



ISP Task Force Update to HITAC

Arien Malec, Co-Chair

David McCallie, Co-Chair

April 15, 2021



Task Force Roster

Name	Organization
Arien Malec (Co-Chair)	Change Healthcare
David McCallie (Co-Chair)	Individual
Ricky Bloomfield	Apple
Cynthia Fisher	PatientRightsAdvocate.org
Valerie Grey	New York eHealth Collaborative
Jim Jirjis	HCA Healthcare
Edward Juhn	Blue Shield of California
Ken Kawamoto	University of Utah Health

Name	Organization
Victor Lee	Clinical Architecture
Leslie Lenert	Medical University of South Carolina
Clem McDonald	National Library of Medicine
Ming Jack Po	Ansible Health
Raj Ratwani	MedStar Health
Ram Sriram	National Institute of Standards and Technology
Sasha TerMaat	Epic
Andrew Truscott	Accenture

Priority Uses of Health IT

21st Century Cures Act

“The National Coordinator shall periodically convene the HIT Advisory Committee to identify priority uses of health information technology...identify existing standards and implementation specifications that support the use and exchange of electronic health information needed to meet the priorities...publish a report summarizing the findings of the analysis...and make appropriate recommendations...”

“The HIT Advisory Committee, in collaboration with the National Institute for Standards and Technology, shall annually and through the use of public input, review and publish priorities for the use of health information technology, standards, and implementation specifications to support those priorities.”



Health IT Advisory Committee (HITAC): Interoperability Standards Priorities (ISP) Task Force 2021

Charge – Identify opportunities to update the ONC Interoperability Standards Advisory (ISA) to address the HITAC priority uses of health IT, including related standards and implementation specifications

The ISP Task Force shall:

1. Identify opportunities to update the “Interoperability Needs” within the ISA sections to address the HITAC priority uses of health IT (including new priority uses of health IT, if necessary)
2. Recommend additional or modified “Interoperability Needs” for consideration in updates to the ISA, including related standards and implementation specifications



Areas of potential interest identified by ISP TF - 1

- Clinical/Administrative Data & Standards Harmonization/Burden Reduction
 - *Specific standards actions related to recommendations from ICAD TF, DaVinci, Fast FHIR, etc.*
- Data sharing between Federal & Commercial Health Care Entities
 - *Address barriers to interoperability data flows that cross from Federal to/from Commercial*
- Vaccine/Immunization Registry Reporting
 - *Lessons learned from COVID on gaps in vaccine registry data flows*
- Health Equity Standards
 - *Improved structure and capture for Race/Ethnicity/Gender and Social Determinants of Health*
- RWE/Comparative Effectiveness/RECOVERY-type data use (from EHRs)
 - *Better leverage EHRs and EHR data for (rapid) hypothesis generation and testing*
- PH Situational Awareness
 - *Improve standards and structures for reporting on real-time status of public health resources*



Areas of potential interest identified by ISP TF - 2

- Syndromic Surveillance
 - *Improve early detection of emergent threats using EHR and other data sources*
- Care plans and chronic disease burden management
 - *Improve capture and sharing of care plans, and coordination of chronic disease mgmt.*
- Adverse Event Reporting
 - *Rationalize structures and improve capture of adverse events (e.g., vaccination reactions)*
- Patient to device (mobile, med device) linking
 - *Better and easier linkages between mobile devices and person/patient enrolled to device*
- Contact and Exposure Notification
 - *Investigate emerging tools / standards for contact tracing and exposure notification*
- Vaccine credentials (AKA Vaccine Passport)
 - *(We have deferred to ONC's ongoing projects in this space)*

Framework for priority scoring

- Is this a Priority Area for ONC (High / Medium / Low)
 - COVID-19
 - Health Equity
 - 21CC
 - ONC Roadmap
- Potential Impact of work
 - Foundational (H)
 - General purpose (M)
 - Specific (L)
- Availability of Applicable Policy Levers
 - Well-defined (H)
 - Maybe / unclear (M)
 - New policies or regulations needed (L)
- Current Burden on target audience
 - High / Med / Low

- High = 9 pts
- Med = 3 pts
- Low = 1 pts

Results of Priority Voting

Project	Priority				Impact				Levers				Burden				Sum
	H	M	L	Average	H	M	L	Average	H	M	L	Average	H	M	L	Average	
Health Equity Standards	6	0	0	9.00	4	2	0	7.00	2	1	3	4.00	2	3	1	4.67	24.67
RWE/Comparative Effectiveness/RECOVERY EHR data use	1	5	0	4.00	6	0	0	9.00	2	3	1	4.67	0	5	1	2.67	20.33
Care plans and chronic disease burden management	2	2	2	4.33	3	3	0	6.00	0	5	1	2.67	2	2	2	4.33	17.33
Vaccine/Immunization Registry Reporting	4	1	1	6.67	1	3	2	3.33	1	2	3	3.00	0	5	1	2.67	15.67
Data sharing Federal & Commercial Health Care Entities	2	3	1	4.67	1	4	1	3.67	1	3	2	3.33	1	4	1	3.67	15.33
Clinical/Admin Data & Standards Harm/Burden Reduction	0	4	2	2.33	1	4	1	3.67	2	2	2	4.33	1	5	0	4.00	14.33
Syndromic Surveillance	2	3	1	4.67	1	3	2	3.33	0	3	3	2.00	0	5	1	2.67	12.67
Contact and Exposure Notification	0	4	2	2.33	1	2	3	3.00	0	0	6	1.00	0	6	0	3.00	9.33
PH Situational Awareness	0	4	2	2.33	0	3	3	2.00	0	1	5	1.33	0	5	1	2.67	8.33
Adverse Event Reporting	0	2	4	1.67	0	2	4	1.67	0	5	1	2.67	0	3	3	2.00	8.00
Patient to device (mobile, med device) linking	0	0	6	1.00	0	2	4	1.67	0	1	5	1.33	0	1	5	1.33	5.33

Seeking Expert Input

- PH Situational Awareness
 - SANER (Audacious Inquiry) – April 1st
- Health Equity
 - Project Gravity (HL7) – April 8th
- RWE / comparative effectiveness / Leverage EHR data
 - OHDSI, PCORI, COVID Cohort Collab – George Hripcsak, Chris Chute, Russ Waitman – April 16th
- Data sharing across Federal and non-Federal boundaries
 - TBD
- CDC Modernization
 - Paula Braun – CDC – April 29th
- Clinical and Administrative data and standards prioritization
 - TBD (ICAD Task Force? DaVinci?)



AUDACIOUS INQUIRY

BOLD SOLUTIONS FOR
CONNECTED HEALTHCARE

April 1, 2020

Situational Awareness for Novel Epidemic Response

Keith Boone, MBI & Lauren Knieser, DrPH





The Gravity Project

HITAC ISP TF Presentation

Robert Dieterle, Gravity Project Technical Director

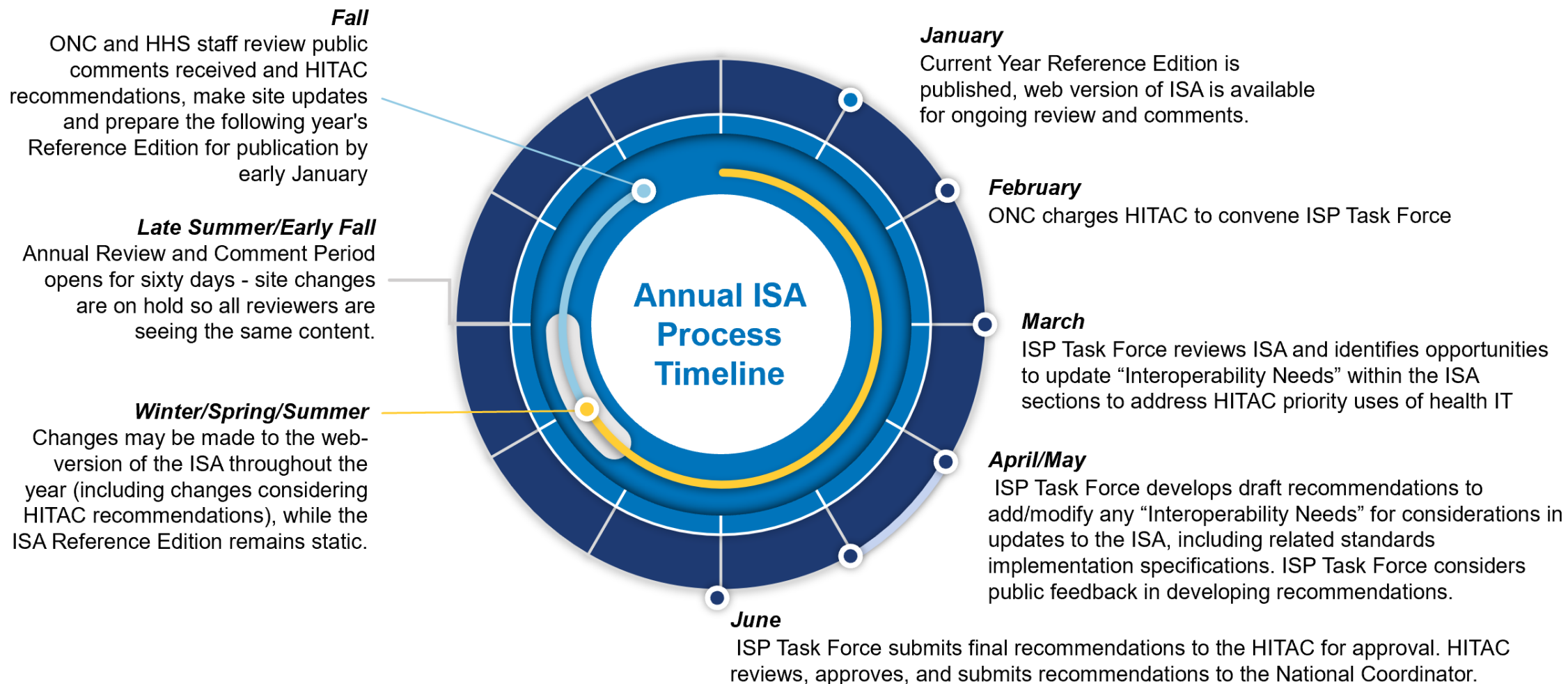
April 8, 2021



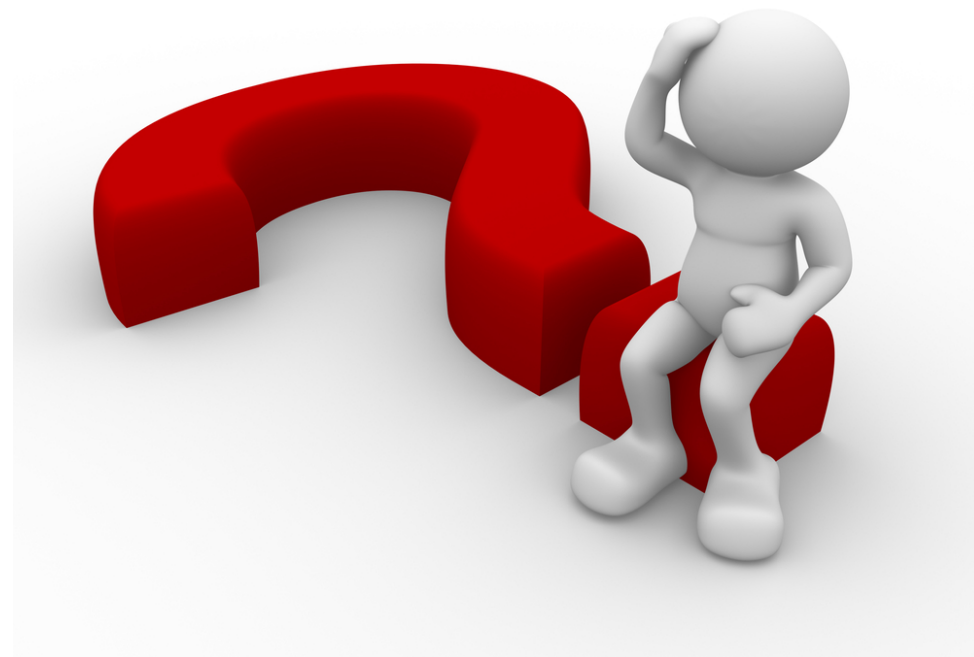
HITAC ISP Task Force Timeline 2021

	February	March	April	May	June
HITAC	ONC charges HITAC to convene ISP Task Force	HITAC reviews ISP Task Force progress		HITAC reviews and approves recommendations	
ISP Task Force	ISP Task Force launches and begins meetings	ISP Task Force reviews ISA and identifies opportunities to update the ISA “Interoperability Needs” within the ISA sections to address HITAC priority uses of health IT	ISP Task Force develops draft recommendations to add/modify any “Interoperability Needs” for considerations in updates to the ISA, including related standards implementation specifications. ISP Task Force considers public feedback in developing recommendations.	ISP Task Force submits final recommendations to the HITAC for approval	

ONC Interoperability Standards Advisory (ISA): Annual Reference Edition Cycle



Questions





ISP TF Appendix

Priority Uses Focus Areas Identified in 2019

Selected Focus Areas

1. Cross Domain – Public availability of health IT standards, including code sets and terminologies, required by federal programs
2. Orders & Results – Availability of laboratory results are in the personal health record (PHR) that is associated with one's electronic health record (EHR)
3. Closed Loop Referrals & Care Coordination – Primary doctor refers a patient to be seen by a specialist and the referral is seen and processed in the EHR
4. Medication & Pharmacy Data – A hospital pharmacy system having the availability to automatically send medication requests based on the patient's current insurance, deductible, and/or individual situation

Future Focus Areas

1. Evidenced-Based Care for Common Chronic Conditions
2. Social Determinants of Health
3. Cost Transparency

Total – 42 Primary recommendations, 159 Sub recommendations

Improving syndromic surveillance

- Address issues of siloed data, especially around disconnected lab data
- Address gaps in roll-up of data to state and local aggregators (HIE, PH)
- Excessive variability of lab messages
- Early detection and reporting of novel variants
- Revisit eCR (?)
- Revisit CMS decision to drop quality measure for lab reporting (incentive)

Improving situational awareness for PH emergencies

- State-by-state variations in required reporting (over and above CDC minimums)
- Non-computable “standards” for the required reporting (PDF, text)
- Private third-party collections caused confusion
- Review the proposed SANER standard
- Is there a role for TEFCA entities?

Address gaps in vaccine reporting data flow

- (Data flow from EHR inbound to local PH ISS is already pretty good?)
- Flows outbound from PH/ISS are lacking
 - Flows to local HIE and/or TEFCA entities
 - Reporting involving groups of people (e.g., IZ status by zip code or region)
 - Consider new simpler standards including “flat FHIR”
 - Push or pull or both?
- Flows from non-standard IZ locations (pharmacy) may be missing
- Flows from mass-immunization events may be missing
 - How does vaccine administer know where to send the IZ message?



Health Equity issues

- SDOH and Health Equity data standards
 - Are they adequate?
 - Which ones should be pushed?
- HL7 “Gravity” project – learn more?
- Why is sensitive race/ethnicity/gender data so often not being captured?
 - Cultural issues
 - Training issues
- Access to critical data for disadvantaged/digital-divide persons and people experiencing homelessness
 - Phone vs browser vs smartphone as the minimum?
- Delegated (proxy) access for people living with disabilities

Better usage of EHR data for PH and other purposes

- Consider priority use-cases for newly required “bulk FHIR” APIs
- On-demand rapid extraction of EHR data for hypothesis generation
 - OMOP / OHSDI work with HL7? (<https://www.ohdsi.org/ohdsi-hl7-collaboration/>)
 - (aggregated vs. distributed query debate)
- Automated extraction of RWE, particularly post-vaccination
- Patient-reported outcome capture and aggregation
- Better support for virtual clinical trials

Gaps in Adverse Event (AE) reporting

- VAERS has an online form + paper, but no electronic standard to transmit AE experience reports from EHRs
- Multiple “profiles” for AE reporting (vaccine, biologic, drug, med device)
- FAERS is an SGML + AS2 reporting format that uses MEDDRA terminology and is oriented for clinical trials but not for clinical submission from EHRs (SNOMED, LOINC)

Contact and exposure tracking

- Improve outbound lab-reported demographics, as per Duke/Margolis recommendations
- What can we learn from Apple/Google/EU experiments in smartphone-enabled exposure tracking?
- What can we learn from NBA and NFL “bubble” tracking?

Care plans and chronic disease burden

- Pick up issues from 2019 discussion?
- New (emerging) FHIR models for plan-of-care

Better / easier binding between persons and their digital devices

- UDI
- Multi-user devices
- Virtual clinical trials

Better integration of clinical and administrative data

- “Fast FHIR”
- DaVinci
- ePA

Improve data sharing across VA/DoD and non-governmental systems

- Security requirements mismatch makes seamless data flow harder
- Direct experience
- eHEx experience
- Carequality experience
- Emerging FHIR API needs?

Proposed Framework for Prioritization

- Assume we have more areas that want to get done than we, ONC and Industry have time, energy and focus to address.
- When prioritizing prefer:
 - Areas that align with ONC declared priority areas
 - COVID-19
 - Health equity
 - 21 Century CURES enablement
 - Unmet needs on the existing ONC Roadmap
 - Avoid areas already being covered through existing ONC initiatives
 - Foundational and/or leveraged areas (solutions that unlock other areas) over
 - General areas over specific solutions
 - Existence of well-defined policy levers over novel policy levers required
 - Areas with where jobs are *already* being done inefficiently over areas we want the health system to focus on



Proposed Framework for Recommendations

- Consider timeframe of recommendations
 - Near term (months) – work can be done immediately
 - Medium term (6m-2 years) – work requires planning and coordination
 - Long term (2-5 years) – work requires standards development, piloting, legislative action, etc.
- Consider type of action required
 - ONC/industry alignment and voluntary action around existing standards
 - ONC/industry/SDO alignment and standards development
 - Incentive alignment
 - ONC and other HHS rulemaking
 - Congressional action/appropriation
 - Multistate action



AUDACIOUS INQUIRY

BOLD SOLUTIONS FOR
CONNECTED HEALTHCARE

April 1, 2020

Situational Awareness for Novel Epidemic Response

Keith Boone, MBI & Lauren Knieser, DrPH



What is Situational Awareness?

- Situational Awareness and Essential Elements of Information are terms of art in Emergency Response
 - Communication of “Essential Elements of Information” or EEI
 - “Strategic EEI attributes are those that are required for the purposes of shared situational awareness, monitoring, and coordination support at regional or national levels.”¹
 - EEIs are Broadly defined in Emergency Response field for
 - Transportation (Air, Water, Rail, Roads)
 - Infrastructure (Power, Water, Fuel)
 - Communications
 - Affected Populations
 - Shelter
 - Command and Control
 - Healthcare
 - Typically under-specified in the Healthcare context
 - e.g., Operational Status and Location of Hospitals

¹ Essential Elements of Information Publication Guidance, National Information Sharing Consortium, 2015, https://www.nisconsortium.org/portal/resources/bin/NISC_EEI_Publication_1426695387.pdf

Enabling Legislation

- “The Secretary [of HHS], in collaboration with State, local, and tribal public health officials, shall establish a near real-time electronic nationwide public health situational awareness capability through an interoperable network of systems to share data and information to enhance early detection of rapid response to, and management of, potentially catastrophic infectious disease outbreaks and other public health emergencies that originate domestically or abroad.”
- Pandemic All Hazards Preparedness Act (PAHPA, 2006).
<https://www.govinfo.gov/content/pkg/PLAW-109publ417/pdf/PLAW-109publ417.pdf>
- Pandemic All Hazards Preparedness Reauthorization Act of 2013.
<https://www.govinfo.gov/content/pkg/PLAW-113publ5/pdf/PLAW-113publ5.pdf>
- Pandemic All Hazards Preparedness and Advancing Innovation Act of 2019.
<https://www.congress.gov/116/bills/s1379/BILLS-116s1379enr.pdf>

What is the SANER Project?

- SANER stands for Situational Awareness for Novel Epidemic Response
 - It started with the insanity of needing manual reporting for bed and ventilator availability that hospital staff were required to do in early days of the COVID-19 response.
 - With FHIR APIs, we can do better.

Facility ID #: _____
Summary Census ID #: _____

*Date for which patient impact and hospital capacity counts are reported: ____/____/____

is the average public reporting burden for this collection of information as 25 minutes per response, including the time for reviewing instructions, searching existing data/information sources, gathering and maintaining the data/information needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington, DC 20543-0180. Example, 7 AM

_____	HOSPITALIZED and VENTILATED: Patients currently hospitalized in an inpatient bed who have suspected or confirmed COVID-19 and are on a mechanical ventilator
_____	HOSPITAL ONSET: Patients currently hospitalized in an inpatient bed with onset of suspected or confirmed COVID-19 fourteen or more days after hospital admission due to a condition other than COVID-19
_____	ED/OVERFLOW: Patients with suspected or confirmed COVID-19 who currently are in the Emergency Department (ED) or any overflow location awaiting an inpatient bed
_____	ED/OVERFLOW and VENTILATED: Patients with suspected or confirmed COVID-19 who currently are in the ED or any overflow location awaiting an inpatient bed and on a mechanical ventilator
_____	DEATHS: Patients with suspected or confirmed COVID-19 who died in the hospital, ED, or any overflow location on the date for which you are reporting

Section 2: Hospital Bed/ Intensive Care Unit (ICU)/ Ventilator Capacity Data Elements

_____	ALL HOSPITAL BEDS: total number of all inpatient and outpatient beds in your hospital, including all staffed, licensed, overflow, and surge or expansion beds used for inpatients and for outpatients (includes ICU beds)
_____	*HOSPITAL INPATIENT BEDS: total number of staffed inpatient beds in your hospital including all licensed, overflow, and surge or expansion beds used for inpatients (includes ICU beds)
_____	HOSPITAL INPATIENT BED OCCUPANCY: total number of staffed inpatient beds that are occupied
_____	ICU BEDS: Total number of staffed inpatient ICU beds
_____	ICU BED OCCUPANCY: total number of staffed inpatient ICU beds that are occupied
_____	MECHANICAL VENTILATORS: Total number of ventilators available
_____	MECHANICAL VENTILATORS IN USE: total number of ventilators in use

Assurance of Confidentiality: The voluntarily provided information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).

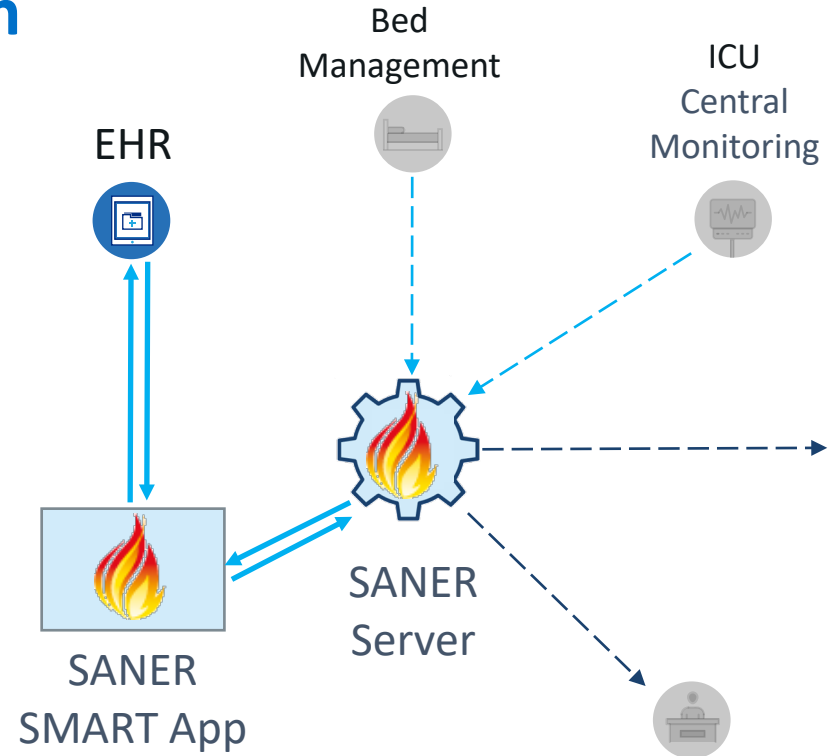
CDC estimates the average public reporting burden for this collection of information as 25 minutes per response, including the time for reviewing instructions, searching existing data/information sources, gathering and maintaining the data/information needed, and completing and reviewing the collection of information. An agency may not

Features of SANER

- Automated Reporting via FHIR
- Integration with non-FHIR based systems through CSV Files
- Data Aggregation across multiple systems
- Applies Process Controls to Measurement
- Links Measurements to Essential Elements of Information
- Enables stratification by any computable attribute: Age, Gender, Race and Ethnicity, Geography, Comorbidity, Health Risk Factors, Outcomes
- Enables line level data reporting for risk adjustments, research and analysis
- Open-Source Implementations

A Complete Reporting Approach

- SANER SMART on FHIR App
 - Authorizes with Hospital EHR
 - Queries for Applicable Data
 - Creates Measure Reports from EHR
 - Stored to SANER Server
- SANER Server
 - Collects Data from
 - SANER SMART on FHIR App
 - Other Data Sources (e.g. Bed Management, ICU Central Monitoring)
 - Report Measure Data to
 - Local Command and Control
 - Regional/State Public Health





The Gravity Project

HITAC ISP TF Presentation

Robert Dieterle, Gravity Project Technical Director

April 8, 2021

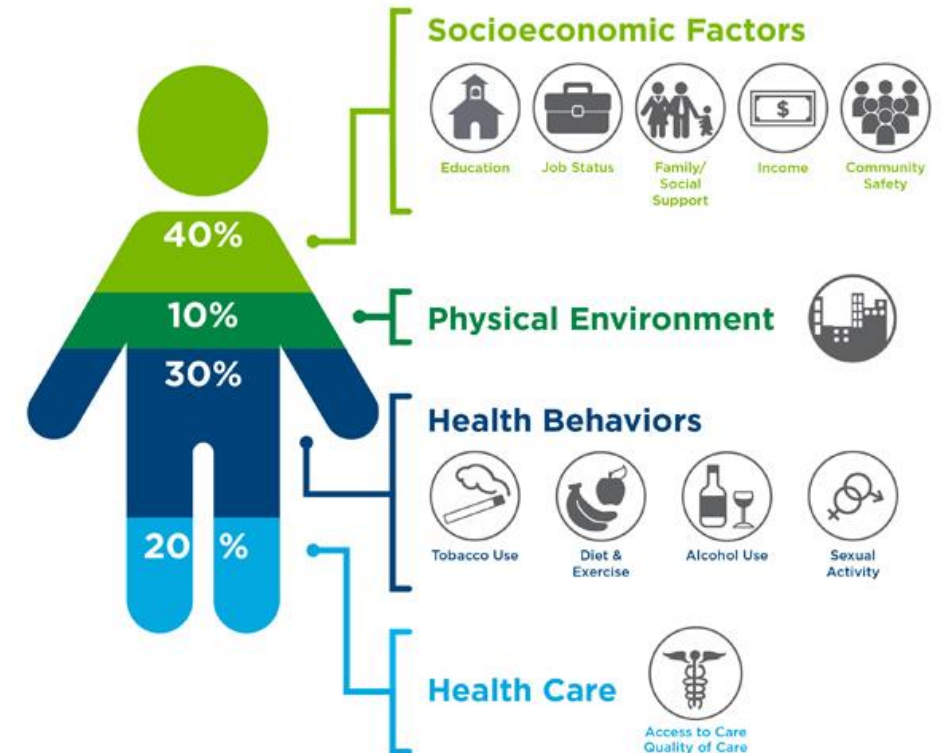


Why Social Determinants of Health (SDOH) are Important

There is growing consensus that SDOH information improves whole person care and lowers cost. Unmet social needs negatively impact health outcomes.

- **Food insecurity** correlates to higher levels of diabetes, hypertension, and heart failure.
- **Housing instability** factors into lower treatment adherence.
- **Transportation barriers** result in missed appointments, delayed care, and lower medication compliance

What Goes Into Your Health?



<https://www.bridgespan.org/insights/library/public-health/the-community-cure-for-health-care-1>
Source: Institute for Clinical System Improvement, Going Beyond the Top 100 (October 2014)
The Bridgespan Group

The Gravity Project...

Goal- Develop consensus-driven data standards to support use and exchange of social determinants of health (SDOH) data within the health care sectors and between the health care sector and other sectors.

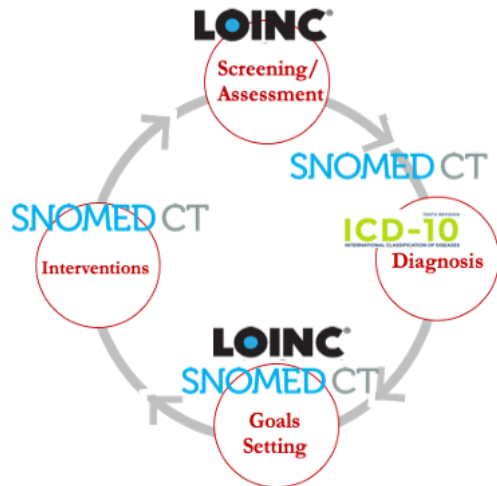


Accelerating Adoption Using Nationally Recognized Standards

Consensus Approved SDOH Data Elements

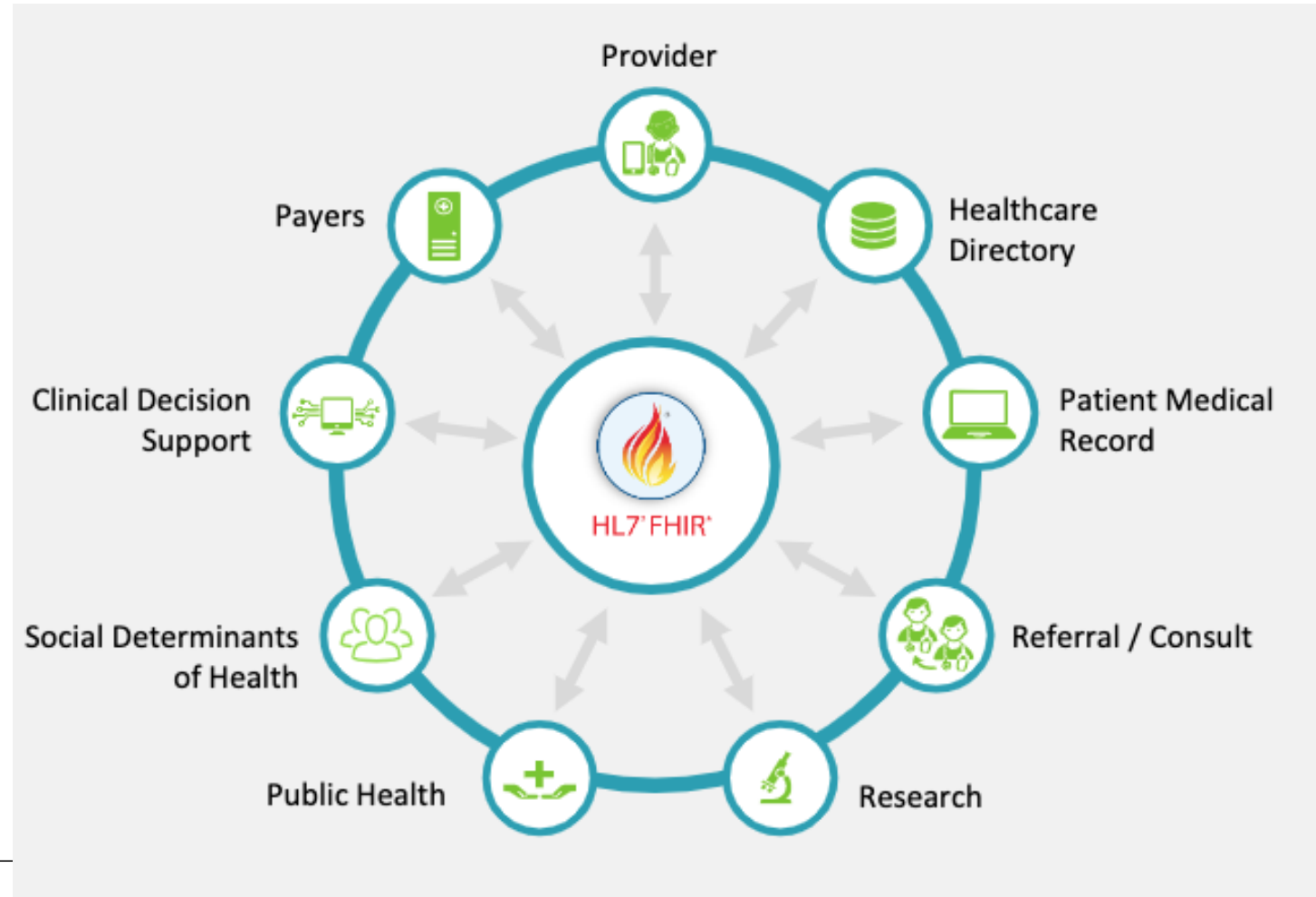


Coded SDOH Data Elements



FHIR

Fast Healthcare Interoperability Resources



How to access ISA?

Interoperability Standards Advisory (ISA) Platform

- <https://www.healthit.gov/isa/>

ISA Sections

- [Vocabulary/Code Set/Terminology](#)
- [Content/Structure](#)
- [Services/Exchange](#)
- [Administrative](#)