Summary of Responses to Request for Information (RFI): Solicitation of Input on Common Data Elements (CDEs) for Lower Limb Loss Research Standards

Notice Number: NOT-HD-21-001

Purpose of RFI: NICHD, together with federal partners, seeks input from the limb loss research stakeholder community on proposed CDEs for limb loss research. The proposed CDEs were prepared by NICHD, other NIH Institutes and Centers as well as federal partners, including other Operational Divisions within the Department of Health and Human Services (HHS; Centers for Medicare and Medicaid Services [CMS]; Food and Drug Administration [FDA]; the National Institute for Disability, Independent Living, and Rehabilitation Research [NIDILRR]; the Agency for Healthcare Research and Quality [AHRQ]), the Department of Defense (DoD), and the Department of Veterans Affairs (VA).

Number of Responses: 13 total responses were received from federal employees, researchers in the field, and stakeholder organizations. Most responses represented stakeholder organizations or companies that collected input from multiple members of their respective organizations.

Disclaimer: This summary is not a review of the current literature or an expression of the opinions of NICHD or NICHD's federal partners.

Summary of Responses: Responses ranged in length and specificity, with some responses contributing information that applied to major components of the CDE document while others provided specific commentary at the level of single data elements. All contributions were responsive to RFI and provided stakeholder insight. Responses were generally supportive of the effort to establish common data elements, and many stated the field would benefit. Responses have been categorized and summarized in the following sections.

Core and Supplemental Data Elements: Respondents suggested that the rationale for assigned core or supplemental status should have been made clearer. Some respondents inquired if core elements would become mandatory for NIH funded research in the future. Multiple respondents suggested that the list of core data elements was too long and that the scope would need to be edited to make the CDEs practical and useful. One respondent requested a minimal dataset.

Number and Scope of Proposed Data Elements: Some respondents indicated that too many data elements were being considered. Other respondents thought the number and scope was appropriate, but that only the definitions of "core" and "supplemental" needed to be revised and clarified. Some respondents suggested that uniform language, definitions, and formatting across domains would add clarity and increase efficiency.

Ongoing Efforts: Multiple respondents indicated that there are ongoing efforts in the broader community to address the need for common data elements in the fields of Limb Loss clinical research, device provision, and Limb Loss basic research.

Methodology: Several respondents stated that the supplied materials provided little detail regarding the process for choosing these data elements. Respondents requested more information

regarding the process and suggested that future changes to the CDEs should include more robust methodology.

Intended Data Use: Multiple respondents stated that the potential use of the commons data elements was unclear. Respondents request clarification on how different federal agencies that partnered on this effort would use data collected in accordance with these common data elements.

Data Collection Domains in Need of Further Consideration: Multiple respondents suggested additional areas of data collection that were missing from the CDE document. Examples include but are not limited to: 1) health status of the contralateral/intact/sound limb for unilateral amputees 2) insurance or payor variables and out of pocket costs 3) assistive technology beyond the affected limb (bracing, orthotics on the contralateral limb) 4) mobile device/wearable monitoring, including metadata 5) prosthetic device name and serial number 6) falls 7) quality of life 8) physical activity assessments 9) social network 10) self-efficacy.

Methodology in Need of Further Consideration: Several respondents requested information about how the CDEs would be finalized, how stakeholder input would be included in the final project, and how CDE's would be updated in the future. Respondents suggested that the CDEs be revised with person-first language and inclusive gender language. At least one respondent suggested revised CDEs emphasize form over function. One respondent stated it was not necessary to separate physical and occupation therapists for this project. FHIR-compatibility was recommended for any data elements that would be retrieved from electronic health records.

Conclusion: In conclusion, stakeholders were largely supportive of NICHD and NICHD's federal partner's efforts to establish Common Data Elements for the Limb Loss research field. Respondents requested greater transparency with the methodology, clearer definitions of core and supplemental items, greater consistency in the detail of data elements (i.e., greater detail for areas less, less detail in others). Respondents also provided numerous item-specific suggestions that cannot be summarized here.