AIRA
AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

April 15, 2024

Dr. Micky Tripathi
Department of Health and Human Services,
National Coordinator for Health Information Technology
Mary E. Switzer Building, Mail Stop: 7033A
330 C St. SW
Washington, DC 20201

RE: **USCDI Version 5**

Dear Dr. Tripathi -

On behalf of the American Immunization Registry Association (AIRA) we are pleased to submit comments on the Office of the National Coordinator's (ONC's) recently released documents related to United States Core Data for Interoperability, version 5. These comments are a compilation of the input of our members which include over 100 organizations representing Public Health Immunization Information Systems (IIS), IIS implementers and vendors, non-profit organizations and partners. IIS interface with a broad range of stakeholders, including providers, pharmacists, schools, child care facilities, health plans and payers, among others.

IIS and our partners are, quite obviously, very invested in promoting smooth interoperability to ensure broad data use. At the point of clinical care, an IIS provides consolidated immunization records and forecasts to support clinical decisions. At the population level, an IIS provides aggregate data and information on vaccinations for surveillance, program operations and public health action. It is critical that the role of Public Health is recognized as a key part of health IT strategy moving forward.

To that end, we have specific input on those data elements selected for inclusion in ONC's USCDI Version 5, and those not currently included.

AIRA provides suggestions on the ONC draft USCDI Version 5 in our comments presented on the following pages, organized by the specific questions asked by

ONC in the draft USCDI version 5. Please feel free to contact me with any questions: mbkurilo@immregistries.org.

We greatly appreciate the opportunity to comment on these resources, and we look forward to continuing to collaborate to ensure high-value health IT interoperability with our many partners.

Sincerely,

Mary Beth Kurilo, MPH, MSW
Senior Director of Health Informatics

1. Suggestions for improvement in the data classes or elements in Draft USCDI v5, including:
    a. Data class and element definitions, usage notes, and examples

    AIRA Comments

    We support the addition of the data element lot number to USCDI V5. Inclusion of lot number will improve overall data quality when immunization information is exchanged across health IT partners. Consistent inclusion of lot numbers for administered doses would improve accuracy and completeness, as well as support inventory management and appropriate autodecrementing. We would encourage clarification, however, that lot numbers would be expected for administered doses, but would not necessarily be expected for historical dose reporting. It is also important to acknowledge that lot number is applicable to medications as well as immunizations, so considering it in a larger context may be helpful.

    We are also concerned that there may be some confusion with the detailed write up that accompanies the lot number addition. The write up references a LOINC code for the lot number data element, which may inadvertently suggest that there is a LOINC code set for immunization lot numbers themselves.

We are also curious if lot number will be removed as a level 2 data element if/when it becomes a USCDI V5 data element.

As we have commented before, we request consideration for renaming the current Immunizations data class containing a data element with the same name as the data class. This is in part to separate the notion of class from element, but also to improve clarity when other elements in level 2 are brought forward into USCDI. This renaming could take a few different forms so long as it is clear the class is about an aggregation of various data elements by a common theme or use case and the element is the most granular level at which a piece of data is exchange as defined by USCDI. This could be Immunization (data class) and Immunization Code (data element).

b. Examples of code sets used by health IT developers and implementers to communicate

AIRA Comments

The Immunizations (Data Element) references CVX and NDC, which are appropriate, but this may be a good location to link to ONC's Interoperability Standards Advisory Vocabulary/Code Set/Terminology which has great information on these value sets, adoption, and usage. https://www.healthit.gov/isa/representing-immunizations

2. Should other data elements, already classified as Level 2 on the USCDI web pages, be added to USCDI v5 instead of, or in addition to, those in Draft USCDI v5? If so, why?

AIRA Comments

Immunizations

We strongly recommend Vaccine Administration Date and Vaccination Event Record Type be added to USCDI v5. Both elements are required for current EHR-IIS immunization exchange. With these lacking from USCDI v5 it would be possible to list only the immunization code a patient received, but not the date the patient received the dose or if the vaccination event originated in the source system, rendering the immunization report fairly unusable.

The "Vaccination Administration Date" proposed for USCDI v5 is crucial for effective immunization management, facilitating accurate tracking and coordination of vaccination schedules. Standardizing this data element, potentially aligning with established terminology and specifying the date format, will enhance interoperability across systems, supporting unified information exchange and improving population health outcomes. Vaccine Administration Date enables accurate record evaluation (e.g., were doses given at the proper age and at a proper interval?). We understand that there has been some internal discussion about using Procedure -> Performance Time which has a description of “Examples include but are not limited to vaccine or medication administration times…” We are concerned that this date/time will be much less precise than actually entering a date of administration, and pulling data from different data classes could lead to significant data quality issues.

The "Vaccination Event Record Type" proposed for USCDI v5 enhances immunization data management by standardizing categorization, promoting adherence to vaccination schedules, and enabling efficient public health monitoring. Its inclusion not only resolves duplicate records but also supports research and streamlines reporting in mass vaccination campaigns, contributing to improved patient care and public health outcomes. Vaccination Event Record Type enables accurate inventory decrementing by public health and aids in vaccine matching/deduplication (e.g., was this an administered dose that needs to be autodecremented, or an historical dose that does not?).

A Level 2 element that is unnecessary is “Immunization Code”, but it is only unnecessary because it is already in USCDI v5 as the data element “Immunizations” (See comments in 1a for renaming suggestion of that element to Immunization Code).

Patient Demographics Class

We believe that Patient Identifier (MRN or other IDs) along with Mother’s Maiden Name should be moved into USCDI v5. These elements can be leveraged in patient matching and greatly improve match rates when compared to records void of these extra data elements. MRN is heavily

implemented in many exchanges today and Mother's Maiden Name is heavily used in pediatric/adolescent use cases such as EHR to IIS exchange.

3. Are there significant barriers to development, implementation, or use of any of these data elements that would warrant a change in definition or removal from Draft USCDI v5?

   AIRA Comments

   We do have some additional concerns about implementation:

   - End users/consumers of immunizations do not and likely would not associate an Immunization Date Administered as a Procedure Performance Time
   - It's not clear when or how classes should/could/must abstract elements from other classes
     - For example, should medication date reference Procedure Performance Time?
     - Should a medication lot number come from the Immunization Lot Number?

   It would be helpful to address/resolve these questions prior to implementation.