Health Information Technology Advisory Committee

September 9, 2021

Micky Tripathi, Ph.D. M.P.P. National Coordinator for Health Information Technology U.S. Department of Health & Human Services 330 C Street, SW Washington, DC 20201

Dear Dr. Tripathi:

On July 14, 2021, ONC's contractor, the Urban Institute, published its draft developer measures and sought public feedback. As part of this public feedback process, ONC charged the HITAC to establish a new Electronic Health Record Reporting Program (EHRRP) Task Force to make specific recommendations on the content for the EHRRP developer measures. This transmittal letter offers these recommendations, which are informed by deliberations among the Task Force and HITAC subject matter experts.

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

Respectfully submitted,

Aaron Mírí	Denise Webb
/s/	/s/
Aaron Miri	Denise Webb
Co-chair, Health Information Technology Advisory Committee	Co-chair, Health Information Technology Advisory Committee





Submitted to the Office of the National Coordinator for Health IT on September 9, 2021





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Background

The Electronic Health Record Reporting Program was required in Section 4002(c) of the 21st Century Cures Act. Data collected and reported under the program will address information gaps in the health IT marketplace and provide insights on how certified health IT is being used. On July 14, 2021, ONC's contractor, the Urban Institute, published its draft developer measures and sought public feedback. As part of this public feedback process, ONC charged the HITAC to establish a new Electronic Health Record Reporting Program (EHRRP) Task Force for 2021 to make specific recommendations on the content for the EHRRP developer measures.

ONC CHARGES TO THE EHRRP TASK FORCE

Overarching Charge

The EHRRP Task Force 2021 was charged with making recommendations to prioritize and improve the draft set of developer-reported, interoperability-focused measures for the EHR Reporting Program.

Detailed Charge

The Task Force's specific charges were to provide recommendations on the following:

- Consider background research, reports, and other sources as relevant to inform analysis of draft measures.
- Consider both established and emerging measurement practices and capabilities, as well as technical, legal, and policy requirements.
- Consider the use, technical feasibility, and potential policy impacts of the draft measures.
- Prioritize the draft measures to elevate those with the most potential for addressing gaps and providing insights in the certified health IT marketplace.
- Consider ways to avoid placing undue disadvantage on small and startup health IT developers in reporting measures.
- Develop recommendations to inform revisions to improve an initial set of developer-reported measures.
- Suggest additional measures and measure categories to prioritize for subsequent iterations of the developer-reported measures.
- Approve recommendations for submission to the HITAC by September 9, 2021

ADDITIONAL BACKGROUND INFORMATION

The Task Force (TF) first assembled a robust group of subject matter experts across various stakeholder groups. The roster included in the Appendix to this document reflects the TF membership at the time these recommendations were finalized.

We support the majority of the details, processes and published priorities included in this process, and appreciate the consideration given to the recommendations herein. The TF has identified specific recommendations for modifications to the EHRRP developer measures with diligence and thoughtfulness.



DEFINITIONS

The following definitions were established for common ground while developing the recommendations but are not necessarily recommended for ONC to adopt:

- The definition of clinicians, for the sake of this reporting, should include all licensed independent practitioners and all nursing/MA/clinical support staff.
- The definition of encounter, for the sake of this reporting, should be based on SNOMED and CPT codes.
 - Use NCQA's Outpatient Value Set for the outpatient codes. For inpatient codes, use SNOMED codes 4525004, 183452005, 32485007, 8715000, 32485007, and 48951000124107.
 - If a reporter does not support encounters as defined in the code sets above, they can attest to that and submit a substitute code set that represents the majority of encounters in their system and use that definition for reporting.
- The definition of an active patient, for the sake of this reporting, should be one that had an encounter within the reporting period.
- The definition of successful transmission to an IIS registry, for the sake of this reporting, should be the total messages submitted minus acknowledgments with errors (2.5.1, severity level of E). This way IIS jurisdictions that don't send HL7 Acknowledgement messages (ACKs) will not be a limitation. This approach assumes that submitted messages are at a minimum reaching Public Health.
- The definition of site, for the sake of this reporting, should be based on individual locations of care as specified using the <u>CMS Place of Service Code Set</u>.





Recommendations

INTRODUCTION

The focus of the EHRRP TF 2021 was to make recommendations and improve the draft set of developer-reported interoperability-focused measures for the EHRRP.

HIGH LEVEL / CROSS-CUTTING RECOMMENDATIONS:

EHRRP-TF-2021_Recommendation 01 – ONC should keep the following considerations in mind across all measures:

- Developers may have to change their agreements with providers to be able to report their data.
- A goal should be to minimize burden on provider organizations in data collection.
- Measures should be reported annually for a 12 month reporting period.
- July 1 June 30 should be used as the default for a 12 month reporting period. e.g., to prevent differences in seasonal vaccine popularity from complicating analysis.
- A lookback beyond the reporting period is not necessary; measures should include the population at the time the data is collected and be collected after the year/reporting period is over.
- When possible, metrics should be reported at the product level (e.g., ambulatory, inpatient, or ED EHR product), not at the vendor level as products from the same developer may have different functionality and performance.
- More precise definitions should be developed for terms listed in the 'Definitions' section of this report, including clinicians, encounter, active patient, and successful transmission to an IIS registry; as well as for app reauthorization.
- When implementing, avoid unintended consequences as the measures are specified to ensure we are getting relevant information.

LIST OF SPECIFIC RECOMMENDATIONS

Patient Access measures

Use of different methods for access to electronic health information

EHRRP-TF-2021_Recommendation 02 – For the measure on use of different methods for access to electronic health information, ONC should:

- Consider this measure as the highest priority in the Patient Access set of measures.
- Aggregate by product, where possible; understanding actions such as app authorization or portal access are not necessarily ambulatory/inpatient product specific, and the denominator of encounter types should determine the product association. The numerator should not distinguish between ambulatory and inpatient encounters.
- Consider examining app usage for patients that have an encounter in the reporting period, as well as for patients that do not have an encounter in that reporting period.
- Consider measuring the ratio of access to patient portal versus third party apps.



- Consider collecting patient gender assigned at birth, sexual orientation, and gender identity (SOGI) and Social Determinants of Health (SDOH) data as defined in USCDI V2. Any additional stratification adds to the complexity of data collection and reporting.
- Remove the sustained use dimension from measure 1 and capture it only in measure 2.

Use of 3rd party patient-facing apps

EHRRP-TF-2021_Recommendation 03 – For the measure on use of 3rd party patient-facing apps, ONC should:

- Consider this measure as the 2nd highest priority under Patient Access measures.
- Report on apps by the number of users within the reporting period: less than 10 users, 10+ users, 100+ users, 10,000+ users.
- Consider collecting patient gender assigned at birth, sexual orientation, and gender identity (SOGI) and Social Determinants of Health (SDOH) data as defined in USCDI V2. Any additional stratification adds to the complexity of data collection and reporting.

Collection of app privacy policy

EHRRP-TF-2021_Recommendation 04 – ONC should remove the measure on collection of app privacy policy.

• The EHRRP is not the correct mechanism for collection of app privacy policy information since privacy policies may fall outside of certified health IT requirements.

Public Health Information Exchange measures

Sending vaccination data to Immunization Information Systems (IIS)

EHRRP-TF-2021_Recommendation 05 - For the measure on sending vaccination data to

immunization information systems (IIS), ONC should:

- Update denominator to "Number of immunizations administered."
- Update numerator to "Number of administrations from which the information was electronically submitted to a registry successfully."
- These updated denominator/numerator suggestions should help address the confusion of the numerator being larger than the denominator.
- Stratify numerator by the registry submitted to, and avoid the complexity of attempting to stratify by state or jurisdiction. This would also provide additional data where there are multiple registries within a state.

Querying of IIS by health care providers using EHRs

EHRRP-TF-2021_Recommendation 06 – For the measure on querying of IIS by health care providers using EHRs, ONC should:

- Update denominator to "Number of encounters."
- Update numerator to "Number of query responses from the IIS received."



- These updated denominator/numerator suggestions should help address the confusion of the numerator being larger than the denominator.
- Note for interpretation that not all clinicians consider immunizations in their scope of practice, and that this will affect data reported. Not every encounter would necessarily have a query. Some queries may also be performed outside the concept of an encounter.

Clinical Care Information Exchange Measures

Viewing summary of care records

EHRRP-TF-2021_Recommendation 07 – For the measure on viewing summary of care records, ONC should:

- Base metrics on any C-CDA document type received including but not limited to Summary of Care (CCD) documents.
- Incorporate future EHR certification requirements that will allow for the reporting to differentiate counts of documents received by push from those received by query/pull.
- Define "viewing" a document as having an open document displayed to a user, whether the display includes all or a subset of the data received, and regardless of whether the user scrolls through or clicks on any of the data in the document itself.
- Align the reporting period with the reporting period of the other metrics and reflect any view of documents received during that time period.
- In lieu of the terms "parse and integrate", consider referencing and utilizing the existing Certification criteria for "incorporation" of received outside data from https://www.healthit.gov/test-method/clinical-information-reconciliation-andincorporation.
- Define "incorporation" as to electronically process structured information from another source such that it is combined (in structured form) with information maintained by health IT and is subsequently available for use within the health IT system by a user.

EHRRP-TF-2021_Recommendation 08 – For future reporting on viewing summary of care records, ONC should consider revising numerator 2 and denominator 2 of the measure on viewing summary of care records to capture how often data was parsed, incorporated, and viewed separately from the received document with the following specification:

- Numerator 2: Number of unique C-CDAs received where any parsed/incorporated/reconciled data is viewed in integrated form by end users and clinicians.
- Denominator 2: Number of unique C-CDAs received using certified health IT that are parsed and have data incorporated or reconciled into the local system.

Use of 3rd party clinician-facing apps

EHRRP-TF-2021_Recommendation 09 – For the measure on use of 3rd party clinician-facing apps, ONC should:

- Report on app usage vs. app registration with the vendor or enablement in a customer system.
 - App enablement could be measured by apps listed as being allowed access.
 - App usage could be measured via API audit trail.



- Report on apps with active registration within the reporting period: < 10 users, 10+ users, 100+ users, 10,000+ users.
- Align these measures with the Standards Adoption and Conformance measures domain to eliminate any duplicity.

Standards Adoption and Conformance measures

Supporting the 21st Century Cures act goals of promoting interoperability, reducing provider burden, and promoting patient engagement requires both agreement on a standard representation of health data and wide availability of standardized public, open APIs to exchange machine understandable data with no special effort. These EHR Reporting Program metrics focus on the systematic use of two APIs, support for which is required in the ONC Rule: SMART on FHIR and SMART/HL7 Bulk FHIR Access. The former supports an ecosystem of apps which are substitutable (can be added to or deleted from an EHR with no special effort) and reusable (the same app can run, unmodified, across diverse platforms). In such an ecosystem, there is an opportunity for a competitive market in which innovators can reach the point of care and compete on price, features and eventually outcomes. The latter API enables "push button population health", in that datasets on cohorts of patients can be extracted in a common format and exchanged with no special effort. Without a public API, there are many barriers to exchange of population data as extraction and mapping to common formats requires expert resources at each site of care.

We further seek statistics on overall use of the electronic health information export function which enables individuals to "take out" their full set of EHR data well beyond the USCDI, or for clinicians to export the full set of data on all of their patients.

To guide development of the API-based ecosystem, ONC will need to understand compliance with the regulations in context with uptake of the API technologies by clinicians, patients, industry, public health agencies, and innovators of data-driven software and processes. It will be important to assess whether the public APIs and the required elements of the USCDI are serving health system needs. It is important to assess whether developer implementations of the public APIs provide stand-alone functionality, or whether supplemental proprietary technologies and additional data elements are needed to enable health care, public health, and research use cases. Further, whether end user costs of API use are consistent with broad uptake. To track adoption and evaluate the success of regulations, the ONC needs information to determine if additional efforts and requirements are necessary to support the 21st Century Cures goals and related objectives.

The goal of the measures should be to support metrics that allow ONC to understand for both clinician and patient facing apps as well as Bulk FHIR capabilities. This approach defines the minimum numerator and denominator measures needed to enable ONC to combine them to gain a host of useful insights. We recognize that at times the numerators may be used as denominators and vice versa.

Some recommended metrics may require more development time. ONC should assess in detail feasibility and time to implementation when considering phasing these recommendations.

- Important goals for measures and metrics
- FHIR Versions
- Read versus write-back capabilities



- Types of resources being exchanged
- Volume and activity usage metrics
- Volume of exchange for infrastructure burden
- Understanding reusable versus non reusable apps availability and use
- Bulk FHIR availability, use and reason for use
- Distribution of app availability and utilization for insights into equity of use across sites and geographies
- Ability to identify denominators that allow insights into normalize the data as well as context
- Insight into the cost to client for API calls
- Understanding use and cost for EHI export

Use of FHIR APIs and resources by clinician-facing apps

EHRRP-TF-2021_Recommendation 10 – for the measure on use of FHIR APIs and resources by clinician-facing apps, ONC should consider the following numerators:

- For clinician facing endpoints, number of API calls (queries/reads) by resource type and FHIR version
- For clinician facing endpoints, number of creates/updates (writebacks) by resource type and FHIR version and resource type (writeback)
- For clinician facing endpoints, total volume of data transferred (gigabytes), by resource type and FHIR version
- For clinician facing endpoints, number of FHIR resources transferred, by resource type and FHIR version
- For clinician facing endpoints, number of SMART on FHIR (SoF) apps with at least one launch
- For clinician facing endpoints, number of SoF app launches

EHRRP-TF-2021_Recommendation 11 – for the measure on use of FHIR APIs and resources by clinician-facing apps, ONC should consider the following denominators:

- Number of Clinicians with at least one EHR session in the period (active clinicians)
- Number of EHR documented encounters in period (EHR use)
- Per site, based on individual locations of care¹

Use of FHIR APIs and resources by patient-facing apps

EHRRP-TF-2021_Recommendation 12 – for the measure on use of FHIR APIs and resources by patient-facing apps, ONC should consider the following numerators:

For patient facing endpoints, number of API calls (queries/reads) by resource type and FHIR version

¹ Understanding distribution of use of standardized data and interoperable technologies requires some understanding of the provider sites where they are used and will support measurement of diversity, equity, and inclusion in receipt of benefits of standards and interoperability. And yet the concept of a site requires further definition or a proxy for geographical and SES definition. Developers may not be able to currently draw an association between an API call and a particular hospital, clinic, etc. One option would be to look at deployment - for example, OCHIN or Sutter. But this would lose important resolution across different site types. There may be variability from vendor to vendor in ability to measure, based on configuration of deployments. It was also pointed out that healthcare providers would have to authorize release of their data with that granularity. There is a proposal above to use a CMS definition.





- For patient facing endpoints, number of creates/updates (writebacks) by resource type and FHIR version
- For patient facing endpoints, total volume of data transferred (gigabytes) transferred, by resource type and FHIR version
- For patient facing endpoints, number of FHIR resources transferred, by resource type and FHIR version
- For patient facing endpoints, number of SoF apps with at least one launch
- For patient facing endpoints, number of SoF app launches

EHRRP-TF-2021_Recommendation 13 – for the measure on use of FHIR APIs and resources by patient-facing apps, ONC should consider the following denominators:

- Number of patients with at least one patient-facing app login in period (active patients with portal access)
- Number of patients with at least one patient-facing app login without an EHR documented encounter in period (patients interacting with health tools outside of a clinician visit)
- Patients with at least one EHR documented encounter in period (active patients)
- Per site based on individual locations of care (as per above)

Use of FHIR bulk data

EHRRP-TF-2021_Recommendation 14 – For the measure on use of FHIR bulk data, ONC should consider the following numerators:

- For bulk data endpoints, number of API calls by resource type and FHIR version
- For bulk data endpoints, total volume of data transferred (gigabytes) transferred, by resource type and FHIR version
- For bulk data endpoints, number of FHIR resources transferred, by resource type and FHIR version
- Number of registered Smart Backend Services apps with at least one API request

EHRRP-TF-2021_Recommendation 15 – For the measure on use of FHIR bulk data, ONC should consider the following denominators:

- Number of EHR documented encounters in period (EHR use)
- Per site based on individual locations of care (as per above)
- Per user type (Initial focus should be on payor, clinician, or other; later phases can have more granularity)
- Per HIPAA-supported reason for access (TPO, research, care coordination)

Standards Adoption and Conformance Additional Recommended measures

EHR Full Electronic Health Information (EHI) Export Metrics

EHRRP-TF-2021_Recommendation 16 – ONC should add a measure on EHR Full Electronic Health Information (EHI) Export Metrics with the following specifications:

- Numerator recommendations:
 - o Number of individual patient-initiated EHI export requests processed
 - o Number of individual non-patient-initiated EHI export requests processed



- o Number of full data EHI export requests processed
- Fees assessed to client or requestor
- Other costs to the provider/client (e.g., hardware costs, cloud costs to support infrastructure and data transfer)
- Denominator recommendations:
 - o Per number of sites

Vendor - availability of apps

EHRRP-TF-2021_Recommendation 17 – ONC should add a measure on vendor – availability of apps with the following specifications:

- Numerator recommendations (along with lists):
 - o Counts and lists of apps using the SoF API
 - o Counts and list of apps using the SoF API in vendor-associated app galleries²
 - Counts list of apps not using the SoF API in vendor associated app galleries
 - o Counts and list of apps using the SoF API plus additional APIs
 - Counts and list of apps with at least one launch in the measure period, registered for SoF API write permissions
- Denominator recommendations:
 - Count of EHR documented encounters in period (EHR use)
 - Per site
 - Per user type (Payor, Researcher, Internal user)

Costs of API Use

EHRRP-TF-2021_Recommendation 18 – ONC should add the following measures on costs of API use:

- Total fees charged per unit time to clinician for facing API calls
- Total fees charged per unit time for bulk data API calls

Data Quality and Completeness measure

By data element, percentage of data complete (e.g., not missing)

EHRRP-TF-2021_Recommendation 19 – Each data element proposed should be clarified in a measure and prioritized as worth the additional reporting development and data processing effort. If some of these are prioritized, further definition is needed before consideration (e.g., address needs to be better defined as home, work, address parts, etc., and gender needs to be clarified). ONC should:

- Not prioritize mother's maiden name.
 - Mother's maiden name is low utility given it is often a missing data field, however, there is value for patient matching, particularly for children.
- Consider preferred language for future prioritization.
- Consider phone numbers (e.g., mobile, home, work) and email for prioritization.

²There was discussion of app galleries not being part of the certification requirement. It was also commented that understanding whether the ecosystem is evolving around apps using the public API vs. proprietary APIs is important for ONC's shepherding the evolution of and regulating health IT.

- Consider the use for the data in prioritization. Completeness of individual elements is not all that meaningful. Focus on equity and patient matching.
- Clarify or remove "Potential subgroup by client (reported by quintiles)."
- Revisit these measures if future industry efforts develop new best practices around data completeness and quality.

EHRRP-TF-2021_Recommendation 20 – ONC should consider the following items regarding interpretation of the data quality and completeness measure:

- Different system approaches need to be considered.
 - Required fields may lead to high completion rates but may not indicate data quality or usability.
 - Some systems may capture data at the encounter level, making reporting at the patient level difficult.
 - If certain data elements are required to create a patient record, then reporting on them is not useful in this way.
 - Similarly, if a default value (say, unknown) is populated, what we are really interested in is the non-default values.
- Aggregation cannot account for patients with multiple records across systems.
- Required vs optional fields within the EHR has ramifications for patient matching and public health use of data, Data gathered from this measure may help inform how changes in data elements can be best explained in implementation guides. Required (R), Required if Exist (RE), Conditional (C), Optional (O) listed in HL7 standards may need to be rethought given the impact that incomplete or poor data have on value. Optional but really important fields need to be communicated via the EHR to end users.
- ONC should consider evaluating adopted/mandated USCDI terminology and code use in future data quality and completeness measures.

HITAC Recommendations on the EHR Reporting Program September 9, 2021

Appendix A

Task Force Roster

Name	Organization
Raj Ratwani (Co-Chair)	MedStar Health
Jill Shuemaker (Co-Chair)	American Board of Family Medicine
Zahid Butt	Medisolv Inc
Jim Jirjis	HCA Healthcare
Bryant Karras	Washington State Department of Health
Joseph Kunisch	Harris Health
Steven Lane	Sutter Health
Kenneth Mandl	Boston Children's Hospital
Abby Sears	OCHIN
Sasha TerMaat	Epic
Sheryl Turney	Anthem, Inc.
Steven Waldren	American Academy of Family Physicians