



November 10, 2022

Micky Tripathi, Ph.D., M.P.P.
National Coordinator for Health Information Technology
Department of Health & Human Services (HHS)
300 C Street, SW
Washington, DC 20201

Dear Dr. Tripathi:

The Health Information Technology Advisory Committee (HITAC) asked the Public Health Data Systems Task Force to build upon recommendations from previous HITAC public health-focused task forces to inform ONC's continued collaborative work with CDC on improving public health data systems, and in support of CDC's greater Data Modernization Initiative (DMI) efforts.

This transmittal letters offers the final report from the HITAC with recommendations therein which are hereby submitted to you for your consideration.

Respectfully submitted,

<i>Aaron Miri</i>	<i>Denise Webb</i>
/s/	/s/
Aaron Miri Co-chair, Health Information Technology Advisory Committee	Denise Webb Co-chair, Health Information Technology Advisory Committee





Final Report of the Health Information Technology Advisory Committee on Public Health Data Systems

Submitted to the Office of the National Coordinator for
Health IT on November 10, 2022



Table of Contents

Background	3
Charge	3
Overarching Charge:	3
Specific Charge:	3
Additional Background Information	3
Definitions	4
Recommendations	5
Introduction	5
List of Recommendations	7
General Recommendations	7
Recommendations on New Standards, Implementation Guidance, and Certification Criteria	10
(f)(1) - Transmission to Immunization Registries.....	13
(f)(2) - Transmission to Public Health Agencies – Syndromic Surveillance	14
(f)(3) - Transmission to Public Health Agencies – Reportable Laboratory Tests and Value/Results.....	14
(f)(4) - Transmission to Cancer Registries.....	17
(f)(5) - Transmission to Public Health Agencies - Electronic Case Reporting.....	17
(f)(6) - Transmission to Public Health Agencies - Antimicrobial Use And Resistance Reporting	19
(f)(7) - Transmission to Public Health Agencies - Health Care Surveys	19
Appendix A – Rosters	20
Task Force Members	20
Presenter Roster	21



Background

CHARGE

Overarching Charge:

The Public Health Data Systems Task Force 2022 will build upon recommendations from previous HITAC public health-focused task forces to inform ONC’s continued collaborative work with CDC on improving public health data systems, and in support of CDC’s greater Data Modernization Initiative (DMI) efforts.

Specific Charge:

The Public Health Data Systems Task Force 2022 shall examine existing public health certification criterion, known as the “(f) criteria” in the ONC Health IT Certification Program, certifying the transmission of data to public health agencies to:

Identify gaps in the functionalities and standards included in existing (f) criteria, including gaps in 1) functionality, and 2) implementation by developers. Provide recommendations advancing criteria, testing guidance, and/or standards to address gaps.

Assess the specific functions (e.g., receipt of data, ingestion of data, analysis of data) supported by public health data systems that would benefit from further standardization and potential certification.

Recommend which data flows, aligned with existing (f) criteria, should be prioritized for standardized receipt of data.

ADDITIONAL BACKGROUND INFORMATION

Recommendations within the HITAC are intended to both directly inform the Certification Program and to inform decisions made within the Centers for Disease Control and Prevention’s (CDC’s) Data Modernization Initiative (DMI).

Several points regarding the structure of the Certification Program are important to mention to provide background for recommendations within the report. The Certification Program is a voluntary certification program established by the ONC to provide for the certification of health IT. Requirements for certification are established by standards, implementation specifications and certification criteria adopted by the Secretary at the Department of Health and Human Services (HHS). The Certification Program supports the availability of certified health IT for its encouraged and required use under other federal, state and private programs. To date, the existing criteria certifying the transmission of data to public health supports measures for public health reporting within the Promoting Interoperability (PI) Programs (previously Medicare and Medicaid EHR Incentive Programs) administered by the Centers for Medicare & Medicaid Services (CMS). Similar incentives or requirements will need to be considered for any new criteria proposed within this report.

The CDC Data Modernization Initiative is a multi-year initiative to modernize core data and surveillance infrastructure across the federal and state public health landscape. The recommendations made within this



report may be used to support efforts within DMI, at the discretion of the National Coordinator. To inform DMI strategy, the [CDC's Advisory Committee to the Director \(ACD\), Data Surveillance Workgroup \(DSW\)](#) recently was tasked with examining a number of questions relevant to nationwide public health data exchange. Specific questions regarding policy, funding, and sustainability may complement recommendations made within this transmittal letter.

The Task Force held 12 meetings between August 25, 2022, and November 7, 2022. A range of different partners were consulted by the Task Force as a part of deliberations, with particular focus on representatives from STLT Public Health Agencies and their partner organizations. A total of nine subject matter expertise hearings were held, with seven meetings focused on collecting information on data flows aligned with existing (f) criterion (see Appendix A for the complete presenter roster). Technology vendors, including those technologies used by public health agencies, also provided input as a part of forming recommendations presented within this report.

DEFINITIONS

Please note that we refer in this document to “Public Health Authorities” This term is understood to be inclusive of:

State, Territorial, Local, and Tribal Public Health Authorities, as defined under Federal regulation (e.g., 45 CFR § 164.501), in whom public health authority primarily rests

Where we use the term “Public Health Authorities and their partner organizations” we mean “Public Health Authorities” as defined above and additionally include

Public health partner and advocacy organizations such as CSTE, ASTHO, NACCHO, APHL, AIRA, and others as identified by the Public Health Authorities.

Where we use the term “provider” we mean the definition provided in 42 U.S. Code § 300jj.

Where we use the term “Public Health Technology” we mean any technology component used, deployed, provisioned or consumed as a service by a public health authority to address the public health mission. As noted in our detailed recommendations, we believe that certification approaches used for public health data systems should be modular (independent of technology vendor), inclusive of services and intermediaries, focused on interoperability, and flexible so as to allow Public Health Authorities to select the system, using Certified Public Health Technology, that best meets their functional needs and program requirements while preserving a baseline floor level of interoperability consistent with achieving the public health mission.

Where the term “modular certification,” is used we mean that a technology being certified is able to certify to a single criterion within its scope, rather than be obliged to certify to a specific group of criteria beyond their scope. However, the combination of technologies deployed would need to conform to the full scope of the criteria, rather than an isolated aspect of a criterion. We also intend certification that is aligned with the SVAP¹ in order to enable technology developers’ ability to incorporate newer versions of Secretary-adopted standards and implementation specifications.

¹ <https://www.healthit.gov/topic/standards-version-advancement-process-svap>



Recommendations

INTRODUCTION

The experience during the COVID-19 pandemic highlighted the need for a robust ONC Health IT Certification Program (Certification Program) to support public health response. Although end-to-end public data flows were imperfect, many public health jurisdictions had comprehensive electronic laboratory reporting for reportable conditions, flexible surveillance systems to support case investigations, immunization registries to track COVID-19 immunizations in close to real time, and syndromic surveillance data for situational awareness. While case reporting early in the pandemic was primarily manual and clinician-based, early work on and live testing of electronic case reporting (eCR) demonstrated the utility of eCR. Jurisdictions that had access to eCR experienced rapid and timely case notifications. At the same time, well publicized data gaps remained, and the successes achieved within the public health surveillance infrastructure were achieved through massive effort and critical federal investment. It is necessary to continue to build on the success patterns of a digital public health infrastructure by improving public health data flows across the health ecosystem.

The certification of health IT, including electronic health record (EHR) technology, for use by health care providers and others was developed as a federal program through the Health Information Technology for Economic and Clinical Health (HITECH) Act. The ONC Health IT Certification Program ensures that certified health IT conform to specific functions and technical data and implementation standards, including the ability to produce messages that are nominally compliant with specified message formats used to transmit data to state, tribal, local and territorial (STLT) Public Health Authorities and to some federal government agencies. The Certification Program, however, has not included real-world testing criteria and content, nor testing of the ability of systems to successfully receive and utilize the data. Further, the Certification Program does not require the use of a validator for messages formed by deployed systems that are operating in real-world conditions.

Health care providers are concerned about their efforts to efficiently report data to public health and seek to leverage the investment in EHR technologies to reduce manual activities regarding data reporting. Additionally, providers would prefer that there be minimal customization of reporting to different Public Health Authorities.

Similar to specialties within health care, which may rely on different sets of data regarding a patient (e.g., oncology, podiatry, obstetrics) to manage a patient's care, public health also has specialties and different functions that require and utilize different data (e.g., infectious disease response, maternal and child health, mortality, immunizations, cancer registries, birth defects). A singular, limited set of data cannot be used in either public health or health care to meet all programs' requirements. As a result, each practice area has developed a dataset of critical information related to the problem, and needs those data, in a standardized format, to best meet the public health mission. Public health needs to receive the relevant data and in the correct format from health care providers, to be able to efficiently use the data for public health purposes and to support timely, data-driven decision-making. The inability of providers' systems to efficiently supply data can further create a manual reporting burden on providers.



Recent experience with Zika, COVID-19 and Monkeypox have highlighted the needs to address health disparities and address the unique public health needs of specific populations. In practice, we have discovered that the data required to implement health equity by design is not collected at source or not transmitted to Public Health Authorities.

The gaps in real-world testing and certification of providers' EHRs and the absence of any certification of technologies used to receive data are believed to contribute to significant issues regarding data quality and completeness in the exchange of data between information systems used by Public Health Authorities and health care providers.

The HITAC recommends that ONC establish certification criteria for technologies used by public health, focused on the certification of interoperability functions such as the exchange, access and use (inclusive of response to/acknowledgement) of (as appropriate) both correctly and not-correctly formatted/complete messages that are efficient (do not require "special effort") and effective (provides a common floor that addresses the relevant needs of the public health mission). We do not recommend certifying other functions and behavioral attributes of public health data systems outside of interoperability functions, nor do we recommend certifying the programs of Public Health Authorities.

Where the HITAC makes comments on the specifics of the (f) criteria in the Certification Program, we are aware that the HITAC has already made recent recommendations to the National Coordinator by adopting the Adopted Standards Task Force 2022 recommendations; we note that the charge of that task force (to "maintain or phase out") standards and those underlying this task force and these recommendations are different. Differences in recommendations related to specific versions of standards are due to this report focusing forward on standards, implementation guidance and certification criteria underlying public health data technology and modernization.

We recognize that the public health responsibilities rest with STLT Public Health Authorities, as created and directed by STLT governments and federal law. Accordingly, the intent of certification criteria for public health technologies is not to limit or circumscribe public health or STLT authority to request and receive in the manner it specifies to fulfill the authority's missions or address emergent needs. Rather, the goal of certification criteria for public health technologies is to create a common floor to support the exchange of data inclusive of all providers and public health inclusive of the methods by which data are primarily electronically exchanged by Public Health Authorities. A properly constructed common floor, supported by robust certification criteria for public health technologies and compliance with submitted message formatting and completeness requirements, will assist the health care system and Public Health Authorities to address the missions of public health at lower overall burden and reduced special effort and will support common local jurisdictional variation through well-defined profiles. The HITAC recognizes the need for standards or technologies adopted through Standards Version Advancement Process (SVAP) to support backwards compatibility to ensure interoperability.

These recommendations are put forth under the assumption that resources will be provided to STLT Public Health Authorities to achieve and maintain certification of the relevant technologies. As described in the [Public Health Information and Technology Infrastructure Modernization Funding Report HIMSS report](#), the public health infrastructure requires significant investment and support for the certification of public health technologies and will necessitate new and robust funding specifically designated for this purpose. As such, the HITAC recommends that ONC work with federal partners, Public Health Authorities and their partner



organizations, technology developers and partners, and other entities to establish a cost estimate and funding schedule for this work.

LIST OF RECOMMENDATIONS

General Recommendations

We here provide a number of recommendations that are foundational, overarching or cut across specific discussion of existing (f) criteria.

Public Health Data Systems-TF-2022_Recommendation 01

We **recommend** that ONC establish certification criteria for public health technologies used by Public Health Authorities in support of their responsibilities in exchanging data for public health purposes including those defined in the existing (f) criteria. These criteria and future certification criteria should be focused on interoperability functions, such as the ability to receive, consume, and respond to both properly and not-properly formatted and/or complete messages.

Public Health Data Systems-TF-2022_Recommendation 02

We **recommend** that ONC work with CDC and other Federal agencies to ensure that the certification criteria consider the timeline, disruption, effort and funding needs associated with technology modernization to achieve and maintain certification.

Public Health Data Systems-TF-2022_Recommendation 03

We **recommend** that ONC work with CDC, Public Health Authorities and their partner organizations, technology developers, provider organizations, and others to create a set of metrics and outcome measures associated with the ONC Certification Program. These metrics and outcome measures would be used to assess the impact associated with one time and ongoing efforts to establish and maintain interoperability and the effort required to achieve certification. Such metrics should be used to guide future modification and the expansion of certification criteria for public health technologies.

Public Health Data Systems-TF-2022_Recommendation 04

We **recommend** that any certification criteria of public health technologies be modular, align with the functionalities specified in the (f) criteria for other certified technology, and evolve in coordination with the overall certification program. That is, a public health technology used by a public health authority or partner does not need to be certified for use unless the public health authority is using that particular technology for a purpose for which certification is applicable. It should be noted that public health data systems may have multiple technologies and functions, and it is therefore necessary to certify the functionality, not the system itself. Any certification criteria must provide Public Health Authorities with maximum flexibility in selecting and implementing certified technology. These technologies may be owned or managed by the public health authority, shared between and among Public Health Authorities, or consumed as a service, and/or through intermediaries such as Health Information Exchanges (HIEs)/Health Information Networks (HINs), Association of Public Health Laboratories (APHL), and others, according to the legal, policy and procurement practices, and rules governing public health data systems in the relevant jurisdictions.



Pathways to use certified technology should include the use of third-party testers as well as the capability of Public Health Authorities to self-certify. Both must utilize the common set of testing criteria.

Public Health Data Systems-TF-2022_Recommendation 05

We **recommend** that ONC work with Public Health Authorities and their partner organizations, standards development organizations, technology developers, and healthcare providers to ensure that data used in (f) criteria standards and implementation guides reference standardized code and value sets.

Public Health Data Systems-TF-2022_Recommendation 06

We **recommend** that in order to improve patient matching capabilities, demographic, contact and address information must be aligned across the different standards development organizations and inclusive of common standards such as Project US@.

Public Health Data Systems-TF-2022_Recommendation 07

We further **recommend** that ONC work across Federal agencies and standards development organizations to specify value sets (and data element phrasing) for all data elements included in USCDI and ensure alignment across the different standards.

Public Health Data Systems-TF-2022_Recommendation 08

The Task Force heard testimony that provider health information technology systems did not consistently produce satisfactory data when technology has been deployed in the field. When the versions of value sets in use by provider organizations differ from those in use by Public Health Authorities, this limits the ability of EHRs to correctly send high-quality, accurate, timely, and complete messages and the ability of Public Health Authorities to successfully consume messages. Accordingly:

We **recommend** that ONC include in the Certification Program the demonstrated ability of technologies to include and regularly update relevant standardized value sets without special effort. For computable semantic interoperability, technologies must adopt standardized vocabularies and terminologies. For example, for ELR and eCR to provide consistent quality data, technologies need to utilize LOINC/SNOMED-CT specifically, as both are used by the Reportable Conditions Knowledge Management System (RCKMS) for trigger codes.

Public Health Data Systems-TF-2022_Recommendation 09

We **recommend** that the ONC coordinate with other Federal Agencies to include incentives for all relevant actors to adopt certified technology, for example, creating the provision of both LOINC coded test names and SNOMED coded result data.

Public Health Data Systems-TF-2022_Recommendation 10

We **recommend** that ONC, in conjunction with relevant partners including Public Health Authorities and their partner organizations, create operating rules for timely updating of such value sets supportive of public health reporting.



Public Health Data Systems-TF-2022_Recommendation 11

We **recommend** that ONC work with Federal partners to create incentives that encourage provider organizations and Public Health Authorities to adhere to validated operating rules for timely updating of value sets.

Public Health Data Systems-TF-2022_Recommendation 12

We **recommend** that ONC work with Public Health Authorities and partner organizations, CDC, other Federal Agencies, providers, and standards development organizations including, but not limited to HL7, to update and align the relevant HL7 v2, C-CDA, FHIR based implementation, and other guidance to reflect updates to the latest SVAP version of USCDI relevant to public health, inclusive of SDOH and SOGI data included in the USCDI. Ongoing development of USCDI and/or USCDI+ should consider the needs of public health inclusive of the exchange of structured information. As part of this alignment, we **recommend** that ONC work with Public Health Authorities and their partner organizations to ensure that standards and implementation guidance addresses predictable policy-based jurisdictional variation in data needs and requirements in order to then update certification criteria to include support for those changes.

Public Health Data Systems-TF-2022_Recommendation 13

As public health seeks to better track the health of populations and identify health equity issues:

We **recommend** that ONC work with the Office of Management and Budget (OMB), CDC, and Public Health Authorities and partner organizations, technology developers, providers, and standards development organizations, to develop a race/ethnicity value set mapped to a vocabulary that is more granular than the current OMB set historically used by public health, and satisfies jurisdictional requirements, without creating an unnecessary burden on providers, public health, and patients, and ensuing high-quality, accurate data are recorded. In particular, Tribal or Alaska Native affiliation needs future consultation with the sovereign authorities. Although outside of our charge, any change must be reflected across all government programs utilizing these standards, including the US Census and any other program collecting race/ethnicity data.

Public Health Data Systems-TF-2022_Recommendation 14

Because of Public Health Authorities' ability to define minimum needed data to support public health reporting, it should be recognized that local interoperability established with STLT Public Health Authorities may require support for data elements currently designated as "optional" according to conformance requirements in the referenced standards. Therefore:

We **recommend** that certification programs utilize a core set of minimum data elements, as well as a pre-identified common subset of optional data elements, to be defined and agreed to by STLT Public Health Authorities and their public health partners and CDC, to ensure the inclusion of minimum necessary data needed for public health reporting and response. These minimum data elements will necessarily vary by (f) criteria as appropriate.



Public Health Data Systems-TF-2022_Recommendation 15

We **recommend** that ONC work with Public Health Authorities and their partner organizations, health care providers, technology developers, and other key partners to develop certification criteria and testing methodologies that close the gap between technologies as certified and real-world testing situations that include both the ideal (“Happy Path”) and the imperfect. Certification processes should include testing against public health-defined use cases and establish a minimum threshold for conformance inclusive of values marked as “Optional” that are relevant and critical to the public health mission as defined by Public Health Authorities and their partner agencies. Test scenarios should account for missing source data, data missing from messages, non-compliant value sets and the semantics of data transmitted or received.

Public Health Data Systems-TF-2022_Recommendation 16

We additionally **recommend** that ONC establish real world, post-implementation testing to test for gaps between systems as certified and as implemented, especially in the use of local coding schemas mapped to code sets supporting interoperability and to identify opportunities to close real-world data gaps.

Public Health Data Systems-TF-2022_Recommendation 17

We **recommend** that ONC, in collaboration with Public Health Authorities and their partner organizations, review existing standards and implementation guidance to address harmonization and use across separate data flows, where data eventually need to be integrated and used together by Public Health Authorities.

Recommendations on New Standards, Implementation Guidance, and Certification Criteria

In addition to the existing (f) criteria, the HITAC believes other standards, implementation guidance and certification criteria are important to help public health receive data efficiently and effectively.

Public Health Data Systems-TF-2022_Recommendation 18

We **recommend** that ONC convene Public Health Authorities and their partner organizations, additional disaster preparedness and response experts, technology developers, health care providers, and others to develop a comprehensive approach with standards and implementation guidance that defines relevant data sets and elements for situational awareness. Subsequent to development and testing, the HITAC believes this would be an appropriate avenue for future certification (potentially adding new target systems for certification, such as inventory management). For background purposes, we note the current development of the SANER implementation guide and expected HL7 FHIR R5 based alignment of the HL7 SANER and DEQM guides currently being used for early pilot and proof of concept efforts.

Public Health Data Systems-TF-2022_Recommendation 19

We **recommend** that ONC coordinate with Public Health Authorities and their partner organizations, technology developers, and standards development organizations to advance standards and implementation guidance for the exchange of timely, accurate, and high-quality data used by public health to produce vital statistics, such as identifiable, line-level birth and death data. The technical standards for the successful and complete exchange of data are separate from legal and policy guidance reflecting data availability.



Public Health Data Systems-TF-2022_Recommendation 20

We **recommend** that newborn blood spot screening is another opportunity for the expansion of standards and implementation guidance to be recognized in Federal Regulations and eventually supported through certification. This certification may be tied directly to other lab-related certification both by senders of test requests, including hospitals, birthing centers, and other entities attending births and collecting samples and laboratories that conduct relevant testing, including but not limited to public health laboratories.

Public Health Data Systems-TF-2022_Recommendation 21

We **recommend** similar development of standards, implementation guidance and eventual criteria should be developed for other newborn screening services, such as audiology. Here again, eventual certification criteria should apply both to technologies sending messages and those technologies responsible for receiving messages.

Public Health Data Systems-TF-2022_Recommendation 22

We **recommend** that ONC work with Public Health Authorities and their partner organizations, the Recognized Coordinating Entity (RCE), Qualified Health Information Networks (QHINs), QHIN participants and sub-participants, including provider organizations and their technology developers, to develop, publish and test an implementation guide for secure and privacy sensitive Trusted Exchange Framework (TEF) queries to support public health case investigation beyond the data already submitted through already defined reporting mechanisms. These queries can take advantage of the anticipated comprehensive record location capabilities across QHINs as specified in the TEF QHIN Technical Framework enabling access to a patient's complete record across multiple providers participating in TEF.

Public Health Data Systems-TF-2022_Recommendation 23

We **recommend** that ONC, subsequent to testing the implementation guide for public health TEF query, establish certification criteria for public health TEF query, inclusive of the major actors who could participate in such queries (public health technology, QHINs or local HIEs, and EHRs). Certification requirements must include both public health's ability to generate and receive data as well as all potential respondents' ability to process and respond to said query.

We note that FHIR-based query may offer public health additional avenues to meet the needs of case investigation to supplement electronic case reporting and emerging public health threats. FHIR may support a more focused and relevant response by providers to meet public health queries, and further respect the requirements of Minimum Necessary under HIPAA. At the same time, we note that public health will need technical assistance and funding to transition to FHIR-based technologies.

Public Health Data Systems-TF-2022_Recommendation 24

We **recommend** that ONC work with Public Health Authorities and their partner organizations, EHR developers, standards development organizations and other relevant stakeholders to coordinate the development and testing of standards to enable public health to push notifications and further enable decision support in workflow in EHRs. Work in this area should build on early demonstrations for decision support for Zika, COVID-19, and antibiotic resistant infections, and consider present standards such as



CDS Hooks and address existing work for immunization forecasting in Immunization Information Systems (IIS).

Public Health Data Systems-TF-2022_Recommendation 25

We **recommend** that ONC work with Public Health Authorities and their partner organizations, standards development organizations (SDOs) and other key stakeholders to develop and test standards and implementation criteria that allow for transmission of data between Public Health Authorities.

Public Health Data Systems-TF-2022_Recommendation 26

We **recommend** that ONC work with other Federal Agencies to study and align public health interoperability for provider settings outside of current acute and ambulatory scopes that do not require or have incentive programs encouraging use of certified health IT. Specific settings of focus should include, but not be limited to, Long Term Post Acute Care (LTPAC), Pharmacies, Home and Community-based Services, and Behavioral Health.

Public Health Data Systems-TF-2022_Recommendation 27

There is broad federal and state variation of privacy and consent laws, policies, and policies; these often impact immunization registry workflows, but may also impact sensitive results or other privacy sensitive data captured as part of case investigation. Variance often causes complexity for health systems and technology developers that work across jurisdictions and impedes interjurisdictional data sharing. Therefore:

We **recommend** that ONC work with Public Health Authorities and their partner organizations to explore how Trusted Exchange Framework and Common Agreement (TEFCA)'s consent practices might be leveraged to enable sharing across jurisdictions and with Federal partners within established privacy/consent policies and directives.

Public Health Data Systems-TF-2022_Suggestion 01

The HITAC noted that policy variance among Public Health Authorities may create issues for provider organizations and technology developers that operate across jurisdictions. Without limiting the ability for Public Health Authorities to develop and enforce local policy, we note that where equivalent alternatives approaches achieve the same policy outcome, it is helpful to establish policy uniformity. At the same time, many relevant policies are enshrined in state or other jurisdictional law-making alignment non-trivial. While a significant set of the task force agreed on the following suggestions, we did not receive consensus on a final recommendation. Therefore:

We **suggest** that ONC coordinate with Public Health Authorities and their partners as well as CDC, providers, and technology developers to identify policy barriers that slow or impede data exchange in service of the public health mission. Where barriers are identified, we **suggest** that ONC coordinate the definition and promulgation of standard best practice policies that maximally enable interoperability to serve the public health mission.



(f)(1) - Transmission to Immunization Registries

Public Health Data Systems-TF-2022_Recommendation 28

The current (f)(1) certification criteria for immunization registries do not include transport standards and implementation guidance, despite the existence of a well adopted CDC implementation guide. Therefore:

We **recommend** that ONC coordinate with Public Health Authorities and their partner organizations, and technology developers to define certification criteria for immunization reporting and query/retrieve to the same standards. The certification criteria should include standard mechanisms for transport.

Public Health Data Systems-TF-2022_Recommendation 29

The HITAC noted that while the HIMSS-AIRA-IIP implementation guidance has driven down local variation in immunization reporting and query/retrieve, there is still some local variation associated with differential handling of local inventory control requirements and local consent policies. Therefore:

We **recommend** that ONC coordinate with Public Health Authorities and their partner agencies, technology developers, and standards development organizations to update the immunization implementation specifications and, if necessary, underlying standards, to better support predictable variation in inventory and consent requirements.

Public Health Data Systems-TF-2022_Recommendation 30

There are currently two test methods for the (f)(1) criteria. While the “2015 Edition Test Procedure” is the default test method, AIRA and HIMSS have aligned on a common test method that better addresses IIS interoperability and is available as an “Alternative” test method. New testing should use the common HIMSS-AIRA-IIP test methods. Therefore:

We **recommend** that ONC update the (f)(1) criteria to recognize the HIMSS-AIRA-IIP test method as the standard test method used for certification and deprecate the current primary test method.

Public Health Data Systems-TF-2022_Recommendation 31

We **recommend** that ONC, in collaboration with Public Health Authorities and their partner organizations, providers and technology developers review existing standards and implementation guidance for immunization query response and USCDI to ensure that immunization data can be efficiently and effectively incorporated into the patient record. This work should address patient identity and provenance data to enable EHRs to query for a complete immunization record across IIS registries and reconcile without special effort by clinicians.

Public Health Data Systems-TF-2022_Recommendation 32

The HITAC notes that different settings of care (e.g., primary care, hospitals, pharmacies, LTPAC, etc.) have different regulatory and policy requirements for timely updating of immunization registries. It would be helpful to have a standard policy floor for providing timely and accurate information to public health independent of care setting. Therefore:



We **recommend** that ONC coordinate with CDC and other Federal departments and agencies to establish consistent requirements (including appropriate incentives) for timely and accurate immunization registry reporting, while reducing reporting burden and complexities for providers.

Public Health Data Systems-TF-2022_Recommendation 33

The HITAC notes that [Immunization Gateway \(IZ Gateway\)](#) is a useful component in the immunization reporting landscape and may have a critical role to play in the transition to a modular certification approach to public health data systems. Therefore:

We **recommend** that ONC work with CDC to certify IZ Gateway via modular certification for Immunization reporting and query/retrieve.

(f)(2) - Transmission to Public Health Agencies – Syndromic Surveillance

Public Health Data Systems-TF-2022_Recommendation 34

We note that existing incentives to certify and deploy technology for syndromic surveillance is currently focused on Emergency Departments, but a broader syndromic surveillance net would capture potential signals from additional settings of care, including primary care, LTPAC, and urgent care, and would include inpatient events as well as ED-based events. Therefore:

We **recommend** that ONC work with CMS, CDC, Public Health Authorities and their partner organizations, and technology developers to expand the set of health IT systems to which certification is available and address appropriate incentives to adopt certified technology. In particular, we recommend syndromic surveillance certification of systems used in representative primary care, urgent care, inpatient acute care and LTPAC.

Public Health Data Systems-TF-2022_Recommendation 35

We **recommend** that ONC phase out and replace the reference to the version of the Syndromic Surveillance standard included in the Cures Act Final Rule and coordinate publication and maintenance of the most current version during the next relevant regulatory update. The HITAC specifically suggests collaborating with Public Health Authorities and their partner organizations, CDC, health care providers, and HL7 to determine whether the then most current version indeed provides sufficient updates to warrant a transition and that any transition plan addresses the availability of resources to ensure that both sending and receiving systems are capable of supporting any standards change. Similar to immunization messaging, some stakeholders may not utilize systems that incorporate certified health IT and, as such, do not receive automatic updates from vendors.

(f)(3) - Transmission to Public Health Agencies – Reportable Laboratory Tests and Value/Results

Public Health Data Systems-TF-2022_Recommendation 36

We **recommend** that ONC follow the relevant guidance provided by the Interoperability Standards Workgroup and approved by the full HITAC regarding laboratory orders and results, particularly those addressing:



- Transmission and receipt of orderables and results sufficient to trigger reporting criteria for eCR, ELR, transmission to cancer registries, and other key public health information flows
- Transmission of minimal demographic and contact information with orders sufficient to enable case investigation and record linking
- Comprehensive use and normalization at the source of key terminologies, including LOINC, SNOMED-CT, UCUM, UDI, and others relevant to public health data flows.
- Adoption of latest LOI and LRI implementation guides.

We note that addressing these concerns solely via certification of the ELR interface (laboratory to public health) does not address the upstream workflows where data necessary to the public health mission originates.

Public Health Data Systems-TF-2022_Recommendation 37

We **recommend** that ONC adopt certification criteria (supporting modular certification) of Public Health Technology to receive electronic laboratory results (ELR) with baseline and target syntax and semantic certification criteria as defined below:

- Baseline: Following the HL7 Version 2.5.1: Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 with Errata and Clarifications and ELR 2.5.1 Clarification Document for EHR Technology Certification, HL7® Version 2 Implementation Guide: Laboratory Value Set Companion Guide Release 1, STU Release 3 - US Realm HL7® Standard for Trial Use (June 2018).
- Target: HL7 Version 2.5.1: Implementation Guide: Laboratory Results Interface, Release 1, STU 4- US Realm.

Public Health Data Systems-TF-2022_Recommendation 38

We **recommend** that ONC adopt certification criteria (supporting modular certification) of technologies used by Laboratories (including Public Health Laboratories, and CLIA and CLIA-Waived laboratories) to send electronic laboratory results (ELR) with standard and advanced syntax and semantic certification criteria providing a path from current state (“Baseline”) to the target state as defined below:

- Baseline: Following the HL7 Version 2.5.1: Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 with Errata and Clarifications and ELR 2.5.1 Clarification Document for EHR Technology Certification, HL7® Version 2 Implementation Guide: Laboratory Value Set Companion Guide Release 1, STU Release 3 - US Realm HL7® Standard for Trial Use (June 2018).
- Target: HL7 Version 2.5.1: Implementation Guide: Laboratory Results Interface, Release 1, STU 4- US Realm.



Public Health Data Systems-TF-2022_Recommendation 39

We **recommend** that ONC update the Certification Program criteria for ELR (supporting modular certification) for EHR-related certified technology to send electronic laboratory results (ELR) with baseline and target syntax and semantic certification criteria as defined below:

- Baseline: Following the HL7 Version 2.5.1: Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 with Errata and Clarifications and ELR 2.5.1 Clarification Document for EHR Technology Certification, HL7® Version 2 Implementation Guide: Laboratory Value Set Companion Guide Release 1, STU Release 3 - US Realm HL7® Standard for Trial Use (June 2018).
- Target: HL7 Version 2.5.1: Implementation Guide: Laboratory Results Interface, Release 1, STU 4- US Realm.

Public Health Data Systems-TF-2022_Recommendation 40

We **recommend** that ONC adopt certification criteria for certified health IT to send electronic laboratory orders and receive electronic laboratory results with standard syntax and semantic certification criteria as defined below:

- Following HL7 Version 2.5.1 Implementation Guide: Laboratory Orders from EHR (LOI) Release 1, STU Release 3 - US Realm HL7 Standard for Trial Use May 2018, HL7 Version 2 Implementation Guide: Laboratory Value Set Companion Guide, Release 3 - US Realm, HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface, Release 1 STU Release 4 - US Realm

Public Health Data Systems-TF-2022_Recommendation 41

We note that many Public Health Authorities maintain web-based systems to collect electronic results data on behalf of small provider organizations or regional reference laboratories that are not able to send data electronically due to economic impracticalities. Therefore:

We **recommend** that certification criteria should be sufficiently flexible to certify such electronic results capturing systems.

Public Health Data Systems-TF-2022_Recommendation 42

We **recommend** that ONC add laboratory information technologies (e.g., Laboratory Information Management Systems (LIMS)/Laboratory Information Systems (LIS), and interface engines) and their supporting intermediaries and technologies to the list of certified health IT for which certification is available. We **recommend** that ONC adopt a certification criteria and work with other Federal Agencies including CMS (CLIA) for laboratory information technologies to receive electronic laboratory orders and send electronic results (to ordering provider and to public health via ELR) with standard syntax and semantic certification criteria as defined below:

- Following HL7 Version 2.5.1 Implementation Guide: Laboratory Orders from EHR (LOI) Release 1, STU Release 4 - US Realm, HL7 Version 2 Implementation Guide: Laboratory Value Set



Companion Guide, Release 2 - US Realm, HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface, Release 1 STU Release 4 - US Realm

Public Health Data Systems-TF-2022_Recommendation 43

In the current state, where eCR is in its early stages of adoption, ELR has to carry additional information to support case investigation. However, capturing this information on test order or at the performing laboratory may require updates to legacy systems and is burdensome. As eCR becomes more broadly deployed, much of the additional data needed for public health is more appropriately captured during a clinical encounter and better communicated through eCR; ELR data should be focused on the data set required for interpretation of the result as well as contextual demographic and contact information required for patient matching and jurisdictional assignment for follow up. Therefore:

We **recommend** that ONC support and coordinate with Public Health Authorities and their partner organizations, CDC, and SDOs to continue to delineate laboratory-based reporting from electronic case reporting. In a context where eCR is widely available, the ordering provider will often be the most appropriate to submit contextual data. Where laboratories perform walk-in testing, they also play the role of ordering provider and thus should use electronic case reporting for observations collected at the point of collection.

(f)(4) - Transmission to Cancer Registries

Public Health Data Systems-TF-2022_Recommendation 44

We **recommend** that ONC collaborate with Public Health Authorities receiving cancer data, public health professional organizations, CDC, NACCR, provider organizations, academic health centers, and research entities, regarding future, updated standards for the exchange of cancer-related information. For background purposes, we note that many advanced organizations report using PCORI or OMOP-based reference data models and that foundational work is being performed via MedMorph. It should also be noted that existent technologies used by public health and the National Cancer Institute may be leveraged to support cancer reporting to Public Health Authorities.

(f)(5) - Transmission to Public Health Agencies - Electronic Case Reporting

Public Health Data Systems-TF-2022_Recommendation 45

We **recommend** that ONC work with Public Health Authorities and their partner organizations, as well as SDOs and technology developers to ensure that certification criteria and associated test methods are robust enough to reduce and eventually eliminate paper-based reporting.

Public Health Data Systems-TF-2022_Recommendation 46

We **recommend** that ONC modify the existing certification criteria for case reporting to require certification to eCR and establish associated test methods.



Public Health Data Systems-TF-2022_Recommendation 47

We **recommend** a base set of capabilities for the transmission of an eICR following (at minimum) HL7 CDA® R2 Implementation Guide:

- Public Health Case Report - the Electronic Initial Case Report (eICR) Release 2 STU 3.1, and optionally following HL7 FHIR® Implementation Guide: Electronic Case Reporting (eCR) - US Realm.

Public Health Data Systems-TF-2022_Recommendation 48

We **recommend** that ONC adopt a certification program for health IT developers to receive and consume reportability responses from reporting of STLT reportable conditions with standard and advanced syntax and semantic certification criteria as defined below:

- Standard: Following HL7 CDA® R2 Implementation Guide: Reportability Response, Release 1, STU Release 3.1.1- US Realm
- Optional: Following HL7 FHIR Implementation Guide: Electronic Case Reporting (eCR) v1.0.0: STU 1 – US Realm (Balloted Draft)

Public Health Data Systems-TF-2022_Recommendation 49

We **recommend** that ONC adopt certification criteria for Public Health Technology to receive electronic initial case reports and send reportability responses for reporting of reportable conditions with syntax and semantic certification criteria as defined below:

- Target: Following HL7 CDA® R2 Implementation Guide: Public Health Case Report - the Electronic Initial Case Report (eICR) Release 2, STU Release 3.1 - US Realm, Following HL7 CDA® R2 Implementation Guide: Reportability Response, Release 1, STU Release 1.1- US Realm, or HL7 FHIR Implementation Guide: Electronic Case Reporting (eCR) v1.0.0: STU 1 – US Realm (Balloted Draft).

Public Health Data Systems-TF-2022_Recommendation 50

We **recommend** that ONC work with CDC, CMS, state Medicaid agencies, RCE, and Public Health Authorities and their partner organizations to establish a national organization directory including OIDs, national provider identifiers (following needed refinement to reduce overlap and redundancies), and other critical identifiers for relevant organizations/facilities enabling consistent use and lookup.

Public Health Data Systems-TF-2022_Recommendation 51

We **recommend** that ONC adopt a certification program for standard adoption of distribution of trigger codes to EHRs following the HL7 FHIR Implementation Guide: Electronic Case Reporting (eCR) v1.0.0: STU 1 – US Realm or then most current implementation guidance. Specifically, the direct electronic consumption of the eRSD for trigger code implementation in emergent and routine use should be included in certification.



Public Health Data Systems-TF-2022_Recommendation 52

We **recommend** that ONC develop a certification program of Public Health Technology relevant to reporting trigger code identification, maintenance and distribution accommodating both infectious and non-infectious (chronic) codes associated with STLT reportable conditions, events, or observations.

(f)(6) - Transmission to Public Health Agencies - Antimicrobial Use And Resistance Reporting

Public Health Data Systems-TF-2022_Recommendation 53

We **recommend** that ONC phase out and replace the reference to the version of the Healthcare Associated Infection Reports implementation guide included in the Cures Act Final Rule and consider adopting a reference to the then most current version during the next relevant regulatory update.

The HITAC notes that the version in the Cures Act Final Rule is not aligned with the version(s) that CDC's National Healthcare Safety Network (NHSN) requires for healthcare associated infection reports and suggests ONC collaborates with CDC and Public Health Authorities and their partner organizations to determine a single version, or set of versions, that can be used both for certification and bi-directional NHSN reporting inclusive of optional values. Until such alignment has been achieved, adoption of a newer version for certification is premature.

(f)(7) - Transmission to Public Health Agencies - Health Care Surveys

No recommendations not covered elsewhere.



Appendix A – Rosters

TASK FORCE MEMBERS

Name	Organization
Gillian Haney (Co-Chair)	Council of State and Territorial Epidemiologists (CSTE)
Arien Malec (Co-Chair)	Change Healthcare
Rachelle Boulton	Utah Department of Health and Human Services
Hans Buitendijk	Oracle Cerner
Heather Cooks-Sinclair	Austin Public Health
Erin Holt Coyne	Tennessee Department of Health
Charles Cross	Indian Health Service
Steven Eichner	Texas Department of State Health Services
Joe Gibson	CDC Foundation
Rajesh Godavarthi	MCG Health, part of the Hearst Health Network
Jim Jirjis	HCA Healthcare
John Kansky	Indiana Health Information Exchange
Bryant Karras	Washington State Department of Helath
Steven Lane	Health Gorilla
Jennifer Layden	CDC
Leslie Lenert	Medical University of South Carolina
Hung S. Luu	Children’s Health
Mark Marostica	Conduent Government Services
Aaron Miri	Baptist Health
Alex Mugge	CMS
Stephen Murphy	The Network for Public Health Law
Eliel Oliveira	Dell Medical School, University of Texas at Austin
Jamie Pina	Association of State and Territorial Health Officials (ASTHO)
Abby Sears	OCHIN
Vivian Singletary	Public Health Informatics Institute
Fillipe Southerland	Yardi Systems, Inc.
Sheryl Turney	Elevance Health



PRESENTER ROSTER

Presenter Name	Organization	Topic
Erin Holt Coyne	Tennessee Department of Health	Overall landscape/current state
Jim Jirjis	HCA	Overall landscape/current state
Jeff Smith	ONC	Overall landscape/current state
Daniel Weber	CDC	Overall landscape/current state
Paula Braun	CDC	Overview of Public Health Informatics Projects
Mary Beth Kurilo	AIRA	(f)(1) Immunization
Aaron Bieringer	Minnesota Department of Health	(f)(1) Immunization
Hans Buitendijk	HIMSS EHRA Chair	(f)(1) Immunization
Ann Kayser	Minnesota Department of Health	(f)(5) eCR
Laura Conn	CDC/CSELS/DHIS	(f)(5) eCR
David DiCesare	New York State Department of Public Health	(f)(3) ELR
Riki Merrick	APHL	(f)(3) ELR
Justin Nucci	Colorado Public Laboratory	(f)(3) ELR
Carmen Pugh	Labcorp	(f)(3) ELR
Prashant Gupta	Labcorp	(f)(3) ELR
Rosa Ergas	Massachusetts Department of Health	(f)(2) Syndromic
Karl Soetebier	CDC	(f)(2) Syndromic
Aaron Miri	Baptist Health	(f)(2) Syndromic
Peter Yu, MD	Hartford Healthcare Cancer Institute	(f)(4) Cancer Registries
Stephanie Hill	NAACCR	(f)(4) Cancer Registries
Jeremy Pine	California Cancer Registry	(f)(4) Cancer Registries
Nigar Salahuddin	North Carolina Cancer Registry	(f)(4) Cancer Registries
Chandrika Rao	North Carolina Cancer Registry	(f)(4) Cancer Registries
Hsiu Wu	CDC	(f)(6) Transmit antimicrobial
Christina Brandenburg	Minnesota Department of Health	(f)(6) Transmit antimicrobial
Carol DeFrances	CDC/NCHS	(f)(7) Transmit healthcare surveys
Craig Newman	Altarum	HL7 Public Health Work Groups
Stephen Murphy	Network for Public Health Law	Network for Public Health Law



Jennifer Layden	CDC, PHDSMI	Vendor/Industry Panel
Tarun Khatri	Conduent Government Services	Vendor/Industry Panel
Kristina Crane	STC	Vendor/Industry Panel