April 15, 2024

Office of the National Coordinator for Health Information Technology(ONC)
Department of Health and Human Services
Washington, DC

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Re: USCDI v5 Draft Feedback

Dear USCDI Team,

Stanton Ventures is a data engineering consultancy that provides technology services including: tracking instrumentation, data pipelines, data warehousing, data unification across sources, and business intelligence reporting. Founded in 2013, it's a Certified LGBT Business Enterprise(LGBTBE) by the National LGBT Chamber of Commerce. This feedback is written based on 20+ years of software and data engineering experience. The last three years have also included immersion in sexual orientation, gender identity and expression, and sex characteristics(SOGIESC) data efforts in healthcare research and state law.

SOGIE related data elements

Name to Use

Addition strongly supported
This is a “no-brainer” addition since nicknames are common and helpful for distinguishing between individuals. Most everyone has had the experience of being in a group with five Michael’s.

In addition, Name to Use will reduce the deadnaming of gender diverse(GD) patients. This will avoid causing harm during a medical encounter and is required for quality healthcare experiences. Name to Use is a new phrase, but the connotation between ‘will be used’ and the way that ‘preference’ implies an option is very important.

The combination of nickname and affirmed name in a data element called Name to Use is commendable for the way it combines nickname and affirmed name as the same concept. This will serve to reduce stigma and confusion around affirmed names. The following underlined changes are recommended for the Name to Use element description. Explicitly stating that the Name to Use field should begin as null or blank ensures that it is not populated with incorrect information and establishes the expectation that not everyone will have a Name to Use value.

Name to Use

Name that should be used when addressing or referencing the patient.

Technical Note: The default value should be null or blank.

Usage note: This information should be provided by the patient.

Examples include but are not limited to nicknames.

Pronoun as Pronouns

Addition strongly supported

The isolation of pronouns as its own data element, instead of being inferred from other data elements, ensures that this information can be a)accurate and b)easily displayed.

The following underlined changes are recommended for the Pronoun data element description. The American College of Physicians[1] agrees that an 's' should be added at the end of Pronoun. As with the Name to Use element, it should be specifically stated that this element begins as null or blank to ensure it gets populated accurately. Because other data elements in the document refer to a "patient" and not a "person" that phrasing should be continued in this data element. Example pronouns should also be displayed with their declension, or their acceptable alternate(s), as they are in conventional usage. The additional example pronouns serve to provide a better understanding to health IT programmers who may not be familiar with the values this field will contain.

Pronouns

Word or words that can replace a person's name when addressing or referring to the patient.

Technical note: The default value should be null or blank. This should be a string field of 30 characters or more.

Usage note: This information should be provided by the patient.

Examples include, but are not limited to: she/her, they/them, he/his, he/they, and ze/zir.

[1] Pandita, Deepti. "ACP Comments on Draft USCDI v5." HealthIT.gov. April 11, 2024. https://www.healthit.gov/isa/comment/reply/node/2281/field_comment/13822 Accessed April 13, 2024.

Pronouns being a string field with at least 30 characters is based on a) rapidly evolving language, b) supporting clarity of grammar differences[2] [3], c) affirming patient's identity, and d) interoperability. Since 2020, the Indian Health Service(IHS) has listed 12 pronoun options[4] [5] including an "Other" answer. The WebPT EMR lists 14 pronouns including Self-described[6]. LGBTQ Nation, a queer publication, lists 17[7].

There are LOINC(R) Pronoun codes[8] but they only contain 10 options without an "Other" answer or a decline to state answer. The Regenstrief Institute says[9] they support the Gender Harmony Project(GHP)'s[10] work, but that goes against HL7 International's statement[11], which the GHP is run out of, that the vocabulary standards need to be done by a consensus-based group. As in, they don't exist yet. You were 100% correct not to list the LOINC codes as an Available Data Standard.

None of those lists include the "use only my name" or the "all pronouns" answers that LW mentioned[12] in their Draft v5 feedback comment. "Use only my name" is another way to say "no pronouns"[13]. That's *before* we get to the *common* ones like she/they or he/they ("rolling pronouns"[7]). Or other combinations like he/ze.

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[2] Pronouns.org. "How do I use personal pronouns?" Pronouns.org. https://pronouns.org/how Accessed April 13, 2024.
[3] Forge Forward. "Pronouns & Trans People." 2015. https://forge-forward.org/wp-content/uploads/2020/08/FAQ-Pronouns.pdf Accessed April 13, 2024.
[4] Indian Health Service. "Patient Registration: Addendum to User Manual. Version 71 Patch 15." September 2020. PDF page 10, document page 7. https://www.ihs.gov/rpms/packagedocs/AG/ag__0710.15o.pdf Accessed December 4, 2023.
[5] Indian Health Service. "Example Intake Form. Manual Exhibit 23-02-A." June 1, 2023. https://www.ihs.gov/sites/ihm/themes/responsive2017/display_objects/documents/circ/ihm_circ_22-03a.pdf Assessed December 4, 2023.
[6] WebPT. "Gender Identity and Pronouns in the WebPT EMR." December 28, 2022. https://help.emr.webpt.com/article/2126-gender-identity-and-pronouns-in-the-webpt-emr Accessed April 14, 2024.
[7] LGBTQ Nation. "An (incomplete) list of gender pronouns." February 18, 2023. https://www.lgbtqnation.com/2022/08/incomplete-list-gender-pronouns/ Accessed April 14, 2024.
[8] LOINC. "Personal Pronouns – Reported." Version 2.66. https://loinc.org/90778-2/ Accessed April 13, 2024.
[9] Patzer, Rachel. "Re: ONC's Draft United States Core Data for Interoperability (USCDI) Version 5." HealthIT.gov. April 11, 2024. https://www.healthit.gov/isa/comment/reply/node/2281/field_comment/13831 Accessed April 15, 2024.
[10] McClure, Robert. "The GHP." HL7's Confluence > Terminology Infrastructure. October 3, 2023. https://confluence.hl7.org/display/VOC/The+Gender+Harmony+Project Accessed April 13, 2024.
[11] HL7 International
[12] LW. "Comments USCDI v5". March 20, 2024. https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#draft-uscdi-v5 Accessed April 12, 2024.
[13] Krauss, Sam. "What do you do when someone doesn't use any pronouns?" PFLAG. https://pflag.org/resource/what-do-you-do-when-someone-doesnt-use-any-pronouns/ Accessed 2024.

Pronouns are personal. That there is such a desire to shove our queer identities into boxes is, at least, problematic. Trying to create and maintain a list of all the possible pronoun values is a fool's errand and you still end up with the need for an "Other" free text value.

Pronouns are essentially another version of a patient's name. At this time, Stanton Ventures recommends specifying it's a string field with a minimum length so that it can adjust to changing and unique values in real time. If people choose to use the LOINC codes, or other codes, then those codes still fit in a string field and have a very easy `CASE` statement for detection. In ten or twenty years, if there's a steady, agreed set of pronoun "boxes", they can be added as an Available Data Standard at that time.

Sex Parameter for Clinical Use(SPCU)

Addition supported

Stanton Ventures aligns with many other respondents in strongly recommending and requesting all USCDI efforts align with the GHP's recommendations. From the latest available information[14] [15], they want a SPCU at the patient level and context-specific SPCU elements.

It's unclear to me how the USCDIv5 draft intends to use the proposed Observations > SPCU element. Is the Observations data class meant to have multiple instances per patient? How does the Observations data class relate to other data classes such as Laboratory, Diagnostic Imaging, and Medications? Since the Observations Data Class also contains the Advance Directive Observation element, which only makes sense at patient level, this letter is written assuming there is one instance of the Observation data class per patient.

Regardless of anyone's intent, it's clear simply from the realities of human body complexities, that we will end up having granular, specific SPCU data at some point. We ignore that at the peril of data modeling our way into multiple, generally duplicative, fields and tech debt. Stanton Ventures also believes that there are additional existing data classes beyond those that the GHP has proposed Level 2 elements[16] for, such as Health Insurance Information and Vital Signs, where an SPCU could potentially be helpful. It's

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[14] HL7 International. "Implementer Considerations." https://hl7.org/xprod/ig/uv/gender-harmony/implementer.html#exchanging-a-sex-parameter-for-clinical-use Accessed April 12, 2024.
[15] rmcclure. "Please update the name of Sex Parameter for Clinical Use(SPCU)." April 17, 2023. https://www.healthit.gov/isa/uscdi-data-class/sex-clinical-use Accessed April 14, 2024.
[16] Clinical Test Sex Parameter for Clinical Use, Laboratory Sex for Clinical Use, Procedure Sex for Clinical Use, Diagnostic Imaging Sex for Clinical Use, Medication Sex for Clinical Use.

also reasonable to assume there will be new data classes in the future that will need SPCU data.

In short, Stanton Venture's data architecture proposal would be:

1. Have a patient level SPCU in a data class that is also at patient level.
2. Have a data class that serves as a sub-class for all/most other data classes which stores variables that can differ for the same patient across data classes and/or across their lifespan. SPCU could be one such element.

The use of the patient level SPCU could be the default value unless the optional sub-class is used to provide an override. It would DRY up the data model instead of having many SPCU fields. It would provide the level of granularity and flexibility to support transgender and intersex patients who have different sex characteristics(SCs) within the same body. It would especially support transgender patients as they proceed through their personal transition treatments over time. For a transgender patient, one year their SPCU for Lab Test A could be female and Lab Test B could be male. The next year the appropriate SPCU for Lab Test A and B could be male. For an intersex patient perhaps there is only ever one type of Diagnostic Imagery that needs an SPCU "override" of the patient's SPCU. It would keep the SPCU differences isolated and thereby, presumably, make implementation costs lower.

Regardless of whether this proposed sub-class is a good idea or not, a patient level SPCU will be needed and should be added in the v5 standard. EHRA's[17] and OCHIN's[18] feedback agrees. Oracle Health[19] states "it would be helpful to reference the same data element[SPCU] in multiple classes." In context, it reads like they support a sub-class-like concept. NCQA[20] and CMS-CCSQ continue to support[21] [22] context-specific SPCU's.

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[17] EHRA

[18] Stoll, Jennifer. "Re: Draft U.S. Core Data for Interoperability (USCDI) version 5." HealthIT.gov. April 15, 2024. https://www.healthit.gov/isa/comment/reply/node/2281/field_comment/14001 Accessed April 15, 2024.

[19] Buitendijk, Hans J. "USCDI v5 Proposal Feedback." HealthIT.gov. April 15, 2024. https://www.healthit.gov/isa/comment/reply/node/2281/field_comment/13858 Accessed April 15, 2024.

[20] O'Kane, Margaret E. "NCQA Comment on Draft USCDI v5." HealthIT.gov. April 15, 2024. https://www.healthit.gov/isa/sites/isa/files/2024-04/NCQA%20Response_USCDI%20v5_Final.pdf Accessed April 13, 2024.

[21] Schreiber, Michelle. "CMS-CCSQ Public Comment Leter on United States Core Data Interoperability (USCDI) Draft Version 5." HealthIT.gov. April 11, 2024. https://www.healthit.gov/isa/comment/reply/node/2281/field_comment/13923 Assessed April 15, 2024.

[22] Schriber, Michelle. "CMS-CCSQ Submission for United States Core Data for Interoperability (USCDI) Version 5." HealthIT.gov. September 2023. https://www.healthit.gov/isa/sites/isa/files/2023-09/CMS-CCSQ%20USCDI%20v5%20Submission%20Letter.pdfsign.pdf Accessed April 13, 2024.

We bring this idea up, even though so many people have done so much work on the GHP because sometimes groups have siloed thinking that focuses on what fields(data elements) to have and forget, or don't know, about class hierarchies and relationships.

Separately, the Regenstrief Institute[9], which is responsible for LOINC codes, recommends the use of LOINC code: 99501-9 Sex Parameter for Clinical Use[23]. However, we see no sample values on their webpage and therefore cannot determine whether they follow the GHP's recommendations. Please do not include a reference to this LOINC code as an Available Data Standard until it's confirmed to conform to the GHP's recommendations and is assured to continue following the GHP's recommendations.

Data Elements that need SOGIE implication review

Patient Demographic Information > Sex
Currently, we request that you consider adding a sentence like the following to the Sex data element description: "Technical note: At a minimum this field must support the values, or their equivalents, of F, M, X, and U." "X" is included because it is a sex/gender marker used on government issued ID and birth certificates in many jurisdictions including US Passports. "U" is specifically included because there are at least some places that CMS allows[24] that value.

In future, with Gender Identity and SPCU data elements available, it is worth starting to consider separating out the meaning of the Sex element so that it stops having conflated and different meanings. Potentially, it should move towards the meaning of Legal Sex. The implications for communications with legacy systems that only take a binary M/F or 0/1 value, need much consideration.

Goals and Preferences > SDOH Goals
Health Status Assessments > SDOH Assessment
Problems > SDOH Problems/Health Concerns
Procedures > SDOH Interventions

All of the impacts of SOCIESC, pronoun and preferred name(PPN), and SPCU changes need to be considered by the respective standards bodies that the USCDI references. We request that the USCDI highlights this fact to them.

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[23] LOINC. "Sex parameter for clinical use." LOINC. https://loinc.org/99501-9 Accessed April 15, 2024.
[24] CMS. "National Hospital Inpatient Quality Reporting Measures Specifications Manual Release Notes For Manual Version: 5.14." QualityNet. Implement by July 1, 2023. https://qualitynet.cms.gov/files/6391ead376962e0016ad91bd?filename=HIQR-ReleaseNotes_v5.14.pdf Accessed November 20, 2023.

Health Status Assessments > Pregnancy Status
USCDI doesn't currently list an applicable vocabulary standard for this data element. Should USCDI ever consider changing that, you must take into account the SPCU data element along with broader issues of transgender and intersex patients. This is similar to CMS's changes to their pregnancy questions at the same time they updated the Sex element in their health quality measures[15].

Laboratory > Result Reference Range

It would be helpful if USCDI pointed out that the values for this data element should take SPCU into account in some way.

Responses to Other Commenters on SOGIE elements

Stanton Ventures supports calls to include an Intersex specific data element(s) and consider Intersex individuals more broadly throughout medical standards.

Multiple commenters request that you work with interACT: Advocates for Intersex Youth[25] for intersex inclusion in USCDI standards. Stanton Ventures repeats and insists that interACT be involved in any and all work for Intersex health data standards. To our knowledge, interACT is working with at least two efforts for SC specific and integrated health questions. The first is Project Recognize[26], an NIH RO1 grant. Stanton Ventures consults on Project Recognize. The second is in connection with Massachusetts state government.

Non-SOGIE related fields in v5 Draft

Patient Demographics > Interpreter Needed

Addition strongly supported
We believe this field is crucial. First, it infuses the importance of bi-directional understanding of health information into health care in a systemic way. Second, it can be used to ensure an interpreter is scheduled for a patient's visit instead of hoping that one will be available ad hoc. Third, it can help researchers more accurately count those who need an interpreter and/or different mediums of communication and/or translated materials.

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[25] https://interactadvocates.org/
[26] Phillips, Gregory, Lauren B. Beach. "Project Recognize: Improving Measurement of Alcohol Use and Other Disparities by Sex, Sexual Orientation, and Gender Identity through Community Engagement." NIH RePORT > RePORTER. September 21, 2021. https://reporter.nih.gov/search/aOoekvH1xUuR-NRFBifSzg/project-details/10491297 Accessed 2022.

Right now, most United States health care is performed, and research is conducted, only in English. Published papers calling for doing non-English research get nods, but no follow through. With numbers to demonstrate the reality of what patient language needs are, then health equity advocates, health quality administrators, and health researchers have a much better chance of getting funding for the inclusion of non-English speakers, non-verbal communication mediums, and non-English materials in the services and research that so many need.

The v5 Draft standard lists that LOINC or SNOMED CD codes are usable. However, the active LOINC code for Interpreter Needed[27] only lists the options of No, Yes, and Unable to Determine. Stanton Ventures, along with AHIMA[28], Oracle Health[29], and The Joint Commission[30] call out the need for more specific data about interpretation needs. An old 2020 version of the SNOMED CD Requires Interpreter code[31] catalogs a much wider variety and detail of translation needs. As an example, the SNOMED CD codes also allow for the encoding of the language of the translation needed. That would allow for situations where a patient's Preferred Language is French but a Spanish interpreter, which is easier to find, would also work for the patient. We are not well versed enough to be able to comment on EPIC's proposal[32] of the HL7 Language Communication CDA class. Assuming there has not been a reduction in the precision in SNOMED CD codes since 2020, they provide much more precise and helpful information. The extreme differences between the comprehensiveness of the SNOWMED CD codes and LOINC codes leads to our **recommendation that the SNOWMED CD codes should be the only Applicable Data Standard for the Interpreter Needed element**

Further, we believe that v6 needs to consider adding Interpreter Needed as an element related to the Encounter Information data class in addition to the one in the Patient Demographic data class. Some example use cases include support for when a patient will have a friend or family member with them to translate and when they won't. Maybe the patient doesn't need an interpreter to see their Primary Care Provider(PCP) because their

[27] LOINC. "Interpreter Needed." Version 2.66. https://loinc.org/54588-9 Accessed April 12, 2024.
[28] Riplinger, Lauren. "AHIMA Comments on Draft USCDI v5." HealthIT.gov. April 11, 2024. https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#draft-uscdi-v5 Accessed April 13, 2024.
[29] Oracle Health
[30] Dardis, Michelle. "The Joint Commission Comments on Draft USCDI v5." HealthIT.gov. April 15, 2024. https://www.healthit.gov/isa/comment/reply/node/2281/field_comment/13887 Accessed April 15, 2024.
[31] SNOMED CT. "Requires interpreter codes." Opencodelists. https://www.opencodelists.org/codelist/nhsd-primary-care-domain-refsets/reqinterpreter_cod/20201016/#tree Accessed April 12, 2024.
[32] EPIC

PCP is multi-lingual, but they will need a translator to see any other provider(also stated by HL7 International[33]). Honestly, Interpreter Needed is a potential additional element for the above proposed sub-class related to SPCU data.

Provenance > Author

Provenance > Author Role

Addition strongly supported

Every data professional understands that `created_at` and `created_by` are fields required for minimum viability of 99% of objects. As data professionals we also understand that people's names change over time(e.g. getting married), they get entered differently in different systems, some times someone uses their nickname, etc. Indeed, AHIMA's v5 feedback[28] lists why identity resolution is a large problem in healthcare. Adding Author and Author Role without a unique identifier for the Author is a recipe for data headaches. You already represent persons in the Care Team Members object. ***We HIGHLY recommend adding a Care Team Member Identifier data element under the Provenance object at the same time.*** Alternatively, the standard could state that the Author field needs to specify the Care Team Member Identifier. HL7 International's point that a Care Team Member may be in a different medical system[34] and therefore have a colliding ID, is extremely important. Clarification on how to handle that needs to be included in the standard.

Many v5 feedback commenters mention that you list a patient can have authorship. The reactions have a wide range of viewpoints. We highly encourage you to ignore those who don't want patients to be able to have participation in creating their own EMR. The reality is under HIPAA a patient, at the minimum, has the right to make an amendment request in their medical record.

An author can NOT be a machine

Stanton Ventures *intensely disagrees* with HL7 International that an author could be a device. We agree with FEHRM's[35] comment that computer-generated(e.g. AI) information still needs to be attributable to a human being. This is extremely important for patient safety, patient privacy, and patient trust.

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[33] hl7 feedback

[34] HL7

[35] Guntepe1. "USCDI v5 Comments." HealthIT.gov. September 9, 2023. https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#draft-uscdi-v5 Accessed April 13, 2024.

At this point in time, it's extremely Orwellian to propose an EHR could start including Fitbit or other wearable data directly. Especially because Fitbit, as the named example, will require logging in with Google credentials in less than a year[36], and will require sending health data through Google's systems. That already places individuals' wearable data at extreme risk for discriminatory uses by insurance companies, employers, and other entities, just like cars now spy on their owners and occupants[37] [38]. Stanton Ventures is the first to complain that health care providers need to start taking Fitbit and wearable data seriously. That physicians currently despise wearable data – even for trend data and not specific values – is infuriating. Despite that, there's just no way that wearable data belongs in an EHR unless and until patients' privacy rights are law again[39] and it should only ever be a mentioned in a text-based note when applicable.

Laboratory > Test Kit Unique Device Identifier

Neutral

Should this element include the phrase Test Kit? It seems to be discussed as if it's the lab equipment unique device identifier.

Meditech[40], the Regenstrief Institute[41], HL7 International[42], EHRA[43], Oracle Health[44], FAH[45], and EPIC[46] make decent cases for why Test Kit Unique Device Identifier may not be ready for "primetime." If this element is added, we recommend adding the following to the

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[36] Google. "Fitbit-compatible devices." Google Support. https://support.google.com/product-documentation/answer/14226283?hl=en-FI Accessed 2023.

[37] Mozilla. ";Privacy Nightmare on Wheels': Every Car Brand - including Ford, Volkswagen, and Toyota – Flunks Privacy Test." Mozilla Foundation. September 6, 2023. https://foundation.mozilla.org/en/blog/privacy-nightmare-on-wheels-every-car-brand-reviewed-by-mozilla-including-ford-volkswagen-and-toyota-flunks-privacy-test/ Accessed 2024.

[38] Hill, Kashmir. "Automakers are Sharing Consumers' Driving Behavior With Insurance Companies." The New York Times. https://www.nytimes.com/2024/03/11/technology/carmakers-driver-tracking-insurance.html Accessed April 15, 2024.

[39] Say HIPAA all you want. The overturn of Row v. Wade is a direct attack on doctor-patient confidentiality.

[40] Meditech. "MEDITECH Comments on USCDIv5." April 11, 2024. https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#draft-uscdi-v5 Accessed April 13, 2024.

[41] Patzer, Rachel. "Re: ONC's Draft United States Core Data for Interoperability (USCDI) Version 5." HealthIT.gov. April 11, 2024. https://www.healthit.gov/isa/comment/reply/node/2281/field_comment/13831 Accessed April 15, 2024.

[42] Solarf3050. "HL7 Comments on Draft USCDI Version 5." HealthIT.gov. April 12, 2024. https://www.healthit.gov/isa/comment/reply/node/2281/field_comment/13844 Accessed April 15, 2024.

[43] EHRA

[44] Buitendijk, Hans J. "USCDI v5 Proposal Feedback." HealthIT.gov. April 15, 2024. https://www.healthit.gov/isa/comment/reply/node/2281/field_comment/13858 Accessed April 15, 2024.

[45] ktenoever. "Re: United States Core Data for Interoperability, Draft Version 5 (Jan. 2024)." HealthIT.gov. April 15, 2024. https://www.healthit.gov/isa/comment/reply/node/2281/field_comment/13929 Accessed April 15, 2024.

[46] Fuhrmann, Dave. "Re: Draft USCDI Version 5." HealthIT.gov. April 15, 2024. https://www.healthit.gov/isa/comment/reply/node/2281/field_comment/13941 Accessed April 15, 2024.

description: “Technical Note: A unique device can be used on more than one patient.” This should help avoid a programmer assuming that “unique” means unique across all patients, which won’t be true(e.g. EKG machines, actigraphy).

Responses to Other Commenters on non-SOGIE elements

Stanton Ventures supports:

- All of FEHRM’s requests, including:
    - Add Exposures as a data class. Also supported by APHL[47]. In addition, to the reasons they listed, this would have significant positive impact for ME/CFS and similar patients.
    - Their comments on Care Team Location and Care Team Member
    - AI content needs attribution to a person. To me, this is critical for holding healthcare staff accountable.
    - Laboratory result values. Also supported by HL7 International[48].
    - Specimen collection datetime. Also supported by Vizient[49] and APHL[50].
- CMS-CCSQ's request[24] and NCQA’s[51] request to:
    - Move Disability Status from the Health Status Assessments data class to the Patient Demographics/Information data class. Also supported by the CDC and the PACIO Project.
- NCQA’s[25] request to move the Race and Ethnicity data elements to align with the OMB revisions to the Statistical Policy Directive No. 15[52]. Emory Healthcare[53] mentions their intent to monitor USCDI’s updates to the directive.
- Lisa R. Nelson, MS, MBA feedback[54] is well considered. SV supports the following:,

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[47] minigrrl. ”APHL Comments on USCDI Draft V5.” HealthIT.gov. April 15, 2024. https://www.healthit.gov/isa/comment/reply/node/2281/field_comment/13995 Accessed April 15, 2024.
[48] Scarpelli, Brian, Leanna Wade. ”Comments of the Connected Health Initiative Regarding the Office of the National Coordinator for Health Information Technology’s v5 of the U.S.
Core Data for Interoperability.” HealthIT.gov. Connected Health Initiative. April 30, 2022(can’t be accurate). https://www.healthit.gov/isa/sites/isa/files/2023-09/CHI%20Comments%20re%20v5%20USCDI%20%2820%20Sept%202023%29.pdf Accessed April 13, 2024.
[49] Vizient
[50] minigrrl. ”APHL Comments on USCDI Draft V5.” HealthIT.gov. April 15, 2024. https://www.healthit.gov/isa/comment/reply/node/2281/field_comment/13995 Accessed April 15, 2024.
[51] O’Kane, Margaret E. “NCQA Comment on Draft USCDI v5.“ HealthIT.gov. April 8, 2024. https://www.healthit.gov/isa/comment/reply/node/2281/field_comment/13796 Accessed April 13, 2024.
[52] Federal Interagency Technical Working Group on Race and Ethnicity Standards. ”Final Recommendations Report.” Census.gov. https://www2.census.gov/about/ombraceethnicityitwg/final-recommendations-for-csotus.pdf Accessed March 2024.
[53] Erskine, Alistair. ”Emory Healthcare’s Comments on the Draft USCDI v5.” HealthIT.gov. April 15, 2024. https://www.healthit.gov/isa/comment/reply/node/2281/field_comment/13920 Accessed April 15, 2024.
[54] Nelson, Lisa R. ”USCDI v5 Feedback.” HealthIT.gov April 12, 2024. https://www.healthit.gov/isa/comment/reply/node/2281/field_comment/13839 Accessed April 15, 2024.

    - USCDI v5 needs to recognize the notion of “documents.” This was also brought up by another commenter in the context of the proposed Advanced Directive Observation element.
    - **Advanced Directives** should be a data class with multiple elements, not a data element under Observations. Besides the multiple documents diagramed in this feedback, there are multiple data elements that need to be parsed from those documents.
    - Personal Goals, Treatment Intervention Preference, and a Care Experience preference are different concepts.
- Allegheny Health Network’s[55] highlight of the cybersecurity threats of tracking **Medical Devices > Unique Device Identifier – Implantable** in interoperable data. Health care systems are routinely being targeted for cyberattacks and health records held hostage. We have to assume those same records are being sold to bad actors. It’s not a matter of *if* someone will be killed via a technical attack on their medical device, but *when*. That medical devices now receive ”over-the-air" updates is both a great accomplishment and terrifying. We understand this is an existing element in the USCDI standard and that it can add value. That said, we believe there needs to be much more attention paid to this component of US infrastructure, medical treatment, and patient safety so more safeguards can be put in place.
- Wolters Kluwer’s[56] and many others request that **Vital Signs > Vital Signs Results: Date and Timestamps** be added to the standard.
- In general, date and timestamps are basic, crucial pieces of data and should consistently be included without having to make requests.

Stanton Ventures strongly opposes:

- Vizient’s[41] request to elevate the proposed **BMI** data element. Why on Earth would we promote an element that is discriminatory and in the process of being devalued?
    - The American Medical Association(AMA) recognizes[57] the historical harm, racism, and ageism of BMI and intends to educate physicians about the problems with BMI and using alternative measures.
    - No one needs BMI included in a standard when EMRs put it all over the place already. Recalculation as a problem? We are not running mainframes from

[55] Bauer, Jacqueline. ”Re: U.S. Core Data for Interoperability (USCDI) version 5.“ HealthIT.gov. April 15, 2024. https://www.healthit.gov/isa/comment/reply/node/2281/field_comment/13925 Accessed April 15, 2024.
[56] Hussey, Robert. ”Comments from Wolters Kluwer on USCDI v. 5”. HealthIT.gov. April 15, 2024. https://www.healthit.gov/isa/comment/reply/node/2281/field_comment/13935 Accessed April 15, 2024.
[57] AMA. ”AMA adopts new policy clarifying role of BMI as a measure in medicine.” AMA. June 14, 2023. https://www.ama-assn.org/press-center/press-releases/ama-adopts-new-policy-clarifying-role-bmi-measure-medicine Accessed April 15, 2024.

the 1980s anymore. Plus, even if someone thinks it's a worthwhile measure, you have to update it every time there's a new weight input anyways.
    - It's fatphobic.
    - Providers use BMI to discriminate against patients[58], including negatively impacting patient treatments[59] to the point of withholding treatments[60].
    - It's an ableist measure, even if only for how it "Compromises Cares of Patients with Disabilities."[61]
- The addition or elevation of any employer data outside of SDOH information.
- The addition or elevation of any other pregnancy related elements until bodily autonomy is legal again.

Level 2 Data Elements

Allergies and Intolerances > Criticality

Addition to v5 supported.

We are surprised it isn't already in the standard.

Immunizations > Reason Immunization Not Performed

Addition to v5 strongly supported.

The United States has a crisis of individuals, especially children, not getting their routine, basic, required vaccinations. This poses a threat to all Americans, particularly those with compromised immune systems, those who are required to be in situations that expose them to bacterial and virological risks(e.g. teachers), those that rely on the health of others for their financial support, etc. We literally are having measles outbreaks in the United States in the 2020s.[62] There are legitimate reasons for an individual not getting vaccinated. Herd immunity protects those folks. However, when a vaccination is not performed we

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[58] Gupta N, Bombak A, Foroughi I, Riediger N. Discrimination in the health care system among higher-weight adults: evidence from a Canadian national cross-sectional survey. Health Promot Chronic Dis Prev Can. 2020 Nov/Dec;40(11-12):329-335. doi: 10.24095/hpcdp.40.11/12.01. PMID: 33296298; PMCID: PMC7745830.

[59] Phelan SM, Burgess DJ, Yeazel MW, Hellerstedt WL, Griffin JM, van Ryn M. Impact of weight bias and stigma on quality of care and outcomes for patients with obesity. Obes Rev. 2015 Apr;16(4):319-26. doi: 10.1111/obr.12266. Epub 2015 Mar 5. PMID: 25752756; PMCID: PMC4381543.

[60] Clare, Eli. "Anti-Ableism Action Steps for Health Care Provision." February 2023. https://eliclare.com/wp-content/uploads/2023/02/Action_Steps_for_Medical_Providers-12pt.pdf Accessed April 15, 2024.

[61] Jacobs, Alexander E. *AMA J Ethics.* 2023;25(7):E545-549. doi: 10.1001/amajethics.2023.545. Accessed April 15, 2023.

[62] CDC. "Measles Cases and Outbreaks." CDC.gov. April 12, 2024. https://www.cdc.gov/measles/cases-outbreaks.html Accessed April 14, 2024.

must make data about it visible to researchers including immunologists, epidemiologists, and even future contract tracers.

Level 0 Data Elements

Patient Demographics > Medical Record Number

Oppose until there is more detail, then strongly support

"The Texas Birth Defects Epidemiology and Surveillance Branch agrees with the CDC's recommendation for the inclusion of the "Medical Record Number"(MRN) in the USCDIv5."[63] A patient has different medical record numbers in every health systems. Until an answer is provided about how to keep track of all of them and which system each belongs to, we do not believe this data element can be included in the USCDI standard.

Additional Notes

- We recommend making an example, or at least a template, available of the USCDI standard for a single patient. This would be extremely helpful when reviewing, implementing, and referencing the standard. During review of the v5 proposal there were many times there was a need to know if the acceptable values were key-value pairs, something more akin to key-JSON blobs, or something else entirely. Even more importantly, cardinality, hierarchy, and direction of relationships between data classes matter. Therefore, we believe an example patient's record that follows the standard would add clarity and provide for easier onboarding of programmers to the standard.
- While other commenter's feedback is cited in this letter, you can not consider this an exhaustive representation of related feedback.
- We ask that the USCDI team start to consider the difference between the *capability* of data to be interoperable and whether *all of it should always communicated by default*. Other commenters have brought up safety and privacy concerns in general and vague ways. We would like to get concrete about it. There need to be tiers of what in this standard can be shared under what parameters. This is a topic for a different letter, but the concept of open health data within the health system does not provide for adequate patient safety.

If you would like to contact us, you can reach Alison at alison@stantonventures.com.

[63] hjeon. "Inclusion of the Medical Record Number in the USCDI v5." HealthIT.gov. April 11, 2024. https://www.healthit.gov/isa/comment/reply/node/2281/field_comment/13829 Accessed April 14. 2024.

We would like to start our expressions of gratitude with a thank you for producing a standard document that is user friendly. It's clear, DRY by referencing other standards, short without compromising value, and well formatted. WeIknow we will refer to it in the future as an example of a standards document that should be emulated.

As everyone else does, we want to thank you for the ability to provide comments on Draft v5. More significantly, however, we would like to thank you for making submitted comments immediately public. This allows for responses to other's comments within the comment period. You absolutely met your goal of a predictable, transparent, and collaborative process.

Sincerely,

Alison Stanton
she/her/hers
Founder, Stanton Ventures