

Laboratory Data Sharing & Interoperability: Addressing a Pandemic

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May 13, 2021

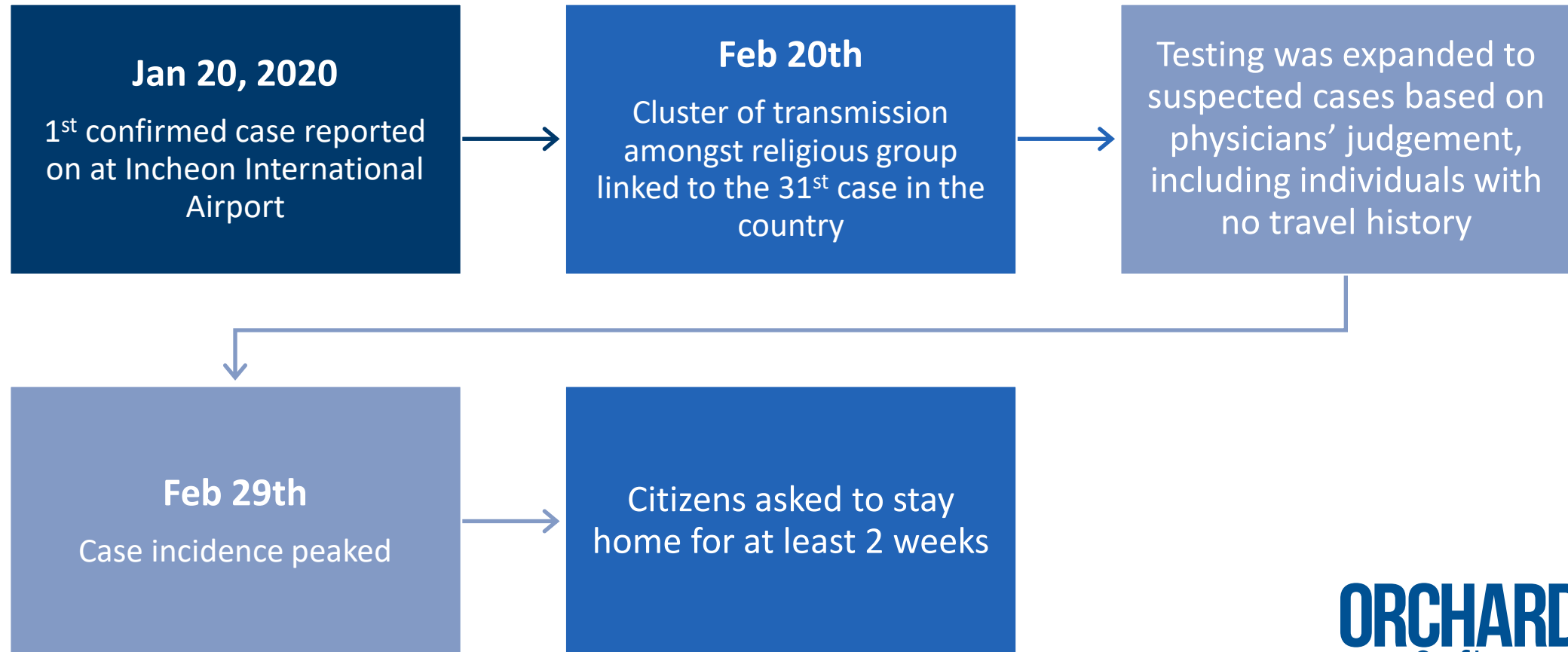


Learning Objectives

1. Review the successful components of South Korea's COVID-19 response & identify differences in the U.S. response.
2. Understand the role of interoperable systems to a pandemic response & the value to healthcare overall.
3. Define the current barriers to interoperability adoption in the U.S.
4. Evaluate the lessons learned from South Korea's pandemic response that can be applied to the U.S.
5. Recognize the laboratory's role in data sharing as it relates to pandemic response & to overall healthcare interoperability.

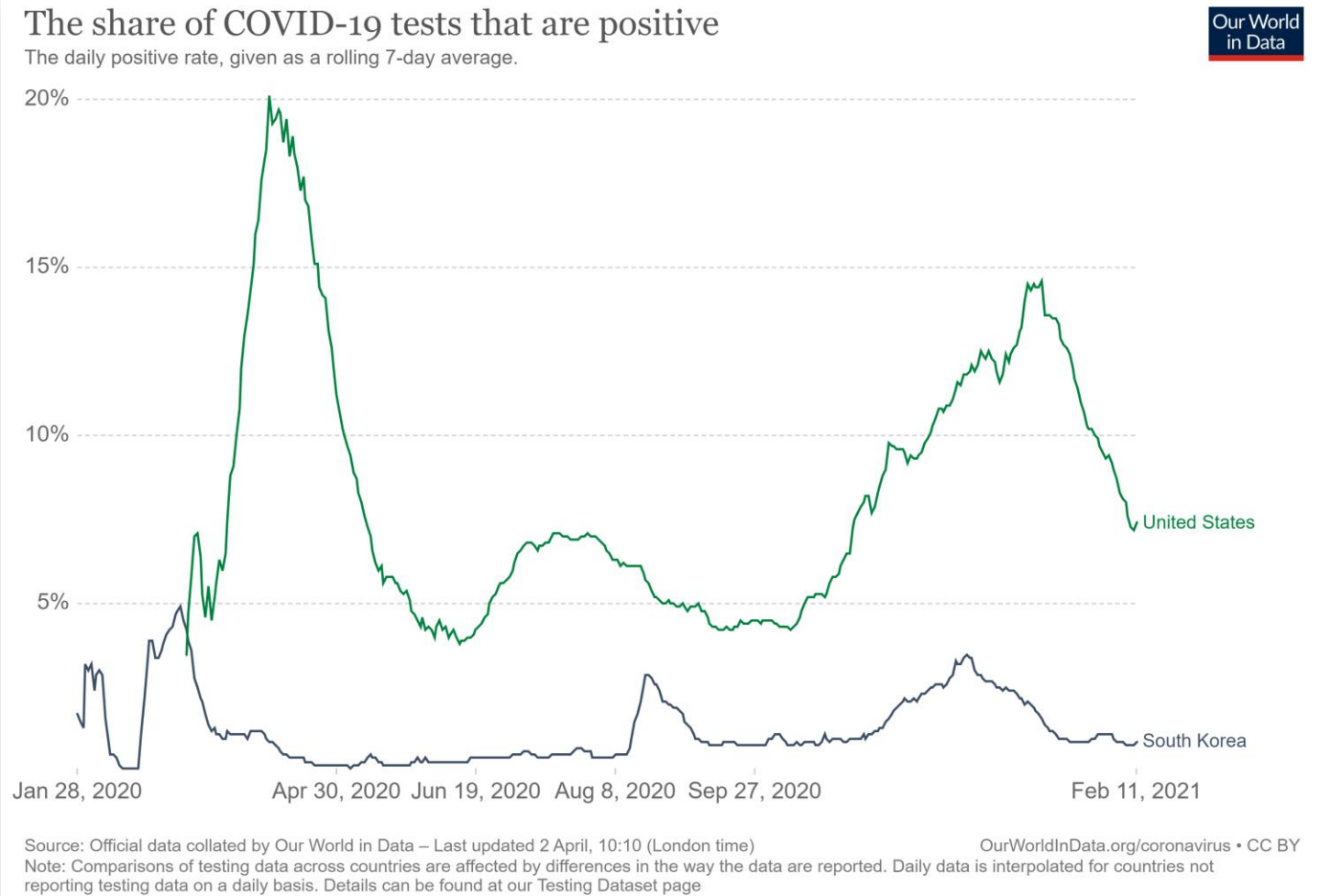
South Korea's COVID-19 Success Story

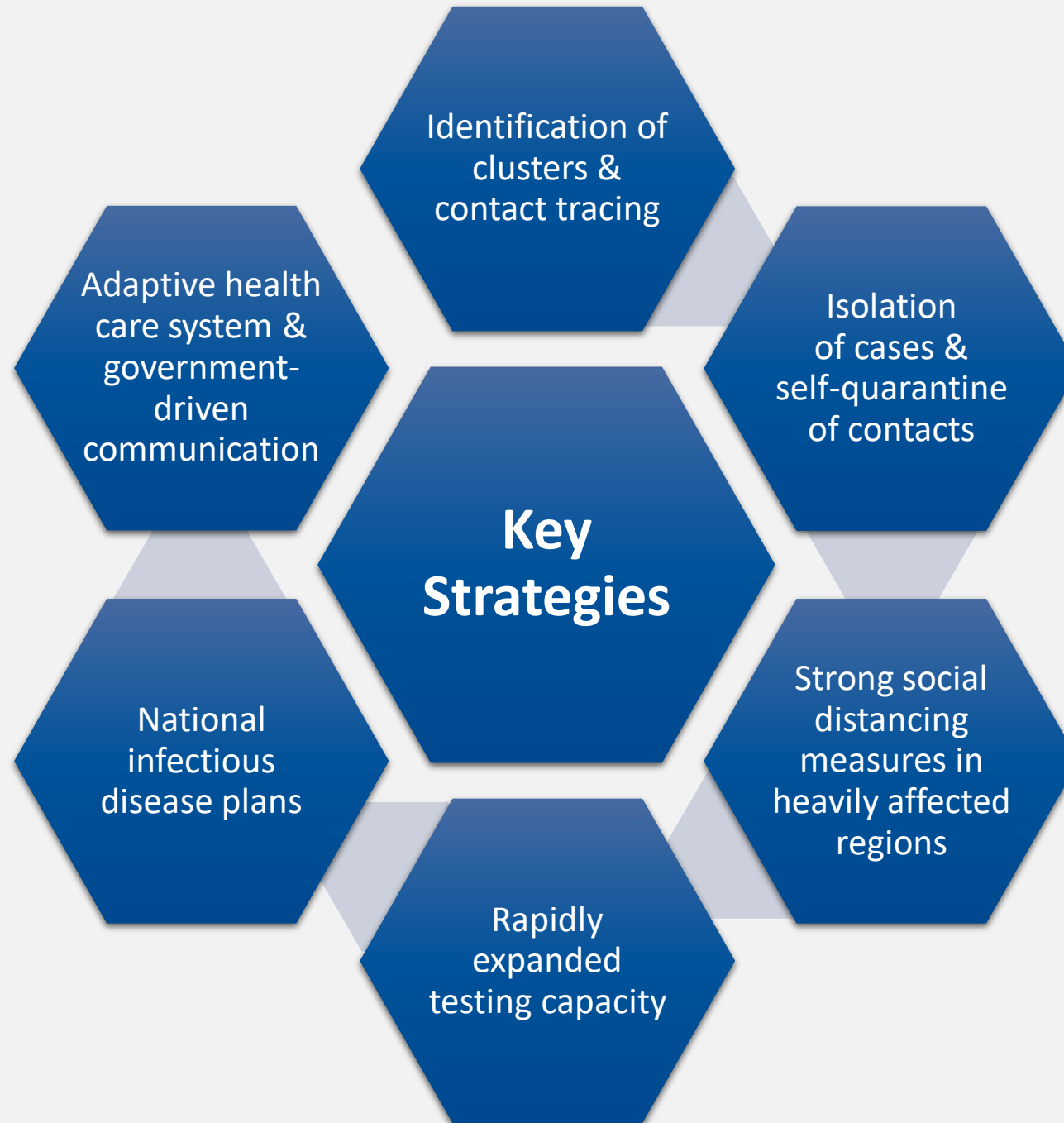
One of the first countries to be affected by COVID-19



What did South Korea do well?

- Substantial interest in their “test, trace, isolate” strategy
- Initial spike in COVID-19 cases rapidly contained with less stringent social distancing measures than UK & US





Identification of
clusters &
contact tracing

Isolation
of cases &
self-quarantine
of contacts

Strong social
distancing
measures in
heavily affected
regions

**Key
Strategies**

Rapidly
expanded
testing capacity

National
infectious
disease plans

Adaptive health
care system &
government-
driven
communication

Detection, Containment, & Treatment

Detect

Built innovative, high-capacity screening facilities & worked closely with the private sector to ensure adequate supply of tests

Contain

Isolated infected patients, increased compliance by supporting those in quarantine, & thoroughly traced contacts

Treat

Restructured the hospital system, built temporary hospitals to increase capacity, addressed PPE shortages with centralized government purchasing

Rigorous & Extensive Epidemiologic Field Investigations

84% of South Koreans accept the loss of privacy as a necessary tradeoff for public health security.

- 2020 Institute for Future Government survey

Included interviews with patients & triangulation of multiple sources of information

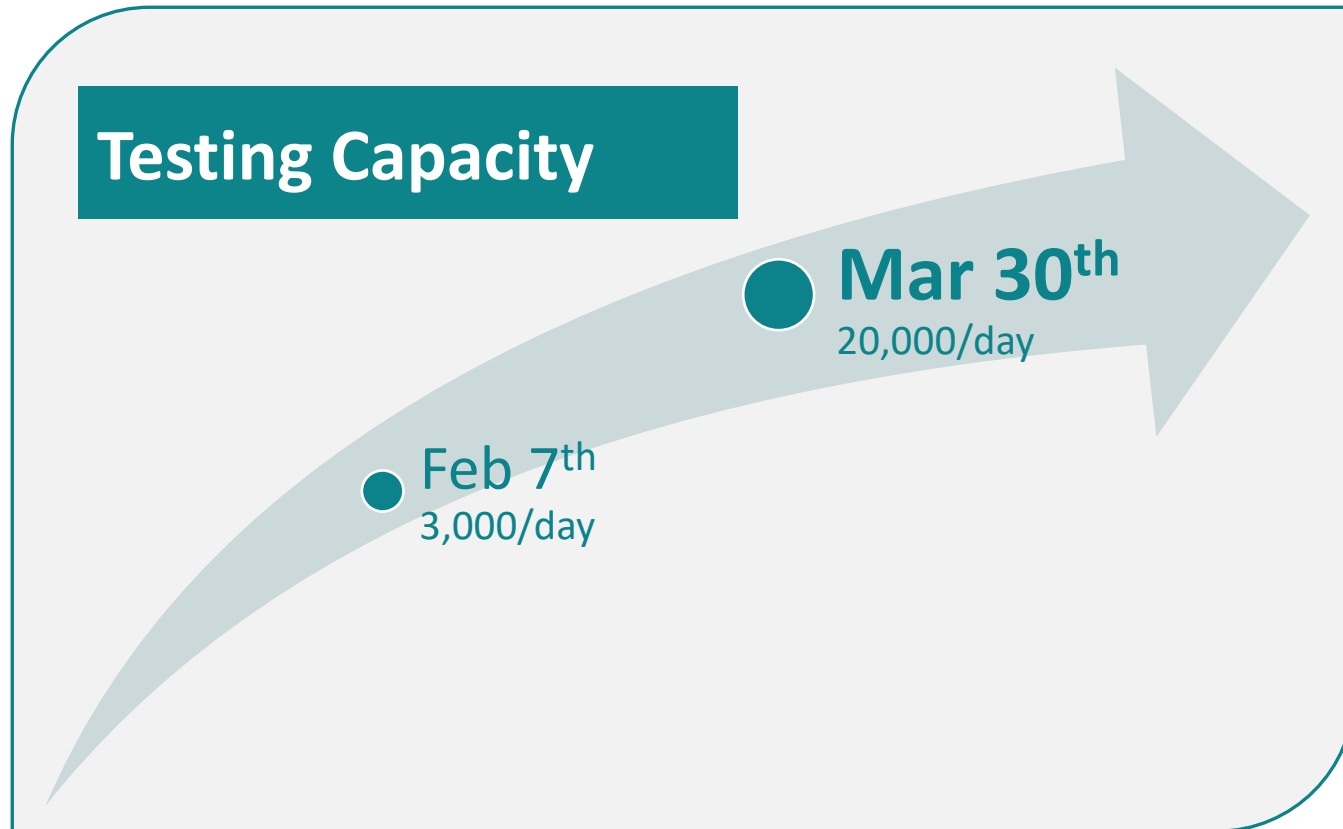
- Medical records
- Credit card data
- GPS data

“Only 17% of Americans today say they can trust the government to do what is right...”

- Emerging COVID-19 success story: South Korea learned the lessons of MERS. March 2021. <https://ourworldindata.org/covid-exemplar-south-korea>
- Americans' Views of Government: Low Trust, but Some Positive Performance Ratings. Sept. 2020. <https://www.pewresearch.org/politics/2020/09/14/americans-views-of-government-low-trust-but-some-positive-performance-ratings>

Testing

- Licensed private companies & clinics to conduct tests early in the pandemic
- TAT = 6–24 hrs



By late March

- Performed > 300,000 tests
- > 40X higher per capita than the US at that time

South Korea MERS Fatality Rate ~ 20%

**2015 Middle
East Respiratory
Syndrome (MERS)
outbreak**

Changes Made

- Government expanded legal & administrative boundaries for pandemic responses
- Boosted infrastructure & processes
 - Legal powers for quarantine
 - Surveillance systems
 - Digital technologies

Lessons Learned from MERS

- 48 reforms to boost public health emergency preparedness and response
- Well-functioning national health insurance system
- Ample human resources and infrastructure
- Constructive relationships between key institutions
 - President's office
 - Ministries of Health, Education, & Foreign Affairs
 - Korean Centers for Disease Control and Prevention
 - renamed the Korea Disease Control and Prevention Agency (KDCA) during the pandemic



Data Access Changes Following the 2015 MERS Outbreak

Permitted to access 4 types of information in addition to patient and doctor interviews:

1. Facility visit records (pharmacies & medical)
2. Cellular GPS data (cell phones)
3. Credit card transaction logs
4. Closed-circuit television

Information was cross-checked with other data to trace contacts and take appropriate containment measures.

Aggressive Approach to Contact Tracing

1. Scaled up network of contact tracers
2. Workers given access to data beyond typical patient interview
3. Public communications to empower citizens to assist with contact tracing



In Response to COVID-19

- June 2020
- Added system called KI-Pass to help contact tracing efforts at high-risk locations
- QR codes at high-traffic facilities like bars and gyms replace manual sign-in sheets

To respond to public concern about data use and privacy, the government instituted additional data protections, including automatically deleting data after 14 days.

Amended Infectious Disease Control and Prevention Act

Mandatory Mask-wearing

- Enforceable by fines of up to 100,000 Korean won (KRW)
 - ~\$90.52 US



Data-driven Agility

- Clearly stands out in the global COVID-19 response
- Key to the response:
 - clear, effective communication with the public about prevention
 - aggressive testing & contact tracing
 - strict quarantine policy backed by support that made it easier for patients to comply

**< 80,000 cases
& 1,500 deaths a full
year after the 1st case
reported**

Culturally and legally, South Korea is more tolerant of personal data-sharing, and its success has been heavily dependent on its ability to rapidly scale up technological solutions.

What lessons can the U.S. learn from South Korea's pandemic management?

“South Korea's extensive surveillance and contact tracing using ICT (information and communications technology) may not be applicable at the federal level in the U.S. due to different cultural norms.”

- Jongeun You, University of Colorado Denver Researcher

The Value of Interoperability

- To the U.S. Healthcare System
- In a pandemic response

Healthcare Interoperability: What Does it Mean?

Enablement of communication and exchange of data between different information technology systems to allow providers access to all data for a patient being treated



Structural Interoperability

- HL7 interfaces
- Transmission of patient data from connected devices



Semantic Interoperability

- Health Information Exchanges (HIE)
- Data collection methods for population health

Interoperability & COVID-19

Collective data can help...

- improve coronavirus surveillance efforts
- monitor the spread of the virus & its impact on the healthcare system
- identify hospital supply needs & bed capacity
- devise approaches for case identification, containment, & resource allocation to protect the public health

Even de-identified data can be meaningful.



What would an interoperable healthcare system look like?

- Patient with symptoms visit provider
- Provider has immediate access to their full medical record to address any underlying conditions
- Alleviates time wasted tracking down records
- Reduces or eliminates duplicate testing

Shared data improves the providers' ability to provide prompt and effective patient care.

Barriers to Interoperability

If it's so great, why don't we have it yet?

A Multitude of Barriers



Data silos



Resistance to change



Inconsistent guidelines



Missing or conflicting incentives



Incentives not tied to revenue

Data Silos

Data silos can make patient care cumbersome and, in some cases, dangerous.



Interoperability Barriers – Pandemic Related

- Transmitting COVID-19 results to government officials often remains a manual process involving **paper and faxing**.
- Each state has its own guidelines for COVID-19 response
 - statistics are inconsistent
 - vary based on the information source and location



Systems are in place...



- U.S. healthcare system has spent billions of dollars to incorporate the use of EHRs through the Meaningful Use program
- EHRs are commonplace in hospitals & most ambulatory provider offices
- Renamed **Promoting Interoperability**

...but are not properly incentivized \$\$\$\$

Healthcare
reimbursement
system remains
fragmented

PI program relies
on provider grants
& incentives

Does not encourage
data sharing



Only Where Revenue Comes Into Play Does Integration Occur



Most medical claims are transmitted electronically, because this accelerates payments.



Laboratories are generally well-connected to the internal providers who order tests, because this link supports reimbursement.

What we already do...

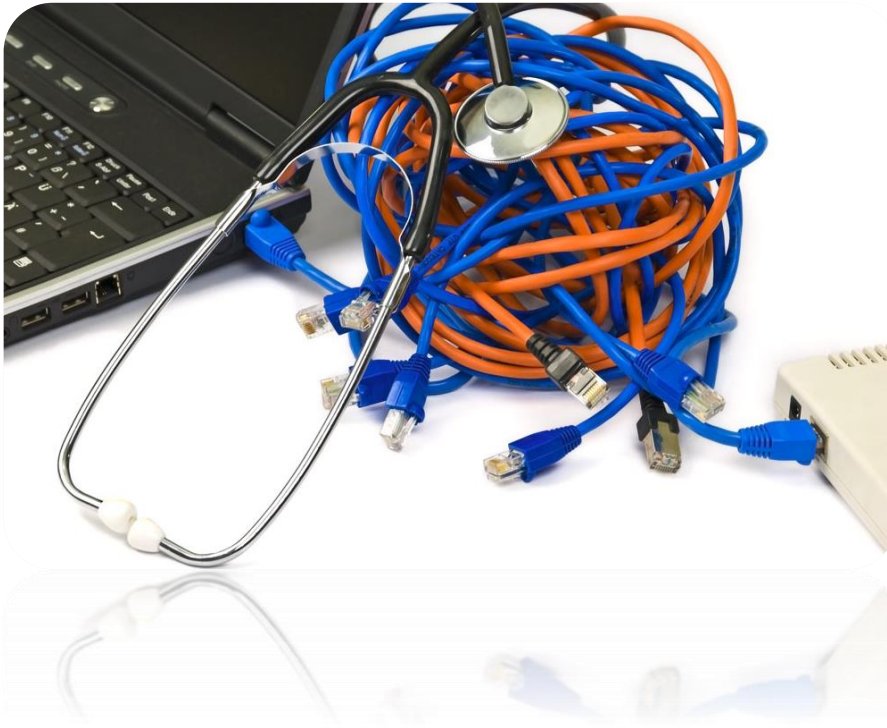
Foundational technology (LIS + EHR)

Standards

ELR

LRN

LIS + EHR = Interoperability Foundation



LISs predate EHRs and have been a strong component of laboratory workflow for decades.



Often, these two information systems are interfaced and share data, creating a foundation for data sharing.



Yet, the industry has made less progress in connecting systems and data among providers and across geographic locations.

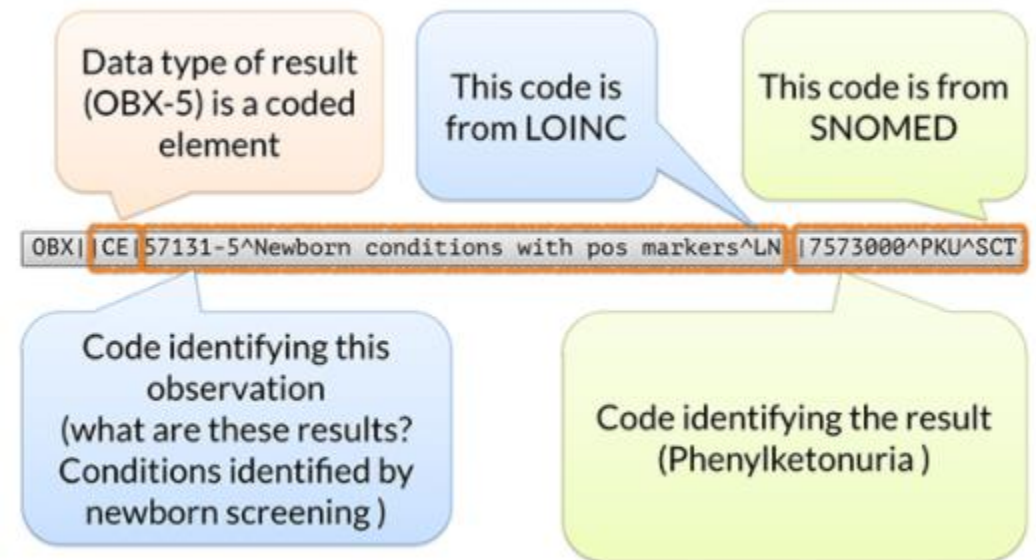


The technology is available, but data is still not easily shared.

Terminology Standards

Observational data findings from a provider encounter, laboratory data, and other diagnostic information is translated into standard terminologies that can be understood by all information systems

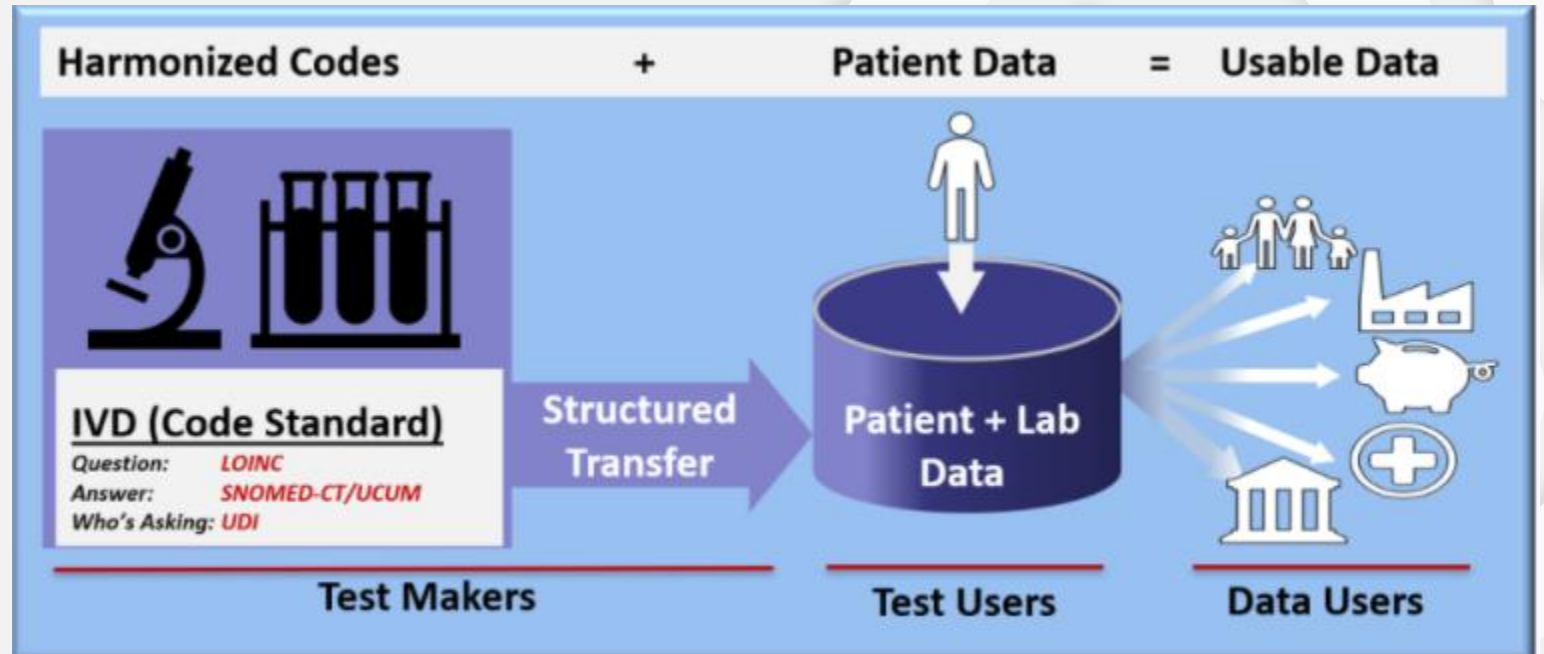
- Key element of laboratory interoperability
- Reduces time spent exchanging, tracking, and reporting tests
- Includes LOINC & SNOMED-CT codes



SHIELD

“improve the quality, utility, and portability of electronic laboratory data through the harmonized implementation of semantic data standards that have been appropriately qualified by a sole authoritative source”

Systemic Harmonization and Interoperability Enhancement for Lab Data



Supports the provision of LOINC & SNOMED codes from manufacturers to laboratories to consistently identify tests in the LIS & EHR

COVID-19 Interoperability Alliance

Goal:

Allow the nation to gain a greater understanding of the pandemic

Collaboration between healthcare industry stakeholders

Provides value sets for clinical, demographic, and administrative terms relating to COVID-19

Supports data aggregation and interoperability

Electronic Laboratory Reporting (ELR)



Electronic transmission of laboratory data from laboratories to public health entities for reportable conditions

Included as part of the Meaningful Use program

Has been in place for quite some time in many healthcare organizations

Laboratory Response Network (LRN)

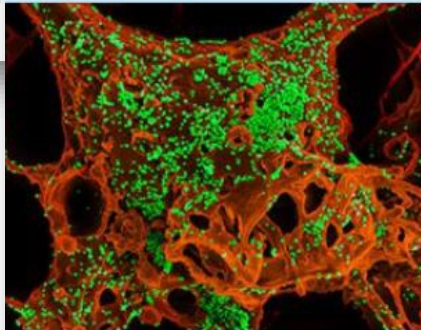
LRN - Chemical



The LRN-C detects chemical threats.

- Created by the CDC > 20 years ago
- Variety of networks that handle emerging threats using a standardized approach

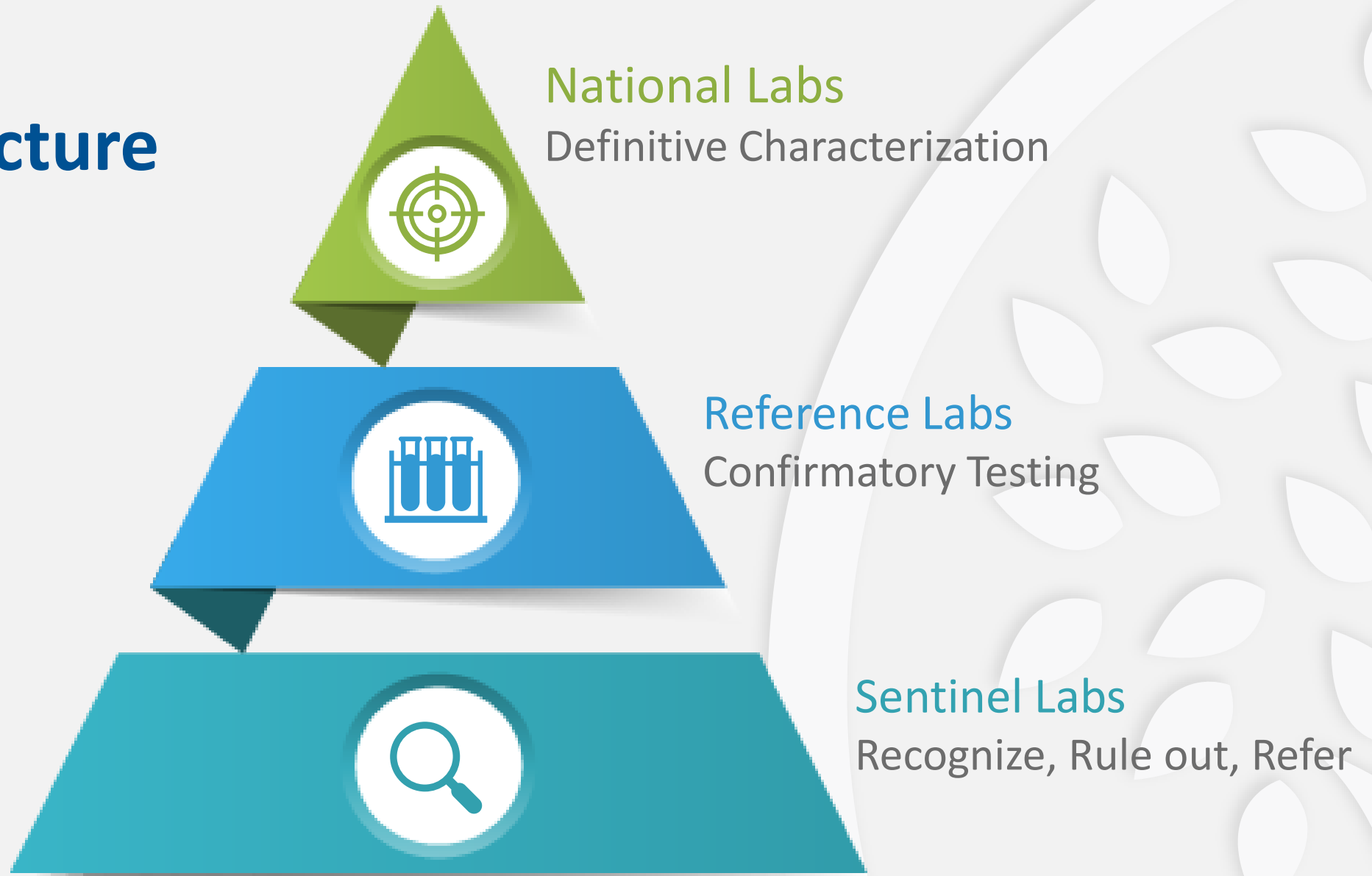
LRN - Biological



The LRN-B detects biological threats and emerging infectious diseases.

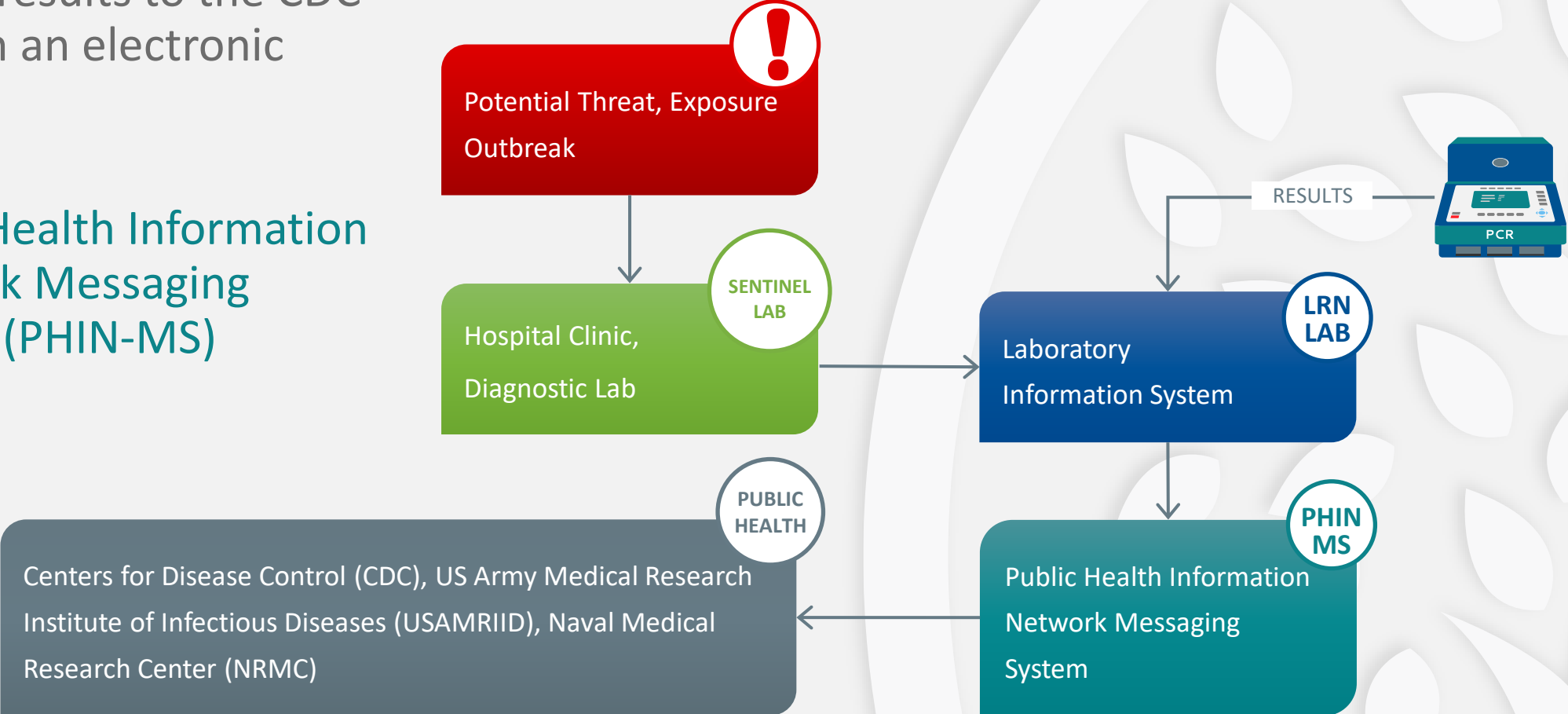
- Primary function is rapid detection of bio-threat & emerging agents of infectious diseases
- Quickly recognize, rule-out, or refer potential bio-threat agents to the LRN reference laboratories

LRN Structure



LRN Structure for Biological Threats

- Report results to the CDC through an electronic portal
- Public Health Information Network Messaging System (PHIN-MS)



Participation in ELR

The LRN receives about 20 million reports annually

- ~80% are electronic, via an HL7 interface

Participation in electronic reporting remains uneven

- With larger labs reporting electronically
- Hospital labs less likely to do so

What we are trying to do...

21st Century Cures Act

CARES Act

21st Century Cures Act

- Signed into law December 2016
- Covers a wide range of initiatives, including a **big push toward nationwide clinical data sharing**
- Intends to provide \$6.3 billion over a decade to the National Institutes of Health
 - Precision Medicine Initiative
 - Cancer Moonshot
 - BRAIN Initiative
 - Regenerative medicine (adult stem cells)

21st Century Cures Act Interoperability Goals

1. Achieve widespread interoperability among health IT systems
2. Improve patient accessibility to their medical information

- The Cures Act includes specific measures that promote these initiatives
- Implemented through separate rules issued by:
 - ONC-HIT
 - CMS

21st Century Cures Act Delayed

- Due to the COVID-19 pandemic
- ONC announced a second delay in implementation
- Enforcement for specific regulations implemented by CMS ranges from 2021 to 2022



- Information blocking and the ONC health IT certification program: extension of compliance dates and timeframes in response to the COVID-19 public health emergency. Federal Register. November 2020. www.federalregister.gov/documents/2020/11/04/2020-24376/information-blocking-and-the-onc-health-it-certification-program-extension-of-compliance-dates-and.
- Reducing provider and patient burden by improving prior authorization processes and promoting patients' electronic access to health information. Centers for Medicare & Medicaid Services. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index>.

2020-2025 Federal Health IT Strategic Plan

How the government intends to use HIT to:

1. Promote health & wellness
2. Enhance the delivery & experience of care
3. Build a secure, data-driven ecosystem to accelerate research & innovation
4. Connect healthcare with health data

The Coronavirus Aid, Relief, and Economic Security (CARES) Act

Created in response to the SARS-CoV-2 pandemic

A \$2.2 trillion economic stimulus bill

- Signed into law in March 2020
- Intends to provide timely economic assistance to American families & small businesses
- Addresses several areas of need
 - (e.g., direct payments, unemployment, payroll taxes, retirement funds, support for hospitals, PPE, testing supplies, vaccination costs, etc.)

CARES Act

- A portion of the CARES Act, Section 18115, requires laboratories to report results of COVID-19 testing daily to
 - DHHS
 - state or local public health departments



CDC COVID-19 Reporting Guidelines

Laboratories should make every reasonable effort to provide the following data elements to state and jurisdictional health departments.

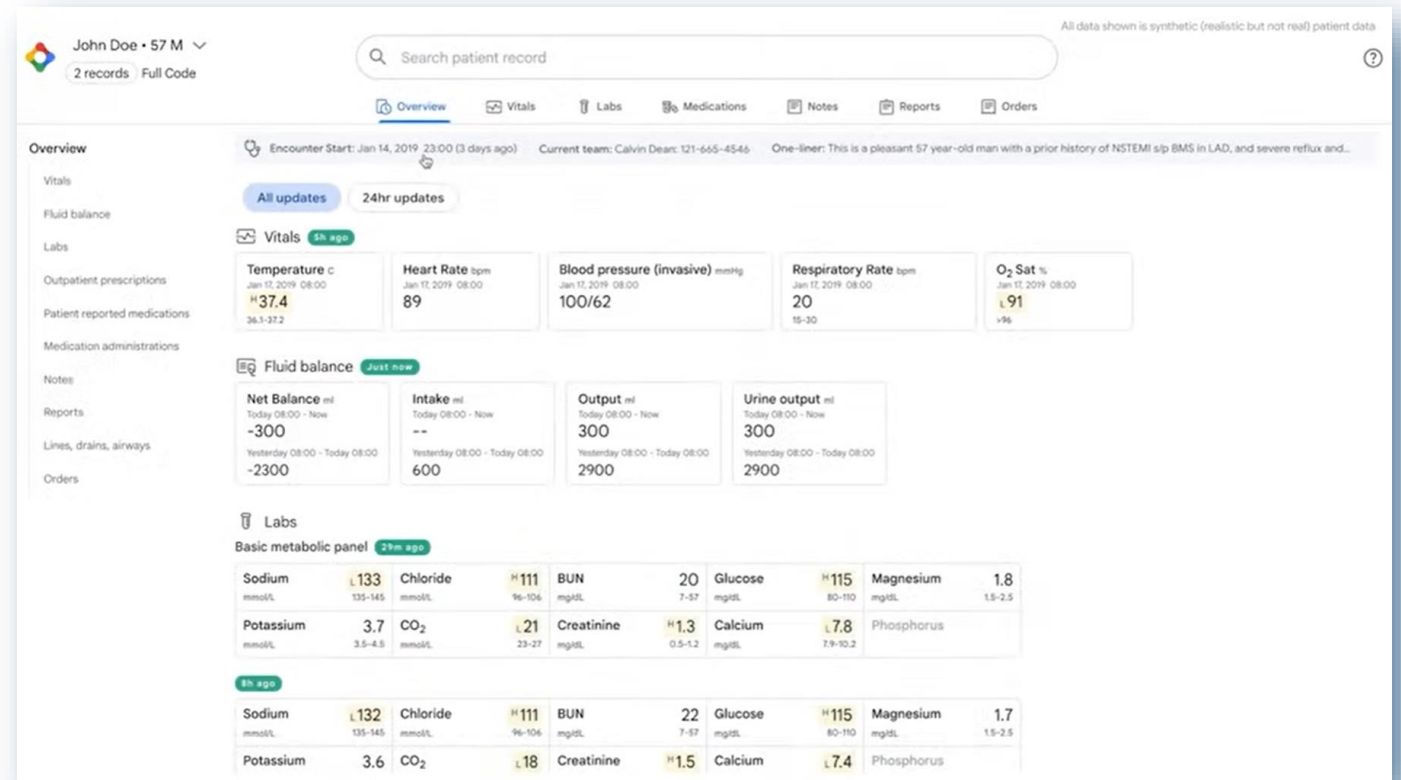
1	Test ordered – use CDC harmonized LOINC codes	10	Patient residence ZIP code
2	Device identifier	11	Patient residence county
3	Test result – use appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC	12	Ordering provider name and nonpharmaceutical interventions (as applicable)
4	Test result date (date format)	13	Ordering provider ZIP code
5	Accession # / Specimen ID	14	Performing facility name and CLIA number
6	Patient age	15	Performing facility ZIP code
7	Patient race	16	Specimen source – use appropriate LOINC, SNOMED-CT, or SPM4 codes, or equivalently detailed alternative codes
8	Patient ethnicity	17	Date test ordered (date format)
9	Patient sex	18	Date specimen collected (date format)

The following additional demographic data elements should also be collected and reported to state or local public health departments.

1	Patient name (last name, first name, middle initial)	4	Patient date of birth
2	Patient street address	5	Ordering provider address
3	Patient phone number with area code	6	Ordering provider phone number

Care Studio

- Collaboration between Google Health & Ascension
- Cross-platform EHR tool that provides a centralized view of patient information
 - hospital visits
 - outpatient events
 - lab tests
 - medications & treatments
 - progress notes
- “leverages Google’s expertise in organizing information to help clinicians find health record information faster”



Peck, A.D. Google Health and Ascension Are Piloting A Cross-Platform EHR Search Tool That Helps Physicians Locate and View Patient Data, Including Clinical Laboratory Test Results. April 12, 2021. Dark Daily. Accessed at <https://www.darkdaily.com/google-health-and-ascension-are-piloting-a-cross-platform-ehr-search-tool-that-helps-physicians-locate-and-view-patient-data-including-clinical-laboratory-test-results/>

Why this is important to all of us (including laboratory professionals)...

Dire Need for Healthcare Data Sharing

Disparate Data

- Prevents providers from accessing a comprehensive view of the patient record
- Slows the shift to value-based care
- Diminishes the healthcare industry's ability to respond to the COVID-19 pandemic and future pandemics

Necessary to advance healthcare system & for pandemic preparedness

Lack of data interoperability (clinical & financial data residing in different systems) has caused challenges for years

Sharing Patient Data

- Effective communication of lab orders and results across care locations and between treating providers
- Foundational need for the management of public health crises, such as COVID-19

The importance of interoperability needs to be understood, communicated, and embraced within the healthcare system, backed with regulatory measures and an incentive structure that encourages interoperability between vendors and healthcare organizations.

Key Messages

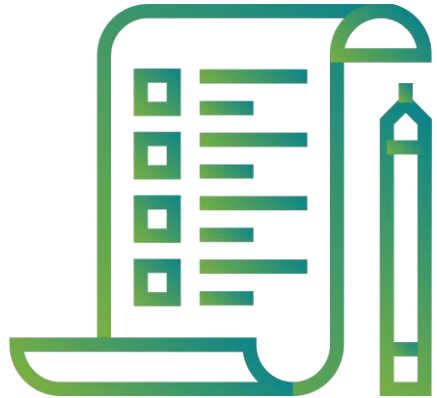
Secure sharing of patient data across healthcare systems and organizations – interoperability – is widely recognized as part of the solution to improve patient outcomes.

The laboratory is an important part of the move to interoperable healthcare systems because of the tremendous amount of data it manages and the value of that data in making patient care decisions.

The SARS-CoV-2 pandemic has made the need for an interoperable healthcare system blatantly evident.

Action Items

What Laboratories Can Actually Do...



Rethink about interoperability and how your lab fits into the bigger picture



Think about small steps to take toward the interoperability goal & how it aligns with laboratory stewardship



Implement LOINC & SNOMED CT Codes where applicable



Standardize test menus and test names across laboratories

Thank you

Confidential & Proprietary

Futrell, K. Feb 2021. COVID-19 highlights need for laboratory data sharing and interoperability. <https://www.mlo-online.com/information-technology/lis/article/21210723/covid19-highlights-need-for-laboratory-data-sharing-and-interoperability>

