the family about treatment planning (Figure 4.3.4). Family caregiver and rehabilitation
practitioner participants wanted a complex supplement to chart the patient’s progress for the rehabilitation team conferences and/or for conversations with the family (Figure 4.3.5). Two of the four family caregivers stated they would ‘want to see all the information’ when asked about receptiveness to the graphs for the complex supplement. When reviewing the backside of the recovery ruler, no content was suggested to be changed or removed. Content that was added to the backside of the recovery ruler were definitions of acronyms (Figure 4.3.6).
Phase Three: Evaluation of Pre-Implementation Factors for Uptake of the Recovery Ruler in Clinical Practice

**Design Group One.** Participants completed the SUS and three implementation measures, the AIM, IAM, and FIM. Due to the small sample size, descriptive statistics present both the median and the mean (Table 4.3.2). The median (Mdn=75, Range: 57.5 to 100) and mean (M=79.6,SD 14.1) SUS scale scores were above the national average of 70 for all SUS scale scores (Bangor et al., 2009). The three implementation measures had all
elements averaged for complete data to provide an average scale score. Overall, acceptability (AIM), appropriateness (IAM), and feasibility (FIM) scored well with the median and mean both ≥4 (agree) on the average scale score (Table 4.3.2).

**Table 4.3.2**

*Descriptive Statistics of Usability Measures During Design Group 1 and Design Group 2*

<table>
<thead>
<tr>
<th></th>
<th>Median</th>
<th>Mean (95% CI)</th>
<th>SD</th>
<th>SE</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>DG1 SUS Total (n=13)</td>
<td>75</td>
<td>79.6 (71.1, 88.1)</td>
<td>14.1</td>
<td>3.9</td>
<td>57.5</td>
<td>100</td>
</tr>
<tr>
<td>DG2 SUS Total (n=12)</td>
<td>80</td>
<td>83.3 (75.8, 90.9)</td>
<td>11.9</td>
<td>3.4</td>
<td>67.5</td>
<td>100</td>
</tr>
<tr>
<td>DG1 AIM Average (n=13)</td>
<td>4</td>
<td>4.33 (4.07, 4.58)</td>
<td>0.43</td>
<td>0.12</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>DG2 AIM Average (n=11)</td>
<td>4.5</td>
<td>4.55 (4.23, 4.86)</td>
<td>0.47</td>
<td>0.14</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>DG1 IAM Average (n=13)</td>
<td>4</td>
<td>4.37 (4.08, 4.65)</td>
<td>0.46</td>
<td>0.13</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>DG2 IAM Average (n=11)</td>
<td>5</td>
<td>4.68 (4.37, 4.99)</td>
<td>0.46</td>
<td>0.14</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>DG1 FIM Average (n=13)</td>
<td>4.25</td>
<td>4.37 (4.09, 4.64)</td>
<td>0.45</td>
<td>0.13</td>
<td>3.75</td>
<td>5</td>
</tr>
<tr>
<td>DG2 FIM Average (n=11)</td>
<td>4.75</td>
<td>4.57 (4.25, 4.89)</td>
<td>0.48</td>
<td>0.14</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

*Note.* DG1 = Design Group 1; DG2 = Design Group 2; SUS = System Usability Scale; AIM = Acceptability Intervention Measure; IAM = Intervention Appropriateness Measure; FIM = Feasibility Implementation Measure; SD = Standard Deviation; SE = Standard Error

**Design Group Two.** Participants completed the SUS and three implementation measures, the AIM, IAM, and FIM based on the simple design presented during Design Group 2. Descriptive statistics present both the median and the mean for the total score on all four scales (Table 4.3.2). The mean (M=83.3, SD=11.9) and median (Mdn=80, Range:
67.5 to 100) SUS scale score was above the national norm (70). The three implementation measures for acceptability, appropriateness, and feasibility demonstrated strong agreement for use in clinical practice as the average scale scores were \( \geq 4.5 \) (agree/strongly agree) for both the median and mean (Table 4.3.2).

A paired sample, one-way t-test for SUS data and a Wilcoxon signed-rank test for the three implementation measures determined if there was a statistically significant difference between the results of the two design groups. There was a significant difference in the difference between the SUS scores from Design Group 2 (M=83.3, SD=11.9) and Design Group 1 (M=77.9, SD=13.3); \( t(11) \) 1.84, \( p=0.045 \).

The Wilcoxon signed rank test indicated that the results from Design Group 2 on the AIM and IAM were statistically significantly higher than the results on these scales from Design Group 1 (Table 4.3.3). The FIM did not show a statistically significant difference between scores from each design group. The quantitative and qualitative data was synthesized and integrated after each design group to inform adaptations of the recovery ruler resulting in a final prototype.

**Discussion**

Overall, complex information from a Rasch co-calibration was transformed into a recovery ruler that is perceived as usable, acceptable, appropriate, and feasible for clinical practice. The Rasch co-calibration supports the inclusion of additional rating scale steps and items to categorize patients as MCS and eMCS. Alignment between the CRS-R items and

<table>
<thead>
<tr>
<th>Measures</th>
<th>Z</th>
<th>P value (one tail)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIM</td>
<td>1.706</td>
<td>.045</td>
</tr>
<tr>
<td>IAM</td>
<td>1.992</td>
<td>.023</td>
</tr>
<tr>
<td>FIM</td>
<td>1.604</td>
<td>.055</td>
</tr>
</tbody>
</table>
rating scale steps to states of consciousness facilitates quick and timely pattern recognition in the person’s responses. The participation of the end-users in the development of the recovery ruler resulted in valuable input and feedback for the content and design of the recovery ruler. Stakeholders identified ways to make the recovery ruler easier to understand and include meaningful content that is relationship-focused. Incorporation of the stakeholders’ perspectives resulted in the recovery ruler presented during the second design group statistically significantly improving its usability, acceptability, and appropriateness.

The Rasch co-calibration was able to identify salient information for practitioners and caregivers to quickly interpret the CRS-R scores on each item and see how they aligned with states of consciousness. State of consciousness is important to communicate because it can influence post-acute care options in the United States (Giacino et al., 2020). The high misdiagnosis rate is cited to occur because of challenges practitioners have differentiating between VS/UWS and MCS (Schnakers et al., 2009). Motor impairment has been cited as a complication for behavioral assessment and by visualizing the non-motor items on the same equal-interval ruler it enables interpretation (Schnakers et al., 2009). By plotting a patient’s response to each item on the recovery ruler, a visual representation of the rating scale steps will show which rating scale steps cluster vertically aligning to a state of consciousness (Hoffman et al., 2012). The Rasch co-calibration solves these problems by clearly delineating which rating scale steps of the CRS-R items align to each state of consciousness for timely pattern recognition.

The equal-interval recovery ruler enables direct comparison of the rating scale steps across items and states of consciousness. The communication item’s rating scale step ‘2’ and motor item’s rating scale step ‘6’ indicate eMCS and was found to be of comparable
challenge for patients as rating scale steps ‘4’ on Auditory, ‘3’ on Arousal, and ‘3’ on Verbal/Oromotor (Figures 4.3.2 & 4.3.3). Furthermore, additional rating scale steps from three items were found to indicate MCS, these were a ‘2’ on auditory, arousal, and verbal because they were comparable with the range of MCS measures. These empiric findings support revisions to the consensus-based recommendations developed by the Aspen workgroup for diagnostic criteria delineating MCS and eMCS (Giacino et al., 2002). By aligning these additional items and rating scale steps to the Aspen criteria, it is possible for practitioners to identify MCS and eMCS earlier in the care process. The additional criteria also rely less heavily on motor, a commonly cited factor that influences assessment results. Visualization of the states of consciousness as they align to the CRS-R facilitates timely assessment result information, which may foster transparency of the data with the family caregiver(s).

Another benefit of the equal-interval recovery ruler is that practitioners and caregivers can see when it might be more challenging for the patient to demonstrate increased neurobehavioral function, specifically at the low and high end of the scale (Figures 4.3.1 & 4.3.2). For example, a total raw score change at the beginning of the scale illustrates the difference between a “0” to a “1” as 11.2 Rasch units whereas, a total raw score change in the middle of the scale illustrates the difference between a “10” to an “11” as 1.9 Rasch units (Supplemental Table S4.3.1). Visualizing the increased differences between total raw scores at the low and high end of the scale compared to the decreased differences in the middle of the scale may support clinical reasoning and treatment decision making.

**Supplemental Table S4.3.1**

*CRS-R Raw Scores Transformed to a 0-100 Equal Interval Rasch Measure*
<table>
<thead>
<tr>
<th>CRS-R Raw Score</th>
<th>CRS-R Rasch Person Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>1</td>
<td>11.18</td>
</tr>
<tr>
<td>2</td>
<td>18.91</td>
</tr>
<tr>
<td>3</td>
<td>24.46</td>
</tr>
<tr>
<td>4</td>
<td>29.28</td>
</tr>
<tr>
<td>5</td>
<td>33.83</td>
</tr>
<tr>
<td>6</td>
<td>38.06</td>
</tr>
<tr>
<td>7</td>
<td>41.69</td>
</tr>
<tr>
<td>8</td>
<td>44.66</td>
</tr>
<tr>
<td>9</td>
<td>47.11</td>
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<td>10</td>
<td>49.23</td>
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<td>11</td>
<td>51.13</td>
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<td>12</td>
<td>53.03</td>
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<td>13</td>
<td>54.98</td>
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<tr>
<td>14</td>
<td>57.14</td>
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<tr>
<td>15</td>
<td>59.66</td>
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<tr>
<td>16</td>
<td>62.56</td>
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<tr>
<td>17</td>
<td>65.77</td>
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<tr>
<td>18</td>
<td>69.21</td>
</tr>
<tr>
<td>19</td>
<td>72.91</td>
</tr>
<tr>
<td>20</td>
<td>77.06</td>
</tr>
<tr>
<td>21</td>
<td>82.05</td>
</tr>
<tr>
<td>22</td>
<td>89.24</td>
</tr>
</tbody>
</table>
Overall, both stakeholders felt the recovery ruler provided transparent assessment results in a timely manner. Minor revisions were made to the initial recovery ruler to improve its comprehensibility. Significant additions were included with the recovery ruler to provide meaningful content. For example, both stakeholders wanted to be able to track the patient’s progress over time. However, the way in which tracking recovery was displayed generated ample conversation about the complexity of the graphs. Overall, consensus was reached between both stakeholder that a simple tracking mechanism could be used across settings and patients. However, family caregivers that experienced prolonged disorders of consciousness with their loved one wanted more information, such as the response patterns graphed over time to display strengths and weaknesses by domain. The incorporation of these changes on the recovery ruler facilitates a relationship-focused approach to treatment planning by gathering information about the patient’s preferred stimuli from the family (American Institutes for Research, 2017).

Capturing the patient’s and family’s preferences aligns with the practice guideline recommendations to identify preferences early and throughout the continuum of care (Giacino et al., 2018b). The recovery ruler provides a dedicated space to describe personal preferences as they relate to different types of sensory stimuli. By having a space for personal preferences, communication between rehabilitation practitioners and family caregivers is fostered. When asking the family caregiver for the patient’s personal preferences, the rehabilitation practitioner can describe treatment options.

The data from the Rasch co-calibration and design groups were integrated to adapt the recovery ruler. This adaptation is a necessary and iterative process in the KTA
framework. During the design groups, rehabilitation practitioners provided suggestions for implementing the recovery ruler. For example, it was important to have a recovery ruler with a front and back side that was laminated so it could be placed next to the patient’s bedside. The family caregivers also liked this suggestion as it makes the assessment data transparent for all clinical team members and family members. Rehabilitation practitioners also requested for a short training video on how to use the recovery ruler. Developing education materials and the promotion of adaptability will be important implementation strategies to consider when testing the feasibility of the recovery ruler (Powell et al., 2015; Waltz et al., 2015).

Feasibility was the only pre-implementation factor that did not show a statistically significant improvement. However, all four questions about feasibility were answered positively by respondents (e.g., agree or completely agree). Implementation strategies such as evaluation and iterative strategies, interactive assistance, adapt and tailor to context, and developing stakeholder interrelationships will likely enhance the uptake and adoption into clinical practice (Waltz et al., 2015).

The recovery ruler demonstrated improved usability, acceptability, appropriateness, and feasibility for implementation into clinical practice. Information about pre-implementation factors will be useful to continue capturing during an implementation feasibility study to identify how receptive practitioners and organizations are to adopt the recovery ruler into clinical practice and whether it supports shared decision-making about treatment planning.

*Future Directions*
To support a future implementation pilot study, a feasibility study is needed. The feasibility study will need to evaluate change in communication around treatment planning when using the recovery and to analyze the acceptability of the recovery ruler in a real-world practice setting. An uncontrolled, pre-intervention and post-intervention single group study design will involve rehabilitation practitioners and family caregivers in a rehabilitation facility that routinely uses the CRS-R. Before the recovery ruler (intervention) is presented, implementation strategies such as education about the recovery ruler, information on the recovery ruler’s intended use, and how shared decision making will provide requisite knowledge to the rehabilitation practitioners. This requisite knowledge will facilitate communication between the rehabilitation practitioners and family caregivers about assessment results so that this clinical data is transparent for shared treatment decisions.

**Limitations**

This study used Rasch co-calibration to place CRS-R items and states of consciousness on an equal interval ruler and findings include recommending revisions to the Aspen Workgroup consensus diagnostic criteria for states of consciousness. These findings may reduce the misdiagnosis rate. However, this new criteria for MCS and eMCS should be further examined in a study that uses additional methods to detect brain activity, such as EEG. This study used a participatory approach for tailoring a recovery ruler for clinical practice and therefore, focused on individual-level factors for implementation. This study did not include the perspectives of an organization’s administration to elicit whether the recovery ruler would be supported by leaders in healthcare settings. It is possible that after a pilot study, the recovery ruler will need additional revisions to enhance usability.

**Conclusions**
This experimental mixed methods study identified salient features of a recovery ruler using a Rasch co-calibration, participatory design groups, and surveys evaluating pre-implementation factors. The Rasch co-calibration created a visual depiction of the CRS-R that facilitates timely assessment results. Furthermore, the co-calibration identified additional CRS-R rating scale steps that aligned with the states of consciousness which may improve classification. The participatory design groups ensured that the recovery ruler was comprehensible and included elements that were relationship-focused. Overall, the practitioners and family caregivers felt that the recovery ruler would improve transparency of assessment results and that the recovery ruler could be laminated and kept at the patient’s bedside. The design groups were successful in improving the recovery ruler’s usability, acceptability, appropriateness, and feasibility.
Afterword

The Knowledge to Action framework provides a process to create the recovery ruler (creation funnel) with iterative design cycles that adapt the recovery ruler for future uptake in clinical practice and identify barriers to implementation (action cycle) (Graham et al., 2006). During the design phase, rehabilitation practitioners and family caregivers described ways in which the person-centeredness of the recovery ruler could be improved. Future work for the recovery ruler will include the creation of education materials and suggestions for use (e.g., laminated card at the bedside). A feasibility study is needed to identify whether additional adaptations of the recovery ruler are needed, barriers to real-world implementation, and alignment between implementation strategies and the clinical site to facilitate adoption and implementation of the recovery ruler.

The process of incorporating person-centered measurement principles to a Keyform can be executed for other assessments. This paper provides details on co-calibrating state of consciousness and the CRS-R, design groups to transform the Keyform into a recovery ruler prototype, and evaluation methods to ensure the recovery ruler was adapted to the stakeholders’ preferences.
Chapter 5: Discussion

Introduction

The purpose of this mixed methods project was to create a recovery ruler that facilitates effective communication about assessment results between family caregivers and rehabilitation practitioners as a preliminary step in advancing shared treatment decision-making. This chapter includes a summary of key findings from each study nested within the greater research project, discussion of the conceptual frameworks that informed design and execution of the project, reflection on the translational nature of the project, and implications of the findings for theory, research, and clinical practice. The chapter concludes with a discussion of the limitations of the project, recommendations, and an overall conclusion.

Summary of Key Findings

Restatement of Research Questions

Aim 1. Describe the decision-making process for family caregivers and rehabilitation practitioners when treatment planning for a person with disorders of consciousness.

Research Question 1: How do family caregivers and rehabilitation practitioners make decisions when treatment planning for a person with disorders of consciousness?

Aim 2. Examine the extent to which the CRS-R displays psychometric properties that make it useful for communicating about assessment results when making treatment decisions.

Research Question 2: What are the underlying psychometric properties of the Coma Recovery Scale-Revised, including step and item calibrations, measurement precision (e.g., reliability), and hierarchical item order?

Aim 3. Identify salient features of the Recovery Ruler that facilitate effective communication between family caregivers and rehabilitation practitioners about treatment
goals and options. Research Question 3: How should assessment result information be displayed to facilitate effective communication about treatment decisions?

Overall, this research study developed a recovery ruler so that a rehabilitation practitioner and caregiver can now engage in conversation about assessment results in a timely manner. During these conversations, the practitioner has knowledge from the scoping review of evidence-based treatments as well as the components that can be tailored to the patient’s preference. The Coma Recovery Scale-Revised demonstrated good psychometric properties such that individual level decisions can be made that are reliable and consistent. The practitioner can be confident in the interpretation of the CRS-R assessment results, which facilitates the ability to be transparent about assessment result information. The transparency of information is an opportunity for the practitioners and caregivers to exchange information so that the family caregiver provides information about the patient’s preferred interests and activities so together a relationship-centered treatment plan is developed. Furthermore, when treatment planning and making decisions in the moment, the practitioner now has knowledge of two ways to share the decision with the family caregiver.

*Rehabilitation Shared Decision Making Is Distinctly Different From Medical Shared Decision Making*

There is burgeoning literature about shared decision-making in health care. Shared decision making has been shown to improve the quality of information discussed between practitioners and patients/caregivers, resulting in care that is more person-centered and improves healthcare quality and outcomes (Figure 1.1) (Agency for Healthcare Research and Quality, 2017). Therefore, it is important to know whether and how shared decision-making occurs in rehabilitation when patients are unable to advocate for themselves. This study
uncovered nuanced differences between shared rehabilitation micro-decisions (Karlsen et al., 2020) and shared medical decisions (Chapter 4.1). In medical shared decision making, the process generally occurs during one clinical encounter and appears linear in that it includes the 1) introduction of a choice, 2) description and deliberation of options, and 3) integration of the patient’s preferences into a decision (Elwyn et al., 2012; Joseph-Williams et al., 2019). In rehabilitation, a shared decision-making appears to differ in important ways. Decisions are ‘micro’ in the sense that they are about daily life activities that can occur at the patient’s bedside and during continuous interactions (Karlsen et al., 2020). These micro-decisions may use information (e.g., the patient’s or caregiver’s preferences, priorities, and values) that was elicited in previous encounters with the patient and family caregiver. Deliberation between two treatment options did not occur during rehabilitation shared decision-making. This study’s analysis of the data described how the family, patient, and rehabilitation practitioner form a partnership to share a decision.

The initial design of this ethnographic study included the use of the OPTION-5 (Barr et al., 2015; Dillon et al., 2017; Elwyn et al., 2012). The OPTION-5 is a measure that evaluates the process of shared decision-making over single or multiple encounters (Barr et al., 2015). The OPTION-5 scores shared decision making in five areas: 1) the clinician draws attention to or confirms an alternate treatment exists, 2) the clinician supports the patient to become informed, 3) the clinician gives information or checks understanding about treatments, 4) the clinician makes an effort to elicit the patient’s preferences, and 5) the clinician makes an effort to integrate the patient’s preferences into the decision (Barr et al., 2015). In rehabilitation, shared micro-decision-making was observed to occur multiple times daily at the bedside. Micro-decisions about what flavor of juice to place on a patient’s lips to
evaluate behavior change differs from medical decisions about whether to order a CT scan (Ijaz et al., 2018) in ways that are not easily captured by an assessment such as the OPTION-5. For example, discussion of risks and benefits is less relevant when deciding between juice flavors. As a result of the ethnographic study, the design was adapted to focus on exploring how decisions occur in rehabilitation rather than imposing a pre-determined framework from medical shared decision-making that clearly was not aligned with rehabilitation practice.

Family caregivers and rehabilitation practitioners make treatment decisions that are shared or unilateral. Shared decision making during rehabilitation treatment encounters occurred in two ways—integrative and declarative. Integrative decision making embeds the family caregiver into the treatment delivery and evaluation of the patient’s behavioral response to the treatment. Declarative decision making occurs when the rehabilitation practitioner presents treatment options to the family caregiver (or patient) and, following those discussions, the rehabilitation practitioner enacts the decision by executing the treatment. A key difference in these two types of shared decision making is the extent to which the family caregiver is involved in delivering the treatment and evaluating the patient’s response. Delineating between these two types of shared decision making likely reflects the different clinical reasoning approaches that occur in rehabilitation.

Clinical reasoning approaches have been described in rehabilitation (Mattingly & Fleming, 1994), two of which align with the shared decision making types. Interactive reasoning occurs when the practitioner wants to know the patient better for who they are as a person (Mattingly & Fleming, 1994). Integrative shared decision making follows this approach in that the practitioner often engages with the family caregiver to deliver a tailored treatment that includes personally-relevant stimuli for the patient. Whereas procedural
reasoning is used when the practitioner identifies treatments to address the patient’s functional performance deficit. Procedural reasoning is the process that occurs before the practitioner brings treatment approaches to the family to discuss. In this study, the treatment approaches that occur after the declarative shared decision making process focus on targeting protective reactions, visual tracking, and bladder retraining; all of which target a functional performance deficit.

**Coma Recovery Scale-Revised Supports Individual Level Treatment Decisions**

Analysis of the six Coma Recovery Scale-Revised (CRS-R) items found stable step and item calibrations and good measurement precision that support individual-level decision-making (Chapter 4.2). Conceptually, all CRS-R items reflect the same concept of interest, neurobehavioral function, as indicated by the fit of the items and strong disattenuated correlations supporting unidimensionality. The dimension of neurobehavioral function was defined by the ordering of the items from hardest to easiest to respond to: Communication, Auditory, Visual, Motor, Arousal, and Verbal/Oromotor. The hierarchical order makes clinical sense based on apriori information from the Aspen Statement regarding criteria for the states of disordered consciousness (J. T. Giacino, 2005). The CRS-R item hierarchy and good measurement precision support the use of this assessment when making individual level treatment decisions that are reliable and consistent.

**Revising Criteria for States of Disordered Consciousness Using Empirical Evidence**

The CRS-R has been aligned to the states of disordered consciousness (Schnakers et al., 2009). This alignment enabled the creation of an Aspen-based state of disordered consciousness variable. In Chapter 4.3, the Aspen-based state of disordered consciousness variable was aligned with the CRS-R items and rating scale steps on the same ruler. The co-
calibration of the CRS-R and Aspen-based state of disordered consciousness identified thresholds for vegetative state/unresponsive wakefulness syndrome, minimally conscious state, and emerging minimally conscious state. The co-calibration identified rating scale steps with similar calibrations. Similar calibrations indicate that the patient needs the same neurobehavioral capacity to respond to those stimuli. Of significance, additional rating scale steps were found to classify states of disordered consciousness, particularly the minimally conscious state and emerging MCS. These additional rating scale steps were included in a second variable, Rasch-derived states of disordered consciousness, to determine thresholds for when patients were likely in three different states. These new rating scale steps and thresholds for states of disordered consciousness, from the Rasch-derived variable, provide insight to family caregivers and rehabilitation practitioners about how the patient is progressing functionally, specifically based on different sensory domains. The Rasch co-calibration was useful for visualizing assessment results because it aligned the CRS-R items, rating scale steps, and states of disordered consciousness on the same ruler.

**A Participatory Approach Develops a Relationship-Centered Recovery Ruler**

This study designed a visual report that intuitively displays and describes assessment results so as to facilitate effective communication about treatment decisions between family caregivers and rehabilitation practitioners (Chapter 4.3). In order to describe assessment results, a Rasch co-calibration was used to align states of consciousness to the CRS-R items and response categories (Hoffman et al., 2012; Hughes et al., 2003; Perkins et al., 2008; Wright et al., 2000). Design groups with rehabilitation practitioners and family caregivers provided feedback regarding what details and formatting needed to be added, changed, or removed from the keyform to display assessment information intuitively. Person-centered
measurement principles including comprehensible and timely, transparency, and relationship-focused informed how this feedback was implemented in revised versions of the tool. The long-term goal is for the recovery ruler to be implemented in clinical practice so as to facilitate communication between rehabilitation practitioners and family caregivers when treatment planning. Therefore, usability and pre-implementation factors were evaluated to inform implementation strategies to facilitate uptake into clinical practice.

Applying the principles of person-centered measurement to the visualization of the CRS-R assessment results was appropriate as these principles have been shown to result in better health, better care, and lower costs (American Institutes for Research, 2017). The recovery ruler was adapted during two design groups with family caregivers and rehabilitation practitioners in order to tailor the recovery ruler. Stakeholders also indicated that the usability and three pre-implementation factors (acceptability, appropriateness, and feasibility) improved with the recovery ruler revisions. Stakeholders suggested that an important future implementation strategy would be to develop training for practitioners, such as a short video describing the recovery ruler’s features. Overall, complex information resulting from the interpretation of a Rasch co-calibration and person-centered measurement principles were transformed into a recovery ruler that was perceived as usable, acceptable, appropriate, and feasible for clinical practice.

**Each Conceptual Framework Brings Added Value to the Project**

This project utilized Rasch Measurement Theory to transform an ordinal scale into an equal interval measure, applied person centered measurement principles to translate clinical assessment data into a communication tool, and utilized the Knowledge to Action Framework to guide the research process.
Rasch Measurement Theory Improves Inferences for Coma Recovery Scale-Revised

Assessment Results

The Rasch Measurement Model uses mathematical operations for analyzing categorical data as a function between the person’s ability and item difficulty (Bond & Fox, 2015). Rasch Measurement has been cited as a solution to the challenges with ordinal rehabilitation assessments (Malec, 2020; Merbitz et al., 1989). The Coma Recovery Scale-Revised provided rehabilitation practitioners with a total score where each value was not equidistant from one another. In Chapter 4.2, Rasch analysis transformed the unequal Coma Recovery Scale-Revised scores into equal interval measures. Equal interval measures inform practitioner’s and family caregiver’s clinical reasoning about the patient’s response to treatment. Rasch analysis also indicated the unidimensional item and rating scale step hierarchy for the CRS-R which informs goal setting and conversations around what behavioral responses might start to emerge should the patient progress with rehabilitation. More advanced procedures, such as co-calibration, can align concepts on the same ruler. In Chapter 4.3, a Rasch co-calibration aligned the CRS-R with Aspen-criteria for states of disordered consciousness. A Keyform was produced from the analyses which instantaneously describes the relationship between person ability and item difficulty (Linacre, 1995). Ultimately, Rasch Analysis was critical for informing how assessment results could be interpreted in-the-moment for clinical decision making.

Person-Centered or Relationship-Centered Measurement Principles

From the outset, it was important to apply person-centered measurement principles to development of the recovery ruler because these principles have been linked to improved healthcare quality and outcomes (Figure 1.1) (American Institutes for Research, 2017;
Kogan, Mosqueda, et al., 2016; Kogan, Wilber, et al., 2016). Although person-centered care is becoming more widely accepted, integrating person-centered principles into measurement has been overlooked (American Institutes for Research, 2017). Incorporating person-centered principles into measurement so that what is measured is important to families and patients as well as providing information that is useful for practitioners is beginning to receive more attention (American Institutes for Research, 2017).

This project focused on incorporating three person-centered measurement principles into a visualization of CRS-R assessment results: 1) comprehensible and timely, 2) transparency, and 3) patient-focused. The comprehensible and timely principle was easily incorporated. The transparency principle was initially thought to make clinical assessment data transparent to the family caregiver(s). However, practitioners noted the importance of making the assessment result information transparent to other practitioners so that progress was described in the same way by each discipline seeing the patient and their family. The patient-focused principle was reconceptualized to relationship-focused recognizing that the patients who cannot advocate for themselves rely on their family caregiver to reflect on their own personhood as well as their loved one’s personhood. Beach and Inui (2006) describe relationship-centered care as an understanding of the quality and nature of the relationships being central to health care and that these relationships are nested within the larger context of the healthcare system. In this model of relationship-centered care, the focus is on the clinician-patient, clinician-clinician, and clinician-community relationships (Beach et al., 2006). In Beach & Inui (2006)’s description of relationship-centered care, both the patient and the practitioner bring their own experiences and emotions to a clinical encounter that occurs within an organization and community. This definition alone did not suffice for
patients with disordered consciousness. In this project, relationship-centered care was redefined to be inclusive of the relationships between the patient and other individuals, such as family, friends, and practitioners within the context of health care. It is within these relationships, between the patient, family, and practitioner, that information is exchanged, treatments are identified and tailored, and outcomes are assessed which supported the expansion of the patient-focused principle.

**Adapting the Knowledge to Action Framework to Further Serve Translation Research**

The Knowledge to Action (KTA) framework allowed the research to oscillate in a dynamic and iterative process between the creation funnel and action cycle (Figure 1.3). The KTA framework provided a useful structure for planning and executing this research. However, several important limitations with the framework were identified over the course of the project. These limitations include 1) the lack of depicting engagement with stakeholders on the framework’s graphic and 2) the creation funnel depicting knowledge inquiry and synthesis as unidirectional.

The textual description of the KTA framework supports the engagement of stakeholders throughout all phases of the action cycle and creation funnel (Graham et al., 2006). For example, the first step is described as finding relevant stakeholders to inform the KTA process (Graham et al., 2006). Graham et al., (2006) go on to describe that the stakeholders needed may change depending on the knowledge phase of the project. Unfortunately, engagement with stakeholders is not explicitly depicted in the KTA framework graphic. The importance of community engagement as a core tenet of translational research (Gilliland et al., 2019; National Center for Advancing Translational Sciences (NCATS), 2020) suggests an adaptation to the KTA framework is needed (Figure
5.1). Explicitly displaying stakeholders can be engaged throughout each of the knowledge phases would improve the relevancy of this framework to translational science. In this project, stakeholder engagement was needed in the very beginning to ensure the project was relevant to the community of stakeholders (e.g., family caregivers and rehabilitation practitioners) who care for persons with disorders of consciousness and were also essential at different phases of the project.

According to the KTA framework, this research project had one thread of knowledge synthesis and three threads of knowledge inquiry (creation funnel, Figure 1.3). First, knowledge was needed about effective treatments for patients with disorders of consciousness which was achieved via a scoping review of literature (knowledge synthesis). Second, how practitioners and family caregivers make treatment decisions together and this was gathered via ethnographic observation. Third, establishing the measurement precision of the CRS-R and alignment with states of consciousness was achieved via application of the Rasch model to secondary clinical and trial data. Fourth, incorporating person-centered measurement principles co-created a recovery ruler using a participatory approach. All, but the scoping review reflects first generation knowledge because they are considered primary studies (Graham et al., 2006). In contrast, the scoping review is more reflective of knowledge synthesis since it reflects the amalgamation of multiple primary studies (Graham et al., 2006).

Clearly delineating between knowledge inquiry (first generation knowledge) and knowledge synthesis (second generation knowledge) is challenging when first generation knowledge is synthesized and distilled into information that can inform a product or tool (third generation knowledge) (Graham et al., 2006). For example, the exploratory
ethnography study observing how rehabilitation practitioners and family caregivers make treatment decisions identified two types of shared decision-making processes. Initially, there was a knowledge inquiry which led to the gathering of multiple data points and then the information was synthesized and constantly compared to identify the two types of shared decision-making. Knowledge of how the stakeholders engage in shared decision-making will inform how the stakeholders might use a product like the recovery ruler, which is intended to facilitate conversation about assessment results for treatment planning. Furthermore, the recovery ruler was created with first generation knowledge that aimed to align states of consciousness to the CRS-R. The recovery ruler was then refined and co-designed by the rehabilitation practitioners and family caregivers. In order to implement the recovery ruler in clinical practice, knowledge was first needed about 1) treatments, 2) how decisions occur, and 3) that the CRS-R had good measurement precision and unidimensionality. Therefore, knowledge synthesis was not only occurring during the scoping review, but across all components of the research process to identify implementation strategies for the recovery ruler. Each research study iterated between knowledge inquiry, knowledge synthesis, and creating a tool/product because all the information led to selecting, tailoring, and identifying implementation strategies for the recovery ruler.

The creation funnel makes it appear that the phases must occur sequentially, yet during this study, some of these phases occurred concurrently. For example, the scoping review (knowledge synthesis) occurred in tandem with the exploratory ethnography and Rasch analysis of the CRS-R (knowledge inquiry) and informed the interpretation of data from those two phases. All of these studies produced products and tailored knowledge. Multiple knowledge inquiry phases are likely needed when a complex topic is being
explored. In this dissertation project, identifying and creating a useful product for practitioners and caregivers was multi-faceted.

The three studies (Chapters 4.1, 4.2, and 4.3) that started at the knowledge inquiry phase would ultimately always enter a synthesis of the findings to determine what aligned or was different from current literature. To demonstrate the fluidity between each of these phases, the KTA framework in Figure 5.1 is more reflective of the research process for this dissertation project. A creation funnel (Figure 5.1) does not indicate a sequential approach but suggests a more iterative nature across all three phases. It continues to support the notion that the phases in the creation funnel and action cycle can occur concurrently and intertwine, also reflective of the original author’s interpretation (Graham et al., 2006). As currently depicted, the creation funnel displays the process as more linear. This limits the creative process to knowledge inquiry leading to knowledge synthesis and not recognizing that synthesis of knowledge often leads to new research questions.

**Figure 5.1**

*Adapted Knowledge to Action Framework Based on Application to the Research Study*
Translational Nature of the Study

Translation is defined as ‘the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public—from diagnostics and therapeutics to medical procedures and behavioral changes’ (National Center for Advancing Translational Sciences (NCATS), 2020). This study was situated in clinical research to better understand how family caregivers and rehabilitation practitioners use assessment results to make treatment decisions. The goal of this work was to create a recovery ruler that could ultimately be tested in a real-world clinical practice setting using a hybrid implementation effectiveness design to demonstrate the translation between clinical research and clinical implementation (National Center for Advancing Translational Sciences (NCATS), 2020).

Translational scientists are needed to address complex and wicked problems (National Center for Advancing Translational Sciences (NCATS), 2020). Addressing communication and decision-making between family caregivers and rehabilitation practitioners who need to impart information to one another about the patient in a disordered state of consciousness constitutes a wicked problem because the solution will not be right or wrong but will make the situation either better or worse (Brownson et al., 2012). As such, this challenge requires research that will engage the stakeholders to advance the state of the science, be flexible in modifying knowledge that is needed, a mixed methods approach, and multiple disciplines to collaborate and bring rigor and diverse expertise.

A Personal Reflection on Becoming a Translational Scientist
Gilliland and colleagues have identified seven characteristics of effective translational scientists which include individuals who are: rigorous, boundary crossers, process innovators, domain experts, skilled communicators, team players, and systems thinkers (Gilliland et al., 2019). These characteristics were essential to addressing this research project’s wicked problem. In this section I will describe how I cultivated these characteristics within myself and applied them to the research project.

I applied the concept of rigor by being transparent with methodological procedures as evident in Chapters 3 and 4. Furthermore, prior to conducting this research project, I developed a strong skill set in both qualitative and quantitative research to maximize trustworthiness and reproducibility, key tenets of rigor (Gilliland et al., 2019; Shenton, 2004). Rigorous research from a quantitative perspective indicates that study design maximized reproducibility (Gilliland et al., 2019). We demonstrated this particularly in Chapter 4.2. The qualitative perspective uses the term transferability to describe how the reader of the research may apply the knowledge to another context, therefore it is critical for the researcher to describe the context so that the reader can determine how confident they can be when transferring information to another setting (Shenton, 2004). In Chapter 4.1, we described the context of the environment as well as the positionality of the research team for transparency. Detailed descriptions of the coding process using transcript data highlights the context and actions of the participants. In the quantitative study, the analytic procedures are detailed to foster reproducibility and the sample size of 262 participants also increases the likelihood of reproducible findings because a higher sample size increases precision (smaller standard errors) and more robust estimates of item and person measures (less likely that
misfitting data will distort results) (Linacre, 1994). Using two distinct methodological perspectives requires boundary crossing within the research team (Gilliland et al., 2019).

Boundary crossers fosters collaborations across methodological perspectives and disciplines to advance the state of the science (Gilliland et al., 2019). When I was mixing data from the qualitative ethnographic approach and the quantitative Rasch analysis, I needed to traverse and negotiate the disciplinary perspectives of my mentors (e.g., committee members). This skill set was useful during the design phase when rehabilitation practitioners and family caregivers were co-creating the recovery ruler. I was able to foster this collaboration by being mindful of both stakeholders during the focus groups and ensuring there was time for each stakeholder to share their perspective. Breaking down silos methodologically can lead to new innovation. Bringing together multiple disciplines to understand communication practices required deep understanding of processes.

Developing the recovery ruler in itself was a process innovation. Process innovation is a key characteristic of a translational scientist that offers clear delineation from research in health sciences (Gilliland et al., 2019). The long-term goal of this work is to translate complex information from assessment results to patients and their families. From the outset, I designed this research project with my committee with the idea that it could be a proof of concept and applied in the future to other rehabilitation assessments. Rehabilitation assessments are typically ordinal level data which only allow us to categorize people into groups. Rasch analysis is a contemporary approach to transform ordinal data into equal-interval data so it can be interpreted like a ruler or thermometer (Bond & Fox, 2015). The output from the Rasch software programs is complex and not intuitive for clinical practice. Chapter 4.3 used concepts from design-thinking and participatory research to have both
rehabilitation practitioners and families co-design the recovery ruler and overcome this weakness of the Rasch software program.

I came to the doctoral program with deep disciplinary knowledge in particular clinical settings, specifically post-acute care with my background in rehabilitation. During my doctoral training, I was exposed to knowledge across the translational spectrum specifically, clinical research and clinical implementation. I gained additional domain expertise in Rasch analysis, qualitative methodology, mixed methods, implementation science, and disorders of consciousness; all of which were needed to carry out this research project. Deep disciplinary knowledge of rehabilitation therapy was useful in understanding the individual, contextual, and external factors that influence uptake of new innovations in clinical practice. Knowledge of the rehabilitation field, particularly how practitioners conduct patient evaluations and plan treatments, led to the identification that Rasch analysis provides useful information for clinical practice, but not in a quick, interpretable manner. This led to designing a study that included the stakeholders that would be reviewing assessment result information to inform treatment planning. Inclusivity of stakeholders has been shown to maximize resources, expand scientific knowledge, and increase participation in clinical research, which ultimately leads to the innovation reaching the stakeholders faster (Bonham-Werling et al., 2021; National Center for Advancing Translational Sciences (NCATS), 2020). Inclusion of stakeholders from different disciplines requires skilled communication and a team science approach.

The translational nature of this study required me to be a skilled communicator so that the complexity of the science behind the recovery ruler could be communicated across research team members and to the stakeholders. Multiple disciplinary insights were leveraged
for this dissertation study, specifically committee members with disciplinary expertise in psychometrics, phenomenology, grounded theory, implementation science. Stakeholders, such as family caregivers and rehabilitation practitioners of patients with disorders of consciousness, also contributed to the overall approach and findings. Each committee member had a specific role for each aim of the dissertation study and the collaboration and engagement with family caregivers and rehabilitation practitioners led to the development of a recovery ruler that is now ready for a feasibility study. Prior to this research project, I was a project manager for a community-based exploratory sequential mixed methods study which truly developed not only my skillset as a communicator but awareness to power dynamics when engaging multiple disciplines and stakeholders. Multiple disciplinary insights on the research team required increased meetings with each team member to relay information from each aim of the research study. Communication with stakeholders relayed complex topics in ways that were easy to understand so that they could provide critical insights to facilitate the success of the recovery ruler in practice. My communication skills were needed to leverage each committee member’s contribution as well as the feedback from the stakeholders.

The project team had a shared goal of improving communication about assessment result information to foster shared decision making between family caregivers and rehabilitation practitioners. A shared goal is essential for fostering a team-oriented environment in research (Gilliland et al., 2019). When we formed this shared understanding of the research problem during the dissertation proposal phase, it fostered open communication across team members and stakeholders when thoughts and opinions were not in alignment with one another. For example, some stakeholders felt the recovery ruler would be more feasible if the items were not in a hierarchy as determined by the Rasch analysis but
were in alignment with how the information was entered into the chart. Meanwhile, stakeholders that had more knowledge of an item hierarchy placed more value on keep items in that particular order because it provided them with information about how they might set goals around behaviors the patient is likely to exhibit in the near future if the patient progresses in rehabilitation. Therefore, we ultimately kept the item hierarchy as part of the recovery ruler but, we recognized that the value of the item hierarchy will need more explanation during training to demonstrate its value to clinical practice.

The last characteristic of a translational scientist is embracing a *system’s thinking* approach. During my professional training to become an occupational therapist and during my doctoral training, I was exposed to complexity science. Complexity science describes a complex system such as healthcare that has many components and they can interact on small and large scales within the system (Plsek & Greenhalgh, 2001). This approach recognizes the unpredictable nature of healthcare and that the stakeholders within the healthcare system are adaptive (Plsek & Greenhalgh, 2001). Organizational, external, and individual level factors can influence the complex adaptive system. During the development of the recovery ruler the research team considered how it could be implemented within current clinical workflow patterns. We recognized that organizational policies and structures impact the frequency in which rehabilitation practitioners administer the CRS-R and how they record the information in the patient’s chart. External practice guidelines also provide recommendations to practitioners about the frequency of administering assessments to evaluate state of consciousness (Giacino et al., 2018b). Our thoughtfulness about individual, organizational, and external factors will be critical to ensure clinical uptake of the recovery ruler. The ethnography study (Chapter 4.1) allowed us to explore how treatment decisions are made in-
the-moment. It was during this study, that it was clear a timely and quickly interpretable assessment was necessary for patients in the intensive care setting. The recovery ruler addresses this individual-level and setting specific need because each item and rating scale step are on an equal interval ruler so that the rehabilitation practitioner and family caregiver can see how a patient’s response to one item aligns with the different states of consciousness.

During the design phase of co-creating the recovery ruler, family caregivers and rehabilitation practitioners brought up the need to keep the ruler at the bedside. For the rehabilitation practitioners it addressed the need of ensuring that practitioners from different disciplines would be on the same page when communicating about states of consciousness. For family caregivers, they brought up the importance of needing the information in the patient’s room so that they could use it to explain the information to other family members when they visit in the evenings which is typically outside of the hours when rehabilitation is provided. The participatory and systems thinking approach allowed the research team to consider factors that may stagnate the uptake of the recovery ruler in a future feasibility and pilot testing phase. Including the stakeholders who will ultimately use the innovation at an early stage of the research process fosters the potential for clinical uptake (Bonham-Werling et al., 2021; Gilliland et al., 2019).

These seven characteristics of a translational scientist elucidate the translational nature of this research study. The inclusion of the family caregivers’ and rehabilitation practitioners’ perspectives were the most critical to developing a tool that translates measurement into clinical practice. Both of these perspectives were included early on during the exploratory study which aimed to understand standard practice around communicating about assessment results when treatment planning. Once a preliminary prototype of the
recovery ruler was developed, these stakeholders brought forth their perspectives to re-design the recovery ruler so that their voices were incorporated into the design process. Preliminary results from the pre-implementation surveys indicate that the recovery ruler is acceptable, adaptable, and feasible.

**Implications and Recommendations for Research and Clinical Practice**

Findings from each study can be translated for use in rehabilitation practice for patients with disorders of consciousness. The scoping review is the first to highlight the elements of rehabilitation treatments that can be tailored to the patient’s preferences and needs. Knowing which components of the treatment can be tailored is critical for rehabilitation professionals who practice in a field with little empirical evidence can further guide treatment planning. Future research is needed to understand what types of training are needed so that practitioners can implement tailored evidence-based treatments.

Tailoring treatments to reflect the patient’s preferences and priorities was also observed during the exploratory ethnography study. That study illustrated the ways in which family caregivers can provide rehabilitation practitioners with relevant, contextual information when making treatment decisions together. This is the first exploratory study to uncover how shared decision-making occurs during rehabilitation sessions. Other rehabilitation studies have looked at shared decision making in rehabilitation using approaches developed from the medical decision-making literature (Dierckx et al., 2013; Rose et al., 2017). Knowledge of how shared decisions occur in rehabilitation practice for patients with disorders of consciousness offers ways in which the field can now begin to think about how to train future and current practitioners to incorporate this approach to treatment decision making in their practice. Future research is needed to identify the barriers
and facilitators to shared decision making so that strategies can be identified to facilitate
uptake into clinical practice.

Because Rasch analysis is based on the concept of a hierarchy of items that is
consistent across patients, the hierarchically arranged items and rating scale steps provide a
unique format for translating results of the analysis into a communication tool.
Demonstrating that the CRS-R was reliable, valid, and unidimensional provided the
foundation for creating and developing a recovery ruler. The analyses also indicated that the
CRS-R had alignment with states of consciousness and indicated additional behaviors for the
minimally conscious state and emerging minimally conscious state. This information needs
to be disseminated via conference presentations and manuscripts to add to the credibility of
the findings. Additional work is needed to translate this information to practitioners. To
further support practitioners in making sense of a patient’s progress, additional research is
needed on how to interpret change by examining the responsiveness of the CRS-R.

The alignment between the CRS-R and states of disordered consciousness have
implications for how treatment and discharge recommendations are made for patients with
disorders of consciousness. Therefore, information about the limitations of the CRS-R and
states of disordered consciousness were included on the recovery ruler that was co-created
with rehabilitation practitioners and family caregivers. Co-creation of products or tools can
impact the uptake into clinical practice (Bonham-Werling et al., 2021) because it improves
the quality of the research and builds trust with the end-user (National Center for Advancing
Translational Sciences (NCATS), 2020). During the co-creation phase of the recovery ruler,
participants provided insights into barriers and facilitators for translation into clinical practice
such as needing to know the rigorous research behind the transition zones for states of
disordered consciousness and the value of the recovery ruler being laminated and at the patient’s bedside. A future feasibility study would facilitate application of the recovery ruler in practice by describing how it can be further adapted for use to the clinical setting including how it might align with electronic data entry in an EHR. A key question to be address by a future feasibility study is related to the type(s) of training that would provide practitioners the confidence and skills to implement the recovery ruler.

This research study engaged stakeholders early on in to create a product for clinical practice. It was hypothesized that engaging stakeholders early in the research process facilitates the translation of scientific discoveries into clinical practice (Bonham-Werling et al., 2021; Gilliland et al., 2019). The success of 1) whether the recovery ruler facilitates communication between stakeholders and 2) the uptake of the product in clinical practice, is unknown until a feasibility and pilot study evaluate these two success criteria.

Limitations

A detailed description of the limitations for the scoping review and each aim are described in Chapters 2 and 4. This section describes the limitations as they relate to changes in the study design that occurred during the implementation of the project. Research is a process in which the team needs to make decisions to respond to unanticipated challenges and opportunities.

The original plan for the exploratory ethnography was to observe patients, rehabilitation practitioners, and family caregivers in an inpatient rehabilitation setting. However, the local inpatient rehabilitation hospital did not always have patients with disorders of consciousness available to participate. The intensive care unit at George Washington University Hospital often had patients that are unconscious following a brain
injury and offered an opportunity to observe the first encounter with rehabilitation practitioners that the patient and family would receive. The first encounter allowed the researcher to see the initial rapport building between practitioners, caregivers, and patients. The exploratory ethnography capitalized on the value of observations of these very early encounters in the intensive care setting; however, these findings may not apply to rehabilitation settings more broadly.

Clinical observations were audio-recorded and combined with detailed field notes to describe the actions of each participant. However, communication between participants also includes non-verbal actions. The lack of video footage to inform how non-verbal actions were incorporated into shared decision-making was not available and it is possible that these data might have provided additional or different interpretations of integrative and declarative decision-making.

In applying Aspen criteria to the CRS-R hierarchy, the category of comatose was not examined, since it has not been explicitly aligned to the CRS-R. In the current data set, it is possible that patients categorized as VS may have been more correctly categorized as comatose. This limitation could have implications for the lower end of the vegetative state/unresponsive wakefulness syndrome transition zone should comatose be added to the CRS-R.

The recovery ruler went through two design groups with both family caregivers and rehabilitation practitioners. The family caregiver participants all had >1 year of experience as a caregiver for a loved one with disorders of consciousness. What was comprehensible to these relatively experienced caregivers may not apply to those who are adjusting to their new role (i.e. <3 months as a caregiver).
Conclusions

Rehabilitation practitioners collaborate in making treatment decisions with family caregivers when treatment planning for individuals with disorders of consciousness following a traumatic brain injury. Sharing decisions occurs in ways that are integrative and declarative. Integrative shared decision making occurs as the family caregiver engages with the practitioner in both selecting and implementing the treatment. Declarative shared decision making asks the family caregiver for input on the selection and tailoring of the treatment and then the practitioner administers the treatment to the patient. Current literature suggests that tailored treatments were more likely to demonstrate positive change in the patient’s recovery of consciousness. Assessment data helps to correctly identify a patient’s level of consciousness, which is important for facilitating shared decision making. The most widely used neurobehavioral function assessment, the CRS-R, was analyzed to describe its psychometric properties and to establish alignment with states of disordered consciousness. The CRS-R was found to be a reliable and valid assessment for neurobehavioral function but that current clinical consensus criteria, known as the Aspen criteria, may not fully describe the transition from one state of disordered consciousness to another. A visual tool, the recovery ruler, for communicating assessment results between caregivers and practitioners was created, and these stakeholders provided feedback that was integrated into a revised tool that embodied person-centered measurement principles.

This dissertation research advances the knowledge in rehabilitation for patients with disorders of consciousness by 1) identifying treatments that can be tailored to the patient’s preferences, 2) distinguishing two types of shared decision-making when treatment planning for patients that are unconscious, 3) better aligning CRS-R items and rating scale steps with
the categories of emerging minimally conscious state and minimally conscious state, and 4) creating a recovery ruler prototype. Furthermore, new ways of conceptualizing how decisions can be shared in rehabilitation were described and can be used to inform future research investigating shared micro-decision making. The recovery ruler is an exemplar for how assessments can be co-created with stakeholders as preparatory for translation into clinical practice. The recovery ruler prototype is now ready to be evaluated during a feasibility study to investigate preliminary implementation strategies.
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Appendix A Family Caregiver Interview Guide

Initial Script

Prior to beginning the interview, I want you to understand that all information will be kept confidential, any people or places identified during the interview will be removed during transcription and not shared with people outside of the research team. As names will be changed, I want to ask you if you have a preferred alias name for yourself and/or your family member with a brain injury.

What would you like your alias name to be?

What would you like [loved one’s name with brain injury] alias name to be?
Interview Questions Suggested Guide

1. When you are caring for [name], what does a typical day look like?
   a. Probe
      i. Think of a specific day and tell me about the things that you do with or for [name].
      ii. As their caregiver, are there others that assist with this role? If so, how often?
      iii. How often are you caring for [name] each day?
      iv. Tell me more about [insert participant’s words].

2. Thinking about your interactions with your rehabilitation team (such as your occupational, physical, and speech therapist), did any of these therapists explain what you should be looking for in [name] that would help you see that s/he is getting better?
   a. If yes:
      i. Share with me this conversation.
      ii. Do you know what the rehabilitation therapists were looking for to show that [name] was getting better? How did they describe this to you?
      iii. How did the therapists describe the assessment results to you?
      iv. What kinds of assessments did they use?
   b. If no:
      i. How did your therapist communicate to you that [name] was getting better?
      ii. What information did your therapist’s give you?

3. Recall a time that [name] did something you didn’t expect. Something that surprised you. Tell me more about [name’s] behaviors, facial expressions, body movements, whatever you can think of to describe that moment.
   a. How did you communicate this to your healthcare team?
   b. What was the healthcare team’s attitude towards your information? What makes you think that?
   c. Probe
      i. Tell me how you made sense of that / what you thought was going on.
      ii. Tell me more about where you were when this occurred.
      iii. Tell me how long that lasted.
      iv. Pretend I am a fly on the wall, help me see what you saw?
      v. Why was that surprising/exciting for you?
      vi. Can you think of another time you were surprised? If yes, repeat questions from above.

4. Now, recall a time that was frustrating for you during [name’s] recovery process. Tell me more about that moment.
   a. How did you communicate this to your healthcare team?
   b. Where were you and [name]? Who else was there?
c. Tell me what was going on in this moment.
d. What was the healthcare team’s attitude towards your information? What makes you think that?
e. Probe
   i. Tell me how you made sense of that / what you thought was going on.
   ii. Tell me more about where you were when this occurred.
   iii. Tell me how long that lasted.
   iv. Pretend I a fly on the wall, help me see what you saw?
   v. Why was that frustrating for you?

5. When [name] was doing [insert participants words reflecting a change in behavior]. Walk me through this time when you were making decisions for [name]. Tell me how you made this decision.
   a. What information did you use to make this decision? Where did you get this information?
      i. Did you talk to others who tried [intervention/therapy], read about it online, talk about it on social media? What did you learn from others?
   b. Who did you talk to when you were trying to decide what to do?
   c. Were you able to communicate this with your health care team? How did it go?
   d. How was this change in [name’s] treatment discussed with your therapist?
      i. How did you and your therapist determine next steps?
      ii. Did you feel heard by your therapist? Give me an example.
   e. Was it easy to start the [intervention/therapy] or did you face challenges in accessing [intervention/therapy]?
      i. Tell me about how long it took to receive the [intervention/therapy].
      ii. Tell me what you needed in order to access [intervention/therapy].

6. Are there any questions I did not ask that you wish I had?
Appendix B Rehabilitation Practitioner Interview Guide

Initial Script

Hello, I am Jennifer Weaver. I am a doctoral student at The George Washington University studying how rehabilitation practitioners make decisions when working with individuals in disordered states of consciousness following severe traumatic brain injury. I want to listen to and learn from your experiences of working with patients recovering from disorders of consciousness following a brain injury.

As a reminder, this interview will be recorded so that I can make sure I can make a written transcript. Participation in this interview is completely voluntary and you may choose not to answer any questions you don’t want to or to end your participation at any time. We have reviewed the consent, but before we get started do you have any questions?

Do you agree to begin with the interview?

Thank you for consenting to participate in this study.
Interview Questions Suggested Guide

1. Think of a particular patient you saw recently for the first time. Do you have someone in mind? What shall we call them? Tell me about how you assessed this person, step me through this.
   a. It sounds like you did [insert participant’s words], how come?
   b. What does that look like? Step me through the process.
   c. Tell me more about [insert participant’s words].
   d. What was your gut reaction/instinct telling you when you first saw [name]? 
   e. Tell me about your discussions with the [name’s] family. Can you walk me through a time when a family caregiver was present?

2. Now, thinking about [name from question 1] what did you do with the assessment information after the first session?
   a. Tell me how you document this information.
   b. Do you talk to anyone about this information? Tell me about that.
   c. Tell me more about how you set your goals for [name].

3. Think of your treatment sessions with [name from question 1]. Tell me what you did to prepare for this session.
   a. All that information you collected in the first session, was it helpful? Did you use it?
   b. It sounds like the session did not go as planned, what did you do to respond to this?
   c. Think back to your treatment sessions, what was something that [surprised/frustrated/was memorable] you when working with [name]?

4. When you gave me an example of [insert name from question 1] it was a un/successful assessment. Am I right? Can you think of another patient when the assessment [did not go as well/went well].
   a. [Repeat Questions 1-4].

5. What does a ‘successful’ assessment session look like? What makes it ‘successful’?
6. Can you describe a time when things didn’t go as planned during an assessment? What did you do? How did you adjust?
7. What do you do with the assessment information after it is completed? How do you document it and who do you share it with?
a. How does this information shape the kinds of intervention/therapy choices you make?
b. How does this information shape the kinds of goals you write?
8. If you could improve your assessment process in important ways, what would that look like? Is there anything you wish you could do with your assessment data that you can’t currently do? In a perfect world, what would this look like?
9. Think back to a time when you were working with a person with disorders of consciousness and they were not responding to your intervention such that you were not seeing progress. Do you have a person in mind? What shall we call this person? Tell me how you knew they were not progressing.
a. Probe
   i. Think back to one of your treatment sessions. Describe this session to me.
   ii. Share with me a specific time when you were talking to [name’s] family about their progress. Tell me about this conversation in detail.

10. Now, think back to a time when you were working with a person and they showed progress. Do you have a person in mind? What shall we call this person? How long ago was this? Tell me about a specific time when you saw this progress. Pretend I am a fly on the wall, tell me what I would have seen.
a. Probe
   i. Tell me how you knew they were progressing. What did you notice? What made you excited?
   ii. Share with me a specific time when you were talking to [name’s] family about their progress.
11. Are there any questions I did not ask that you wish I had?

If the rehabilitation therapist has difficulty thinking of a specific patient with disorders of consciousness, these additional probes will be asked.

12. Tell me about a time when you were surprised during your initial encounter with a patient.
13. Tell me about a time you felt stuck.
14. Tell me about one of your most memorable experiences treating a patient with disorders of consciousness.
15. Tell me about your most rewarding experience treating a patient with disorders of consciousness?
Probing Follow-Up Questions

Use any of these follow up probe questions for any of the questions outlined above:

- How did you communicate the progress/plateau/decline that you saw? How did this look different when you spoke with the clinical team versus the family caregivers? Describe this to me.
- Based on what you said, it sounds like [name] has made some [progress/improvement, or has stayed the same, or has not changed much since (time)]. How did you decide what to do next? Walk me through how you reasoned this new/same behavior?
- Can you give me an example of that?
- Tell me how long that lasted
- Tell me if you saw that again, was it the same? Does [name] respond differently other times? If YES, describe a moment when they reacted differently?
- Tell me how you made sense of that / what you thought was going on
- Please clarify what you meant by [specific response]
Appendix C Observation Log

Observation Log Protocol

Time Commenced: __________  Time Completed: __________ Setting:

__________________________

- Patient only
- Family present, but only intermittently
- Family present throughout session

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<th>Practitioner</th>
<th>Checkmark</th>
<th>Notes</th>
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<td>Deal</td>
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<td>Clinician explores answers</td>
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<td>Encouragement offered</td>
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<tr>
<td>Treatment plan: directed or collaborative</td>
<td>□ patient</td>
<td>□ family</td>
</tr>
</tbody>
</table>

If family is present at any point during the clinical observation, complete this next session.

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<thead>
<tr>
<th>Family</th>
<th>Response Options</th>
<th>Checkmark</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>React</td>
<td>Posture, movements, and gestures</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Facial expressions: smiling or frowning</td>
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<td></td>
<td>Voice pitch and tone</td>
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<td></td>
<td>Autonomic reactions (breathing, blushing)</td>
<td></td>
<td></td>
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<tr>
<td>Respond</td>
<td>Open and talkative</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Withdrawn, reserved</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Appears preoccupied</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reactions</td>
<td>Congruent with response of incongruent</td>
<td></td>
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<tr>
<td>-------------------</td>
<td>----------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reflects</td>
<td>Debriefing about assessment/treatment options</td>
<td></td>
<td></td>
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</tbody>
</table>
Appendix D Control Preferences Scale

Patient/Family Member Version

Instructions: Please select one of these five statements.

1. I prefer to make the decision about which treatment my loved one will receive

2. I prefer to make the final decision about my loved one’s treatment after seriously considering my health care provider’s opinion

3. I prefer that my health care provider and I share responsibility for deciding which treatment is best for my loved one

4. I prefer that my healthcare provider makes the final decision about which treatment will be used for my loved one but seriously considers my opinion

5. I prefer to leave all decisions regarding treatment for my loved one to the health care provider
Control Preferences Scale

Rehabilitation Practitioner Version

Instructions: Please select one of these five statements.

1. For this situation, I prefer to leave all decisions regarding treatment to the family member

2. For this situation, I prefer that this family member makes the final decision about which treatment will be used but seriously considers the information I provided

3. For this situation, I prefer that the family member and I share responsibility for deciding which treatment is best for the patient

4. For this situation, I prefer to make the final decision about the treatment after seriously considering this family member’s opinion

5. For this situation, I prefer to make the decision about which treatment this patient will receive
Design Group 1

- **Background Information**
  - Provide information about the Coma Recovery Scale-revised
    - Information can be retrieved from: [https://www.tbims.org/combi/crs/CRS%20Syllabus.pdf](https://www.tbims.org/combi/crs/CRS%20Syllabus.pdf)
  - Provide information about states of consciousness: comatose, vegetative state, minimally conscious state, and emerging minimally conscious state
  - Explain how the initial prototype of the recovery ruler was designed and how example (see below example of recovery ruler)

![CRSR: Raw Score-to-Measure Nomogram and Wright Map](image)

**Design Group 2**

**Provide Recap of Design Group 1**

- Provide findings from design group 1 (e.g. list of items that were not easy to understand, items that might be missing)
- Provide new recovery ruler prototype based on feedback from design group 1
• Describe the changes that were made in relation to findings from Design Group 1

Example Design Group Questions

7. Describe to me what you see when you look at the current recovery ruler.

8. How easy is it to understand?
   a. Probe about color, shading, spacing, wording

9. Plot some data in real time and then ask the group how they would interpret those assessment results.

10. Plot a second set of data in real time and ask the group how they would interpret that set of assessment results.

11. The group will be viewing two sets of data. Ask how that might inform decisions about treatment planning. Ask if they feel that the information is useful.

12. Ask if they feel if information is missing (e.g. call out boxes with additional information). What other information could go on this recovery ruler to ensure information is transparent and easy to understand.

13. How could it be used to ensure timeliness of assessment results?

14. Provide an example of how you might use it in clinical practice or how might the recovery ruler aid in your understanding/interpretation of assessment results.

15. How useful is this recovery ruler?