



MITA[®]
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF **NEMA**[®]

1300 North 17th Street • Suite 900
Arlington, Virginia 22209
Tel: 703.841.3200
Fax: 703.841.3392
www.medicalimaging.org

April 26, 2022

Steven Posnack, Deputy National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
330 C St SW
Floor 7
Washington, DC 20201

Re: USCDI Draft Version 3

Dear Mr. Posnack,

The Medical Imaging & Technology Alliance (MITA) is the leading trade association representing the manufacturers of medical imaging equipment and radiopharmaceuticals. We are encouraged to see the Office of the National Coordinator for Health Information Technology (ONC) continue its work to improve USCDI and enhance interoperability in healthcare—a goal MITA members share. We submit these comments in support of that shared goal.

Update to Clinical Tests

The Applicable Vocabulary Standards should be updated to include LOINC version 2.71. In addition, the “USCDI Clinical Tests Minimum Set” maintained by ONC should be expanded to include the following LOINC codes:

- 12 lead EKG panel (34534-8)
- EKG study (11524-6)

To improve current and anticipated use of this data element in apps and applications accessing data via FHIR and SMART APIs, additional data EKG elements are needed to facilitate interoperability between ancillary devices and EHRs for data acquisition, processing and analytics. We encourage ONC, via LOINC, to establish and implement additional EKG codes to represent *Resting EKG* and *Ambulatory EKG*. Ambulatory EKG should be further segmented to represent Holter monitor, personal mobile wellness, internal and external loop recorder tests. Each of these tests yield different structured or unstructured (“narrative”) findings that are relevant to the diagnosis and treatment of atrial fibrillation.

Update to Diagnostic Imaging

ONC should update the Diagnostic Imaging Test Data Element description to read:

“Identifies an imaging procedure performed that generated anatomical data (radiographic, photographic, video, waveform, and analysis results etc.) to be interpreted by qualified professionals.”

This language better aligns with industry-accepted language as presented in the Technical Workflow Standard, IHE SWF.b in Section 5.4.3 of ISO 21860:2020, Health Informatics — Reference standards portfolio (RSP) — Clinical imaging¹.

We also encourage the ONC to develop additional guidance to providers and clinicians on the use of relevant LOINC codes for Diagnostic Imaging vocabulary (e.g., LOINC codes for imaging procedures incorporated from the RSNA RadLex Playbook).

Update to Patient Demographics

Race and Ethnicity

The Applicable Standards in USCDI v3 are from 2000 or earlier and should be updated to more recent terminology. ONC should consider the latest CDC Race and Ethnicity Code Set for this purpose (Version 1.2²). This updated version also reflects terminology updates exemplified in Public Law 114-157³.

Sex (Assigned at Birth)

To ensure continued clinical accuracy and patient safety related to applications that process imaging and vital signs data, ONC should maintain the current data element “Sex (Assigned at Birth)” in USCDI v3. We support the work underway within the Gender Harmony project⁴, but note that it is not yet sufficiently mature nor adopted for inclusion in USCDI v3.

Sex (Assigned at Birth) is the most reliable proxy input for some established processing algorithms (such as vital signs monitoring parameters) that rely on the binary deterministic representation of sex as input in order to fulfill their intended use.

We recognize recent proposals for alternatives in this category, such as “Recorded Sex or Gender” and “Sex For Clinical Use (SFCU)” in the HL7 Informative Document: Gender

¹ Health Informatics — Reference standards portfolio (RSP) — Clinical imaging
(<https://www.iso.org/standard/72004.html>)

² Public Health Information Network Vocabulary Access and Distribution System- Race & Ethnicity – CDC
(<https://phin.vads.cdc.gov/vads/ViewCodeSystem.action?id=2.16.840.1.113883.6.238>)

³ Public Law 114-157 (<https://www.congress.gov/114/plaws/publ157/PLAW-114publ157.pdf>)

⁴ HL7 Informative Document: Gender Harmony - Modeling Sex and Gender Representation, Release 1
(https://www.hl7.org/implement/standards/product_brief.cfm?product_id=564)

Harmony - Modeling Sex and Gender Representation, Release 1. However, as described in that document, “Sex (Assigned at Birth)” is an optional sub-element of “Recorded Sex or Gender” and it is not clear that “Recorded Sex or Gender” would otherwise meet the needs of the clinical research and processing algorithms already in use in the field. As for “Sex For Clinical Use (SFCU)”, a consensus methodology to establish this element based on patient and clinical context is still under development. This is not consistent with the ONC prioritization criteria for being considered a Level 2 data element in the USCDI, and we recommend it not be included at this time.

MITA commends the ONC for its continued work towards healthcare interoperability and the development of the USCDI. If you have any further questions, please do not hesitate to contact Zack Hornberger, Director of Cybersecurity & Informatics at zhornberger@medicalimaging.org or by phone at 703-841-3285.

Sincerely,

A handwritten signature in black ink, appearing to read "Patrick Hope". The signature is fluid and cursive, with a large initial "P" and a long horizontal stroke at the end.

Patrick Hope
Executive Director, MITA

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators, and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, radiation therapy equipment, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.