While we recognize that the scope of changes from USCDI v1 to USCDI v2 was limited due to the ongoing COVID-19 pandemic and its burden on health IT developers and the health care community, we believe that the addition or clarification of several additional data classes and elements is important to advancing health data interoperability in the U.S.

USCDI will be implemented by people with a wide range of expertise, including those without prior experience modeling clinical data using standard terminologies. Effective interoperability is accomplished with accurate and precise modeling. As such, we strongly recommend that all USCDI documents include links to modeling resources. For basic information about LOINC modeling, we would like to add the following links to USCDI documents: https://loinc.org/get-started/ and https://loinc.org/kb/users-guide/

To ensure USCDI is implemented correctly, a detailed description with examples showing how each class and element should be modeled would benefit modelers and help ensure modeling is done appropriately. For labs and vitals, at least five pieces of information are needed for each data element. A list and example of all these pieces will help teams model their data. Below is a list of the components and an example:

	Example
Standardized Code	29463-7
Code Type	LOINC
Code Description (optional)	Body weight
Value	105
Units Code	[lb_av]
Units Type	UCUM
Units display (optional)	Pound (US and British)

The description/display names are optional where data is stored with a standard terminology, but in cases where items are stored with local codes these can be helpful downstream if the mapping is not done correctly (or not done).

For most other USCDI data classes, the first four items are needed (code, code type, code description, and data value/result), and inclusion of a list of these items in each class will facilitate accurate modeling.

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Data Received from External Sources

In addition to local data, entities store data from external sources. Common examples include data from immunization registries, claims or clinical data received through provider-payer data exchanges, and hospitalization data received from ADT registries. The USCDI data elements seem most applicable to local data that does not originate from an external source. Mapping would be facilitated by clarification of the rules around data that is received from external sources. Clarification is needed about interoperability requirements for data from external sources, including requirements for standardized codes, as they might not be available. For example, many insurance companies receive regular extracts of clinical data from providers and labs and vaccine information from registries. If this data is sent in a tabular format with the data element identified in the column heading (Weight_Value), clarification is needed around whether or when the insurance company is required to map this to a LOINC code before sharing. In cases where there is insufficient information for mapping, for example if weight is received without units, guidance should indicate how to proceed. In the case of data received from an external source, there are two sources of provenance--the original sender, and the organization complying with the data-sharing requirements. The guidelines should clarify which organization should be used for provenance. If it is the originating organization, please provide guidance on how to handle missing provenance data.

The following comments apply to specific data classes and elements contained in USCDI v2.

Assessment and Plan
Please add LOINC as the code type.

Care Team Members
For **Provider Identifier**, specify NPI (or other) as the applicable standard.

Clinical Notes
As noted in Regenstrief/LOINC's October 2020 USCDI comments, each note type has a generic LOINC concept as well as more specific concepts that vary by setting, specialty, etc, and in most clinical situations, use of a more specific code is encouraged. The USCDI guide shows the codes for the most generic document types. This may lead mappers to believe that these are the only LOINC codes for these document types. The guide should be updated to remove these codes or to indicate that these are generic examples only, and that the most specific code should be used. Including guidance on finding the most specific code for each document will facilitate mapping, and we reiterate the possibility of adding LOINC FHIR ValueSets with associated OIDs and/or webpages with downloadable content on the LOINC website for each note type.

The following note types were previously suggested as new data elements and are listed in the Comments section of USCDI Clinical Notes. We recommend that they be included in USCDI v2 because 1) the set of proposed data elements are complementary to the existing Clinical Notes data elements in USCDI v2; 2) together they better represent the broad scope of clinical documentation that occurs each day in the U.S. Healthcare system; and 3) these data elements are broadly used every day across

healthcare systems, settings, and specialties and would be used by a large proportion of USCDI stakeholders.
- Telehealth note
- Outpatient note
- Plan of Care note
- Referral note
- Transfer summary note

For notes, specify the following data elements:
- Note code
- Note code type
- Note code description
- Note

If the Progress Note is meant to represent the outpatient encounter summary note, in parallel with the discharge summary note representing the inpatient encounter summary note, the designation of "progress note" will prove confusing for several reasons.

1. In most clinical settings, "progress note" refers to clinical notes that are placed in the inpatient chart on a frequent (at least daily) basis while the patient is in the hospital. Most clinicians don't think a progress note refers to outpatient notes unless it involves a series of related encounters (dialysis, chemotherapy, radiation treatments, etc.).
2. LOINC doesn't specify the setting for most of the progress notes, so the category is composed of both inpatient and outpatient notes.
3. Many outpatient encounter summary notes are not Progress Note types for example, "Internal Medicine Outpatient Note" or "Endocrinology Outpatient Note". These will be missed.

It would be better to designate the "Outpatient Summary Note", LOINC 96345-4 as that note, and Regenstrief will create a value set of all notes that meet the criteria of outpatient encounter summaries. That will include telehealth notes, but not plan of care notes (since this does not summarize the encounter).

Diagnostic Imaging
The Report and Narrative will need to contain the following data elements:
- Report/Narrative code
- Report/Narrative code type
- Report/Narrative code description
- Report/Narrative value/contents

Encounter Information
Because of the greater level of detail on SNOMED diagnoses, SNOMED should be emphasized as the preferred standard.

Immunizations
Add code and date of immunization.

Labs and Vitals
Lab data modeling is fairly detailed in the USCDI (test + value), but vitals are not.
For lab and vitals, specify the following data elements to satisfy the requirements:
- Test/vital sign code
- Test/vital sign code type
- Test/vital sign description
- Test/vital sign value/result
- Test/vital sign units code
- Test/vital sign units type
- Test/vital sign units display
- [Labs] Lab test performed date
- [Labs] Result date

For Labs, for the Laboratory Report Narrative and Pathology Report Narrative, specify the following data elements to satisfy the requirements
- Report code
- Report code type with LOINC as the applicable standard
- Report contents

For vitals, add Value and Units to the list of data elements in the diagram

For labs, add Units to the list of data elements to the diagram

Medications
The following items from Level 2 should be added to make this information meaningful:
- Date Medication Administered
- Medication Administration Dose
- Medication Administration Dose Units
- Date Medication Prescribed
- Medication Prescribed Dose
- Medication Prescribed Dose Units