NINDS/NICHD-NCMRR NeuroRehab CDE Project
Treatment/Intervention Data: Devices Subgroup Summary

The NeuroRehab v1.0 CDE project focused on recommendations from existing NINDS and other NIH supported CDEs within the Core and Supplemental – Highly Recommended classifications. New CDEs or those within the Supplemental and Exploratory classification were not reviewed in this initial process. Identified gap areas are an important part of informing future NeuroRehab CDE efforts.

The subgroup reviewed existing NINDS CDE case report form (CRF) modules from the Treatment/Intervention Data Domain, Devices Subdomain. CRFs that overlapped with the Treatment/Intervention Data: Therapies subgroup were reassigned to the Treatment/Intervention Data: Devices subgroup for consideration.

After the subgroup's initial review of available NINDS CDEs that are applicable to the Treatment/Intervention Data: Devices subdomain, a primary impression was that within the field of Assistive Devices, especially with the advent of new devices and mobile technologies, that the data element set would need to expand naturally along with industry standards and technological developments. The subgroup determined that it was important to develop their purview and definitions before considering CDEs/CRFs, instruments and gap items, as chosen definitions will impact future iterations of NeuroRehab CDEs, and Devices CDEs in particular as rehabilitation techniques and assistive technology (AT) advances. Data captured by CDEs would reflect the needs of researchers and clinicians in the NeuroRehab Devices fields of study. For the NeuroRehab Treatment/Intervention Data: Devices subdomain, the subgroup began with existing definitions and taxonomies to address the capturable data details related to Device categories such as, medical devices, mobility/cognitive aids and other assistive technologies, and diagnostic devices.

To conduct their review of the NINDS CDEs, the subgroup needed a definition model to assist with differentiating technology categories/technology classifications. Types of devices identified that do not have existing NINDS/NIH CDEs were recorded by the subgroup as gap areas to be developed in a future phase of the project. To maximize global applicability, the subgroup used existing taxonomies to frame subgroup definitions for CDE review and development. By using existing taxonomies, the subgroup could start with those frameworks and not duplicate work done by previous expert groups. To properly frame and organize CDEs, device categories covered by the taxonomy must include and cover a wide range of assistive technologies and devices designed for treatment/rehabilitation: mobility and wheeled devices, cognitive aids, medical devices, orthotics, robotic devices, diagnostic devices, monitoring sensors, mHealth mobile technologies.

After discussion, the International Classification of Functioning, Disability and Health (ICF) and Assistive products — Classification and terminology (International Organization for Standardization (ISO) 9999:2022) were selected to be the basis of the subgroup taxonomy. The subgroup selected the Assistive Technology Act of 2004 definition for Assistive Technology Devices to describe NeuroRehab devices and device function: the term `assistive technology device' means any item, piece of equipment, or product system, whether acquired commercially, modified, or customized, that is used to increase, maintain, or improve functional capabilities of individuals with disabilities. [Assistive Technology Act of 2004, H.R. 4278 [SEC. 3. <<NOTE: 29 USC 3002.>> DEFINITIONS., Page 118 STAT. 1710]]

ISO 9999 was chosen because of its clear definitions of specific assistive technologies and services. However, the subgroup decided not to recommend the entirety of the ISO 9999 as many sections and

subsections would be out of scope for the Devices subdomain. ICF was included with taxonomy development as the ISO 9999 is linked to the ICF, to address activity, participation, and personal factors and environmental aspects. The starting point for the taxonomy was selected as the ISO 9999, which maps to the ICF. The subgroup reviewed both the ISO 9999: 2016 and draft ISO 9999: 2022 versions.

ICF was determined to be a reasonable place to start as it is a part of a family of classification systems used by the World Health Organization (WHO). By using the ICF to frame CDE selection and use, the subgroup can categorize recommendations based on body structure, body function, activity outcome or participation measures that are device relevant and address personal factors and environmental characteristics.

A combination of the two models was used to frame the subgroup taxonomy as a technology-specific data set would be incomplete by using only the ICF.

The subgroup considered other models for the taxonomy, such as the definitions provided by the Americans with Disabilities Act (ADA), which had the foresight to classify to AT devices and AT services separately. However, it was determined that the subgroup purview is more linked to the actual technology and the details that would be collected related to the technology and user characteristics. While that does not exclude the service delivery types or follow-up/maintenance activity details, these would still be the details related to the actual device itself. Other taxonomies and models considered includes Americans with Disabilities Act (ADA), American Occupational Therapy Association (AOTA) practice framework and Matching Person and Technology (MPT) model.

The subgroup acknowledged throughout their process that it is important to establish limits to reduce the consideration of fringe devices and that proper definitions would assist the group with framing the scope of Devices CDEs to help researchers acknowledge technologies that contributes to outcomes.

Members first considered the value and utility of the CDEs, specifically, how the CDEs could be used by the NeuroRehab clinical and research community. The subgroup reviewed several existing taxonomies used in the field of AT and services. This approach was considered important for future development of CDEs that align with industry standard. To accomplish this, the subgroup determined that a categorical list of technologies and services is needed to guide future development. These efforts were made to maximize the usefulness of existing NINDS CDEs and simultaneously make the first steps to label the demands of the devices domains and guide the first steps of future development.

Additionally, the subgroup reviewed the Rehabilitation Measures Database (Shirley Ryan AbilityLab), to identify useful AT device outcome measures. This list of measures had overlap with the outcome measure recommendations from other NeuroRehab subgroups, such as Motor Function, Quality of Life, and Activities of Daily Living. In general, the subgroup determined that these outcome measures were within the purview of the other subgroups to recommend as appropriate.

The grouping of device CDEs allowed for the development of two NeuroRehab Devices template CRFs. CDEs identified as Supplemental – Highly Recommended for NeuroRehab Devices studies fall into two categories, identified by the subgroup members: Mobility/Manipulation and Communication.

There is a separate subgroup for infants/pediatrics. Any measures that are exclusively infant/pediatric were forwarded to the Infant Pediatrics subgroup for their consideration. The Devices subgroup focused on CDEs developed for primarily adult populations.

After selecting the ISO 9999 taxonomy, the subgroup did a thorough review of NINDS CDEs related to the Devices subdomain. During the review, subgroup members molded their final recommendation based on several observations of the CDEs with respect to their expertise in assistive technologies.

Through this review the subgroup identified useful NINDS CDEs and developed template Case Report Forms (CRFs) to collect data relevant to Assistive Technology in two distinct categories: Mobility and Manipulation and Communication. CDEs related to other Devices categories were considered but were not strong enough data points to stand alone at this point.

When reviewing CDEs, in the effort to create standard data points for NeuroRehab research and treatment, the subgroup made several baseline data considerations. These data points include Impairment level, Device used, Device lifespan, Usage timeline, and Expectation of and Realization of benefit from use. The subgroup considered short term device usage, long term device usage, reasons for device non-use or stopping use, and device setting changes to be important factors in future CDE development to accurately capture a user's usage record and inform healthcare decision making. As technology can be used as the NeuroRehab intervention, the right data needs to be collected to make accurate comparisons. Clinicians need simple, highly validated tools that have minimal burden and, especially from a research perspective, tools should be simple to encourage uptake by those without assistive technology backgrounds.

The subgroup noted several considerations regarding the data points that would be covered by the subgroup taxonomy. These considerations include what kind of data needs to be collected and specifications on what step in rehabilitation process devices are implemented. Consistency of what is measured is needed for Devices CDEs, as devices may be different but what is being measured must be common. An important data consideration when implementing NeuroRehab devices is the need to also measure the qualities and function of the devices themselves in addition to usage metrics. Data points that are included in the taxonomy and will be suggested for future CDE development include: assessment, patient follow-up, function improvement/decline, device replacement due to patient condition or growth, device maintenance activities, training data, fall prevention data, provider/user input, device use satisfaction, realization of benefit from use, enhanced subjective well-being, cost, and device input data.

Other data considerations include hospital readmission data, related medical factors (e.g., pressure sores), participation factors (e.g., employment changes), living situation changes, family structure, and psychosocial issues.

After thorough review of the NINDS CDEs, the subgroup identified many unmet needs in the Devices subdomain. The subgroup's purview included only parts of the ISO 9999 taxonomy and the existing NINDS/NIH device related CDEs are limited. The CDE recommendations for v1.0 are only a subset of the data elements ultimately needed to collect information that fully encompasses the range of assistive technologies used in neurorehabilitation. Other important considerations include advancing assistive technologies such as mHealth technology and mobile applications.

In the Treatment and Intervention Data: Devices field, the subgroup identified a **need for strong outcome measures that are sensitive to the person-device and the environment-device interface**. The subgroup considers the Matching Person & Technology assessment (MPT) process and the Human

Activity Assistive Technology (HAAT) model as important future inclusions for those being matched with a new or different device (assistive technology, educational technology, workplace technology) to enhance their functioning, performance of activities, and participation in desired pursuits. The MPT identifies barriers to use so they can be addressed. When comparing a user's pre-device characteristics at Time 1 with those at post-acquisition and use at Time 2, it gives person-centered, user provided, outcomes data. For those being provided with a new or different device, assessment processes and measures guide the selection of the most appropriate device for a particular end user and assess outcomes of use at follow-up. Additionally, the MPT has multiple validation studies and translations, is available at no cost, and its development was funded by NIH/NCMRR. The HAAT model considers the activity the important factor in considering what assistive technology should be paired with the user.

Additionally, there is a need for outcome measures that are sensitive to how a device is provided and how it is maintained. The juncture at which the outcome measure is being administered also should be specified. Necessary details include manufacture specifications, device maintenance cycle, and device operating condition.

Other important needs to be addressed by future CDE development include the following:

How to collect data for emerging technologies. These technologies include standalone devices that support functioning, cloud-based technologies, implanted devices, wearables, and virtual reality applications. In general, the devices field is moving away from exclusively standalone devices like eating utensils and walkers and using newer assistive technologies which are less stigmatizing.

Measures of device utilization were also discussed by the subgroup as needed for future CDEs. The supportive data from monitoring device input would produce significant user outcome data. Monitoring data includes data points such as those from odometers on powered chairs, and other utilization metrics for wheelchair usage, such as time, distance, or corresponding GPS coordinates. Pain related considerations need to be made as well. For example, pain metrics and pain scales can be used to quantify pain caused by prosthetics/orthotics use to determine proper fit and device selection. The subgroup also considers device cost metrics as important to be recorded by NeuroRehab researchers and clinicians. This includes cost of ownership, including education and training considerations. Training details are considered important for determining how device implementation is impacted by the quality of service delivery. Training details that could be captured by outcome measures include who provided training, how much training was provided, what type of training was provided, as well as the custom fit and device details listed above.

Detailed clinical and user data points also need to be considered for future NeuroRehab Devices CDEs. Disease specific considerations as known covariates are normal in clinic but are not always measured as standard procedures. The comparative efficacy of devices also should be measured, such as the effectiveness of multiple device usage, e.g., prosthetics vs. wheelchairs. The subgroup noted additional questions that need to be asked of the device users and providers. These questions include topics such as, technology as part of the rehab, acute vs subacute rehab, social support and social participation metrics, inpatient vs. outpatient discrepancies, and telehealth vs. in person consideration.

For future iterations of the project, subgroup members believe that informing device developers of existing CDEs could lead to their adaptation in consumer medical products and digital assistive

technologies. The subgroup sees benefit in CDEs, developed by NIH and NCMRR, and how their application could streamline development and inform future health care strategies.

To cover categories that may not have been included in the first version of the NeuroRehab CDE project, the Devices subgroup recommends that for a future iteration, to enhance comprehensiveness, the project should look beyond Occupational and Physical Therapy and consider bringing researchers from other related fields including Prosthetics & Orthotics, Biomedical and Rehabilitation Engineering, Hand Therapy, Speech and Language Pathology, Audiology, Blind and Visually Impaired Rehabilitation , Rehabilitation Psychology, and Vocational Rehabilitation Counseling, and Adaptive Driving.

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