



Elizabeth G. Taylor
Executive Director

Board of Directors

Ann Kappler
Chair
Prudential Financial, Inc.

William B. Schultz
Vice Chair
Zuckerman Spaeder LLP

Miriam Harmatz
Secretary
Florida Health Justice Project

Nick Smirensky, CFA
Treasurer
New York State Health Foundation

L.D. Britt, MD, MPH
Eastern Virginia Medical School

Ian Heath Gershengorn
Jenner & Block

Michele Johnson
Tennessee Justice Center

Arian M. June
Debevoise & Plimpton LLP

Jane Preyer
Environmental Defense Fund (Ret.)

Lourdes A. Rivera
Center for Reproductive Rights

Shamina Sneed
TCW Group, Inc.

Donald B. Verrilli, Jr.
Munger, Tolles & Olson

Ronald L. Wisor, Jr.
Hogan Lovells

Senior Advisor to the Board
Rep. Henry A. Waxman
Waxman Strategies

General Counsel
Marc Fleischaker
Arent Fox, LLP

April 29, 2022

Submitted Electronically via <https://www.healthit.gov/isa/united-states-core-data-interopability-uscdi#draft-uscdi-v3>

Micky Tripathi, PhD.
National Coordinator for Health IT
Office of the National Coordinator for Health IT
Department of Health and Human Services
330 C St SW, Floor 7
Washington, DC 20201

RE: Comments on United States Core Data for Interoperability (USCDI) Draft v3

Dear Dr. Tripathi,

The National Health Law Program (NHeLP), founded in 1969, protects and advances the health rights of low-income and underserved individuals and families by advocating, educating, and litigating at the federal and state levels. NHeLP frequently comments on proposals that address the collection of comprehensive demographic data in federally-funded health programs. Increasing culturally-sensitive methods of demographic data collection builds systems that can address demographic disparities in health care effectively. We thank you for the opportunity to comment on the proposed USCDI v3 standards and to provide additional suggestions that further the Biden-Harris Administration's stated goal of advancing health equity.

We strongly support the Office of the National Coordinator's efforts to expand the potential for uniform demographic data collection in health information technology (IT). ONC can advance the whole-of-government approach required by the Biden-Harris Administration's Executive Order on Advancing Racial Equity and Support for Underserved Communities¹ by adopting demographic data collection standards to track and address persistent health disparities. Comparability of

demographic data is essential to identify, monitor, and develop targeted strategies to address inequities. Health status and health care utilization disparities persist, and in some cases have widened across many demographics including race/ethnicity, socioeconomic status, sex characteristics, gender identity, sexual orientation, disability status, and English proficiency. However, identifying disparities and effectively monitoring efforts to reduce or eradicate them have been limited by a lack of specificity, uniformity, and quality in demographic data collection and reporting procedures. Without uniform taxonomy for the type and categories of demographic data to be collected, program-to-program, project-to-project, and state-to-state comparisons are difficult, if not impossible. The importance of adopting standardized data collection methods across health IT platforms to achieve health equity cannot be understated.

Sex Assigned at Birth

ONC specifically requested comment on the Sex Assigned at Birth data element. We wish to highlight the recommendations of the recently released National Academies of Sciences, Engineering, and Medicine report, *Measuring Sex, Gender Identity, and Sexual Orientation*, which endorses collecting information on sex assigned at birth and current gender identity to identify gender modality (i.e., whether an individual is transgender).² ONC should keep the data element for Sex Assigned at Birth to allow for such documentation in the record. However, we encourage ONC to (1) expand the data elements available for capturing demographic and clinical information about an individual's anatomy, and (2) clarify in its use case description for the Sex Assigned at Birth data element that the data element refers to the individual's sex or gender marker as listed on their original birth certificate.

For many researchers and health care providers, sex assigned at birth is a shorthand way to understand what sex traits—such as chromosomes, hormones, or organs—an individual possesses and whether an individual is transgender. However, as the NASEM report and other research have shown, sex assigned at birth, gender identity, and variations in sex characteristics are not interchangeable and should not be used as a proxy for each other.³ For example, an individual can identify themselves as assigned male at birth, transgender, and

² See Bates, Nancy, Marshall Chin, and Tara Becker, Eds., *Measuring Sex, Gender Identity, and Sexual Orientation*, Nat'l Academies of Sciences, Engineering, and Medicine, at 40 (2022), <https://nap.nationalacademies.org/read/26424/chapter/5#40> [hereinafter, "NASEM Report"].

³ Freeman, Lauren and Lopez, Saray Ayala, *Sex Categorization in Medical Contexts: A Cautionary Tale*, 28 *Kennedy Inst. Ethics J.* 243 (2018), <https://pubmed.ncbi.nlm.nih.gov/30369506/>; Clair A. Kronk et al., *Transgender Data Collection in the Electronic Health Record: Current Concepts and Issues*, 29 *J. Am. Med. Informatics Assoc.* 271 (2022), <https://academic.oup.com/jamia/article/29/2/271/6364772>.



intersex, and a provider would still need to ask questions to determine whether to conduct a prostate cancer screening. Sex assigned at birth and gender identity should still be captured individually to allow for demographic identification of distinct underserved groups, such as transgender individuals, and for clinical care coordination. Sex (or more accurately, gender) assigned at birth is still a necessary data element to serve as a crude proxy for elements of an individual's medical history and a prompt for potentially needed screening where an organ inventory cannot be completed for each patient.⁴ Thus, the data element for sex assigned at birth maintains some utility, but it alone cannot be a proxy for individual anatomy.

Variations in Sex Characteristics (Intersex Traits or Status)

A new, standalone data element is needed to identify intersex populations. The NASEM committee in Chapter 7 of its report explains:

Intersex status is an important component of demographic status, private medical information, and an aspect of identity. ... Because of historical, legal, and medical factors, almost no person in the United States is assigned intersex at birth. Therefore, it is inappropriate to assess intersex status primarily with an 'intersex' response option for sex assigned at birth[.]⁵

Instead, the NASEM report recommends “using a standalone measure” when asking respondents whether they were born with physical variations in sex characteristics (or ever received a related diagnosis). We recommend that ONC add a separate data element or elements to capture specific sex traits and intersex status, in addition to the sex assigned at birth data element. We join the comments offered by the Fenway Institute and encourage ONC to conduct additional research on the most appropriate and valid way to support data collection on people with intersex traits.⁶

⁴ Clair A. Kronk, Transgender Data Collection in the Electronic Health Record: Current Concepts and Issues, 29 J. Am. Med. Informatics Assoc 271 (2022), <https://academic.oup.com/jamia/article/29/2/271/6364772>.

⁵ See NASEM Report, at 103, <https://nap.nationalacademies.org/read/26424/chapter/9>.

⁶ Fenway Institute, Comment Letter on Proposed USCDI v3 Standards (Apr. 30, 2022), <https://www.healthit.gov/isa/sites/isa/files/2022-04/USCDI%20v3%20comment%20Fenway%20Health%20and%2023%20partner%20organizations%20042922.pdf>.



Gender Identity

ONC requested feedback on the language used in the gender identity data element. We encourage ONC to adopt the recommendations of the NASEM committee in Chapter 6 of their report and the Fenway Institute's recommendations in their comments on this proposal.⁷ We support the replacement of response options "male-to-female transgender" and "female-to-male transgender" with response options for "transgender" and "nonbinary." We suggest adopting more response options than recommended in the NASEM report because allowing for response options to be added as necessary, preferably upon regular review of the available response options, enables health IT users to accommodate changing terminology and taxonomy. Since each health IT database user will serve different populations, adopting more options at this stage will ensure that minimum categories are available as their use becomes prevalent. USCDI should adopt detailed definitions of each response option in the rationale and use case descriptors to clarify meaning and allow for selection of multiple response options. We also strongly urge USCDI to replace the use of "other" with "not listed" or "something else," to avoid further pathologizing and isolating underrepresented populations.⁸

We recommend that ONC change the order of the "Gender Identity" and "Sex Assigned at Birth" data element to reflect the recommendations of the NASEM report.⁹ Current gender identity should be asked first in any patient interview to emphasize the significance of the individual's lived experience over the individual's assigned gender. Re-ordering the data elements will ensure that users of health IT systems will be more likely to ask for current gender identity first.

In its rationale and use case descriptions, ONC should take care to clarify that the gender identity of the patient should measure the individual's current gender identity as self-reported by the individual. In addition, as recommended in the NASEM report, the two-spirit response option is only culturally appropriate for, and thus should only be available for, indigenous populations.¹⁰

⁷ See NASEM Report, at 74, <https://nap.nationalacademies.org/read/26424/chapter/8>; *Id.*

⁸ See *id.*

⁹ See NASEM Report, at 74, <https://nap.nationalacademies.org/read/26424/chapter/8>.

¹⁰ *Id.*



Finally, we join the Interoperability Standards Workgroup in recommending that ONC add a data element to the Patient Demographics data class to allow for input of patient's pronouns.¹¹ Pronouns cannot be assumed based on an individual's self-reported gender identity, yet they are a necessary component of interacting with every patient. Using the correct pronouns is just as important to quality of care as is knowing the patient's recent medical diagnoses. We recommend adopting the set of pronoun response options as follows:

- he/him/his
- she/her/hers
- they/them/theirs
- xe/xem
- e/em/eir
- Unsure, questioning, or exploring
- I use all/any pronouns
- None; I avoid pronouns, I only use my name
- I use different pronouns in different contexts
- Prefer not to respond or disclose
- Pronouns/option not listed (please specify)¹²

Disability Status, Functional Status, and Mental Function

We suggest that ONC add a data element to the Patient Demographic data class that reflects a patient's self-reported disability status. In addition to the data elements "Functional Status," "Disability Status," and "Mental Function," which are included in the Health Status data class, we believe an additional data element is needed to serve as a demographic identifier in the medical record. Documenting disability as a demographic identifier in addition to a clinical note ensures that people with disabilities can be counted as distinct groups when organizations seek to measure health disparities. Leaving out disability as a demographic identifier will make it harder for organizations to stratify other encounter and outcome data for people with

¹¹ Health Information Technology Advisory Committee, Interoperability Standards Workgroup Report to the Health Information Technology Advisory Committee, at 10 (Apr. 13, 2022), <https://www.healthit.gov/sites/default/files/facas/2022-04-13-IS-WG-Phase-1-Recommendations-Report-revised.pdf>.

¹² Clair A. Kronk, Transgender Data Collection in the Electronic Health Record: Current Concepts and Issues, 29 J. Am. Med. Informatics Assoc 271 (2022), <https://academic.oup.com/jamia/article/29/2/271/6364772>.



disabilities and make it more difficult to understand whether people with various disabilities receive an equitable quality of care.

To remedy this issue, we recommend that ONC follow the charge of the Interoperability Standards Workgroup in Recommendation 03 and Appendix B and add the seven disability status data elements to the Patient Demographics data class.¹³ At a minimum, the data element(s) must allow for input of multiple, patient-identified disabilities and reflect a range of disabilities, including physical, functional, and intellectual or developmental disabilities. It is critical that the demographic identifier reflects the patient's self-identified disability status as opposed to the provider's observations.

We support additional data elements and classes that allow for input of additional information about patient disabilities, mental, and functional status that serve purposes other than demographic identification. For example, the Interoperability Standards Workgroup recommends exploring an additional data element for "Accommodations" that can inform the health IT user of how to support care for people with disabilities.¹⁴ The provider must also be able to input separate observations about the patient's functional status. As the use case description points out, having provider observations are critical to support an individual's application for disability benefits and can greatly improve care coordination. However, demographic information about self-reported disabilities must also be included because it serves a different purpose altogether: to enable effective monitoring of quality of care at a higher level and to target appropriate equity interventions.

¹³ Health Information Technology Advisory Committee, Interoperability Standards Workgroup Report to the Health Information Technology Advisory Committee, at 5,14 (Apr. 13, 2022), https://www.healthit.gov/sites/default/files/facas/2022-04-13_IS_WG_Phase_1_Recommendations_Report_revised.pdf.

¹⁴ Health Information Technology Advisory Committee, Interoperability Standards Workgroup Report to the Health Information Technology Advisory Committee, at 12 (Apr. 13, 2022), https://www.healthit.gov/sites/default/files/facas/2022-04-13_IS_WG_Phase_1_Recommendations_Report_revised.pdf.



Conclusion

We appreciate the opportunity to provide comments on the Draft USCDI v3 standards. For questions or follow up on these comments, please reach out to Staff Attorney Charly Gilfoil at gilfoil@healthlaw.org.

Sincerely,

A handwritten signature in black ink that reads "Elizabeth G. Taylor". The signature is written in a cursive, flowing style.

Elizabeth G. Taylor
Executive Director

