CURES ACT
PREPARING FOR INTEROPERABILITY
UNTANGLING THE CONFUSION

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Agenda

- Review the legislation impacting of interoperability
- Understand the Information Blocking rules
- Identify if you are an Actor
- Review industry definitions of EHI
- Discuss challenges in defining EHI with the DRS and LHR
- Ensuring the right EHI is released
- Review how governance can address healthcare transformation for today and the future

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Interoperability in Healthcare

- The ability for various healthcare information technologies (HIT) to exchange, interpret and use data cohesively
- Stakeholders are working together to move toward interoperability with EHRs
- Sharing EHI still remains a challenge.
- Landscape is moving quickly!!

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Industry Interoperability Initiatives

- HITECH Act
- 21st Century Cures Act

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2020 Cures Act Final Rule

Purpose

To implement certain provisions of the Cures Act that will advance interoperability and support the access, exchange and use of electronic health information (EHI)

CMS Companion Rule: Patient Access and Interoperability

https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index

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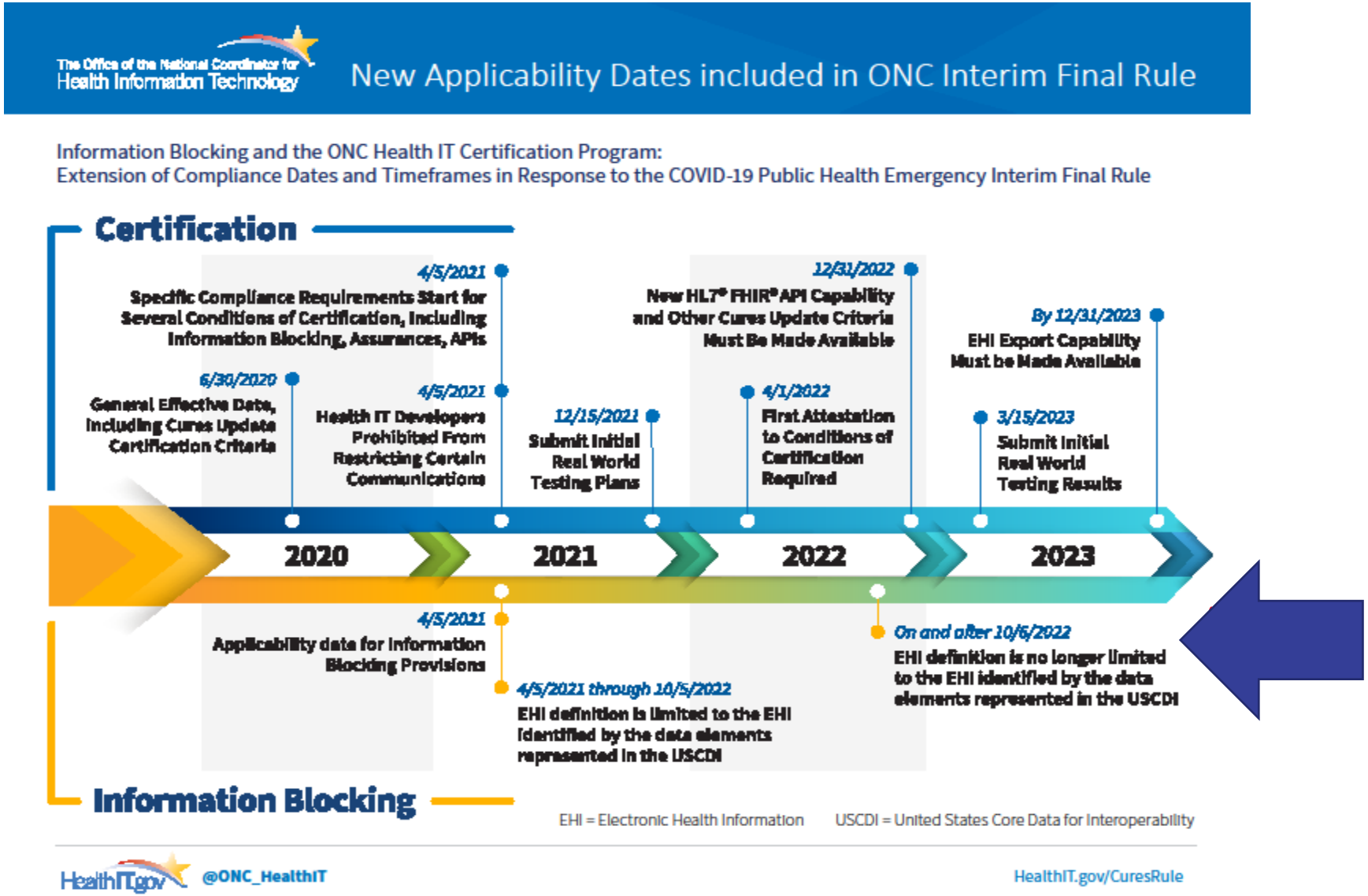
Updated Timeline

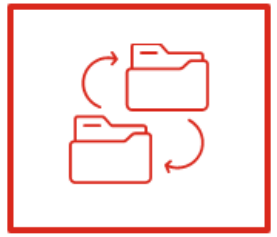


Actors:

“Actors” Regulated in the Final Rule

Health Care Providers

Health IT Developers of Certified Health IT



Health Information Networks (HIN)/ Health Information Exchanges (HIE)

Information Blocking (Part 171) – Definitions

Information Blocking:

- Practices by an **"Actor"** that, except as required by law or specified by the Secretary as a reasonable and necessary activity, **is likely to interfere with, prevent or materially discourage the access, exchange, or use** of **electronic health information.**

What makes an individual or entity an information blocker?

- Actor regulated by the information blocking provision
- Involves electronic health information (EHI)
- Practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI
- Requisite knowledge by the actor
- Not required by law
- Not covered by an exception

Electronic Health Information (EHI)—Definitions

- ePHI, as defined in HIPAA to the extent ePHI, is included in the **designated record set**. Excludes:
  - Psychotherapy notes
  - Information compiled in reasonable anticipation of, or use in, a civil, criminal or administrative action or proceeding
- November 2, 2020 - October 5, 2022
  - **USCDI** must be available for access, exchange and use
- October 6, 2022
  - **Full EHI** is ePHI to the extent it is included in the designated record set
  - This definition is applicable whether the actor is a covered entity or not.

A great resource is https://library.ahima.org/doc?oid=104008#.YxjdhKHMI2w

EHI Task Force

- AHIMA, co-convenor: technical and policy input from HIM community and health system perspective
- AMIA, co-convenor: technical and policy input from clinical informatics, health IT standards, and health system perspective
- EHR Association, co-convenor: technical and policy input from health IT developer and standards implementer perspective.

Objective: Develop consensus recommendations on how to standardize expectations for data classes related to the definition of the DRS and EHI

https://www.ahima.org/media/vxwhhcti/ehi-task-force-report-revision-final.pdf

Approach

- Examined data classes commonly contained in health IT and exchanged today
- Examined data classes less frequently exchanged
- Identified from
  - USCDI
  - ONDEC
  - Health IT developer lists of data classes
  - Best practice previously developed by AHIMA

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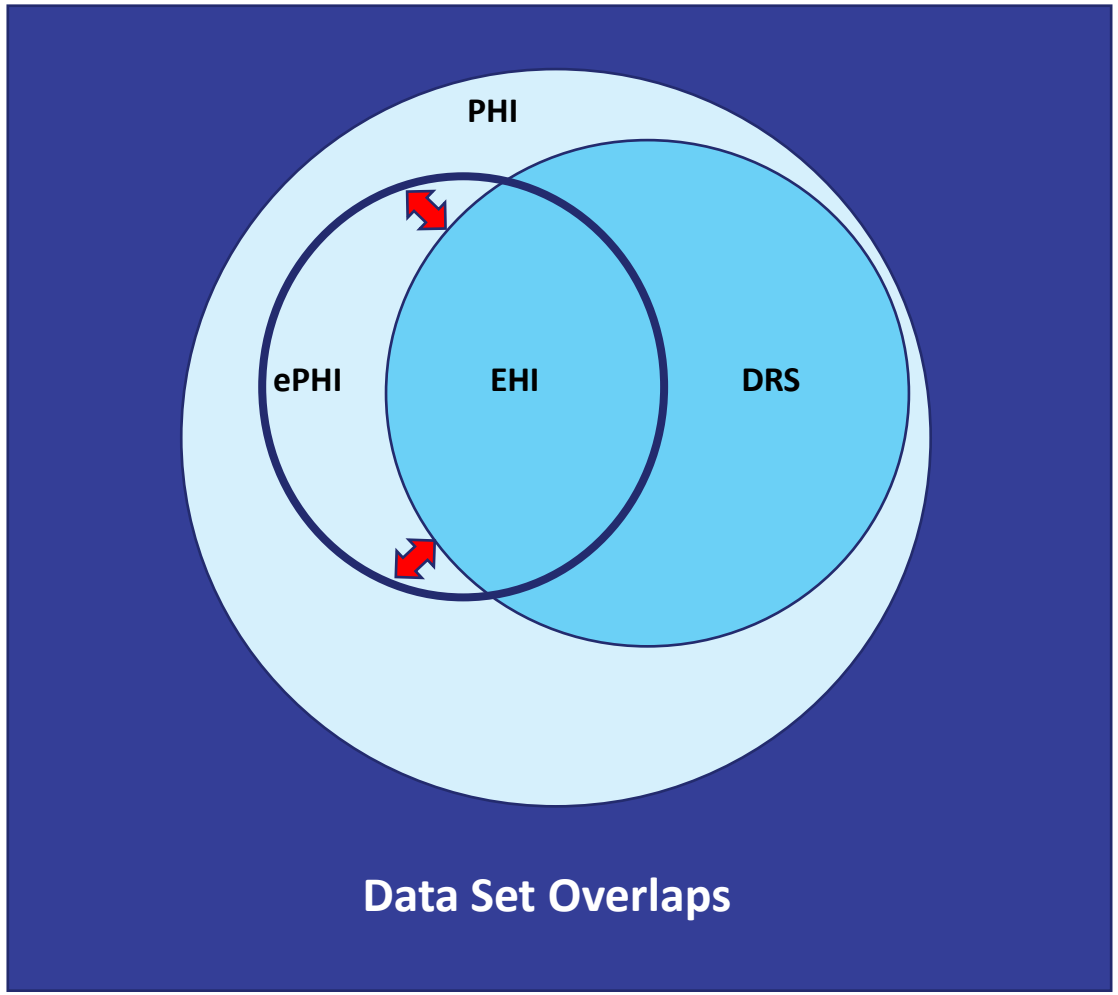
Data Universes under HIPAA and Information Blocking



Definition

- PHI – 45 CFR 160.103
- DRS – 45 CFR 164.501
- ePHI – electronic subset of PHI
- ⇔ EHI – intersection of ePHI and DRS

Challenges

- DRS to some extent is fluid by implementation, thus scope of EHI can change by actor, even though it may involve the exact same data set, ePHI, available

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Key considerations: Status conditions

- Certain data classes may not be considered EHI depending on their “status”
- Task Force identified several status conditions
  - Unvalidated data
  - Draft data
  - Duplicative data
  - Data that does not meet the ePHI definition

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Status condition: Unvalidated Data

- Examples
  - External records prior to clinical review or reconciliation
  - Device readings not reviewed or checked by a clinician
  - Patient-generated data that is submitted prior to clinical review of reconciliation

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Status condition: Draft Data

- Examples
  - Clinical note or report in progress that may be written or edited but not signed
  - Pre-charting
  - Data used in teaching workflows, provided a medical student begins the work and it is later taken over by other authors

Status condition: Duplicative Data

- Examples
  - Audio transcription files and/or transcribed text of lab result information that is both in the lab system and the EHR

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Status condition: Data does not meet the ePHI definition

- Definitions of ePHI and IIHI indicate that the context of collection and HIPAA definitions play a role in defining EHI
- Information must be collected by a covered entity (CE) or business associate (BA) when they are acting as a CE or BA and not as an employer or in other capacities to be considered EHI
  - Employee health service
- De-identified data or data that is not patient identifiable is not considered EHI

Data Class & Next Steps

- Whether a data class is considered EHI will evolve over time
- Standardizing expectations around the definition of EHI important to the operationalization of Cures Act Final Rule
- Task Force Next steps
  - Seek feedback from stakeholders
  - Refine consensus understanding of what data classes are EHI including follow-up actions by the federal government and/or private sector to operationalize the definition of EHI
  - Exploration of whether common characteristics across covered entities could yield a common interpretation of the DRS to serve as a template

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Good News/Bad News

- When the data is generated can matter
- Results from one patient at a time
- APIs can make it easier to get bad data faster
- Data Mapping and Cleaning
  - Extracting, transforming, and loading data from one system to another
- Native data standardization as opposed to after it was collected
- LHR versus DRS as EHI

Federal Information Technology Plan

- Trusted Exchange Framework and Common Agreement (TEFCA)
- Payer to Patient Access Application Provider Interface
- Provider to Patient Access API Requirement
- Payer to payer EHI Sharing Requirement
- HL7 Da Vinci Project

Top Trends in Healthcare

1. Interoperability is progressing
2. Almost all EHR vendors have improved connections
3. Ambulatory clinics and smaller hospitals are connecting to share data now more than ever before
4. High costs and lack of EHR vendor technical readiness make interoperability harder for half of the providers
5. Networks have been steadily increasing since 2017. Providers consider private and public health information exchanges the most valuable sharing method
6. Patient-facing app use is still in the early stages, it is growing. Apple is the most common third party being used. Providers that are not using patient-facing apps are in the process of certifying with Apple to start using FHIR

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https://www.beckershospitalreview.com/ehrs/10-key-ehr-interoperability-trends-outlined-by-klas-and-chime.html

Top Trends in Healthcare

7. Large health systems make up the majority of organizations adopting FHIR application programming interfaces, primarily for patient-record exchange, clinician-enabling tools, and patient-facing tools
8. About one-third of providers with FHIR APIs said they are too early in their interoperability process to rate their satisfaction with the technologies
9. Proprietary APIs, such as patient-record exchange, patient-facing tools and clinician-facing tools are proving to be valuable among provider organizations
10. Over the next two to three years, providers want their vendors to focus on improving patient-record exchange by making it bidirectional and enhancing population health capabilities.

https://www.beckershospitalreview.com/ehrs/10-key-ehr-interoperability-trends-outlined-by-klas-and-chime.html

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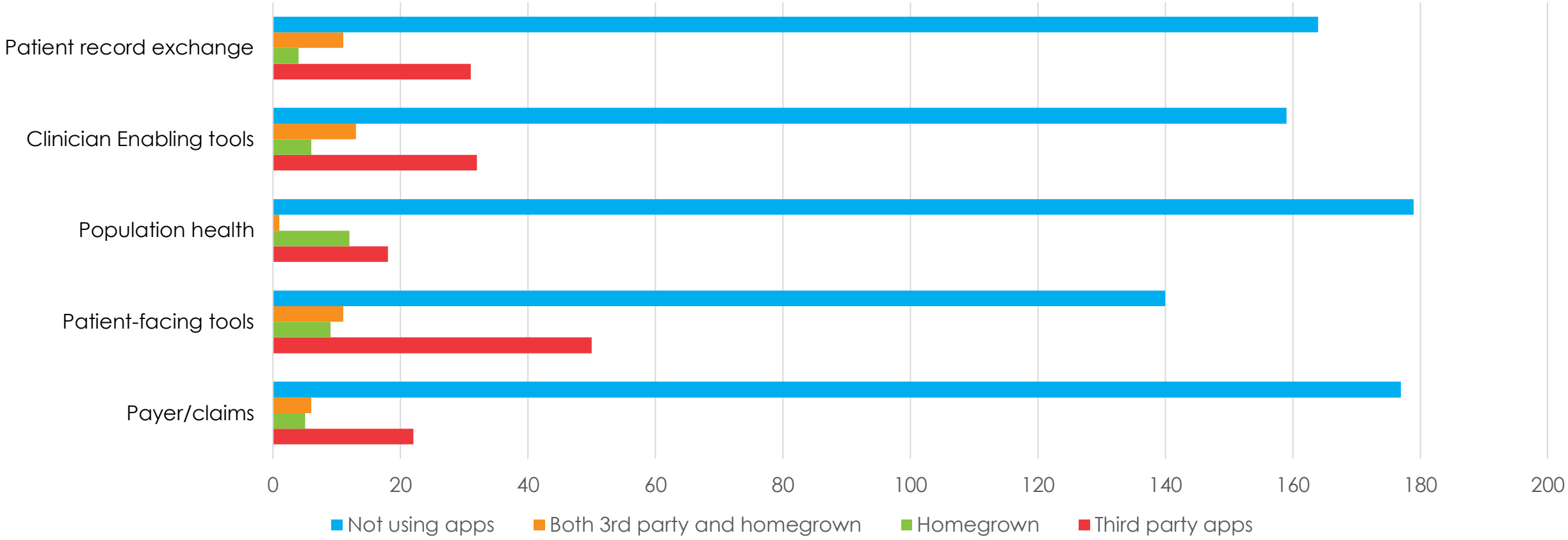
Types of Apps Being Used



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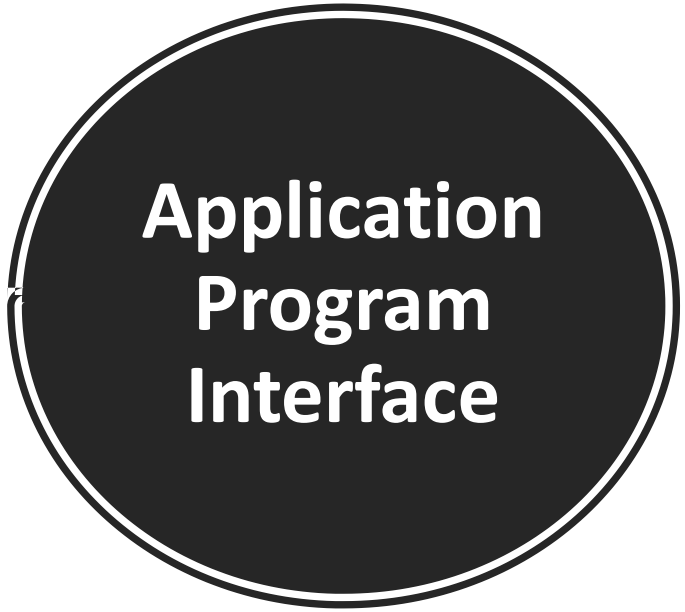
Programming Interfaces Are Key for Healthcare



APIs help applications talk to each other

Transition to value-based care

From EHR implementation & adoption to interoperability

Challenges accessing and sharing data as we migrate to the cloud

FHIR can make it easier to use and share data

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Four Levels of API Integration

- **Read:** Extract Data from the EHR and send it to another application
- **Read and write**: Extract data and send different data back to the EHR
- **Read, write and change**: Extract, send data, and change existing data in the EHR
- **Read, write, change and add**: All of the above and bring in third party data to both the EHR and the other application

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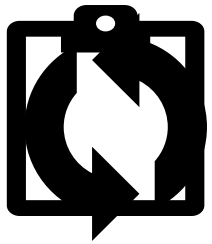
Interoperability and Information Governance

Establishes policy

Determines accountabilities for managing information



Promotes objectivity through robust, repeatable processes

Protects information with appropriate controls

Prioritizes investments

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Conduct a Risk Assessment

Identify staff and processes for monitoring/auditing the organization's incoming and outgoing EHI requests

- Staff
  - HIM
  - IT
  - Quality
  - Revenue Cycle
  - Informatics
  - Vendors/Business Associates
  - Ancillary Departments

- Current processes for
  - ROI
  - API interfaces and third-party linkage
  - Payer & other external party requests
  - Amendments
  - Patient portal
  - Other exchanges – HIEs

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INTEROPERABILITY & INFORMATION GOVERNANCE

- How is interoperability incorporated into our overall Information Governance plan?
- How does my organization access, exchange or use EHI?
- What other organizations request EHI, ie; patients, providers, payors, attorneys, HIEs?
- What processes need to be revised to ensure interoperability?
- How do I incorporate the Information Blocking Exceptions into my policies and procedures?
- How are patients accessing/using the portal?
- How do I educate patients regarding access, exchange and use of EHI?
- How do I respond to a request for EHI?
- Is there anything that limits my response to an EHI request?

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INTEROPERABILITY & INFORMATION GOVERNANCE

Assess Processes for Compliance and Operational Efficiencies

- The United States Core Data for Interoperability (USCDI)
- Data elements to be included in the designated record set
- Designated record set definition
- Data segmentation (as necessary) for sensitive EHI
- Unsigned or incomplete documents
- Lab/test results that require review before availability
- Approvals of 3rd party apps
- Patient identification and matching accuracy

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Patient Search is Not Easy

- EHRs miss 30-90% of duplicate errors*
- Because EHRs use 60's, 70's & 80's search technology

National Patient Identity Misidentification Report 2016

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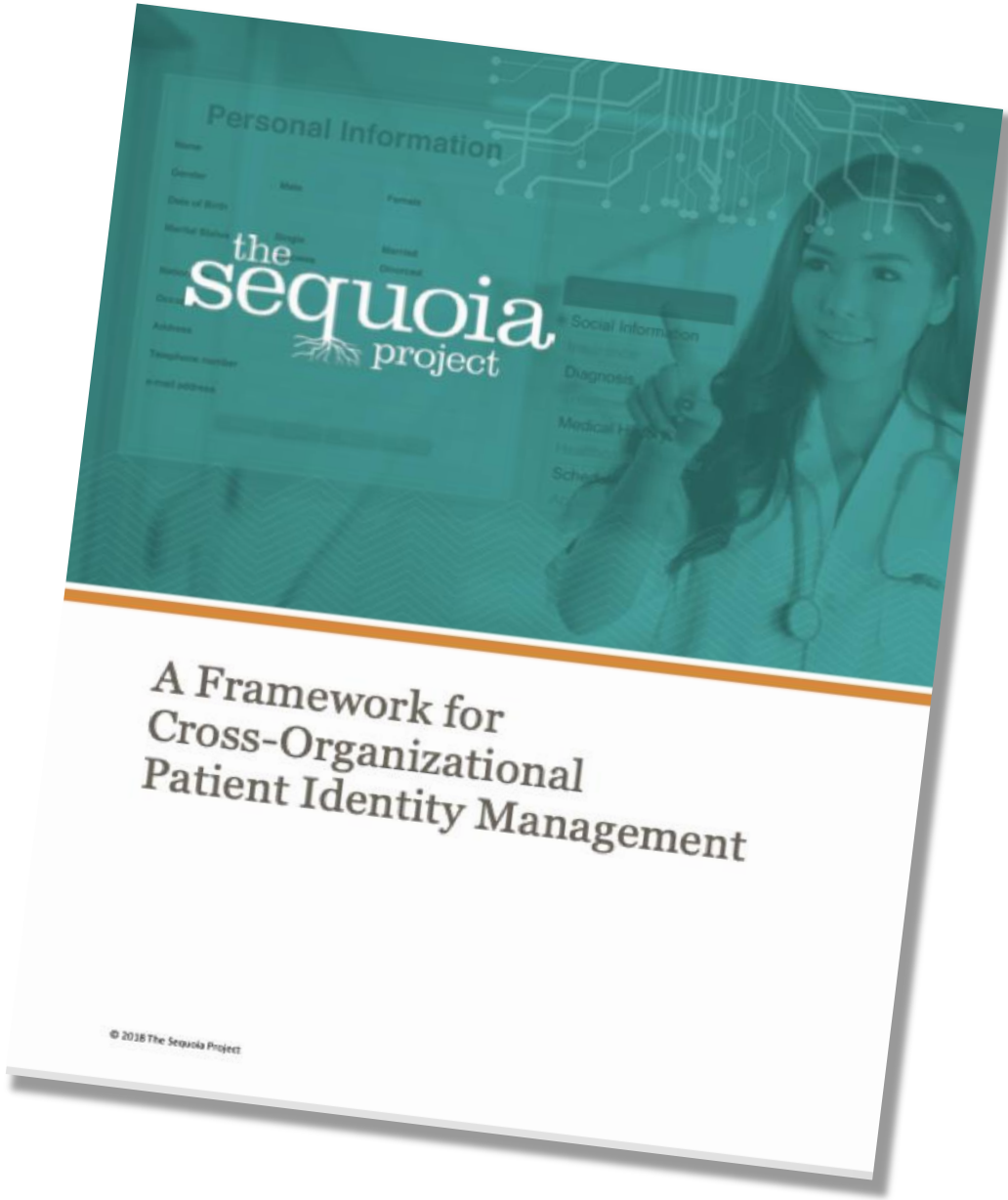
Implications of Old Technology

- This is not good for compliance with the 21st Century Cures Act!
- 70-90% cross-organization matches fail*
- *Why?*
  - Same as the reasons why we have duplicates
  - Different data standards and data quality at different providers



*ONC & The Sequoia Project Research

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Data Standards and Data Quality Matter

- Data standard differences are caused by software, training, priority of data quality, and protocols of each provider
- Data standard differences include
  - Using middle initials instead of middle names
  - Data formats
  - Normalized vs. not normalized
  - Handling of compound-names (space, no space, punctuation)
  - Historical data or lack thereof

Provider	DOB	First Name	Middle Name	Last Name	SSN	Cell Number	Street Address	Street Address 2
Big Hospital System	02/07/1975	CHUNG	HEE	KIM	998-45-7832	555-123-3421	456 S. Sentator Drive #5	
Local Provider	07/02/1975	CHUNGHEE		KIM	9985557832	5551233421	456 Senator	Apt. 5

https://journal.ahima.org/page/patient-identification-ahima-naming-policy

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Interoperability & MPI Search

- Historical patient address, telephone, other names are ev
  more important now
- Be aware of missing data
  - Not all providers collect the same information
    - Full employer data, NOK or guarantor full name and
      contact data are often different between providers
    - Different types of patient names: nickname, other
      names, preferred names, aliases, names as
      registered before
- Lack of a universal patient ID

USCDI v1 Summary of Data Classes and Data Elements

Allergies and Intolerance			
Substance (Medication)	Substance (Drug Class)	Reaction	
Assessment and Plan of Treatment			
Care Team Members			
Clinical Notes			
Consultation Note	Discharge Summary Note	History & Physical	Imaging Narrative
Laboratory Report Narrative	Pathology Report Narrative	Procedure Note	Progress Note
Goals			
Patient Goals			
Health Concerns			
Immunizations			
Laboratory			
Tests	Values/Results		
Medications			
Medications	Medication Allergies		
Patient Demographics			
First Name	Last Name	Previous Name	Middle Name (including middle initial)
Suffix	Birth Sex	Date of Birth	Race
Ethnicity	Preferred Language	Current Address	Previous Address
Phone Number	Phone Number type	Email Address	
Problems			
Procedures			
Provenance			
Author Time Stamp	Author Organization		
Smoking Status			
Unique Device Identifier(s) for a Patient's Implantable Device(s)			
Vital Signs			
Diastolic Blood Pressure	Systolic Blood Pressure	Body Height	Body Weight
Heart Rate	Respiratory Rate	Body Temperature	Pulse Oximetry
Inhaled Oxygen Concentration	BMI Percentile (2-20 years)	Weight-for-length Percentile (Birth - 36 months)	Head Occipital-frontal Circumference Percentile (Birth - 36 months)

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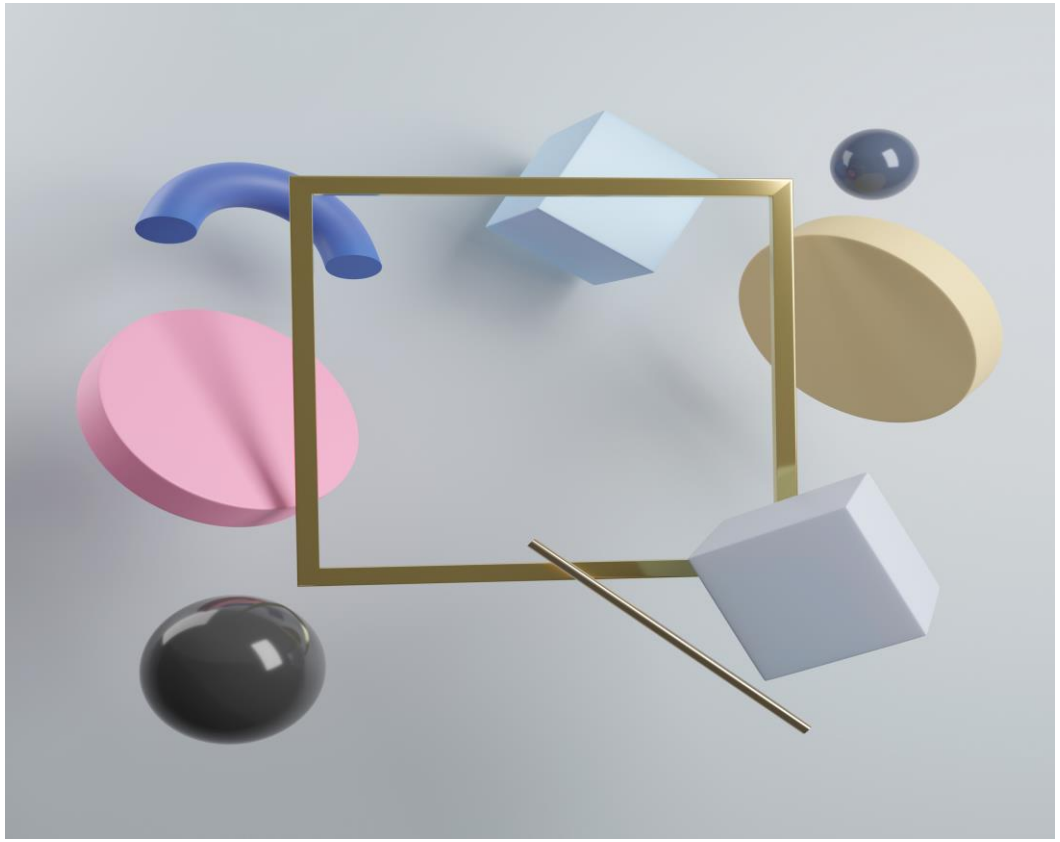
Learning from Our Mistakes

- Significant costs and patient safety issues can be partially attributed to EHR search limitations
- We no longer can do three-letter & DOB only searches!
- We can *Avoid Repeating the Same Mistake* again
- AHIMA Recommended Data Elements for Capture in the MPI



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Name provided at Registration	Legal Name Verified on Government ID	First Name Field	Middle Name Field	Last Name Field
Harvey Garcia Rodriguez	Harvey Davis Garcia-Rodriguez	Harvey	Davis	Garcia-Rodriguez
C Nguyen	C N Nguyen	C	N	Nguyen
Wayne Martinez	R D Wayne Martinez	RD	Wayne	Martinez
George Jones	George 7 Jones	George	7*	Jones
Elena Lusk	Elena Lusk			Lusk
Patty Anderson		Patty		Anderson
Madonna	Madonna	Madonna		Madonna

[41] Note: Health IT systems should be evaluated for inclusion of numeric values in name fields.

Suffixes

Legal Name Verified Government ID	Data Entered in First Name Field	Data Entered In Middle Name Field	Data Entered in Last Name Field	Data Entered in Suffix Field
James R. Billings Jr.	James	Randolph	Billings	JR
Charles Wayne Miller III	Charles	Wayne	Miller	III

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Sex and Gender

- Patient Identified Sexual Orientation
- Sex Assigned at Birth
- HL7 International Standard Publication
- FHIR Standards & Mapping Guidelines
- Ensure Registration Procedures include patient self-identified
- Sex assigned at birth (separate field)
- Legal sex (government-issued ID)

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Best Practices, Policies, and Procedures

- From paper to electronic
- Standardized demographics
- Review, update and implement patient access, interoperability, API and information blocking related patient request workflows, policies, procedures and forms
- Review and revise P&Ps as necessary to meet the information blocking requirements

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Leading with Interoperability

- EHR Interoperability is here and expanding rapidly
- Patient facing APIs and requests will continue to grow
- Assessing your current state will help you begin your journey
- Focus on data integrity and governance
- MPI & demographic accuracy are crucial to patient safety & compliance

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Conclusion

- ePHI and PHI are considered EHI ---
- EHI is defined per HIPAA as DRS
- LHR and DRS may or may not be the same– Must be defined by the organization

References

- file:///C:/Users/dprimeau/Documents/Presentations/AHIMA%202021%20Virtual%20Conference/Trends-in-EMR-Interoperability_CHIME_KLAS.pdf
- https://www.nextgen.com/blog/2020/january/integrated-care-interoperability
- Federal Register :: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (Information Blocking examples – proposed rule)
- CARIN Alliance Code of Conduct: https://www.carinalliance.com/our-work/trust-frameworkand-code-of-conduct/
- ONC Model Privacy Notice: https://www.healthit.gov/topic/privacy-security-andhipaa/model-privacy-notice-mpn
- More information visit https://www.cms.gov/Regulations-andGuidance/Guidance/Interoperability/index

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Thank You

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