Research Protocol

Title: Using the Rehabilitation Treatment Specification System (RTSS) to Maximize Rehabilitation Research Impact: A Video-Based Observational Study

Principal Investigator: Lauren Wengerd, PhD, MS, OTR/L

Funding Sponsor: American Occupational Therapy Foundation (AOTF) Implementation Research Grant

I. Specific Aims

Aim 1. Characterize the active ingredients of occupational therapy (OT) interventions used to treat UE sensorimotor impairment in adult stroke survivors receiving outpatient OT services.

Aim 2. Characterize the active ingredients of occupational therapy (OT) interventions used to treat UE sensorimotor impairment in adult spinal cord injury (SCI) survivors receiving outpatient OT services.

Aim 3. Develop and publish a 'Video-Based Observation Toolkit' to systematically describe OT interventions using the RTSS and principles of implementation science.

II. Significance and Innovation

A. Significance

Stroke Rehabilitation

Stroke remains a leading cause of long-term disability in the United States (Virani et al., 2021). While increasingly rigorous research is being conducted to identify efficacious interventions, there continues to be conflicting evidence on how to best address stroke-related upper extremity (UE) hemiparesis (Stinear, 2016). A recent systematic review on interventions targeting UE hemiparesis found that no experimental interventions were superior to 'standard care' control group interventions (Lin et al., 2018). While it is certainly possible that the experimental interventions were not superior to standard care, it is equally plausible that there was inadequate contrast between the treatment groups (Jolkkonen & Kwakkel, 2016). As a result of inadequate intervention reporting (e.g., using generic treatment labels, inadequate descriptions interventions) less than half of experimental interventions can be replicated (Hoffmann & Walker, 2015; Pino et al., 2012). The problem is even greater for control group intervention procedures – commonly referred to as 'usual care,' 'standard care,' or 'conventional therapy' – with wide variation in study parameters for interventions with the same label (Borschmann et al., 2018; Lohse et al., 2018). The majority of stroke rehabilitation trials provide little to no rationale for why the control group intervention selected is comparable to standard

care rehabilitation (Lohse et al., 2018), which is likely due to limited literature on current practice patterns of OT practitioners in stroke rehabilitation. Given that stroke is the most treated diagnosis across all registered OT practitioners (National Board for Certification in Occupational Therapy (NBCOT), 2022), there is a critical and urgent need to better understand current practice patterns of OT practitioners in stroke rehabilitation to inform future directions in stroke rehabilitation research and elucidate progress and gaps in evidence-based practice.

Previous studies investigating interventions used in stroke rehabilitation are outdated (Ballinger et al., 1999; Lang et al., 2009), were conducted in inpatient settings (Bode et al., 2004; Latham et al., 2006), or investigated practice patterns outside of the United States (De Weerdt et al., 2000). The proposed work is significant in that we will use the Rehabilitation Treatment Specification System (RTSS), a novel framework designed to systematically describe the 'active ingredients' of rehabilitation interventions (Hart et al., 2019), to guide our analysis interventions used in real-world stroke rehabilitation settings. The overall purpose of this study is to investigate the types of treatment activities OT practitioners use to address stroke-related motor impairments in outpatient rehabilitation and characterize them according to the RTSS Framework. Using a comprehensive video observation methodology, we will identify the most frequently used OT intervention ingredients (e.g., time spent on task-oriented training, number of repetitions, modalities used, etc.) to treat adult stroke survivors with UE hemiparesis. This research will address AOTF's priorities of increasing equitable access to healthcare services and improving health management of chronic conditions, like stroke. By understanding, describing, and defining 'standard care' for post-stroke rehabilitation across clinical settings, we can develop a guideline based on evidence-based practice and practice-based evidence that will improve the quality of care for every adult stroke survivor across the continuum of care. This will improve how post-stroke care is delivered and how novel treatment approaches are examined in the research. It will identify what the priority active ingredients are for the best outcomes in clinical practice.

Spinal Cord Injury (SCI) Rehabilitation

The aforementioned critical need for a better understanding of standard care in stroke rehabilitation is also present in SCI rehabilitation. We have an even more limited understanding of SCI rehabilitation interventions being used with only one known article published in the past five years exploring SCI interventions for UE paralysis, and said article only focused on one specific type of intervention, functional electrical stimulation (Dionne et al., 2020). Furthermore, average length of stay in inpatient rehabilitation for SCI patients has decreased by over 50% in the past 20 years (National Spinal Cord Injury Statistical Center, 2020), making the interventions administering in outpatient

rehabilitation even more critical for recovery. We will investigate practice patterns of OT practitioners treating SCI across the three practice settings to address this gap.

B. Innovation

The work outlined in this proposal is innovative in several ways. First, our group will be the first to incorporate the RTSS to characterize standard care in stroke or SCI occupational therapy. This approach will inform not only stroke research but will also elucidate ways OT researchers can use the RTSS in their own work to better describe experimental and control interventions. Additionally, this work will utilize a video-based observational study design to comprehensively analyze and describe intervention details that simply could not to be characterized using other observational methods (e.g., non-video observation, chart reviews). There is a growing body of evidence supporting the use of video-based observation over traditional approaches to capture details that otherwise get missed (Golembiewski et al., 2023). As an example, previous work by Lang and colleagues (2009) published a ground-breaking paper on the number of repetitions stroke patients completed, on average, per treatment session. While the results of that work were incredibly important to the field, the methodology limited the authors to only counting repetitions without characterizing other intervention factors that may have had an influence on neurorecovery (Kleim & Jones, 2008). Non-video observation limits the ability to measure interrater reliability, re-watch the intervention to ensure nothing was missed, and capture other 'ingredients' of the intervention (e.g., the types of verbal cues provided, modalities used, patient level of engagement, etc.) that may play a critical role in intervention efficacy. Our approach will allow us to comprehensively describe all aspects of the intervention, a critical need identified in the field. This innovative research will help researchers 1) identify knowledge gaps and plan future directions in stroke rehabilitation research, 2) provide a rationale for control interventions that are comparable to true 'standard care' in stroke rehabilitation trials, and 3) develop an empirically based approach to video observation using the RTSS and disseminate these findings as a 'toolkit' for OT researchers to use across diagnoses and settings.

C. Approach

Preliminary Studies: Our preliminary work investigating practice patterns of OT practitioners in stroke rehabilitation used a mixed methods approach. First, we conducted a nationwide survey of outpatient OT practitioners (n=257) to identify OT interventions and active ingredients used to treat adult stroke survivors with UE hemiparesis in outpatient rehabilitation (Wengerd, 2019). In conducting this study, we found that less than 93% of outpatient OT practitioners consistently use clinical practice guidelines (CPGs) to guide stroke rehabilitation assessment and interventions. While concerning, we also know that CPGs in their current form are difficult to quickly digest and implement (Juckett et al., 2019) and several barriers exist to utilizing EBP consistently in practice (Juckett et al., 2019). Our preliminary survey also indicated that OT practitioners rank 'techniques to increase UE use in everyday tasks,' 'client-centered

treatment,' and 'occupation-based treatment' as the three most critical 'active ingredients' of stroke rehabilitation for adults with UE hemiparesis, which is largely consistent with OT CPG recommendations (Hildebrand et al., 2023; Wolf & Nilsen, 2015). Additionally, we conducted a feasibility study testing a manual developed by this study's PI to systematically analyze video data using the RTSS in an outpatient setting. We conducted this observational study in a small sample of videos (n=30) at Ohio State Wexner Medical Center (OSUWMC) to determine the feasibility of recruiting participants, collecting data efficiently, and using the RTSS to code video observations (Wengerd, 2019). The results of the study demonstrated that this approach to characterizing standard care is feasible, efficient, and did not place undue burden on patients or therapists during standard care OT sessions. As part of currently proposed project, we will take what we learned from that initial study and expand our methodology to be more robust in order to conduct a large-scale video analysis across 3 practice outpatient settings (rural, urban, and suburban) in central Ohio. We will then use our findings and knowledge gained from the analysis to develop a toolkit that can be used by OT researchers across the field to improve descriptions of OT interventions to further advance rehabilitation research.

Guiding Framework: The overall guiding framework for this project is the RTSS. To demystify the "black box" of rehabilitation, an interprofessional team developed the RTSS (Hart et al., 2019) to assist rehabilitation researchers and practitioners in adequately characterizing treatment activities to improve replicability and interpretation of study results (Whyte et al., 2021). The OT field has called for use of the RTSS framework (Fasoli et al., 2019) along with other rehabilitation disciplines to improve replicability, internal validity, and our ability to conduct meta-analyses on intervention trials in the future (Bernhardt et al., 2019; Walker et al., 2017). According to the RTSS, all treatment activities (referred to as treatment components), require the characterization of three elements: 1) active ingredients (what is done and what materials are used to facilitate change), 2) a mechanism of action (the hypothesized way the ingredients will facilitate change), and 3) a clearly defined treatment target (what specific area of functioning is being addressed through use of the intervention) with accompanying treatment category. Characterization of treatment targets also includes describing what treatment category the intervention falls into: 1) Organ Function (treatments modifying the function of organ systems, such as strengthening muscles or improving cardiovascular endurance), 2) Skills and Habits (activities where learning is accomplished through repetitive practice), and 3) Representations (interventions targeting cognitive and affective information processing) (Hart et al., 2019). In addition to categorizing interventions by RTSS category, we will further break down the specific 'active ingredients' observed of different practice approaches/theories commonly described in the literature (e.g., constraint-induced movement therapy, task-oriented training) without using generic labels. As an example, rather than labeling an intervention 'task-oriented training', we will explicitly look for the 'active ingredients' of task-oriented training including maximizing repetitions, using client-centered, occupation-based activities, and providing extrinsic feedback to encourage hand use.

III. Procedures

A. Research Design

We will conduct a video-based observational study to assess the practice patterns of OT practitioners working across 3 outpatient settings at OSUWMC. Treatment sessions will be recorded and video data will be analyzed and coded for duration-based and frequency-based events using Mangold INTERACT video coding software. We will use the RTSS framework to guide our analyses, as described briefly in the 'Guiding Frameworks' section previously. Examples of the types of interventions we may code and analyze during OT treatment sessions are shown in **Figure 1**.

Our observational study design is appropriate for our descriptive exploratory approach to determine the treatment activities, treatment targets, and active ingredients of OT interventions among OT practitioners and post-stroke patients in outpatient rehabilitation. We previously demonstrated this approach as feasible and wish to expand upon our initial findings to better our understanding of standard care and develop a toolkit which can be used across OT research disciplines for video observation. This methodology will be used to inform a multi-site, nationwide observation study in the future, much like previous groups (Lang et al., 2007, 2009).

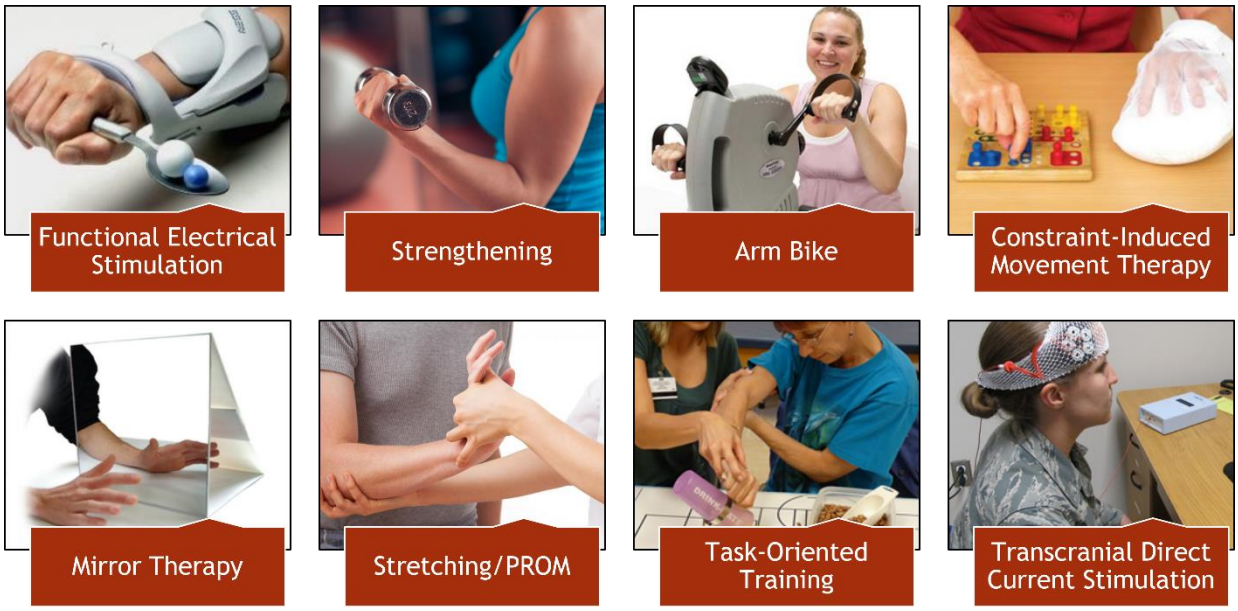

Figure 1. *Examples of rehabilitation interventions*

B. Sample and Recruitment

Participants – OT practitioners

A purposive sample of OT practitioners working in an outpatient rehabilitation at OSUWMC will be recruited for this study. We plan to recruit up to 15 OT practitioners (occupational therapists or occupational therapy assistants) across three different OSUWMC outpatient clinics. OSUWMC employs ~12-15 outpatient OT practitioners who provide services to stroke or SCI survivors on a routine (e.g., monthly) basis. We will record a maximum of 30 sessions per OT participant. We will make our best effort to evenly distribute video recordings across all therapists enrolled, however, this may

vary based on the number of SCI and stroke patients seen by each therapist, number of therapists at each clinic location, etc.

Inclusion Criteria: 1) must be a licensed OT practitioner (occupational therapist or occupational therapy assistant), 2) the OT practitioner must treat at least one adult stroke or spinal cord injury patient with UE sensorimotor impairment per month, 3) the OT practitioner must be willing to be video recorded while treating their enrolled stroke or SCI patients.

Participants – Stroke Patients

A purposive sample of stroke patients receiving OT at an OSU outpatient rehabilitation clinic will be recruited for this study. We plan to record 90 treatment sessions across three practice settings. To maximize representativeness of our sample, we will not record more than 3 videos per stroke patient participant. As such, we plan to enroll up to 45 stroke patients in this study to allow for potential attrition and/or participants who do not have three sessions left at the time of enrollment.

- Inclusion Criteria: 1) must have a medical diagnosis of ischemic or hemorrhagic stroke, 2) must be ≥ 18 years old, 3) must have at least one OT goal related to UE hemiparesis, 4) must have at least one remaining OT treatment session after enrollment, and 5) the patient's OT must be enrolled in the study.

Participants – Spinal Cord Injury Patients

A purposive sample of SCI patients receiving OT at an OSU outpatient rehabilitation clinic will be recruited for this study. We plan to record 60 treatment sessions of SCI patients across three practice settings. To maximize representativeness of our sample, we will not record more than 3 videos per SCI patient participant. As such, we plan to enroll up to 30 SCI patients in this study to allow for potential attrition and/or participants who do not have three sessions left at the time of enrollment.

- Inclusion Criteria: 1) must have a medical diagnosis of cervical spinal cord injury, 2) must be ≥ 18 years old, 3) must have at least one OT goal related to UE sensorimotor impairment, 4) must have at least one remaining OT treatment session after enrollment, and 5) the patient's OT must be enrolled in the study.

Recruitment and Retention

The greatest potential problems associated with this research will include challenges with recruitment of OT practitioners. The PI has established great rapport with therapists across OSUWMC through previous studies and demonstrated the feasibility of conducting this work on a smaller scale. Furthermore, we have the outpatient neurorehabilitation manager and a senior occupational therapist across multiple sites aligned and committed to helping create buy-in and support for this study. To recruit OT practitioners, our study team will initiate contact via secure email, providing an overview of the study, its purpose, and procedures, along with a study flyer. We will collaborate with key stakeholders, such as the rehabilitation manager and OT study collaborator Cheryl Albrechta, to organize informational sessions, either in person or virtually, to accommodate participants across multiple sites. These sessions will provide an

opportunity to learn about the study, receive the informed consent form, and ask questions. For those unable to attend, individual meetings will be arranged to review study details and facilitate the consent process. To protect privacy, all communications will adhere to institutional policies, and personal information will be managed securely. Participants may provide consent during the informational session or in a later, private setting with a study team member. No identifying information will be shared outside the research team. Once enrolled, OT practitioners will be trained on how to recruit patient participants, including sharing study flyers, notifying patients verbally, and providing contact information for the study team. Recruitment materials may also be displayed in public areas of outpatient rehabilitation sites where data collection will occur (e.g., Martha Morehouse, New Albany, Dublin, and Powell). Patient participants will be introduced to the study by their OT. Interested individuals will meet with a study team member in a private or semi-private setting within the clinic to discuss the study procedures and review the informed consent. Formal HIPAA Authorization will be obtained before conducting medical chart reviews. We will also plan to have a member of our study team on site at each location at various times throughout the study, and therapists can make a direct introduction to their potential patient participants in real-time to support recruitment. This approach worked exceptionally well when we collected preliminary data using this approach and we were able to recruit 17 patient participants in under one month. OT participants will be given $25 per video recording of their sessions, up to $750 maximum (30 sessions/therapist max.). Payment will be made via a Greenphire ClinCard, a reloadable prepaid debit card, following university policies upon enrollment. Stroke and SCI patients will be given a physical $25 gift card upon study enrollment for their time and willingness to be video recorded to enhance recruitment and retention efforts.

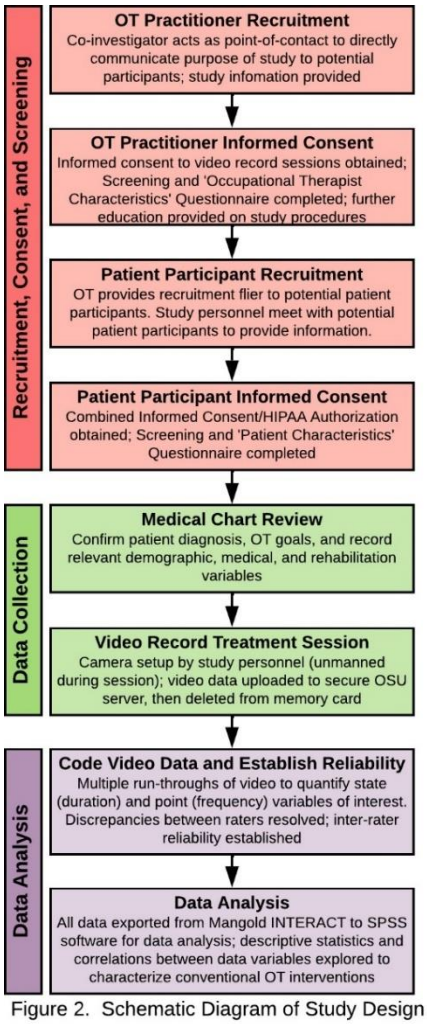

Figure 2. Schematic Diagram of Study Design

C. Detailed Study Procedures

An overview of the study flow is presented in **Figure 2**. Upon enrollment, OT participants will be asked to provide demographic and clinical characteristics using a short questionnaire. To confirm eligibility (medical diagnosis and OT goals) and collect pertinent medical information for future analyses, patient participants will be asked to provide their name, date of birth, hand dominance, and impaired UE (right, left, or bilateral) upon enrollment.

A member of our study team with access to the OSU Integrated Healthcare Information System (IHIS) will access patient participant medical charts to confirm diagnosis, date of injury, and extract relevant data from their medical chart (e.g., comorbidities, rehabilitation frequency/duration, rehabilitation outcomes, etc.). Data extracted from patient participant medical charts will be linked to the participant's research file by subject ID to maintain confidentiality.

Informed Consent and Confirmation of Eligibility

Study participants will be educated on the goals of the study and review the informed consent form with a member of our study team. Consent will be obtained using paper forms (wet signature) at the location of the research (e.g., Martha Morehouse, Outpatient Clinic New Albany, Outpatient Clinic Dublin, Outpatient Clinic Powell,etc.) prior to initiation of any study procedures. After receiving study information and/or reviewing the consent form with potential participants, they will be made aware that they may take the consent form home to review and consider prior to making a decision about participating in the research. A copy of the consent form will be provided to the participant and the original copy will be stored in a secure, locked filing cabinet in Dr. Wengerd's lab. We will also upload a scanned copy of the consent form into REDCap for storage. They will be informed that participation in the study is voluntary and if they choose to not participate or withdraw from the study at any time, no benefits of their employment (OT practitioners) or medical care (patient participants) will be impacted. After completing the informed consent form, a member of our study team will confirm eligibility by reviewing the eligibility criteria checklist with both OT practitioners and patient participants, respectively (refer to 'OT Eligibility Checklist' and 'Patient Eligibility Checklist' case report forms – these forms will be entered into REDCap and data will be collected electronically by a member of our study team).

Video Recording Procedures

After patient participants enroll in the study, therapy schedules will be obtained from clinic staff to facilitate the scheduling of video recordings. Prior to recording a treatment session, a study team member will confirm with the OT that the session is appropriate for recording. Sessions are appropriate for recording if: 1) more than 50% of the session is anticipated to involve interventions targeting functional deficits related to UE motor impairment (e.g., activities of daily living involving use of the hands/arms, UE sensorimotor interventions, etc.); and 2) the session does not include a formal evaluation such as a progress report, evaluation, or discharge report (though intermittent assessment is allowed as this is standard practice). After confirming session appropriateness, study staff will be on-site to set up the video camera. Patient and OT participants will verbally confirm consent to be recorded prior to each recorded session. For each treatment session, every attempt will be made to place the video camera in a way that is both unobtrusive and able capture treatment activities without inadvertently capturing non-participants in the background. A study team member will be on-site during all video recordings, though

not necessarily in the treatment area, in an effort to decrease risk of participant behavior change (Asan & Montague, 2014).

Video Recording Setup: Study team members will set up a stationary camera mounted to a tripod at a fixed point within the treatment area. This positioning will be carefully selected to face the patient and the OT without other patients/therapists in view to the best of our ability. In our previous study using comparable methods, the majority of sessions took place at a table near or against a wall without much movement around the clinic as therapy was focused on tabletop activities. If the therapist anticipates changing locations during the session they will make the study team member setting up the camera aware so they can monitor and adjust as needed. Additionally, we will adhere a bright neon sign to the video cameras stating that video recording is in progress, as well as verbally notify patients and therapists in the immediate vicinity that we will be recording, and they will have the option to verbally request that we choose an alternate spot for treatment/recording. In the event that other patients/therapist are recorded (e.g., walked into the background of the shot) we will blur faces/identifying features if the video is to shared outside of our study team (e.g., during a conference presentation).Of note, in our small feasibility study using video observation methods, we had no trouble with this approach, and it was tolerated well by everyone in the clinical space. Video recording will start when the OT and patient participant are both in the treatment area and end at the conclusion of the last treatment activity. No more than 3 treatment sessions per patient participant and no more than 30 treatment sessions per OT practitioner will be recorded to increase the representativeness of our sample.

Data Collection

- OT Demographics and Clinical Characteristics
  OT participants will be asked to provide demographic and clinical characteristics using a short questionnaire (refer to 'OT Intake Questionnaire' and 'OT Demographics and Clinical Experience' case report form). This data will be entered directly into REDCap by the participant using a secure survey link provided by a member of our study team upon enrollment.

- Patient Demographics and Medical Information
  To confirm eligibility (medical diagnosis and OT goals) and collect pertinent medical information for future analyses, patient participants will be asked to provide their name and date of birth at the time of enrollment (refer to 'Patient Intake Questionnaire' case report form). This data will be entered directly into REDCap by a member of our study team upon enrollment. This information will be used by study personnel with OSU Integrated Healthcare Information System (IHIS) access to extract patient data from their medical chart. Data extracted from patient participant medical charts will be coded and linked to the participant's research file by subject ID to maintain confidentiality.

Patient participants will provide HIPAA authorization with their informed consent to allow a member of our study team to review their medical chart and treatment notes and extract pertinent information for analyses. This data will include demographics (e.g., age, sex, gender), clinical characteristics (e.g., comorbidities, medical diagnosis of stroke or SCI, date of stroke or SCI diagnosis), and rehabilitation data (e.g., inpatient rehab length of stay, outpatient rehabilitation frequency/duration/length of stay, rehabilitation clinical outcomes, rehabilitation treatment notes, etc.). We will review treatment notes for the sessions we observe and analyze to compare our findings with those reported by the OT practitioner (e.g., duration of active treatment time, type of intervention used), as well as confirm treatment targets. Participant data will be coded with their subject ID stored in an access-controlled master key and all other records will only be linked to participants by subject ID. Data collected from the medical chart will be entered directly into REDCap. REDCap provides a secure, web-based application that provides an intuitive data manipulation interface, custom reporting capabilities, audit trail functionality, real-time data monitoring/querying of participant records, and variations of data exporting/importing to common statistical packages (SPSS, SAS, R, etc.). The provisioning of accounts and user access to specific database(s) is integrated with the OSUWMC LDAP authentication service for studies containing protected health information (PHI), the provisioning of access and specific user rights for all studies and review of content are managed by CCTS staff (The Ohio State University Center for Clinical and Translational Science (CCTS): Grants and IRB Language, n.d.).

- Video and Photo Data

  All treatment sessions will be video recorded and coded electronically using Mangold INTERACT video analysis software to allow us to analyze both duration (e.g., time spent on active therapy versus rest/setup) and frequency (e.g., number of UE repetitions) data, as well as control for significant participant behavior change (Asan & Montague, 2014). An overview of the video coding framework is presented in **Figure 3**. We will make every attempt to categorize all treatment activities into these categories, though we may find during our analyses that a sub-category needs to be added (e.g., education) and it may be updated through an iterative process. The primary outcomes for this study are the identification of 1) the types of treatment activities (e.g, 'Organ Function' versus 'Skills and Habits' activities), 2) the targets most often addressed (e.g., increasing strength, improving ability to grasp/release objects, increased independence with dressing, etc.), and 3) the active ingredients of interventions used to treat adult stroke patients with UE hemiparesis.

- Feasibility and Acceptability Surveys

  After data collection is complete, we will administer electronic surveys via REDCap to all OT practitioner and patient participants who had at least one OT session recorded to gauge their acceptability and comfort with being video recorded. In addition to study-specific questions about logistics, scheduling, and overall approach,

we will also incorporate well-established implementation science survey metrics to quantify acceptability of this approach (Weiner et al., 2017). Refer to 'OT Practitioner Feasibility Survey' and 'Patient Participant Feasibility Survey' documents for the questions we will ask. Of note, consent to complete this survey will be provided in the paper consent form at the beginning of the study for both video recordings and the survey at the end of their data collection.

Data Management

Videos will be recorded on SD cards and transferred to a secure electronic repository behind The Ohio State University Medical Center firewall for storage. After transfer, all videos will be deleted from the SD cards. Scanned informed consent forms and all other data (e.g., demographics, clinical characteristics, medical chart data) will be directly entered into REDCap. Upon enrollment, OT participants will provide their name and e-mail address which will be entered into a master key in REDCap with their OT subject ID. They will be provided with a secure survey link from REDCap so that they can complete a survey with their demographics and clinical characteristics. Patient participants will verbally provide their name and date of birth after enrollment to a member of our study team, which the study team member will manually enter into REDCap at which time their subject ID will be assigned. Their information will be stored in a secure, access-controlled electronic master key in REDCap and any data extracted from their medical chart will be tied to their subject ID only in REDCap. Videos may be used for educational or research purposes and participants will be made aware of this. We will blur/cover identifying features if we use videos for educational or research purposes to protect confidentiality. In the event that we wish to use video recordings for educational/research purposes without blurring the face of the participant or therapist, we will obtain additional explicit written permission from the therapist and patient to do so.

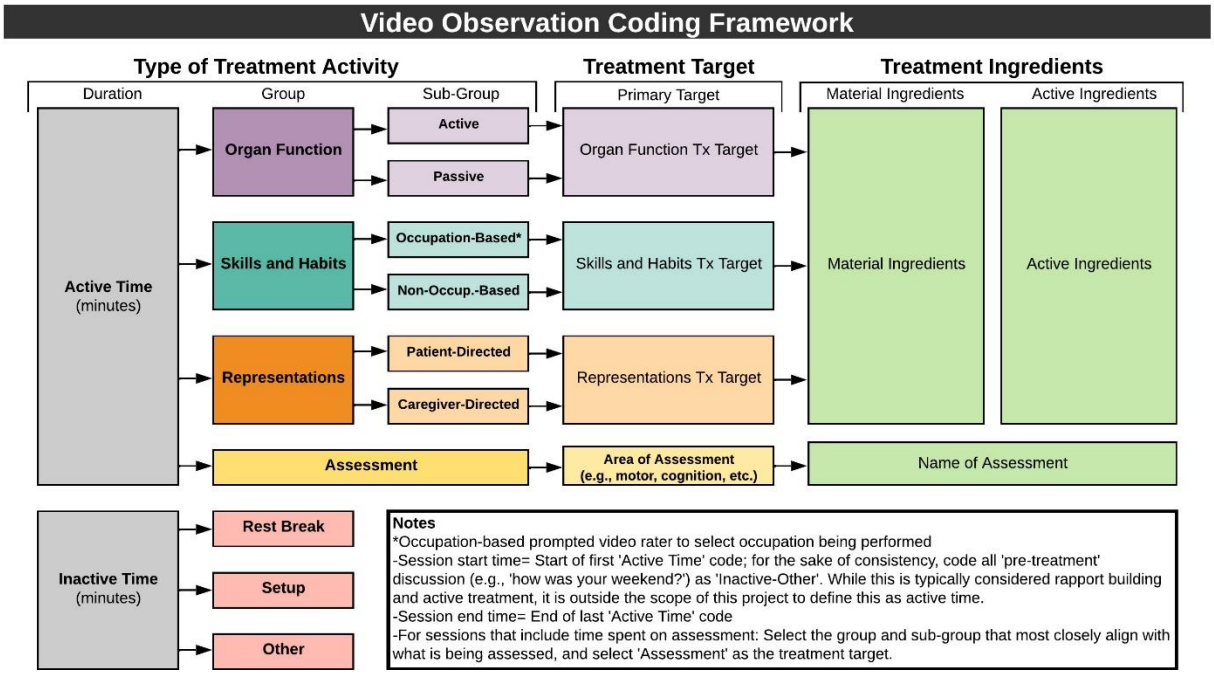

Figure 3. Framework to Guide Analyses of Video Recorded Data

Potential Risks

While this study is incredibly low risk, all studies come with some level of inherent risk. The greatest risk in this study will involve a risk to data security. As such, we will take extra precautions to ensure data is managed effectively and stored appropriately. All information collected from stroke patients and their medical charts will be coded and linked only to them by a secure, access-controlled master key. No personally identifiable information will be collected from stroke participant charts, thus there is minimal-to-no risk of patient privacy being breached. We will put strict quality controls in place to log and upload video data from SD Cards to a secure, firewall-protected server after recording and then delete the data from the SD cards immediately after upload. A full HIPAA waiver will be requested from Ohio State's IRB to allow the research team to access medical charts via IHIS where data will be extracted and tied to participants by subject ID only.

Protection of Privacy and Confidentiality

For all potential participants, the informed consent process and data collection interviews will take place in private or secluded settings with minimal foot-traffic. As almost all data collected will be observational, it will be done within the traditional context and setting of participants' rehabilitation and professional activities. All data collected and stored online will use secured, encrypted drives. We do not anticipate collecting any data using paper forms, however, should we need to do so these documents will be stored in access-controlled, locked filing cabinets.

All participants will be assigned a subject ID which will link them to their data only by an access-controlled master key. Data will be stored in REDCap, as will all data obtained through any electronic surveys. Recordings will be stored on secured drives. Participants whose treatment sessions are observed will be instructed to maintain the confidentiality of the other participants' information.

Protection from Undue Influence

We will make every attempt to minimize undue influence or coercion for employees of our rehabilitation settings. Several strategies will be used. OT practitioners will be made aware that choosing not to participate will not affect performance evaluations (favorably or unfavorably), career advancement, or other employment-related decisions. This information will be reiterated during the initiation of data collection sessions. All informed consents will contain this information and that participation is voluntary. Patient participants will be made aware that not participating or ending their participation at any time will not result in negative consequences or changes to their care.

D. Data Analysis

Video Coding Analysis

A video coding structure has been developed incorporating principles of the RTSS to guide analyses (**Figure 3**; Wengerd, 2019). Treatment Activities: The RTSS recommends that all treatment activities, based on their primary target, be categorized into one of three

categories: 1) Organ Functions, 2) Skills and Habits, or 3) Representations. All observed treatment activities will be categorized into one of the three RTSS categories, and their respective subcategories, or into a fourth category of assessment (not currently existing in the RTSS framework). All seconds of the session will be categorized as 'active time' (i.e., activities in each of the four categories), or 'inactive time' (i.e., when the patient does not engage in therapeutic activity for greater than 15 seconds consecutively). Treatment Targets: Treatment activities will also be coded with a corresponding treatment target, using a list of 75 potential targets developed through a review of three ICF Core Sets: 1) Rehabilitation Set, 2) Stroke Comprehensive, and 3) Neurological Post-Acute Comprehensive (Bickenbach et al., 2012). To help facilitate the categorization of treatment activities and targets, therapists will be asked to state the primary purpose for each treatment activity during video recording (e.g., "let's work on stacking cones to increase your shoulder strength"), however clinical reasoning and chart reviews will also be employed to confirm coding accuracy. Active Ingredients: A coding scheme for measuring active ingredients was developed based on previously reported treatment ingredients (Cirstea & Levin, 2007; Gillen, 2015; Host et al., 2014; Stein, 2015; Taub & Uswatte, 2006; Wolf & Nilsen, 2015), discussion with OT practitioners in the field, and clinical experience. Active ingredients will be coded according to this schema as duration-based (time spent using the ingredient), frequency-based (number of occurrences), or both. Activities will be assessed for the following ingredients and coded accordingly: 1) whether feedback was provided, and in what way (e.g., knowledge of performance versus knowledge of results), 2) types of cues provided (e.g., verbal, tactile, etc.), 3) assistance provided by the therapist (e.g., active assisted range of motion) and 4) whether grading/shaping occurred, and in what way. All active ingredients will be coded as 'present' or 'not present' for each treatment activity. We will also code materials, equipment, and/or modalities used for each treatment activity (e.g., material ingredients). Once all active ingredients are coded with the INTERACT software, we will use the data to systematically describe the activities during treatment sessions using a template recommended by the authors of the RTSS (Tessa Hart et al., 2019). The total number of videos recorded per participant and per therapist will be tracked. This includes videos recorded during each study visit and any additional sessions deemed necessary by the study protocol. The average number of videos recorded per participant and therapist will be reported in the final study analysis to assess consistency in data collection. The number of videos successfully analyzed will be reported, alongside any discrepancies or challenges encountered during the analysis process (e.g., missing data, technical issues). These metrics will be included in the study report to provide transparency in the data collection and analysis process.

Video Coder Training

Each video analysis will be conducted by trained video raters in several passes to determine 1) treatment categories and targets, 2) durations, frequencies, and repetitions, and 3) active ingredients. A minimum of 20% of all the videos will be assessed for interrater reliability (≥90%), and minor adjustments to the coding manual may be made. To ensure fidelity, all raters will participate in comprehensive training with a member of our study team and will

be provided with instruction manuals developed for this analysis. Consistent with previous studies, raters will be required to code a mock treatment session using the established framework and reach 90% agreement with the coinvestigator prior to independently coding video data (Lang et al., 2009; Winstein et al., 2003). Videos will be coded and analyzed largely by occupational therapy doctorate (OTD) students in their second or third year of the program, which we previously demonstrated worked well with high interrater reliability (97%) for RTSS treatment groups (Wengerd, 2019).

Statistical Analysis

Data coded using INTERACT will be entered into REDCap and subsequently analyzed using SPSS Statistics. Descriptive statistics will be used to describe the study sample, and all observed treatment categories, treatment sub-categories, treatment targets, and active and material ingredients. Shapiro-Wilk tests will be conducted to assess for normality. Survey results will be reported using descriptive statistics and will be used to inform our video-based observation toolkit development in order to maximize implementation and acceptability of this approach.

Development of a Video Observation Toolkit

The overarching purpose of this Aim 2 is to manualize an approach for video observation to characterize rehabilitation interventions comprehensively using the RTSS framework. This manual will cover the following areas to advance the fields of rehabilitation and implementation science: 1) a comprehensive overview of the pros and cons of video observation compared to traditional implementation science approaches (e.g., chart review, surveys), 2) a step-by-step guide on how to create buy-in with community stakeholders to conduct this kind of work, and how to setup video observation that is unobtrusive to standard care; and 3) a detailed description of how to comprehensively analyzes video observations using the RTSS framework in OT practice settings.