NATIONAL QUALITY FORUM
Driving measurable health improvements together

February 12, 2024

To: Micky Tripathi, Ph.D., M.P.P.
Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
330 C Street SW, 7th Floor
Washington, DC 20201

RE: Priority data element recommendations to measure and improve diagnosis quality

Dear Dr. Tripathi,

Thank you for the opportunity to provide comments and feedback on data elements for inclusion into United States Core Data for Interoperability (USCDI). Improving diagnostic quality and accuracy is a high priority for our health system as approximately 12 million adults are affected by missed or delayed diagnoses each year in the United States.[1,2] In this memo, we identify key data elements that aim to improve diagnostic quality and enhance measurement of the diagnostic process. Our findings are based on a review of diagnostic excellence measures developed to date, and our recommendations focus on advancing data elements not yet required in ONC Health IT Certification Programs (Certification Programs).

The National Quality Forum (NQF) is a not-for-profit, nonpartisan, membership-based organization that brings together highly diverse experts with unique healthcare quality and safety perspectives to develop consensus-based standards and recommendations to eliminate avoidable healthcare harms and advance optimal patient health outcomes, equity, and affordability. A variety of value-based programs in both the public and private sectors rely on NQF's work to forge quality measurement and improve standards and practices.

Supported by a 3-year grant from the Gordon and Betty Moore Foundation (the Moore Foundation), the National Quality Forum is working with experts and stakeholders to advance measurement of diagnostic excellence. A key aim of the project is to identify priority data elements for interoperability to better support diagnostic excellence measurement. As a first step, NQF has identified priority data elements by reviewing more than 40 diagnostic excellence quality measures developed by Moore Foundation grantees for use in national accountability programs. Overall, we identified 40 data elements across nine data classes that we believe are an essential start to measuring and improving diagnostic quality. These priority data elements support patient care and facilitate broader applications across various contexts, aligning well with ONC's primary use cases.

Recommendations

We are pleased to provide evidence-based recommendations for high priority interoperable data elements that play a pivotal role in the evaluation of diagnostic excellence. These recommendations support the National Academy of Medicine's (NAM) request that ONC take a leading role in advancing

interoperability of the patient data needed to improve the diagnostic process across care settings[3]. While the HITECH Act and the 21st Century Cures Act aimed to promote health information technology adoption and reduce medical errors, additional data standardization and interoperability are still necessary for advancing diagnostic quality.

The data elements identified by NQF as supporting diagnostic excellence are in various stages of maturity and not all of them are available or mandatory to the same extent within the Certification Programs. Of those identified, 15 percent are already required to be interoperable under the 21st Century Cures Act Final Rule, and an additional 45 percent of the data elements will be required to be interoperable by January 1, 2026, under the recent HTI-1 rule. Another 40 percent of the data elements, however, will require ONC's further advancement through the standards version advancement process (SVAP) and rulemaking, and other related processes such as the development of supporting implementation guide content.

The attached appendix groups our data element-level findings and recommendations that support diagnostic excellence into three tables based on their availability and required use in the Certification Programs: data elements that are currently required in Certification Programs or will be required by January 1, 2026; data elements that are not yet required in Certification Programs, but are available in USCDI Version 4; and data elements that are not yet required in Certification Programs, or available in USCDI, but are recommended as future requirements via an expansion of USCDI or Certification Programs. Given the demonstrated use of and need for these data elements to improve healthcare, we recommend ONC accelerate advancement of the identified data elements in Tables 2 and 3. We summarize the recommendations here and present the individual data-element level recommendations and rationale in the Appendix.

1. Table 1: NQF recommended data elements to measure and improve diagnosis quality – required in Certification Programs
    a. This table contains data elements identified by NQF as improving diagnosis and measuring diagnostic quality required in Certification Programs. We are encouraged to see that 60 percent of all the interoperable data elements identified by NQF to support diagnostic excellence are already required or are soon to be required as part of Certification Programs. Requiring interoperability for these data elements represents a significant stride forward in diagnostic measurement, and NQF supports ONC's recent effort to finalize and adopt the HTI-1 rule, which we believe will close many gaps in the evaluation of diagnostic excellence.
2. Table 2: NQF recommended data elements to measure and improve diagnosis quality - NOT required in Certification Programs
    a. This table contains data elements that are not yet required in Certification Programs but are included in USCDI Version 4. For each data element, we state how including the element will support diagnostic excellence. **NQF recommends** that ONC include these data elements in its upcoming SVAP requirements to further support diagnostic excellence.
3. Table 3: NQF recommended data elements to measure and improve diagnosis quality – proposed for inclusion in future Certification Programs
    a. This table contains the remaining data elements that are not yet included in published versions of USCDI or required in any Certification Programs. We describe each data element and note how it will support diagnostic excellence. Additionally, to inform the standards advancement process, we document each data element's level of applicability by or enforcement in US Core version 6.1.0 (i.e., supported, available as an option, or

not present) within a relevant FHIR (Fast Healthcare Interoperability Resources) profile. Additionally, we indicate where some data elements have previously been submitted to USCDI for comment by others. To address the remaining gaps to measure and improve diagnosis quality, **NQF recommends** this initial set of data elements be accelerated into future Certification Programs to support diagnostic excellence..

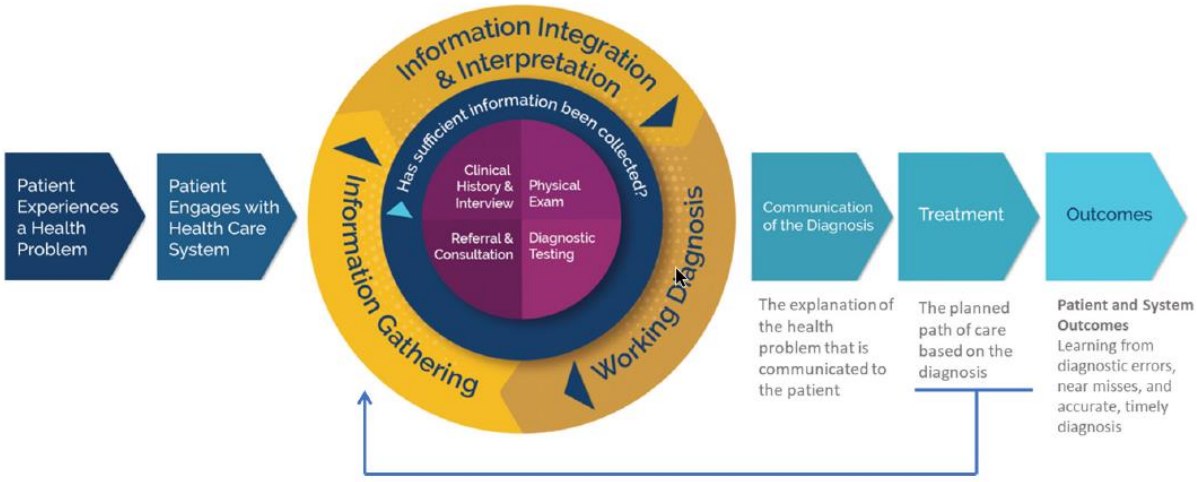
Below we provide additional background supporting these recommendations and further describe the methods we used to generate them.

The critical role of interoperable data in measuring and achieving diagnostic excellence

Diagnostic excellence has been recently defined as **"***an optimal process to attain an accurate and precise explanation about a patient's condition that is timely, cost-effective, convenient, and understandable to the patient*."[3,4] To holistically assess diagnostic quality, it is necessary to collect information on the evidence-gathering process across multiple quality domains of diagnosis, including accuracy, timeliness, and patients' understanding of the diagnosis presented to them. Hence, measuring and improving diagnoses requires aggregating a range of standardized, interoperable data. Measure development work to date has helped identify the specific data needs. Standardizing and advancing key elements through Certification Program requirements are critical for improving diagnostic quality.

Lack of diagnostic excellence leads to errors and high costs.[3,5,6,7] Despite efforts to improve timely and accurate diagnoses, diagnostic errors and associated adverse event rates remain high and represent a major, persistent quality gap.[8,9,10] In the United States, missed and delayed diagnoses remain a formidable healthcare challenge, leading to an estimated 795,000 premature deaths or serious permanent disabilities annually[6] and exerting a significant financial burden on the healthcare system.[7] These diagnostic errors contribute significantly to adverse health outcomes, including prolonged illnesses, unnecessary treatments, and preventable deaths.[6] These figures underscore the urgency of addressing and mitigating the impact of missed and delayed diagnoses on both patient well-being and the overall healthcare system in the United States.

The diagnostic journey is a complex and challenging process that can span multiple care settings or providers and require extensive data integration.[8,11,12] Key barriers in the end-to-end diagnostic journey include lack of specificity in data standards and system fragmentation (i.e., not having the right diagnostic data available at the right time to make the best diagnostic decision), challenges that can be improved by policies requiring data harmonization and interoperability.[9] The National Academy of Medicine's conceptual framework of the diagnostic process included in its landmark report, *Improving Diagnoses in Health Care,*[3] illustrates the steps in the diagnostic process. The diagram below presents the framework. It shows that the information gathering process extends across multiple care settings and across time and suggests the multiple contexts in which improved and more interoperable data can enhance the diagnostic process. Interoperable data can better facilitate information gathering from the onset of the health problem and support its integrating throughout the diagnostic process. The Moore Foundation-funded measures of diagnostic excellence we reviewed spanned many components of the process, creating a rich but not exhaustive set of use cases that we used to prioritize data elements for measurement of diagnostic excellence.



National Academies of Sciences, Engineering, and Medicine. 2015. Improving Diagnosis in Health Care. Washington, DC: The National Academies Press. https://doi.org/10.17226/21794

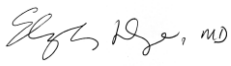
Approach to quality measure-driven identification of data element needs

NQF analyzed more than 40 diagnostic-excellence-related healthcare measures prepared by Moore Foundation-funded developers to extract key healthcare concepts for evaluating diagnostic excellence. We extracted healthcare data and concepts from each measure's specifications (e.g., the inclusion and exclusion criteria, cohort definition, process or outcome measured, code sets, and providers and settings targeted for measurement). We inventoried data elements and specific logic where available, noting the terminologies necessary for the measure's use. When the measure was defined at a more conceptual level, we semantically mapped the measure concepts to data standards. We then mapped the identified data to data elements in existing healthcare IT standards, including multiple versions of USCDI and Fast Healthcare Interoperability Resource (FHIR)[C]. And lastly, to understand the status of each data element under regulatory initiatives for health IT certification, we cross-referenced the versions of healthcare IT standards with those referenced in ONC regulations to identify any gaps for ONC to address. We identified 40 data elements across nine different data classes, and then sorted them into three different tables based on their level of requirement within Certification Programs.

Conclusion

NQF has identified an initial set of priority data elements that, if standardized and made interoperable, will promote improving patient diagnoses and diagnostic quality measurement. We recommend ONC advance the data elements identified in Tables 2 and 3 through the expansion of USCDI, USCDI+, and future Certification Program requirements. We thank ONC for its collaborative efforts in advancing data standards that improve healthcare interoperability and health thus far and considering these recommendations. As our multi-year project progresses, we will share subsequent recommendations for standards advancement with ONC and the broader standards community. Our project committee members and other collaborators have begun to identify other standards advancement concepts that are important for evaluating and making diagnoses, including symptoms and patient preferences, and we look forward to sharing these with you. Finally, we want to express our appreciation for the Gordon and Betty Moore Foundation for supporting this work.

Sincerely,



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Appendix A:

Table 1: NQF recommended data elements to measure and improve diagnosis quality – required in Certification Programs

Data Class	Data Element	Included in USCDI Version	Date Required
Laboratory	**Tests**	USCDI v1	December 31, 2022
Laboratory	**Values/Results**		
Medications	**Medications**		
Patient	**Date of Birth**		
Problems	**Problems**		
Procedures	**Procedures**		
Care Team Member(s)	**Care Team Member Identifier**	USCDI v3	January 1, 2026
Care Team Member(s)	**Care Team Member Role**		
Clinical Tests	**Test**		
Clinical Tests	**Result/Report**		
Clinical Test	**Category** (*via US Core)		
Diagnostic Imaging	**Test**		
Diagnostic Imaging	**Category** (*via US Core)		
Diagnostic Imaging	**Result/Report**		
Diagnostic Imaging	**Timing** (*via US Core)		
Encounter	**Diagnosis**		
Encounter	**Disposition**		
Encounter	**Time**		
Encounter	**Type**		
Encounter	**Class (*via US Core)**		
Medications	**Indication**		
Patient	**Date of Death**		
Problems	**Date of Diagnosis**		
Problems	**Date of Resolution**		
Procedures	**Reason for Referral**		

** Not a data element included in USCDI*

Table 2: NQF recommended data elements to measure and improve diagnosis quality - NOT yet required in Certification Programs

Data Class	Data Element	Rationale supporting diagnostic excellence	USCDI Version
Laboratory	**Result Status**	Promotes accurate and timely diagnosis	Included in USCDI Version 4
Laboratory	**Result Reference Range**	Promotes accurate and timely diagnosis	
Laboratory	**Interpretation**	Promotes accurate and timely diagnosis	
Medication	**Adherence**	Evaluates patient understanding across the diagnostic journey	
Medication	**Indication**	Promotes accurate and timely diagnosis	

Table 3: NQF recommended data elements to measure and improve diagnosis quality – proposed as requirements in future Certification Programs

Proposed Data Class	Proposed Data Element	Description[13]	Rationale supporting diagnostic excellence	Applicable Profile in FHIR US Core v6.1.0
Care Team Member(s)	**Care Team Member Specialty**	Specific specialty of the practitioner	Establishes context of care delivery	Supported in **Practitioner Role**
Clinical Test	**Timing**	The date/time the test was conducted	Promotes accurate and timely diagnosis	Supported in **Observation Clinical Result**
Encounter	**Diagnosis Use**	Role that the diagnosis has within the encounter (e.g., admission, billing, discharge)	Establishes context of care delivery	Available in **Encounter**
Encounter	**Diagnosis Rank**	Ranking of the diagnosis (for each role type)	Establishes context of care delivery	Available in **Encounter**
Encounter	**Hospitalization Admit Source**	From where the patient was admitted (e.g., transfer, physician referral)	Establishes context of care delivery	Available in **Encounter**
Laboratory	**Timing** *USCDI (L-2) Comment*	The date/time the test was collected	Promotes accurate and timely diagnosis	Supported in **Laboratory Result Observation**
Medications	**Administration** *USCDI (L-2) Comment*	When a patient consumes a medicine, or it is otherwise administered to them	Promotes accurate and timely diagnosis	Not Present
Problems	**Problem Status/Clinical Status**	The status of the problem (e.g., active, resolved, remission)	Promotes accurate and timely diagnosis	Supported in **Condition**
Problems	**Stage** *USCDI (L-0) Comment*	Clinical stage of a condition (e.g., stage 3)	Enables identification of missed or delayed diagnosis	Available in **Condition**
Problems	**Stage Type** *USCDI (L-0) Comment*	Kind of staging (e.g., clinical, or pathological)	Enables identification of missed or delayed diagnosis	Available in **Condition**

Appendix B:

Advancing Measurement of Diagnostic Excellence Committee

This multistakeholder committee achieves broad representation across the field of diagnostic excellence by including individuals with expertise and knowledge in diagnostic excellence quality measure development, diagnostic excellence research, health equity related to diagnostic excellence, health information technology and interoperability, the diagnostic process from the perspective of a patient or caregiver, patient registries, and patient safety.

Matt Austin, PhD
Associate Professor, Johns Hopkins Armstrong Institute for Patient Safety and Quality
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Professor of Emergency Medicine and Pediatrics, Chief of Pediatric EM at University of Michigan
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Jennifer Woodward, MD, MPH
Medical Director, Quality & Performance Measurement, American Academy of Family Physicians
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Ronald Wyatt, MD, MHA
Chief Science Officer and Chief Medical Officer, Society to Improve Diagnosis in Medicine
Orange Beach, Alabama

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