USCDI Version 3 Proposal:

Functional Status Assessment

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| Submitted By: Steve Bratt / CodeX (Common Oncology Data Elements eXtensions), a member-driven HL7 FHIR accelerator | |
| Data Element Information | |
| Data Class | Assessment and Plan of Treatment |
| Data Element Name | Functional Status Assessment |
| Description | Functional status assessments are commonly used in healthcare to document a patient’s baseline ability to manage daily routines and life activities. This assessment can be used as an indicator of quality of life (QOL) and help guide delivering patient-centered care. Functional status assessments are used broadly in healthcare, and can be used to: \* screen initially for problems, as well monitor the patient over time \* assess how a disease impacts a patient’s baseline functional status and their overall ability to tolerate certain therapies during serious illness  Functional status assessments can be generic or disease specific. For instance, in oncology, the Eastern Cooperative Oncology Group (ECOG) Performance Status assists in determining a patient’s potential chemotherapy tolerance. |
| Current Status | Submitted |
| Current Classification Level | N/A |
| Use Case Description(s) | |
| Use Case Description | A plethora of functional status assessment tools have been created to assist clinical management and are used broadly in medicine in fields such as oncology, palliative care, surgery, orthopedics, geriatrics, psychiatry, neurology, physical medicine and rehabilitation, nursing, etc. Achieving optimal patient outcomes for health and well-being requires an understanding of factors that affect quality of life (QOL), such as the ability of patients to perform basic activities and participate in life situations.  Although varying functional status assessments exist, these tend to follow a similar structure (e.g. functional status assessment type, assessment criteria, assessment score/interpretation). Many of these functional status assessment criteria/observations already encoded in the standard Logical Observation Identifiers Names and Codes (LOINC). The case for adopting functional status assessment into the USCDI is supported by the following: \* Aforementioned commonalities in functional status assessment structures. \* Ability to represent functional status data in existing standards. \* Widespread use of these assessments across healthcare.  Examples of functional status assessments include: \* Outcome and Assessment Information Set (OASIS) \* Modified Rankin Scale (mRS) \* Katz ADL Scale \* Barthel Index \* Lawton-Brody IADL Scale \* Mini-Mental Exam \* Functional Activities Questionnaire \* Veterans RAND 12-Item Health Survey \* Karnofsky Performance Status (KPS) \* Eastern Cooperative Oncology Group (ECOG) Performance Status  The many existing use cases are evident of the need for a functional status assessment data element:  \* Clinical care management ---- Directs therapy for hearing, speech, vision, cognition, and mobility ---- Monitor well-being and baseline functionality for the elderly, children with special needs, patients with specific chronic conditions, etc. ---- Functional status assessments are particularly helpful for monitoring and managing chronic health disease processes (e.g. aging, heart failure, dementia, etc.). ---- Can assist with determining patient ability to tolerate therapy when considering modalities such as chemotherapy or surgery. Can be used to monitor patients both during and after any such treatments/interventions.  \* Care coordination ---- Can be used to determine patient needs and plan care transition/management across healthcare settings, including ambulatory care, acute care, long-term post-acute care (LTPAC), and home- or community-based services (HCBS). ---- The 2014 Improving Medicare Post-Acute Care Transformation (IMPACT) Act requires standardization and interoperability of patient assessment for reporting for post-acute care (PAC) settings ---- Functional status assessment data is key for informing care decisions and gauging resource needs for patients with significant disabilities limiting their ability to carry out ADLs. One example of this is the use of these assessments in the Program of All-Inclusive Care for the Elderly (PACE), which helps provide Medicare beneficiaries ages 55+ living with disabilities and/or chronic care needs community-based healthcare services and support.  \* Quality assurance ---- Currently used as a standardized metric to track patient outcomes and quality performance across different specialties and organizations. Used in measures for health processes such as cancer, stroke, dementia, chronic heart failure, post-acute care progress, rheumatoid arthritis, etc. ---- President’s Advisory Commission on Consumer Protection and Quality – noted importance of functional status information in 1998 ---- Examples of use in clinical quality measure (CQMS): ---------> MIPS Quality ID #282: reporting on dementia patients whom had functional status assessments performed at least once in the last 12 months ---------> MIPS Quality ID #178: reporting on patients with rheumatoid arthritis (RA) whom had functional status assessments performed at least once in the last 12 months ---------> CMS Measure ID CMS56v8: reporting on patients who received elective primary total hip arthroplasty and completed functional status assessment both prior and post surgery ---------> CMS Measure ID CMS66v8: reporting on primary total knee arthroplasty patients who received functional status assessments both prior and post surgery  \* Research ---- Functional status assessments are commonly used in research studies to correlate their predictive potential for monitoring patient outcomes. For instance, use of a functional status assessment like the modified Rankin scale (mRS), whose validity and reliability in stroke patients has been shown through prior studies, then allows for use of mRS for assessing impact and outcomes of new stroke treatments.  \* Resource and financial management ---- Functional status assessments could be used for cost predictions, and for anticipating service and resource utilization ---- Payers could use this information to adjust payment levels and capitation rates  The National Committee on Vital and Health Statistics (NCVHS) identified functional status assessment data in essential to healthcare, and asserted that it “should be included in patient records (computerized and otherwise) in the range of settings where care is provided.”  Per the Centers for Medicare & Medicaid Services (CMS), the Radiation Oncology (RO) Model will seek to improve quality of care for cancer patient receiving radiation therapy by transition to a more streamlined and predictable reimbursement system, commencing January 1, 2022. Capability Maturity Model Integration (CMMI) is requiring certain clinical data elements (CDEs) as part of this mandatory RO model, with the ECOG functional status being proposed as one of these CDEs.  LINKS:  Use of functional status assessments in PACE program: <https://www.ncqa.org/hedis/measures/hos/> MIPS Quality ID #282: <https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2020_Measure_282_MIPSCQM_v4.1.pdf> MIPS Quality ID #178: <https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2020_Measure_178_MIPSCQM.pdf> CMS Measure ID CMS56v8: <https://ecqi.healthit.gov/ecqm/ep/2020/cms056v8> CMS Measure ID CMS66v8: <https://ecqi.healthit.gov/ecqm/ep/2020/cms066v8> NCVHS reference: <https://www.ncvhs.hhs.gov/wp-content/uploads/2017/08/010617rp.pdf> CMS RO model, where ECOG functional status proposed as a clinical data element: <https://innovation.cms.gov/media/document/ro-clin-data-elements-rfi-v2> |
| Estimated number of stakeholders capturing, accessing using or exchanging | Many Americans are affected by disease processes where clinical functional assessments play vital roles.  As noted above, the IMPACT Act requires standardization and interoperability of patient assessment for post-acute care (PAC) settings. Thus, stakeholder needing a USCDI functional status assessment for data sharing would include PAC facilities like the following: \* long-term care hospitals (LTCHs) \* home health agencies (HHAs) \* skilled nursing facilities (SNFs) \* inpatient rehabilitation facilities (IRFs)  Clinical functional assessments are frequently used in oncology to gauge to assess patient tolerance for certain therapies, estimating prognosis, and for monitoring disease progression. Per the American Cancer Society (ACS), about 1.8 million new cancer diagnoses were made in 2020. In 2019, there were an estimated 16.9 million cancer survivors living in the United States.  Functional assessments are also used frequently for monitoring the effects of aging in geriatrics. These assessments are employed for tracking and managing dementia or other diseases as well.  Per the CDC: \* In 2016, 49 million US adults were 65 years of age or older, representing 15% of the population. That percentage is expected to increase to 25% around 2060. \* 22.2% of noninstitutionalized persons aged 65 and older in fair or poor health (2018) \* 7% of noninstitutionalized Americans 65 years and older need help with personal care from other persons (2018) \* In 2014, about 5.8 million adults at least 65 years and older had dementia.  Other patients whose care can be impacted by functional status includes, but is not limited to, those with heart failure, stroke, rheumatoid arthritis, disability, and recent surgery.  Other stakeholders include: \* CMS: Centers for Medicare & Medicaid Services uses clinical functional status for quality measures as noted above \* Joint Commission requires documentation of clinical functional assessments as part of its requirements to certify comprehensive stroke centers, and for doing advanced certification for total hip & knee replacement (THKR) programs. Thus, any groups seeking these certifications would also be considered stakeholders. \* Medical Specialty Groups: ---- American Speech, Language and Hearing Association ---- American Occupational Therapy Association ---- American Psychological Association ---- American Physical Therapy Association ---- American College of Occupational and Environmental Medicine ---- Eastern Cooperative Oncology Group ---- American Society of Clinical Oncology ---- American Society for Radiation Oncology  \*Note that other USCDI submissions under the “Functioning” category (<https://www.healthit.gov/isa/uscdi-data-class/functioning>) are also testimony to the growing need for a clinical functional status assessment data element.  This submission is made on behalf of CodeX (Common Oncology Data Elements eXtensions), a member-driven HL7 FHIR Accelerator community of professional medical societies, health systems, industry and others seeking to achieve interoperability via the mCODE (minimal Common Oncology Data Elements) standard in order to drive step-change improvements in cancer patient care and research. <https://confluence.hl7.org/display/COD/CodeX+Home> |
| Link to use case project page | <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/IRF-QRP-Function-Quality-Measure-Specifications-August-2018.pdf> |
| Healthcare Aims | * Improving patient experience of care (quality and/or satisfaction) * Improving the health of populations * Reducing the cost of care * Improving provider experience of care |
| Maturity of Use and Technical Specifications for Data Element | |
| Applicable Standard(s) | ICF: International Classification of Functioning, Disability and Health – the WHO framework for measuring health and disability at both the individual and population levels <https://www.who.int/standards/classifications/international-classification-of-functioning-disability-and-health>  LOINC <https://loinc.org/>  SNOMED CT <https://www.nlm.nih.gov/healthit/snomedct/index.html>  HL& FHIR US Core R.4.0 – Functional Status – In Development (Feedback being requested) <http://hl7.org/fhir/us/pacio-fs/2021JAN/index.html>  The CMS Data Element Library provides downloadable functional status data elements: \* Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) \* Resident Assessment Instrument – Minimum Data Set (MDS) \* Outcome and Assessment Information Set (OASIS) \* Functional Assessment Standardized Items (FASI) <https://del.cms.gov/DELWeb/pubHome> <https://loinc.org/> |
| Additional Specifications | HL7 & FHIR US Core.R.4.0 – Functional Status <http://hl7.org/fhir/us/pacio-fs/2021JAN/index.html>  CMS Data Element Library <https://del.cms.gov/DELWeb/pubHome> |
| Current Use | In limited use in test environments only |
| Number of organizations/individuals with which this data element has been electronically exchanged | 1 |
| Supporting Artifacts | The ECOG and Karnofsky functional status assessments are part of the mCODE (minimal Common Oncology Data Elements) FHIR Implementation Guide. Efforts are underway to facilitate data exchange of these assessments in clinical trials through Real-World-Data clinical trial use cases being developed through CodeX (Common Oncology Data Elements eXtensions) projects. <https://confluence.hl7.org/display/COD/EHR+Endpoints+for+Cancer+Clinical+Trials> |
| Potential Challenges | |
| Restrictions on Standardization (e.g. proprietary code) | We are not aware of any current restrictions on standardization of this data element. |
| Restrictions on Use (e.g. licensing, user fees) | Note that there are intellectual property issues related to use of some post-acute care assessments, and detailed further in the proposal put in by the CMS Data Element Library (DEL) Health IT Workgroup: <https://www.healthit.gov/isa/uscdi-data/mental-function> |
| Privacy and Security Concerns | Usual HIPAA restrictions apply. |
| Estimate of Overall Burden | The IMPACT Act requires the reporting of standardized patient assessment data with regard to quality measures and standardized patient assessment data elements (SPADEs). The Act also requires the submission of data pertaining to measure domains pertaining to resource use, and other domains. In addition, the IMPACT Act requires assessment data to be standardized and interoperable to allow for exchange of the data among post-acute providers and other providers. The Act intends for standardized post-acute care data to improve Medicare beneficiary outcomes through shared-decision making, care coordination, and enhanced discharge planning. The requirement of assessment data as part of the impact act supports the inclusion of assessments in USCDI.  <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-of-2014-Data-Standardization-and-Cross-Setting-Measures> |