GORDON AND BETTY MOORE FOUNDATION

1661 Page Mill Road
Palo Alto, CA 94304
650.213.3000

moore.org

June 28, 2023

Micky Tripathi, PhD, MPP
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street SW, 7th Floor
Washington, DC 20201

Dear Dr. Tripathi:

We are grateful for the opportunity to submit comments on the draft USCDI+ Quality on behalf of the Diagnostic Excellence Initiative measure development grantees funded by the Gordon and Betty Moore Foundation. The Gordon and Betty Moore Foundation awarded these 31 grants in four cohorts beginning in 2019 with the intent to support development of measures focused on diagnostic quality for cancer, acute vascular events, and infection. To date, five of these measures have been submitted for consideration to CMS for inclusion in quality programs, and we expect more to follow. It is of utmost importance to these grantees that the USCDI and USCDI+ include data elements that capture attributes of diagnostic processes and outcomes to increase the likelihood of diagnostic quality measure adoption and use. To that end, we submit these comments collected from the Diagnostic Excellence Initiative grantees. Our feedback falls into three categories, requests for clarification on aspects of USCDI+ Quality, recommended additions to USCDI+ Quality, and expressions of support for aspects of USCDI+ Quality.

Clarification requested:

- Does the proposed USCDI+ Quality and USCDI Outcomes Level 1 data element Adverse Events – Causality include lab-related errors? If not, we suggest adding Adverse Events – Laboratory-Related Errors as a data element to USCDI+ Quality to enable quantifying potential harms associated with diagnostic tests.
- Is an autopsy report conducted captured under USCDI and proposed USCDI+ Quality Clinical Notes? Would it fall under USCI Pathology Report Narrative? If not, we suggest adding the data element "Autopsy report" to USCDI+ Quality to enable tracking of diagnostic adverse events.
- Does the proposed Care Experience and Outcomes – Patient Care Experience data element include cancer experiences and outcomes? If not, we suggest adding the data element "Care Experience and Outcomes – Patient cancer care experiences and outcomes" to USCDI+ Quality.

- Does the proposed mCode Cancer Care – Primary Cancer Condition include data elements that provide the ability to calculate cancer diagnostic timing (i.e., time between earliest cancer sign or symptom documented in the EHR to time of histological diagnosis)? Could the proposed Health Status Assessment – Assessment time and USCDI Laboratory data elements or USCDI Indication + Encounter Time data elements and USCDI Laboratory data elements be used to calculate the diagnostic timing? If not, we suggest adding cancer sign or symptom and laboratory results time data elements to USCDI+ Quality to enable assessment of diagnostic delay.
- Does Laboratory – Values/Results include concepts of microbiology values and results such as organism, susceptibility/resistance? If not, we suggest adding microbiology values/results data elements to USCDI+ Quality to enable identification of misdiagnosis of resistant organisms.
- Does the USCDI Level 2 and proposed USCDI+ Quality Date Medication Administered data element include the time the medication was administered? If not, we suggest adding Medications – Time Medication Administered to USCDI+ Quality to enable tracking of antibiotic usage, which is essential for assessing diagnostic error related to infections.

Recommended additions:

- We recommend adding data elements for lab results and imaging studies lost to follow up (LTFU) to USCDI+ Quality, to enable tracking details of potential adverse events associated with diagnostic testing.

Support:

- We support inclusion of Symptoms - Symptom in draft USCDI+ Quality and note this should not be limited to indications for medications, as tracking of symptoms—which may occur in combination and/or change over time--is essential to understanding the diagnostic process.

We appreciate the opportunity to provide comments on the draft USCDI+ Quality and would welcome further opportunity to work with ONC to advance diagnostic quality measures.

Sincerely,

Karen Cosby, MD
Program Director, Diagnostic Excellence Initiative