Séminaires Recherche et Pratique en Santé Publique

Institut de Santé Publique d'Epidémiologie et de Développement

Université de Bordeaux, France

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Interoperability for clinical analytics

Observational Health Data Sciences and Informatics (OHDSI)

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U.S. National Library of Medicine

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Outline

- Observational Health Data Sciences and Informatics (OHDSI)
  - OHDSI in action
    - Analyzing drug treatment pathways for 3 chronic diseases from clinical data warehouse in multiple countries
  - How do they do that?
- The context of clinical data science
  - Datasets
  - Data models
  - Terminologies
- Current trends and future directions

Observational Health Data Sciences and Informatics (OHDSI)

OHDSI Outline

- OHDSI in action
  - Analyzing drug treatment pathways for 3 chronic diseases from clinical data warehouse in multiple countries
- How do they do that?
  - From OMOP to OHDSI
  - Foundational principles
  - OHDSI software, test data and methods

Characterizing treatment pathways at scale using the OHDSI network

CrossMark click for updates

COLLOQUIUM PAPER

Characterizing treatment pathways at scale using the OHDSI network

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www.pnas.org/cgi/doi/10.1073/pnas.1510502113 PNAS | July 5, 2016 | vol. 113 | no. 27 | 7329–7336

Characterizing treatment pathways at scale using the OHDSI network

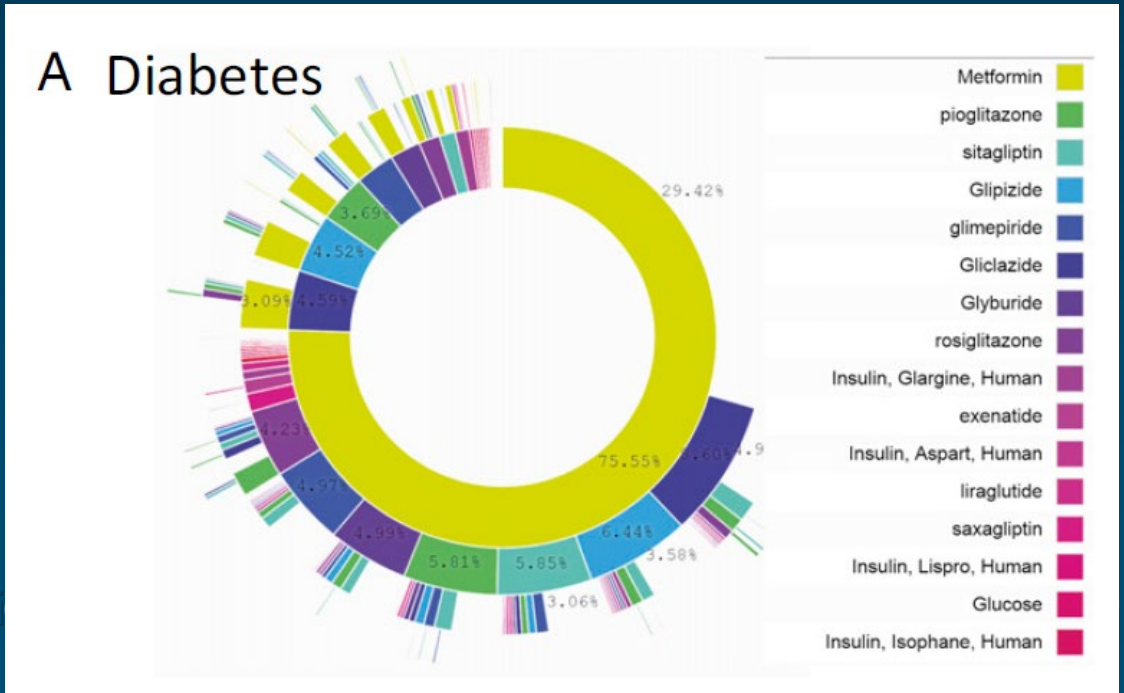
- Objectives: analyze the variability of pharmacological treatment interventions over three years across three diseases (type-2 diabetes mellitus, hypertension, or depression)
- Inclusion criteria: exposure to an antidiabetic, antihypertensive, or antidepressant medication for 3 years, as well as presence of at least one diagnostic code for the corresponding disease
- Exclusion criteria: based on diagnostic data (e.g., exclusion of schizophrenia patients from the depression cohort)

Characterizing treatment pathways at scale using the OHDSI network

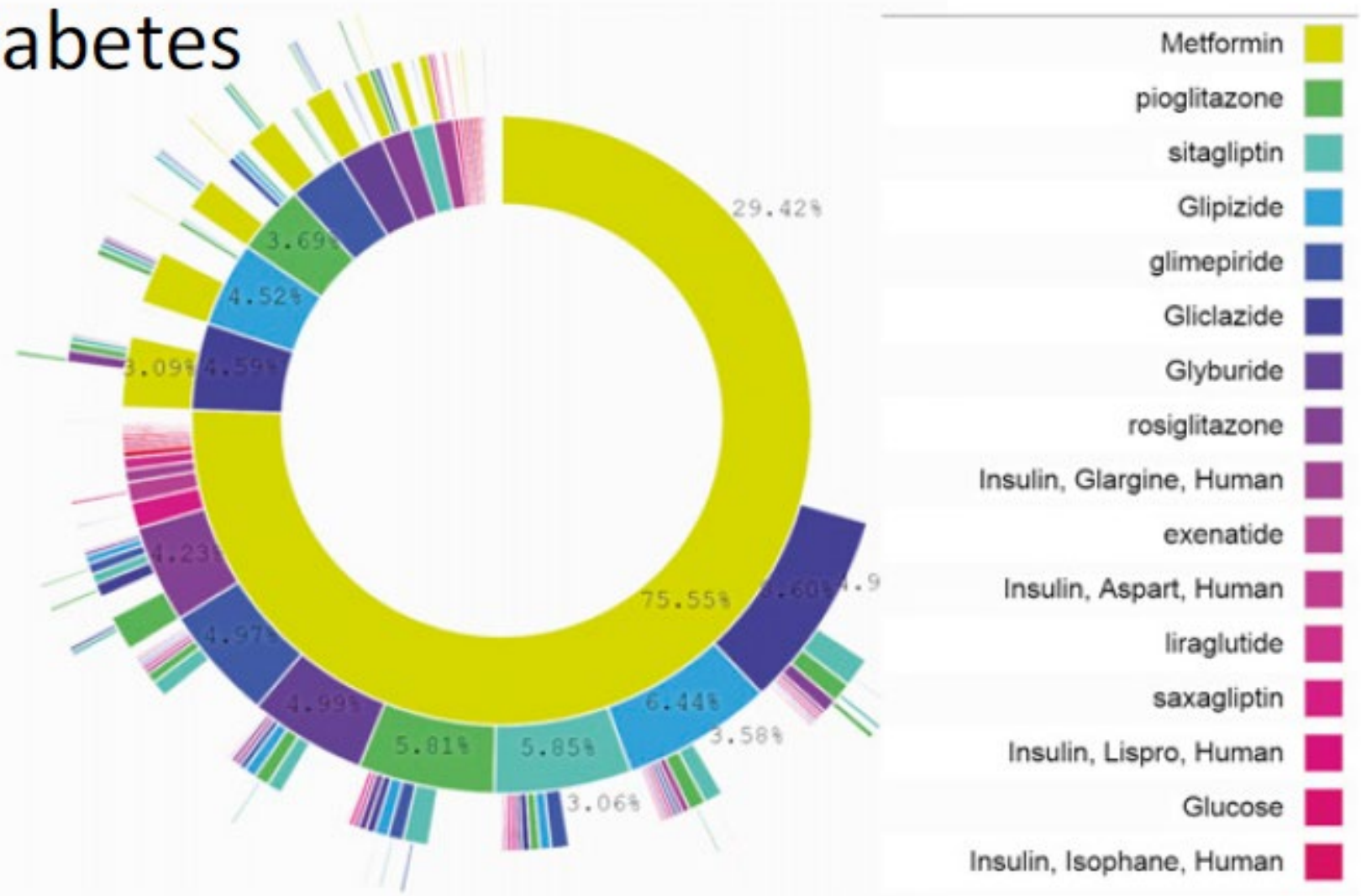
- Materials: 11 datasets representing a total of 255 million patients
  - EHR data (South Korea, U.K., U.S.) 67M
  - Claims data (U.S., Japan) 188M
- Methods: Analyze the sequences of medications that patients were placed on during those 3 years, to reveal patterns and variation in treatment among data sources and diseases

Characterizing treatment pathways at scale using the OHDSI network

- Results
  - Patients with 3 years of uninterrupted therapy
    - 327,110 diabetes patients
    - 1,182,792 hypertension patients
    - 264,841 depression patients
  - Treatment pathways

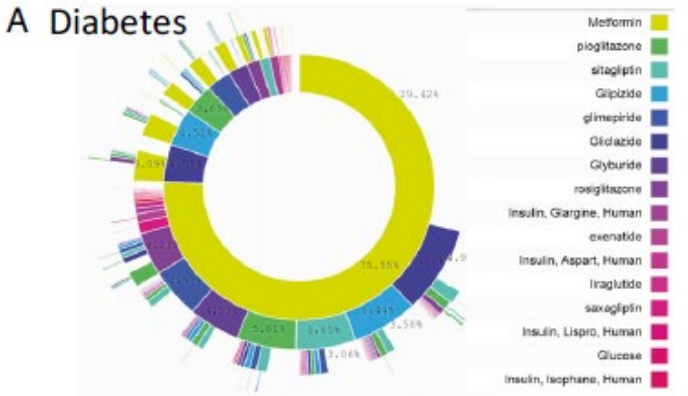


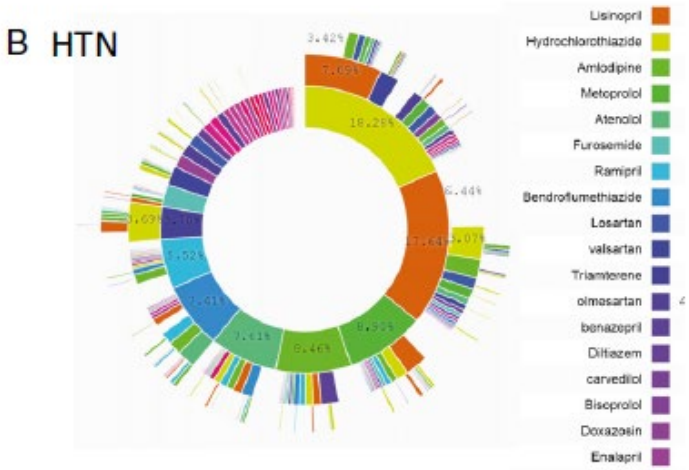
A Diabetes

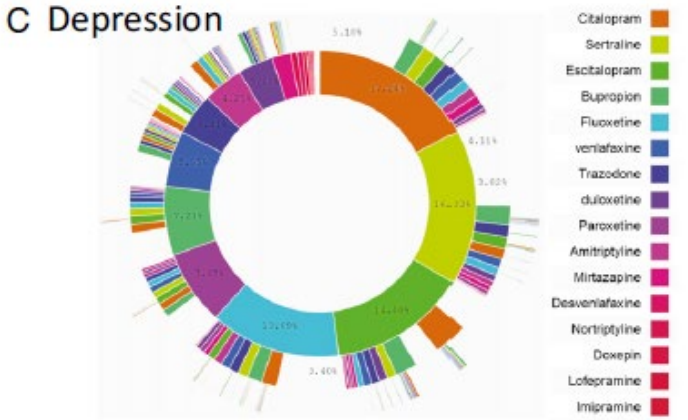

29.42%
75.55%
6.44%
5.85%
5.01%
4.99%
4.97%
4.52%
3.69%
3.58%
3.06%
Metformin
pioglitazone
sitagliptin
Glipizide
glimepiride
Gliclazide
Glyburide
rosiglitazone
Insulin, Glargine, Human
exenatide
Insulin, Aspart, Human
liraglutide
saxagliptin
Insulin, Lispro, Human
Glucose
Insulin, Isophane, Human

Differences across diseases

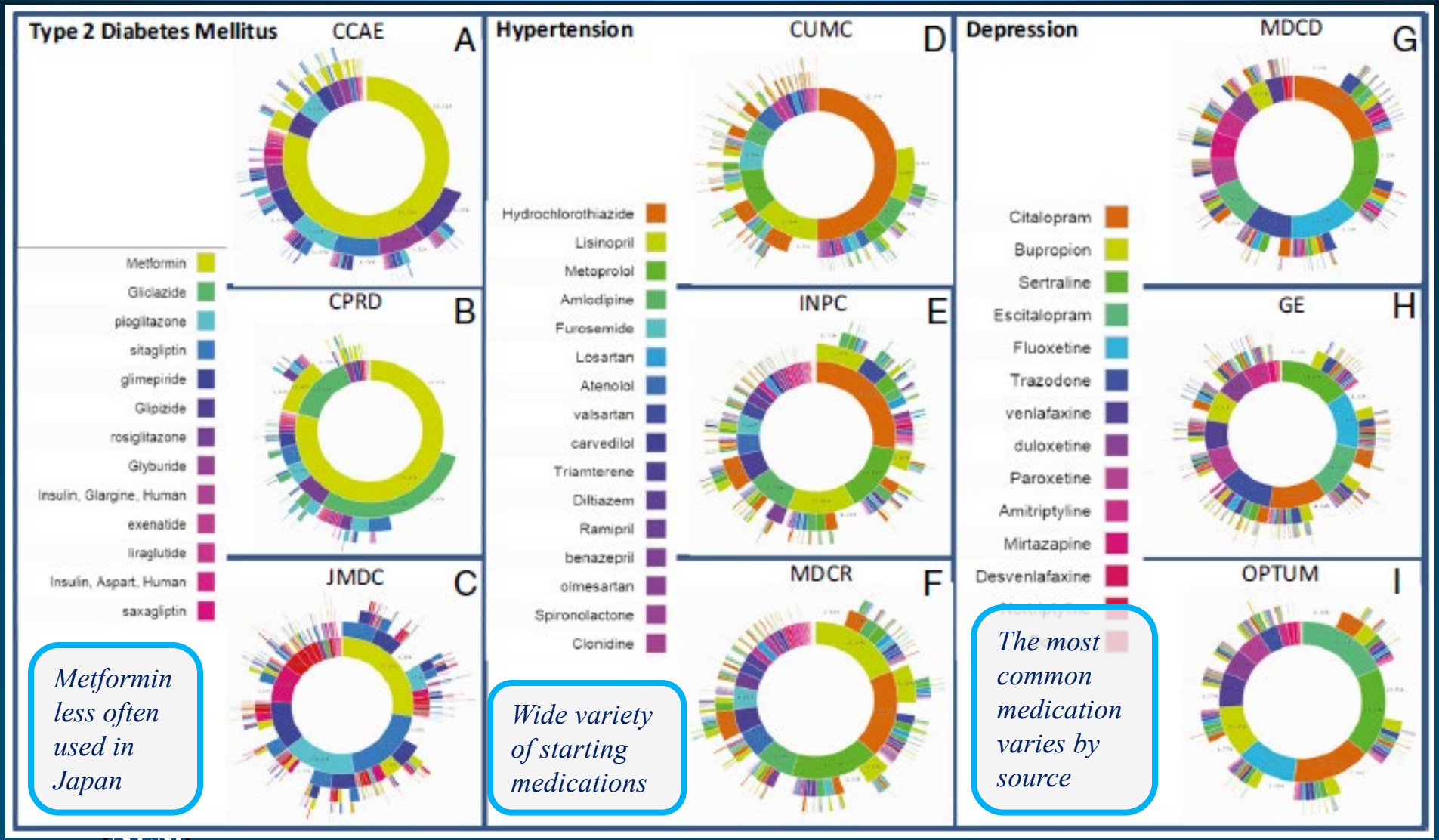
- Diabetes
  - Metformin is the first line of treatment and often the only treatment
- Hypertension
  - Slight predominance of HCTZ, frequently paired with other medications
- Depression
  - Even spread of medications
- Unique treatment pathways (within a cohort)
  - 10% TDM
  - 25% HTN







Differences across countries



From OMOP to OHDSI

- OMOP – Observational Medical Outcomes Partnership
  - Public-private partnership established to inform the appropriate use of observational healthcare databases for studying the effects of medical products (2008-2013)
  - Community of researchers from industry, government, and academia
  - Achievements
    - Conduct methodological research to empirically evaluate the performance of various analytical methods on their ability to identify true associations and avoid false findings
    - Develop tools and capabilities for transforming, characterizing, and analyzing disparate data sources across the health care delivery spectrum
    - Establish a shared resource so that the broader research community can collaboratively advance the science

From OMOP to OHDSI

- OHDSI – Observational Health Data Sciences and Informatics
  - Multi-stakeholder, interdisciplinary collaborative to bring out the value of health data through large-scale analytics
  - International network of researchers and observational health databases with a central coordinating center housed at Columbia University
  - Continues to actively use the OMOP Common Data Model and Standardized Vocabularies
  - Develops open-source solutions [with Greek names]
  - Annual symposium

Foundational principles

- Data standardization through
  - Common data model (OMOP CDM)
  - Standard vocabularies
- Conversion (ETL) of the local clinical data warehouse to the OMOP CDM and standard vocabularies
  - Supported by the *RabbitInAHat* tool
- Applicable to various types of observational data (EHR, claims)
- Data remain local to a clinical institution
- The same query/protocol can be executed at each site and the results aggregated across sites
- Research projects are based on rigorous protocols
- Open science (Open-source software, open protocols, open results)

OHDSI (open-source) software

- Tools for mapping data to OHDSI
  - WhiteRabbit – profile your source data
  - RabbitInAHat – map your source structure to CDM tables and fields
  - ATHENA – standardized vocabularies for all CDM domains
  - Usagi – map your source codes to CDM vocabulary
  - ACHILLES – database characterization and data quality assessment

OHDSI (open-source) software

- CALYPSO – analytical component for clinical study feasibility assessment
- CIRCE – cohort creation
- HERACLES – cohort-level analysis and visualization
- LAERTES – system for investigating the association of drugs and health (adverse events)
- DRUG EXPOSURE EXPLORER – visualize drug exposures (an experimental deployment using the SynPUF 1% simulated patient data set)
- […]

OHDSI methods

- Types of methods
  - Population-Level Estimation
    - Safety surveillance
    - Comparative effectiveness
  - Patient-Level Prediction
- Effect estimation & calibration
  - Confidence interval calibration
- Implemented with open-source tools for large-scale analytics
  - R packages

Examples of network research studies

- Characterizing treatment pathways at scale using the OHDSI network
- Levetiracetam and risk of angioedema in patients with seizure disorder
- Comparison of combination treatment in hypertension (against RCTs)
- Drug utilization in children
- Comparative effectiveness of alendronate and raloxifene in reducing the risk of hip fracture

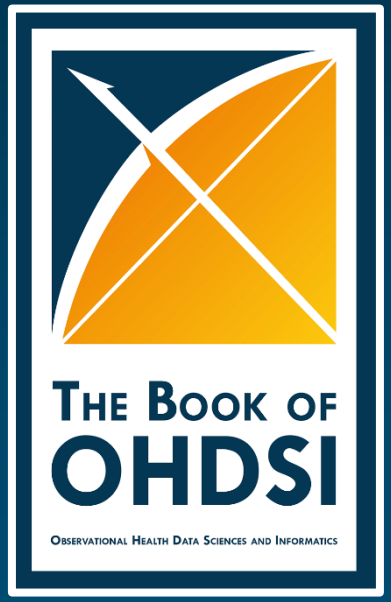
More about OHDSI

- OHDSI Europe

  https://www.ohdsi-europe.org/

- The Book of OHDSI (Aug. 2019)

  https://ohdsi.github.io/TheBookOfOhdsi/



The context of clinical data science

The context of clinical data science Outline

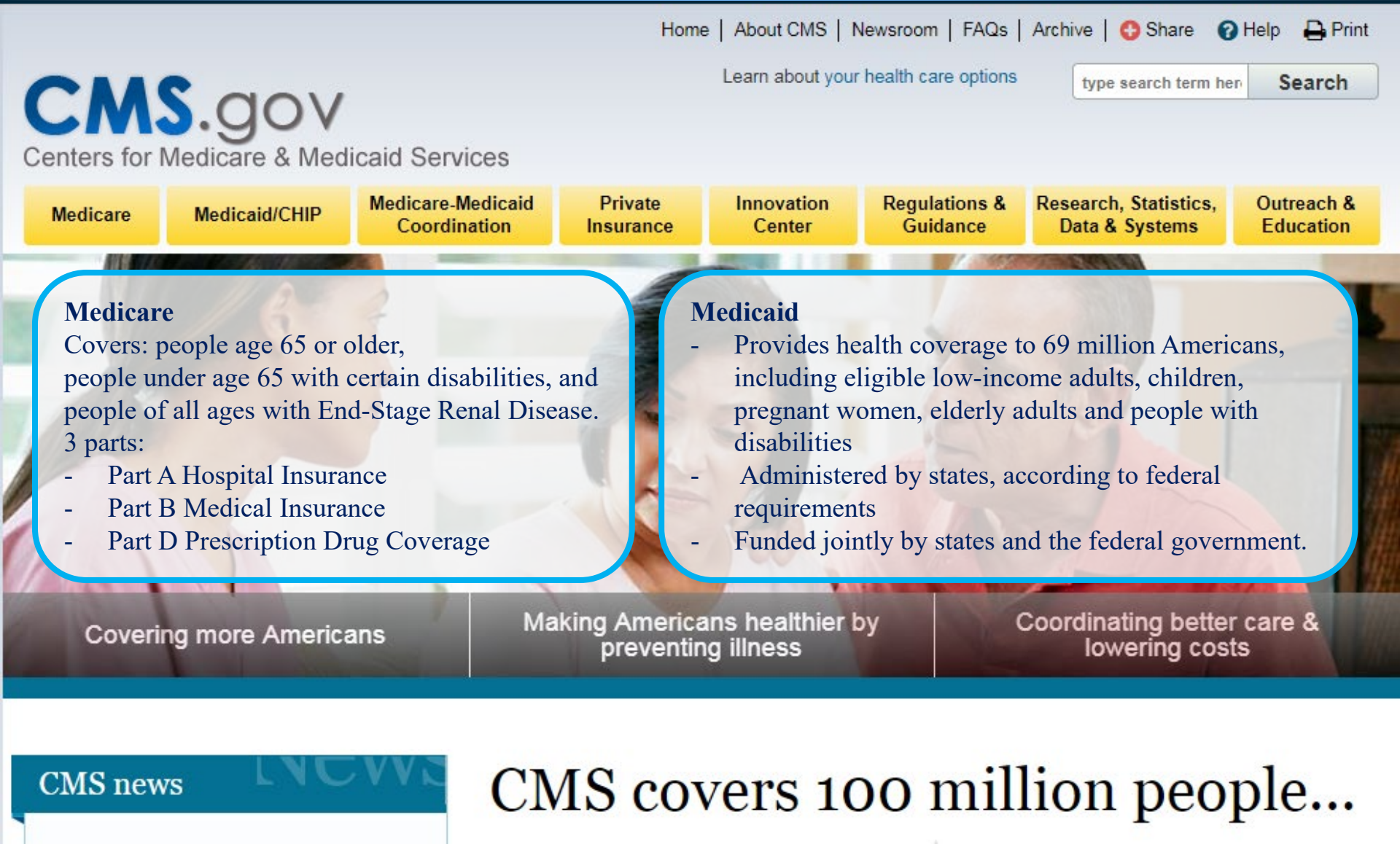
- Datasets
- Data models
- Terminologies

Datasets

- Center for Medicare and Medicaid (CMS) data
- MIMIC III
- Clinical data warehouses (academic medical centers, Veterans Administration)
- EHR vendors (GE Centricity; EPIC Clarity; Cerner Health Facts)
- Commercial datasets (OPTUM, Truven)

https://www.cms.gov/

Center for Medicare and Medicaid (CMS)



Center for Medicare and Medicaid (CMS) data

- Available through the CMS Virtual Research Data Center (VRDC)
  - At a cost
  - Cloud-based environment – data cannot be downloaded
- Longitudinal data available
  - From 1999 for demographics, hospitalization and ambulatory data
  - From 2006 from drug coverage

Example of use of CMS data

Am J Surg. 2017 Jun 24. pii: S0002-9610(17)30289-1. doi: 10.1016/j.amjsurg.2017.06.007. [Epub ahead of print]

Outpatient beta-blockers and survival from sepsis: Results from a national cohort of Medicare beneficiaries.

Singer KE[1], Collins CE[1], Flahive JM[2], Wyman AS[1], Ayturk MD[1], Santry HP[3].

Author information

Abstract

BACKGROUND: Elderly Americans suffer increased mortality from sepsis. Given that beta-blockers have been shown to be cardioprotective in critical care, we investigated outpatient beta-blocker prescriptions and mortality among Medicare beneficiaries admitted for sepsis.

METHODS: We queried a 5% random sample of Medicare beneficiaries for patients admitted with sepsis. We used in-hospital and outpatient prescription drug claims to compare in-hospital and 30-day mortality based on pre-admission beta-blocker prescription and class of beta-blocker prescribed using univariate tests of comparison and multivariable logistic regression models and another class of medications for control.

RESULTS: Outpatient beta-blocker prescription was associated with a statistically significant decrease in in-hospital and 30-day mortality. In multivariable modeling, beta-blocker prescription was associated with 31% decrease in in-hospital mortality and 41% decrease in 30-day mortality. Both cardioselective and non-selective beta-blockers conferred mortality benefit.

CONCLUSIONS: Our data suggests that there may be a role for preadmission beta-blockers in reducing sepsis-related mortality.

PMID: 28666578 DOI: 10.1016/j.amjsurg.2017.06.007

MIMIC III

- Medical Information Mart for Intensive Care
- Freely available to researchers worldwide
- Encompasses a diverse and very large population of ICU patients (~40k)
- Includes demographics, vital signs, laboratory tests, medications, and bedside monitor trends and waveforms
- Contains high temporal resolution data

Example of use of MIMIC data

Lower short- and long-term mortality associated with overweight and obesity in a large cohort study of adult intensive care unit patients

Swapna Abhyankar ✉, Kira Leishear, Fiona M Callaghan, Dina Demner-Fushman and Clement J McDonald

Critical Care 2012 **16**:R235 | **DOI:** 10.1186/cc11903

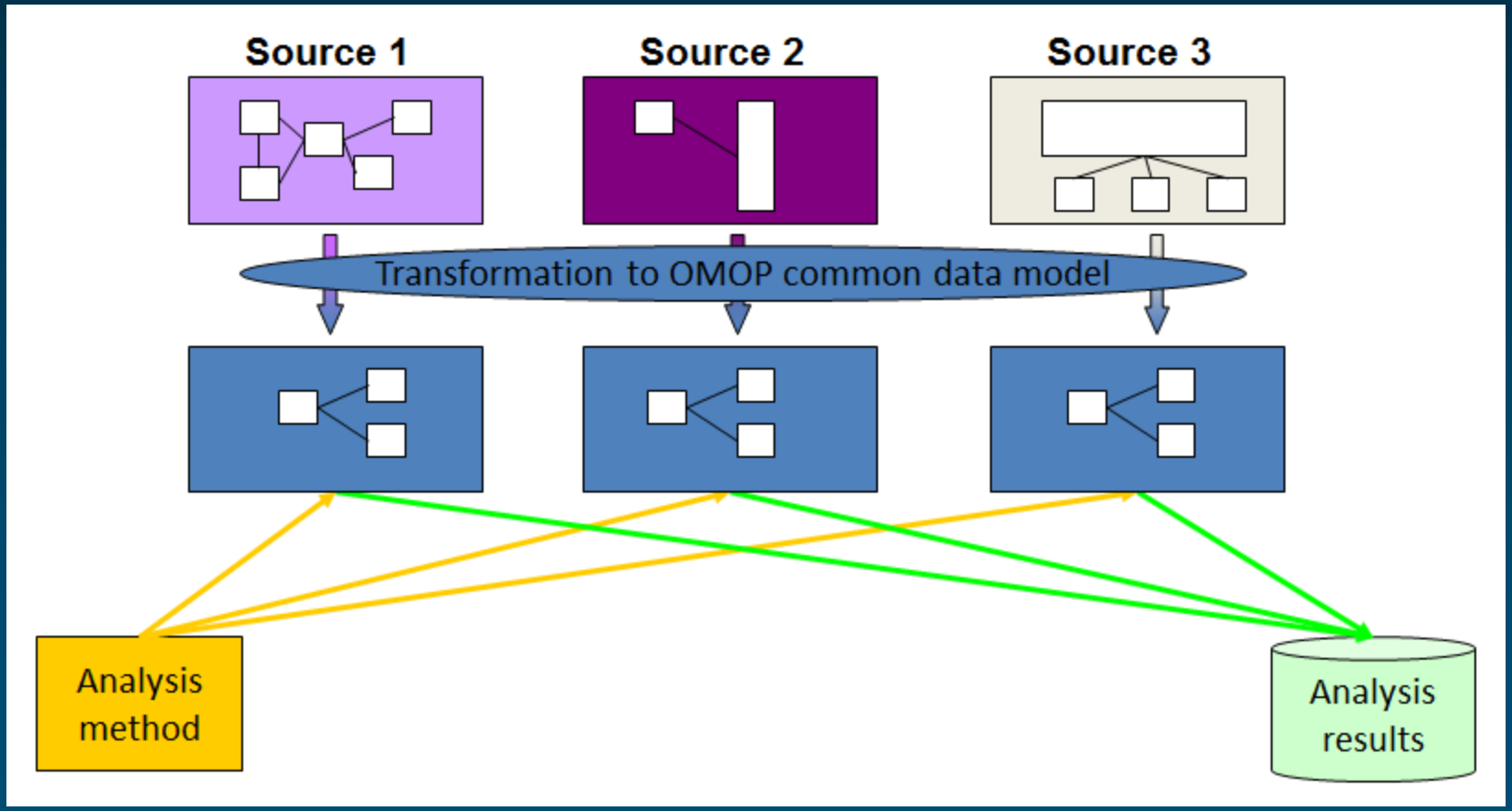
Received: 2 August 2012 | **Accepted:** 13 December 2012 | **Published:** 18 December 2012

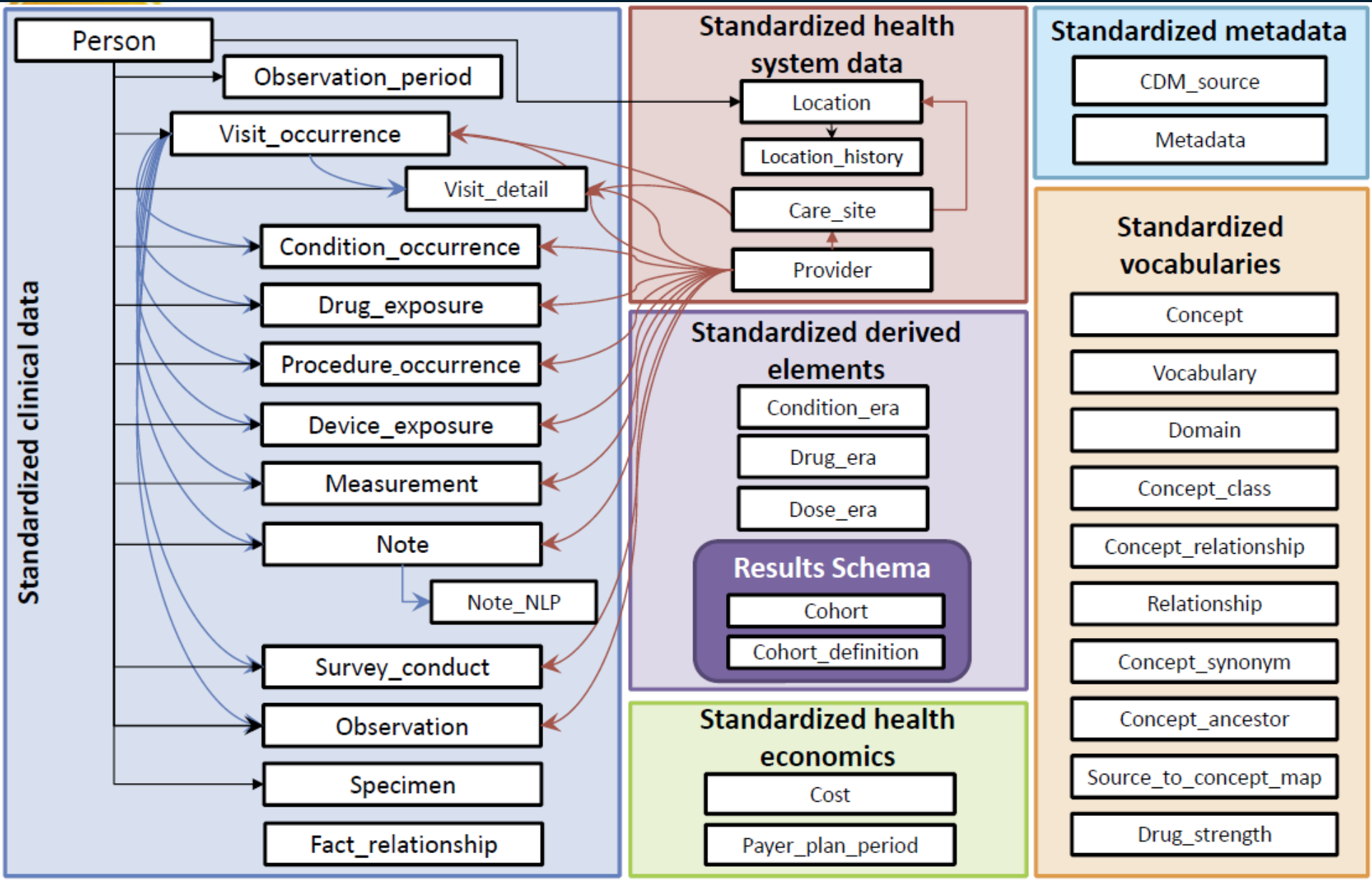
Data models

- OMOP
- i2b2
- PCORnet
- Sentinel
- CDISC

OMOP

- OMOP – Observational Medical Outcomes Partnership

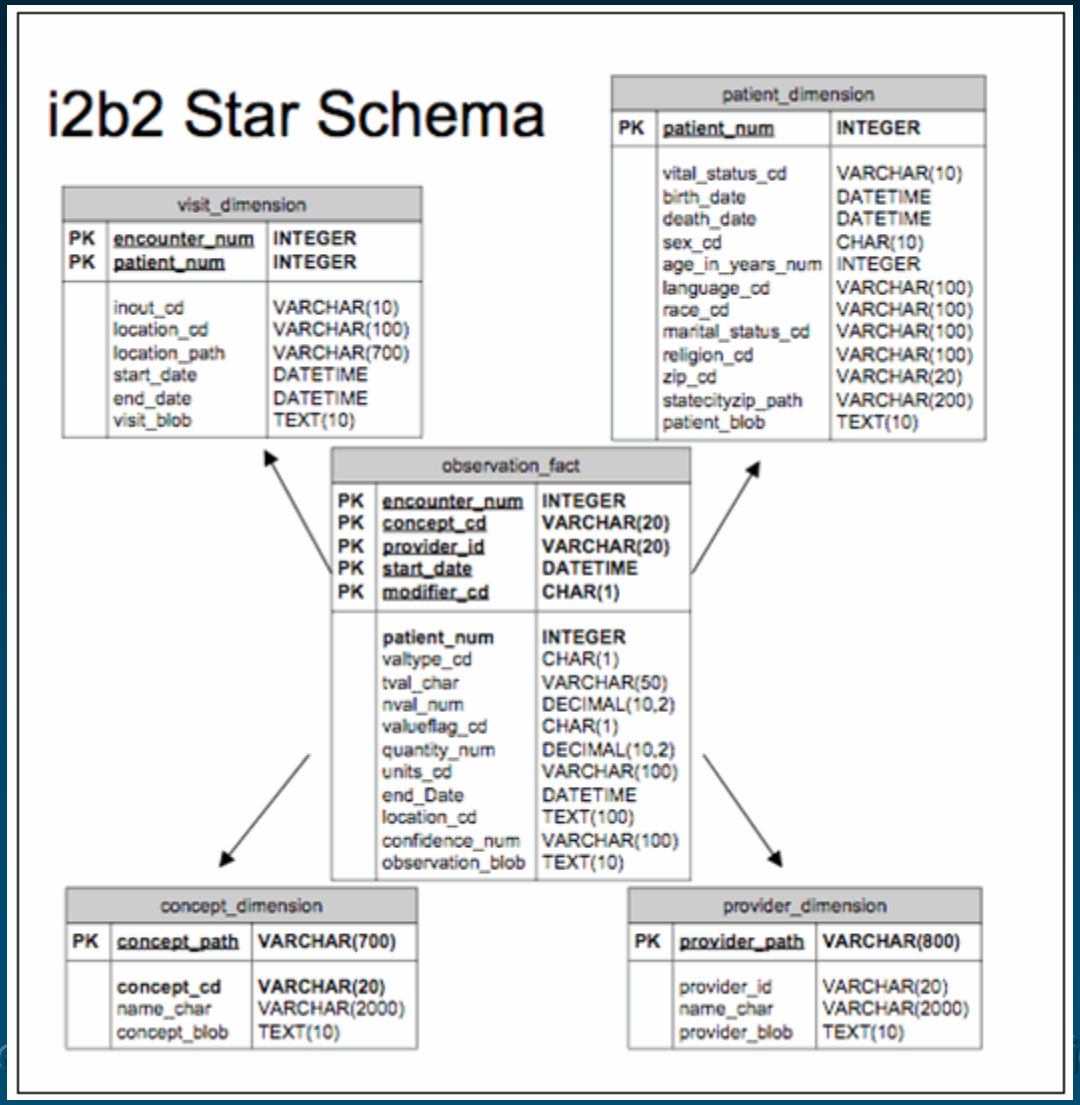



Standardized clinical data
Person
Observation_period
Visit_occurrence
Visit_detail
Condition_occurrence
Drug_exposure
Procedure_occurrence
Device_exposure
Measurement
Note
Note_NLP
Survey_conduct
Observation
Specimen
Fact_relationship
Standardized health system data
Location
Location_history
Care_site
Provider
Standardized derived elements
Condition_era
Drug_era
Dose_era
Results Schema
Cohort
Cohort_definition
Standardized health economics
Cost
Payer_plan_period
Standardized metadata
CDM_source
Metadata
Standardized vocabularies
Concept
Vocabulary
Domain
Concept_class
Concept_relationship
Relationship
Concept_synonym
Concept_ancestor
Source_to_concept_map
Drug_strength

i2b2

- i2b2 – Informatics for Integrating Biology & the Bedside
- Originally developed by the i2b2 National Center for Biomedical Computing (2004-2013)
  - Now i2b2 tranSMART Foundation
- Platform to support translational research
- Widely adopted worldwide

i2b2 data model – original "star schema"



i2b2-OMOP convergence

- i2b2 on OMOP
  - Supports query formulation against an OMOP-compliant data source through i2b2 tools

PCORnet

- PCORnet – National Patient-Centered Clinical Research Network
- Initiative of the Patient-Centered Outcomes Research Institute (PCORI)
  - Funded through the Patient Protection and Affordable Care Act of 2010
- "designed to make it faster, easier, and less costly to conduct clinical research"
- Made up of
  - 13 Clinical Data Research Networks (CDRNs)
  - 20 Patient-Powered Research Networks (PPRNs)

Current version is 4.1

http://www.pcornet.org/pcornet-common-data-model/

PCORnet Common Data Model v3.0

New to v3.0

DEMOGRAPHIC
PATID
BIRTH_DATE
BIRTH_TIME
SEX
HISPANIC
RACE
BIOBANK_FLAG

Fundamental basis

ENROLLMENT
PATID
ENR_START_DATE
ENR_END_DATE
CHART
ENR_BASIS

DISPENSING
DISPENSINGID
PATID
PRESCRIBINGID (optional)
DISPENSE_DATE
NDC
DISPENSE_SUP
DISPENSE_AMT

DEATH
PATID
DEATH_DATE
DEATH_DATE_IMPUTE
DEATH_SOURCE
DEATH_MATCH_CONFIDENCE

DEATH_CONDITION
PATID
DEATH_CAUSE
DEATH_CAUSE_CODE
DEATH_CAUSE_TYPE
DEATH_CAUSE_SOURCE
DEATH_CAUSE_CONFIDENCE

Data captured from processes associated with healthcare delivery

VITAL
VITALID
PATID
ENCOUNTERID (optional)
MEASURE_DATE
MEASURE_TIME
VITAL_SOURCE
HT
WT
DIASTOLIC
SYSTOLIC
ORIGINAL_BMI
BP_POSITION
SMOKING
TOBACCO
TOBACCO_TYPE

CONDITION
CONDITIONID
PATID
ENCOUNTERID (optional)
REPORT_DATE
RESOLVE_DATE
ONSET_DATE
CONDITION_STATUS
CONDITION
CONDITION_TYPE
CONDITION_SOURCE

PRO_CM
PRO_CM_ID
PATID
ENCOUNTERID (optional)
PRO_ITEM
PRO_LOINC
PRO_DATE
PRO_TIME
PRO_RESPONSE
PRO_METHOD
PRO_MODE
PRO_CAT

Data captured within multiple contexts: healthcare delivery, registry activity, or directly from patients

ENCOUNTER
ENCOUNTERID
PATID
ADMIT_DATE
ADMIT_TIME
DISCHARGE_DATE
DISCHARGE_TIME
PROVIDERID
FACILITY_LOCATION
ENC_TYPE
FACILITYID
DISCHARGE_DISPOSITION
DISCHARGE_STATUS
DRG
DRG_TYPE
ADMITTING_SOURCE

DIAGNOSIS
DIAGNOSISID
PATID
ENCOUNTERID
ENC_TYPE (replicated)
ADMIT_DATE (replicated)
PROVIDERID (replicated)
DX
DX_TYPE
DX_SOURCE
PDX

PROCEDURES
PROCEDURESID
PATID
ENCOUNTERID
ENC_TYPE (replicated)
ADMIT_DATE (replicated)
PROVIDERID (replicated)
PX_DATE
PX
PX_TYPE
PX_SOURCE

LAB_RESULT_CM
LAB_RESULT_CM_ID
PATID
ENCOUNTERID (optional)
LAB_NAME
SPECIMEN_SOURCE
LAB_LOINC
PRIORITY
RESULT_LOC
LAB_PX
LAB_PX_TYPE
LAB_ORDER_DATE
SPECIMEN_DATE
SPECIMEN_TIME
RESULT_DATE
RESULT_TIME
RESULT_QUAL
RESULT_NUM
RESULT_MODIFIER
RESULT_UNIT
NORM_RANGE_LOW
NORM_MODIFIER_LOW
NORM_RANGE_HIGH
NORM_MODIFIER_HIGH
ABN_IND

PRESCRIBING
PRESCRIBINGID
PATID
ENCOUNTERID (optional)
RX_PROVIDERID
RX_ORDER_DATE
RX_ORDER_TIME
RX_START_DATE
RX_END_DATE
RX_QUANTITY
RX_REFILLS
RX_DAYS_SUPPLY
RX_FREQUENCY
RX_BASIS
RXNORM_CUI

Data captured from healthcare delivery, direct encounter basis

PCORNET_TRIAL
PATID
TRIALID
PARTICIPANTID
TRIAL_SITEID
TRIAL_ENROLL_DATE
TRIAL_END_DATE
TRIAL_WITHDRAW_DATE
TRIAL_INVITE_CODE

Associations with PCORnet clinical trials

HARVEST
NETWORKID
NETWORK_NAME
DATAMARTID
DATAMART_NAME
DATAMART_PLATFORM
CDM_VERSION
DATAMART_CLAIMS
DATAMART_EHR
BIRTH_DATE_MGMT
ENR_START_DATE_MGMT
ENR_END_DATE_MGMT
ADMIT_DATE_MGMT
DISCHARGE_DATE_MGMT
PX_DATE_MGMT
RX_ORDER_DATE_MGMT
RX_START_DATE_MGMT
RX_END_DATE_MGMT
DISPENSE_DATE_MGMT
LAB_ORDER_DATE_MGMT
SPECIMEN_DATE_MGMT
RESULT_DATE_MGMT
MEASURE_DATE_MGMT
ONSET_DATE_MGMT
REPORT_DATE_MGMT
RESOLVE_DATE_MGMT
PRO_DATE_MGMT
REFRESH_DEMOGRAPHIC_DATE
REFRESH_ENROLLMENT_DATE
REFRESH_ENCOUNTER_DATE
REFRESH_DIAGNOSIS_DATE
REFRESH_PROCEDURES_DATE
REFRESH_VITAL_DATE
REFRESH_DISPENSING_DATE
REFRESH_LAB_RESULT_CM_DATE
REFRESH_CONDITION_DATE
REFRESH_PRO_CM_DATE
REFRESH_PRESCRIBING_DATE
REFRESH_PCORNET_TRIAL_DATE
REFRESH_DEATH_DATE
REFRESH_DEATH_CAUSE_DATE

Process-related data

Bold font indicates fields that cannot be null due to primary key definitions or record-level constraints.

Sentinel

- Initiative of the Food and Drug Administration (FDA)
- Effort to create a national electronic system for monitoring the performance of FDA-regulated medical products (drugs, vaccines, and other biologics)
- Develop a system to obtain information from existing electronic health care data from multiple sources to assess the safety of approved medical products
- Distributed dataset with 300 million person-years of high quality, unduplicated, curated data

https://www.sentinelinitiative.org/sentinel/data/distributed-database-common-data-model

Sentinel Common Data Model

Administrative Data

Enrollment	Demographic	Dispensing	Encounter	Diagnosis	Procedure
Patient ID	Patient ID	Patient ID	Patient ID	Patient ID	Patient ID
Enrollment Start & End Dates	Birth Date	Dispensing Date	Service Date(s)	Service Date(s)	Service Date(s)
Drug Coverage	Sex	National Drug Code (NDC)	Encounter ID	Encounter ID	Encounter ID
Medical Coverage	Zip Code	Days Supply	Encounter Type and Provider	Encounter Type and Provider	Encounter Type and Provider
Medical Record Availability	Etc.	Amount Dispensed	Facility	Diagnosis Code & Type	Procedure Code & Type
			Etc.	Principal Discharge Diagnosis	Etc.

Clinical Data

Lab Result	Vital Signs
Patient ID	Patient ID
Result & Specimen Collection Dates	Measurement Date & Time
Test Type, Immediacy & Location	Height & Weight
Logical Observation Identifiers Names and Codes (LOINC®)	Diastolic & Systolic BP
Etc.	Tobacco Use & Type
	Etc.

Registry Data

Death	Cause of Death	State Vaccine
Patient ID	Patient ID	Patient ID
Death Date	Cause of Death	Vaccination Date
Source	Source	Admission Date
Confidence	Confidence	Vaccine Code & Type
Etc.	Etc.	Provider
		Etc.

Inpatient Data

Inpatient Pharmacy	Inpatient Transfusion
Patient ID	Patient ID
Administration Date & Time	Administration Start & End Date & Time
Encounter ID	Encounter ID
National Drug Code (NDC)	Transfusion Administration ID
Route	Transfusion Product Code
Dose	Blood Type
Etc.	Etc.

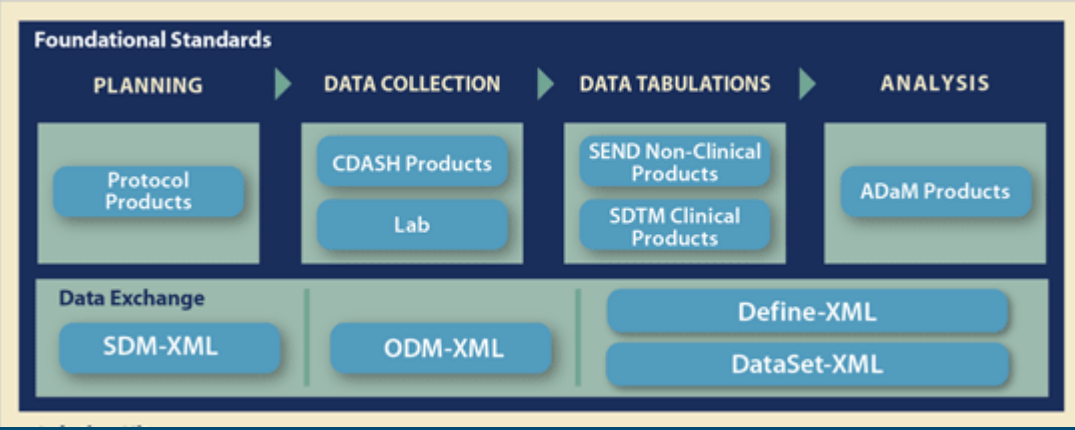
Mother-Infant Linkage Data

Mother-Infant Linkage
Mother ID
Mother Birth Date
Encounter ID & Type
Admission & Discharge Date
Child ID
Child Birth Date
Mother-Infant Match Method
Etc.

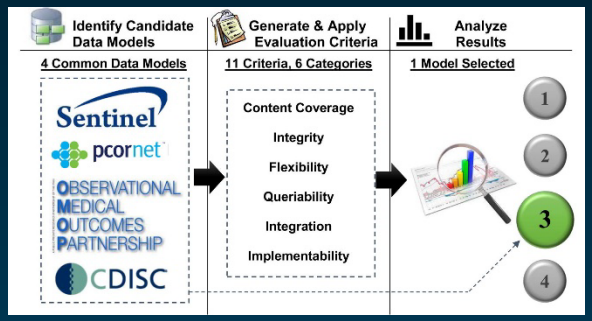
https://www.cdisc.org/

CDISC

- CDISC – Clinical Data Interchange Standards Consortium
- "develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare"
- Set of standards required by FDA for regulatory submissions (clinical research)



Differences among data models



- Comparison of 4 CDMs found OMOP the best for use with a longitudinal community registry
- Examples of differences
  - Derivative data and assumptions
    - Drug eras in OHDSI
  - Terminology binding
    - Commitment to standard terminologies (e.g., OHDSI)
- Ongoing harmonization (?)

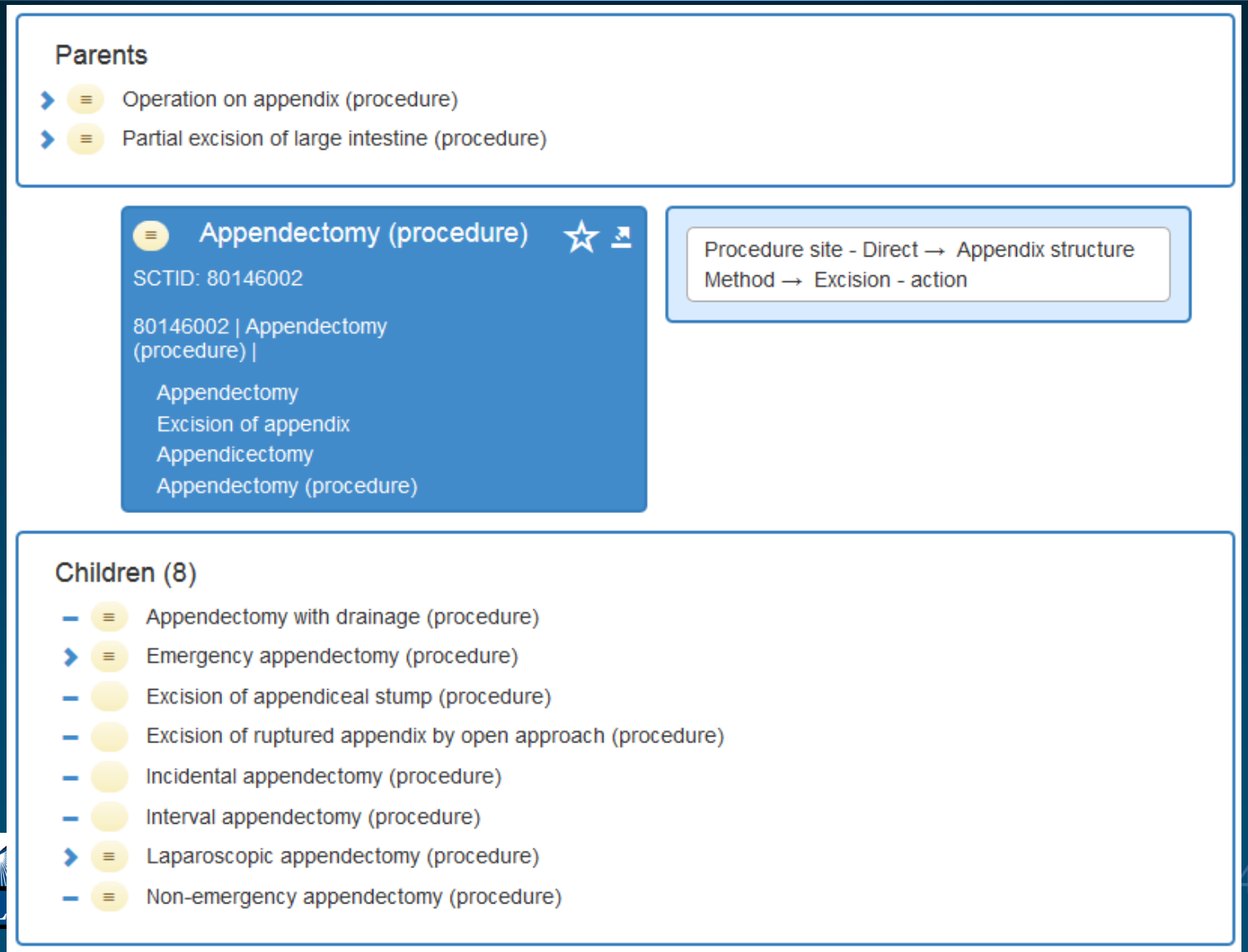
https://aspe.hhs.gov/harmonization-various-common-data-models-and-open-standards-evidence-generation

Terminologies

- Main clinical terminologies for the Meaningful Use incentive program (clinical documentation; clinical quality measures)
  - SNOMED CT
  - LOINC
  - RxNorm
- Legacy terminologies (billing)
  - [ICD9-CM]; ICD10-CM
  - CPT
- Other terminologies (CDISC)
  - NCI Thesaurus

http://browser.ihtsdotools.org/

SNOMED CT Example



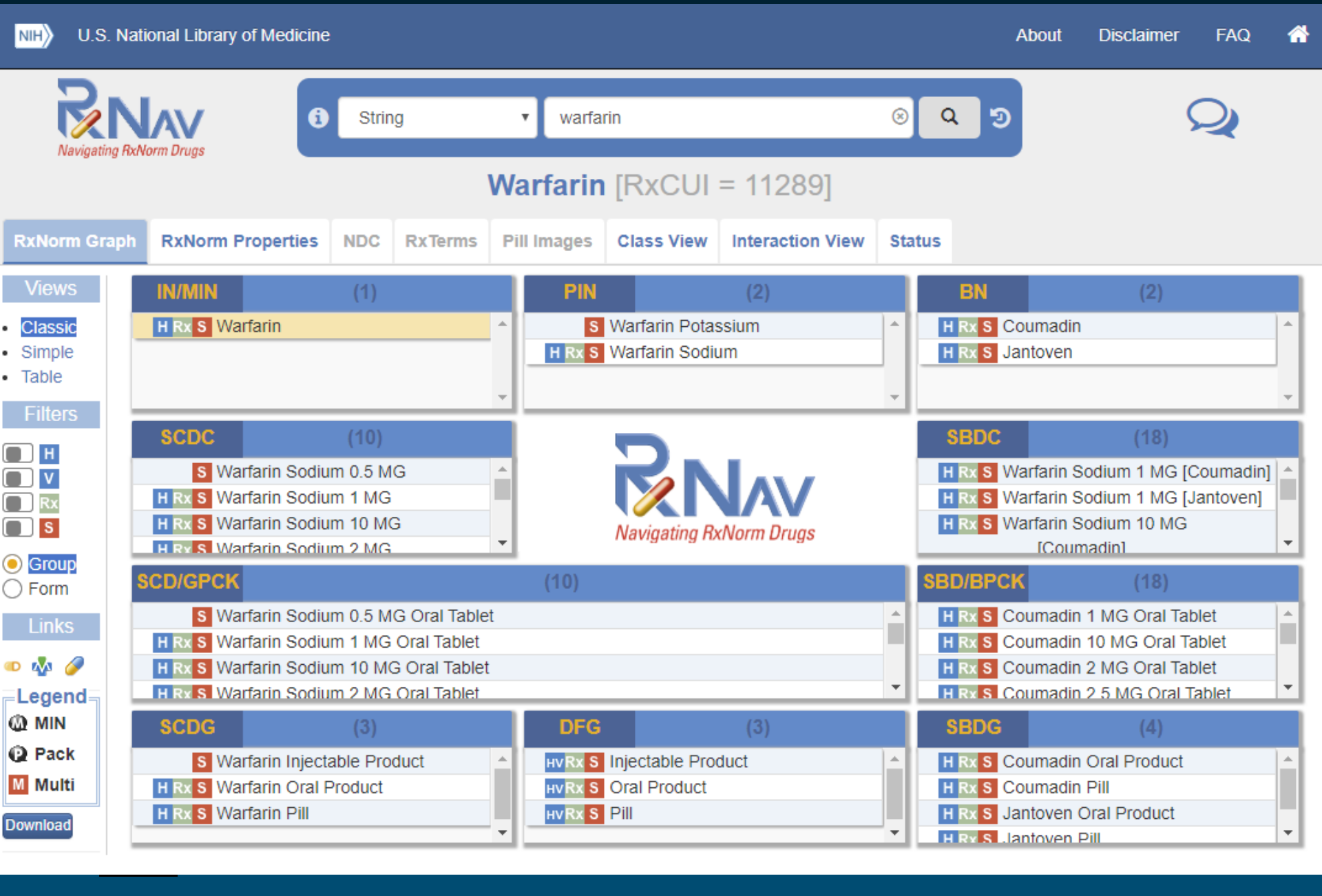
LOINC Example

- *Sodium [Moles/volume] in Serum or Plasma*
  [the molar concentration of sodium is measured in the plasma (or serum), with quantitative result]

Axis	Value
Component	Sodium
Property	SCnc – Substance Concentration (per volume)
Timing	Pt – Point in time (Random)
System	Ser/Plas – Serum or Plasma
Scale	Qn – Quantitative
Method	--

RxNorm Example

https://mor.nlm.nih.gov/RxNav/



ICD-10 vs. ICD-10-CM

E72 **Other disorders of amino-acid metabolism**

Excl.: abnormal findings without manifest disease (R7
disorders of:
- aromatic amino-acid metabolism (E70.-)
- branched-chain amino-acid metabolism (
- fatty-acid metabolism (E71.3)
- purine and pyrimidine metabolism (E79.-

gout (M10.-)

E72.0 **Disorders of amino-acid transport**

Cystine storage disease† (N29.8*)
Cystinosis
Cystinuria
Fanconi(-de Toni)(-Debré) syndrome
Hartnup disease
Lowe syndrome

Excl.: disorders of tryptophan metabolism (E70.8)

x6

E72 **Other disorders of amino-acid metabolism**

Excludes1: disorders of:
aromatic amino-acid metabolism (E70.-)
branched-chain amino-acid metabolism (E71.0-E71.2)
fatty-acid metabolism (E71.3)
purine and pyrimidine metabolism (E79.-)
gout (M1A.-, M10.-)

E72.0 **Disorders of amino-acid transport**

Excludes1: disorders of tryptophan metabolism (E70.5)

E72.00 **Disorders of amino-acid transport, unspecified**

E72.01 **Cystinuria**

E72.02 **Hartnup's disease**

E72.03 **Lowe's syndrome**

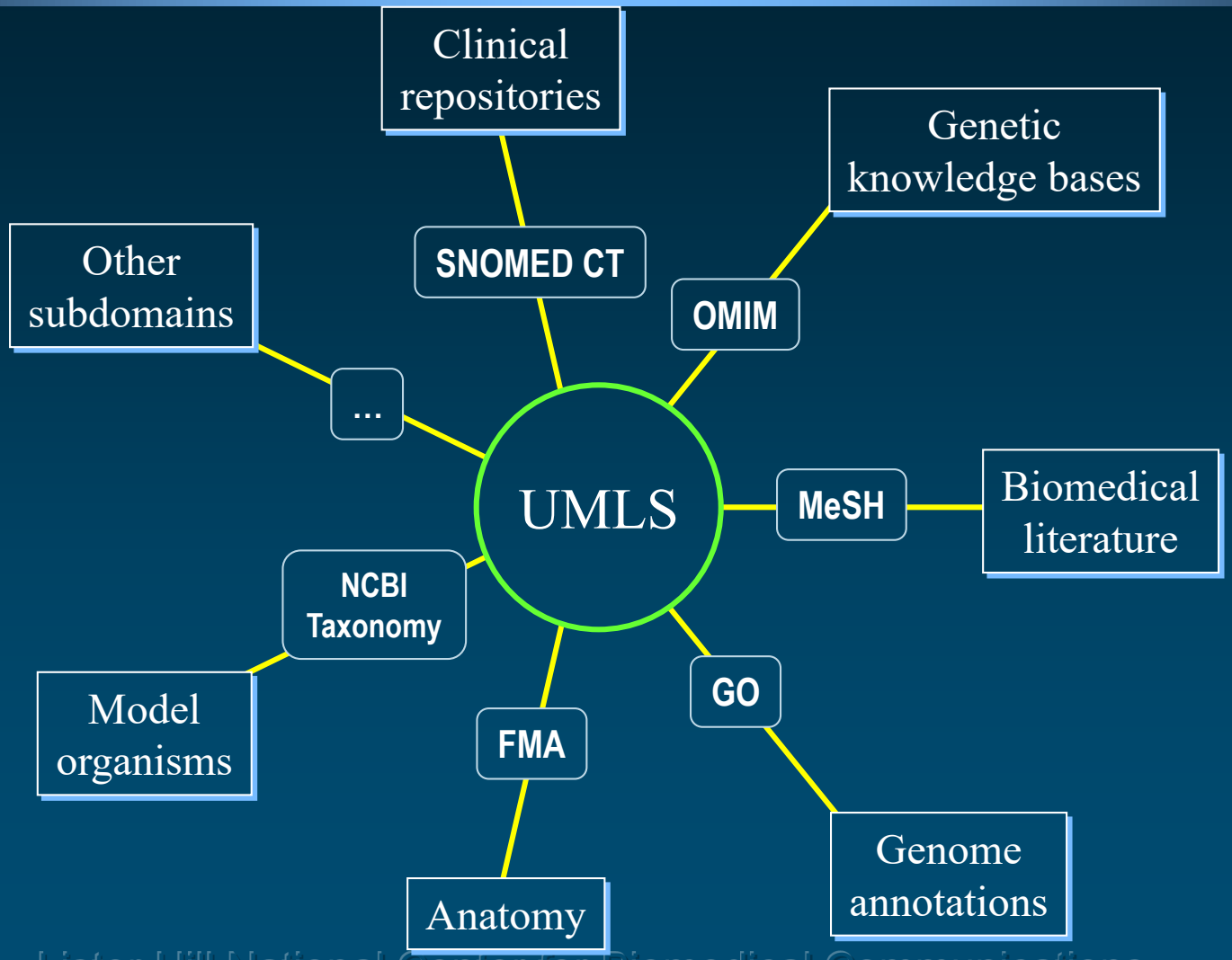
Use additional code for associated glaucoma (H42)

E72.04 **Cystinosis**
Fanconi (-de Toni) (-Debré) syndrome with cystinosis

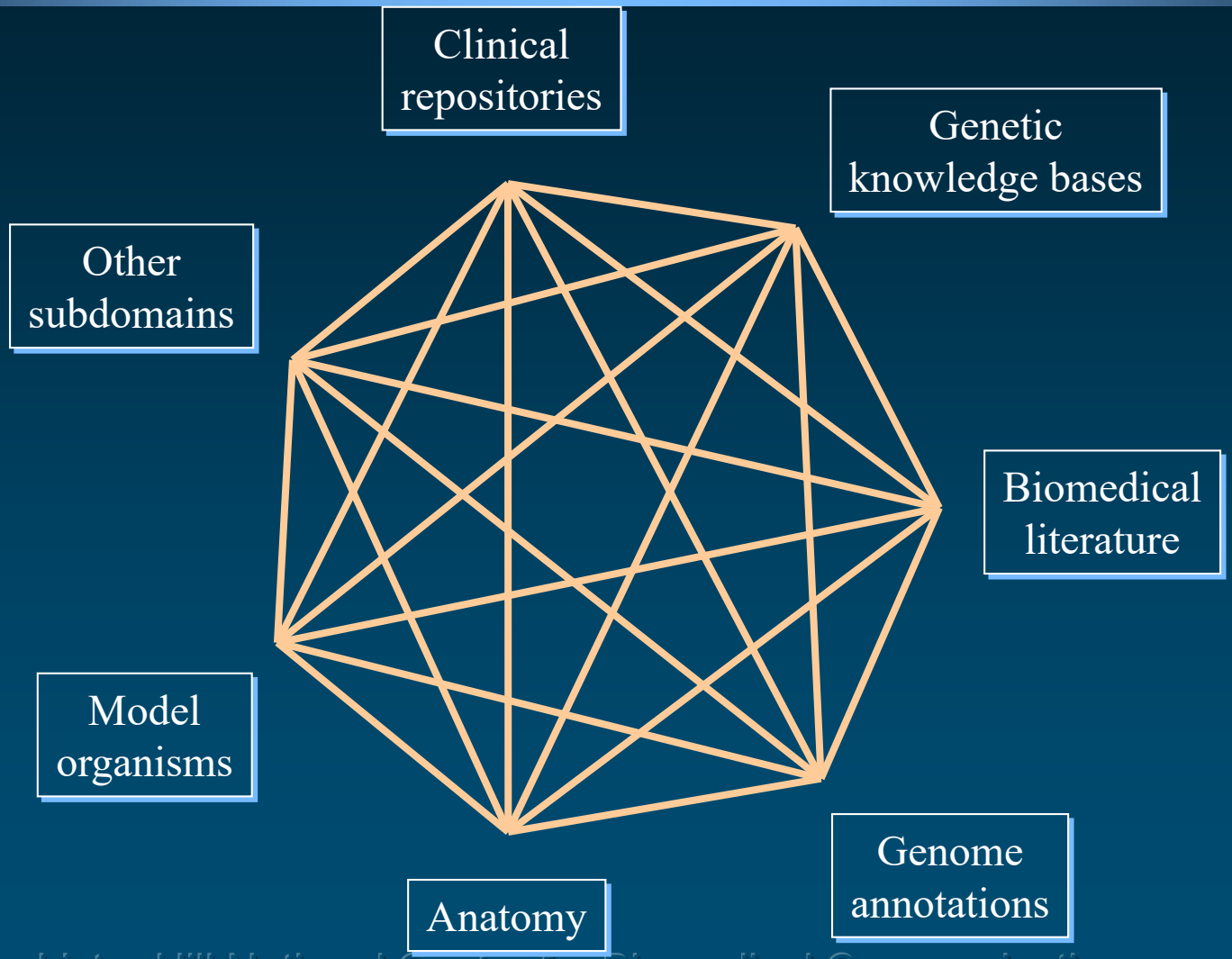
Excludes1: Fanconi (-de Toni) (-Debré) syndrome wit

E72.09 **Other disorders of amino-acid transport**
Fanconi (-de Toni) (-Debré) syndrome, unspecified

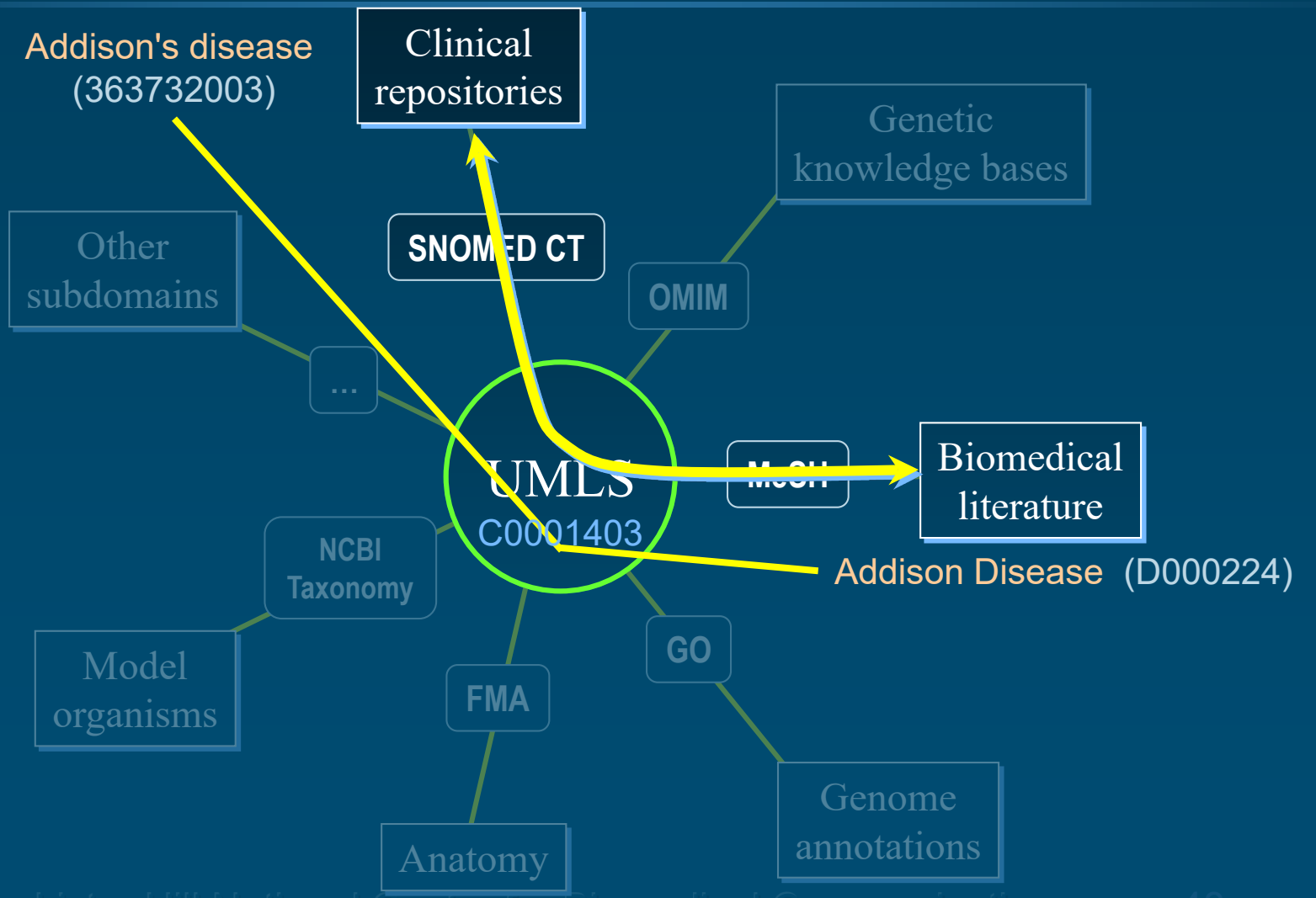
Unified Medical Language System



Integrating terminologies



Integrating terminologies



Current trends and future directions

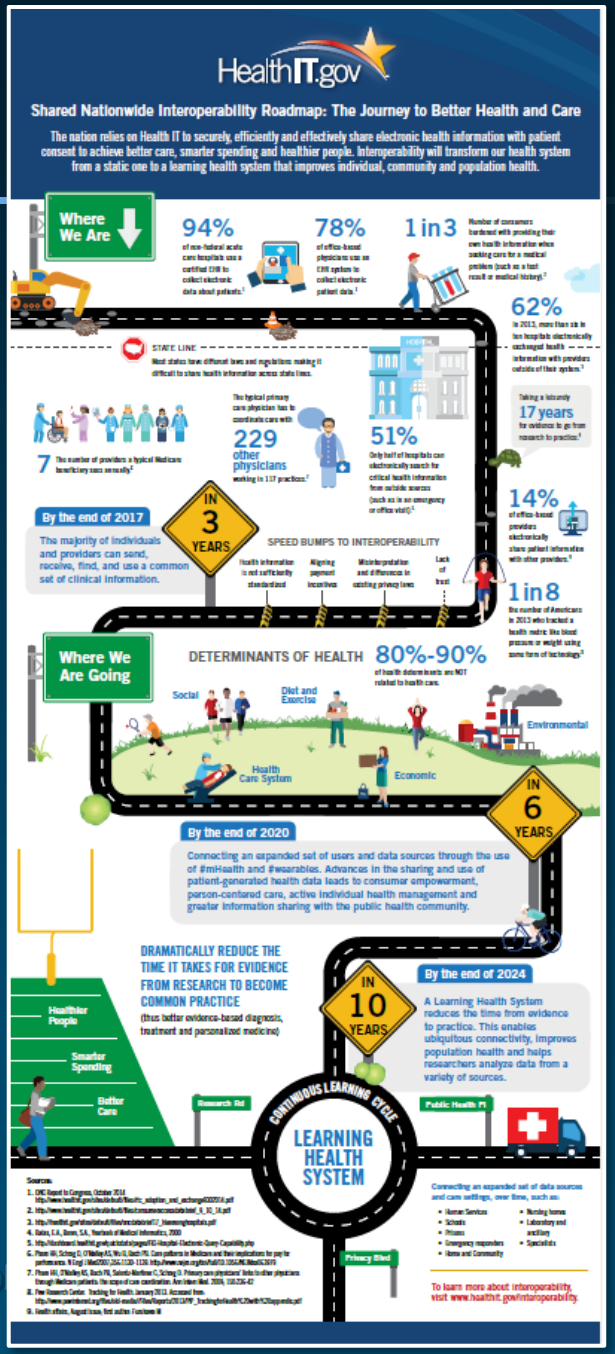
https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf

ONC interoperability roadmap

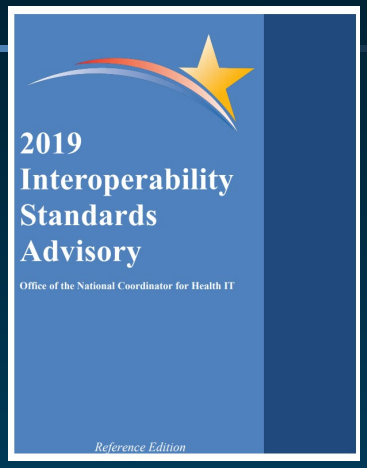
October 2015

The goals are:

- **2015-2017:** Send, receive, find and use priority data domains to improve health care quality and outcomes.
- **2018-2020:** Expand data sources and users in the interoperable health IT ecosystem to improve health and lower costs.
- **2021-2024:** Achieve nationwide interoperability to enable a learning health system, with the person at the center of a system that can continuously improve care, public health, and science through real-time data access.

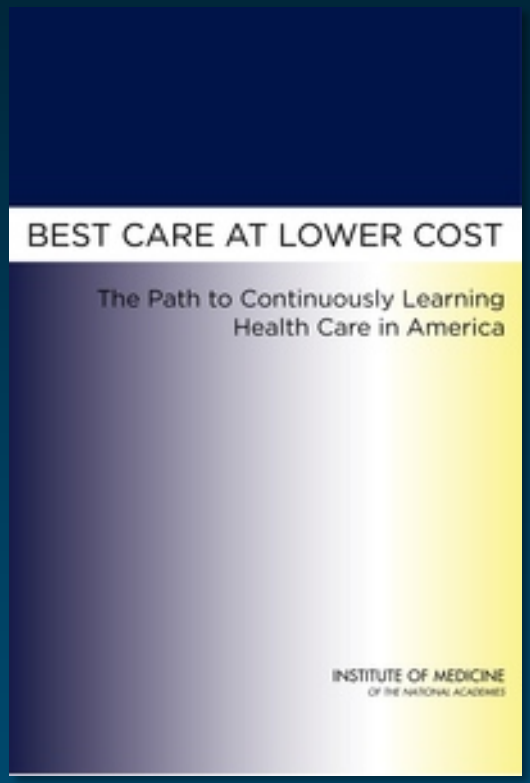


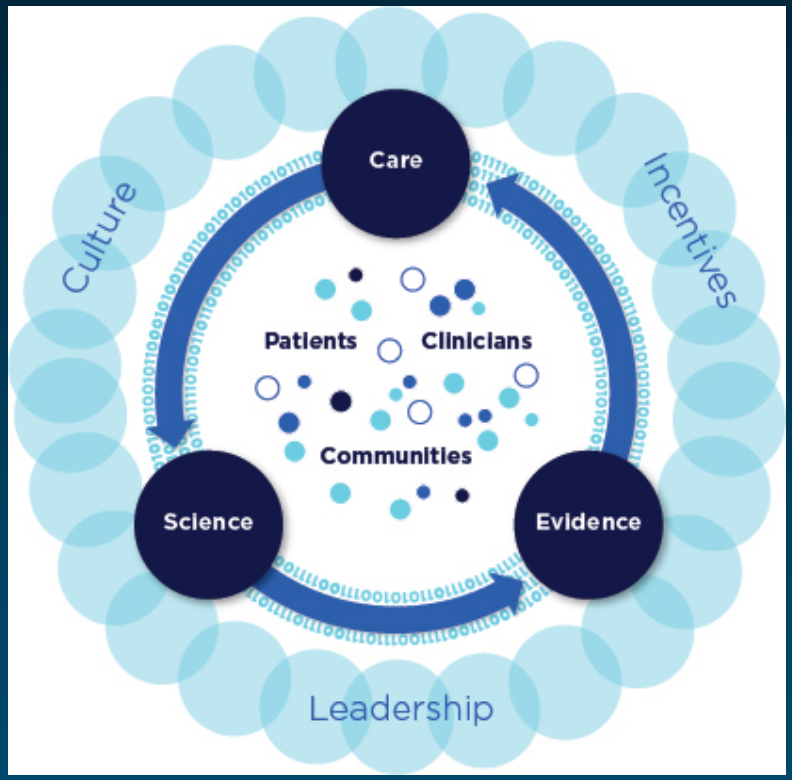
ONC Interoperability Standards Advisory



- Introduction to the ISA
  - Scope; Purpose; ISA Structure
- Sections
  - I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications
  - II: Content/Structure Standards and Implementation Specifications
  - III: Standards and Implementation Specifications for Services
  - IV: Administrative Standards and Implementation Specifications
- Appendices
  - I – Sources of Security Standards and Security Patterns
  - II - Models and Profiles
  - III - Educational and Informational Resources
  - IV - State and Local Public Health Readiness for Interoperability

Learning health system





IOM, May 2013

Fast Healthcare Interoperability Resources

- New standard for exchanging healthcare information electronically
- Developed by HL7 FHIR foundation
- Based on resources
  - Basic building blocks of information (patient, condition, procedure, practitioner)
  - Can be extended as needed
- Supports 4 different paradigms for exchange: the RESTful API, Messaging, Documents, and Services

https://allofus.nih.gov/

All of Us – Precision Medicine Initiative (NIH)

U.S. Department of Health & Human Services | National Institutes of Health

NIH National Institutes of Health
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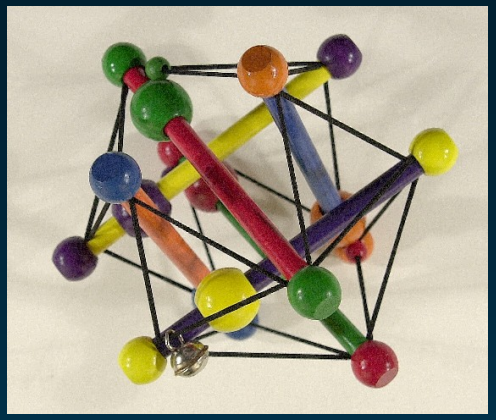

Medical Ontology Research

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