

W17: Informatics and interoperability: Speaking the same language

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What is interoperability?

“the ability of two or more systems or components to exchange information and to use the information that has been exchanged.”

- Institute for Electrical and Electronics Engineering (IEEE)

Levels of interoperability

Foundational

- Ability to communicate
- Send and receive messages

Structural

- Functional understanding
- Can understand data fields, but not contents

Semantic

- Shared understanding
- Recognize and interpret data fields and contents

Foundational Interoperability



Foundational Interoperability

Hospital A

Patient taking APAP, and has
serum creatinine of 1.2

Hospital B

50580-112-06|1|PO|Q4h
OBX|1|CE|A028^S. CRT

Hospital C

D000082_1_PO_MESH
1.2_s crt_1245_pt

Structural Interoperability

CONSULADO GENERAL DE PANAMA

SOLICITUD DE VISAS AUTORIZADAS

FECHA: _____

NOMBRE COMPLETO: _____

PASAPORTE No. _____

EXPIRACION: _____

NACIONALIDAD: _____

OCUPACION: _____
OCCUPATION: _____

FECHA DE NACIMIENTO: _____

PAIS DE RESIDENCIA _____

DEPENDIENTES: _____

VISA QUE SOLICITA: _____

TIEMPO DE ESTADIA: _____

MOTIVO DE VIAJE: _____

VISAS DE OTROS PAISES: _____

Structural Interoperability



Structural Interoperability



- HL7 V2.x
- HL7 V3.x
- Clinical Document Architecture (CDA)

Helps structure the information being sent

Structural Interoperability

Hospital A

OBX||1|CE|2730-72^Creatinine

Hospital B

OBX||1|CE|A028^S. CRT

Hospital C

OBX||1|CE|35^Serum Creatinine

HL7 2.x

Structural Interoperability

The/dog/eats/red/meat

Article/subject noun/verb/adjective/direct object noun

The/cat/sings/blue/trees

Structural Interoperability

When is a cold just a cold?

- Cold – sickness (patient has a cold)
- Cold – temperature (object is cold – give pt. cold packs)
- Cold – feeling (pt. complains of feeling cold in here)
- Cold – symbolism (gave me the cold shoulder)
- COLD - Computer Output to Laser Disk (term for CD or DVD)

Semantic Interoperability

Form 1040 Department of the Treasury—Internal Revenue Service U.S. Individual Income Tax Return	(99) 2014 OMB No. 1545-0074 IRS Use Only—Do not write or staple in this space.
For the year Jan. 1–Dec. 31, 2014, or other tax year beginning _____, 2014, ending _____, 20____	
See separate instructions.	
Your first name and initial _____ Last name _____	Your social security number _____
If a joint return, spouse's first name and initial _____ Last name _____	Spouse's social security number _____
Home address (number and street). If you have a P.O. box, see instructions. _____ Apt. no. _____	
City, town or post office, state, and ZIP code. If you have a foreign address, also complete spaces below (see instructions).	
Foreign country name _____	Foreign province/state/country _____ Foreign postal code _____
Presidential Election Campaign Check here if you, or your spouse if filing jointly, want \$3 to go to this fund. Checking a box below will not change your tax or refund. <input type="checkbox"/> You <input type="checkbox"/> Spouse	
Filing Status Check only one box.	1 <input type="checkbox"/> Single 2 <input type="checkbox"/> Married filing jointly (even if only one had income) 3 <input type="checkbox"/> Married filing separately. Enter spouse's SSN above and full name here. ▶ _____ 4 <input type="checkbox"/> Head of household (with qualifying person). (See instructions.) If the qualifying person is a child but not your dependent, enter this child's name here. ▶ _____ 5 <input type="checkbox"/> Qualifying widow(er) with dependent child
Exemptions	6a <input type="checkbox"/> Yourself. If someone can claim you as a dependent, do not check box 6a b <input type="checkbox"/> Spouse
Dependents: (1) First name Last name	(2) Dependent's social security number (3) Dependent's relationship to you (4) <input checked="" type="checkbox"/> if child under age 17 qualifying for child tax credit (see instructions)
If more than four dependents, see instructions and check here ▶ <input type="checkbox"/>	Boxes checked on 6a and 6b _____ No. of children on 6c who: • lived with you _____ • did not live with you due to divorce or separation (see instructions) _____ Dependents on 6c not entered above _____ Add numbers on lines above ▶ _____
d. Total number of exemptions claimed	_____

Structural vs Semantic

Structural

Source	Lab	Value	Units
Hospital A	2730-72	1.6	mg/dl
Hospital B	A028	0.014	g/L
Hospital C	35	0.9	mg/dl

Semantic

Source	Lab	Value	Units
Hospital A	2160-0	1.6	mg/dl
Hospital B	2160-0	1.4	mg/dl
Hospital C	2160-0	0.9	mg/dl

Semantic Interoperability

Requires standard format and standard terminology



National Drug Codes: Issues in Product Identification

Dan Malone, RPh, PhD

Professor

University of Arizona

Pharmaceutical Claims

- Real-time pharmaceutical claims permit assessment of drug exposure
- National Council for Prescription Drug Programs (NCPDP) establishes standards for claim elements
- Common elements in prescription claims:
 - Date of service
 - Provider (pharmacy)
 - Product identifier
 - Product quantity
 - Prescriber identifier

Drug Knowledge Databases

- Proprietary companies build and maintain drug knowledge databases
- Primary purpose: Drug pricing
- Secondary purposes (not exhaustive):
 - Pharmacy reimbursement
 - Clinician decision support
 - Drug-drug interactions
 - Auxiliary labels
 - Consumer drug information

Some Proprietary Drug Knowledge Databases

- First DataBank (National Drug Data File Plus)
- Wolter Kluwer (Medi-Span Master Drug Data Base)
- Cerner-Multum (Multum Lexicon)
- Thomson Corporation (Micromedex Red Book)
- Others...

Methods to Identify Exposure

- Drug Name
- Manufacturer NDC codes
 - Single source – limited manufacturers
 - Multiple source (generic) – many manufacturers
- Therapeutic classification

Product Name from Medicaid Claims

Product Name	Frequency
COUMADIN	270
COUMADIN TAB	13
COUMADIN TABLET	215
JANTOVEN	130
JANTOVEN TAB	24
JANTOVEN TABLET	262
WARFARIN	1,093
WARFARIN TAB	763
WARFARIN SODIUM	8,717
WARFARIN SODIUM TA	95
WARFARIN SODIUM TAB	516
WARFARIN SODIUM TABL	587
WARFARIN SODIUM TABLET	8,555

Product Names for Warfarin in Medi-Span Drug Database

Product	Frequency	Percentage
Coumadin	117	28.2
Jantoven	42	10.1
Warfarin Sodium	253	61.0
Warfarin Sodium Amorphous	2	0.5
Warfarin Sodium Clathrateform	1	0.2
Total NDCs	415	100.0

Select “Warfarin” Observations from Medi-Span File

prodNam	totPkgQty	pkgDesc	mfgName	labelerTyp	fmtIdNbr	genericNam
WARFARIN SODIUM	1,000.00	BOTTLE	TEVA PHARMACEUTICALS USA	G	00555-0831-05	Warfarin Sodium
JANTOVEN	100.00	BOTTLE	UPSHER-SMITH	O	00832-1211-00	Warfarin Sodium
WARFARIN SODIUM	30.00	BOTTLE	DISPENSEXPRESS	G	68115-0359-30	Warfarin Sodium
WARFARIN SODIUM	15.00	BOTTLE	PHYSICIANS TOTAL CARE	O	54868-4349-02	Warfarin Sodium
COUMADIN	100.00	BOTTLE	B-M SQUIBB U.S. (PRIMARY CARE)	B	00056-0169-70	Warfarin Sodium
WARFARIN SODIUM	100.00	BOTTLE	TARO	G	51672-4027-01	Warfarin Sodium

Brand name product

NDC

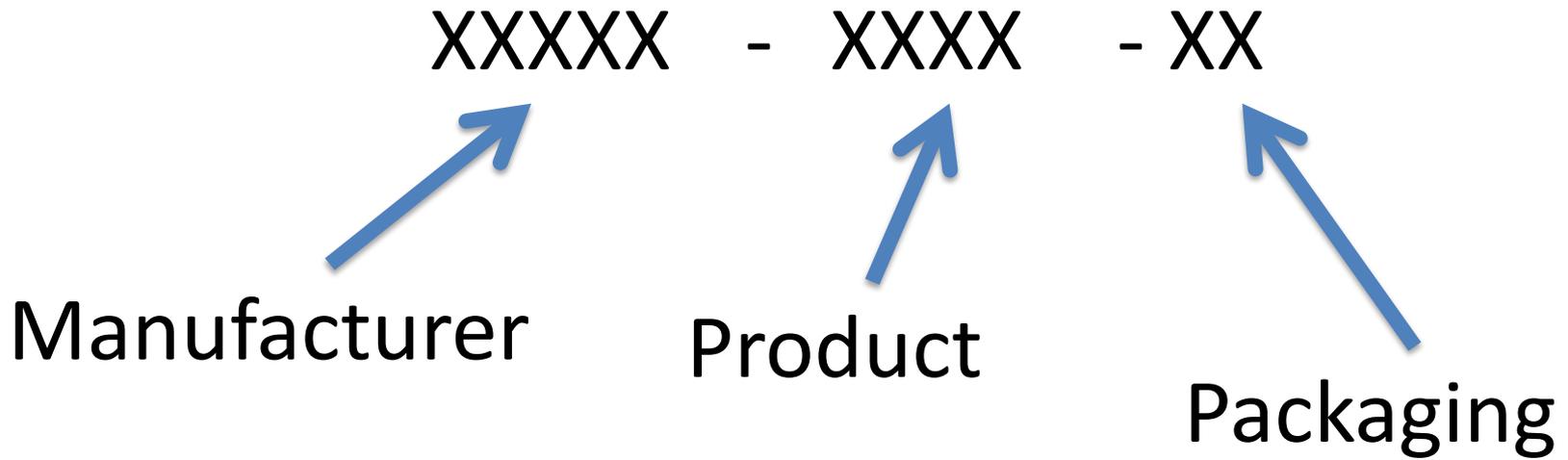
Unique Warfarin Manufacturers Listed in Medi-Span

Manufacturers/Labelers	Manufacturers/Labelers
A-S MEDICATION SOLUTIONS	NUCARE PHARMACEUTICALS
AMERICAN HEALTH PACKAGING	PALMETTO STATE PHARMACEUTICALS
AQ PHARMACEUTICALS	PCCA
B-M SQUIBB U.S. (PRIMARY CARE)	PDRX PHARMACEUTICAL
CORE PHARMACEUTICAL	PHYSICIAN PARTNER
DHS INC. WORKMAN COMP	PHYSICIANS TOTAL CARE
DISPENSEXPRESS	PREPAK SYSTEMS
DISPENSING SOLUTIONS INC.	QUALITY CARE
DRX	SANDOZ
GENPHARM LP	SOUTHWOOD PHARMACEUTICALS
H.J. HARKINS COMPANY, INC.	SPECTRUM
MALLINCKRODT PHARM	TARO
MCKESSON PACKAGING SERVICES	TEVA PHARMACEUTICALS USA
MEDISCA	UPSHER-SMITH
MEDVANTX	VA CMOP DALLAS
	ZYDUS PHARMACEUTICALS (USA)

Product Identification: NDCs

- National Drug Codes
 - Product identification system
 - Three components
 - Manufacturer
 - Product
 - Packaging
- Introduced in 1972 by FDA
- Only format permitted by NCPDP
- Mandated by HIPAA regulations for drug transactions

NDC Elements



NDC Forms

9999-9999-99 (4-4-2)

99999-999-99 (5-3-2)

99999-9999-9 (5-4-1)

NDC Characteristics

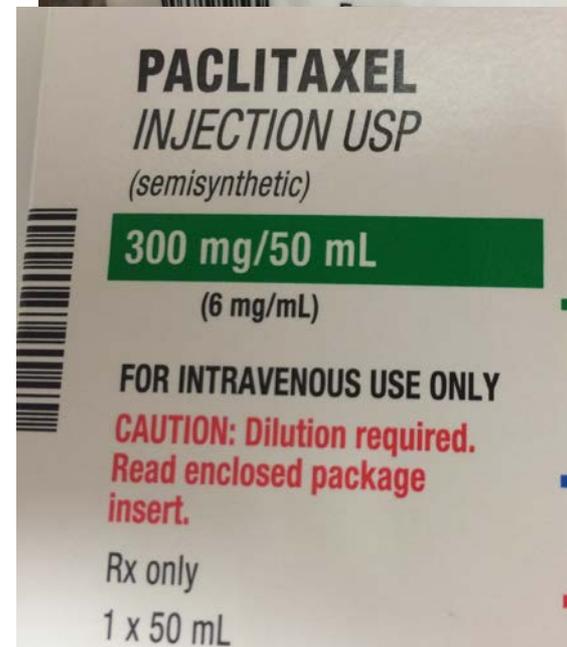
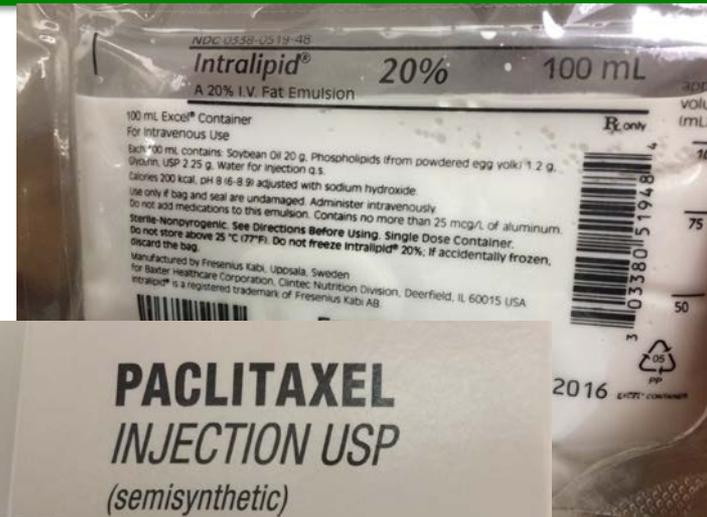
- 11 Digit code (leading zero for 4-4-2 format)
- Hyphens between segments are missing in claims transmission (Field 407 in NCPDP claim format)
- NDC codes set by the manufacturer/labeler
- Approximately 200 NDC's added/deleted per month (Source: First DataBank: AMIA 2002 annual meeting)
- Product codes are unique to manufacturer – not to the chemical entity
- Package codes are unique to the manufacturer and product – there is no standardization for packaging codes

Issues with NDCs

- NDC is specific to the manufacturer
- Corporate mergers will affect the NDC value (sometimes)
- Bulk purchasers and relabelers must use a new NDC code
- NDC codes can be re-used after 5 years
- Manufacturers may not follow coding “rules”
 - See Simonaitis and McDonald (AJHP 2009)

Issues with NDCs

- Reused NDC codes
 - 00074-4335-01(Liposyn)
 - 00074-4335-01 (Paclitaxel)



Therapeutic Classes: An Alternative Methods for Product Identification

- Therapeutic classes are present in all proprietary databases
- Class and sub-class designation varies by vendor
- Medications might fall into multiple therapeutic categories

Other Considerations in using DKBs

- “Old” NDCs deleted
 - Some vendors provide comprehensive database of all NDCs ever used
- Non-prescription items
 - Not available in all DKBs
- Non-drug items
 - Some DKBs have significant number of non-drug items

Non-Proprietary Drug Databases

- Food and Drug Administration
- Department of Veterans Affairs
- RxNorm (National Library of Medicine)

Summary

- Defining drug exposure can be difficult
- Numerous approaches to selecting drugs of interest
- No approach is 100% accurate
- Don't limit NDCs to originator's codes

RxNorm in action

Olivier Bodenreider, MD, PhD



Lister Hill National Center
for Biomedical Communications
Bethesda, Maryland - USA

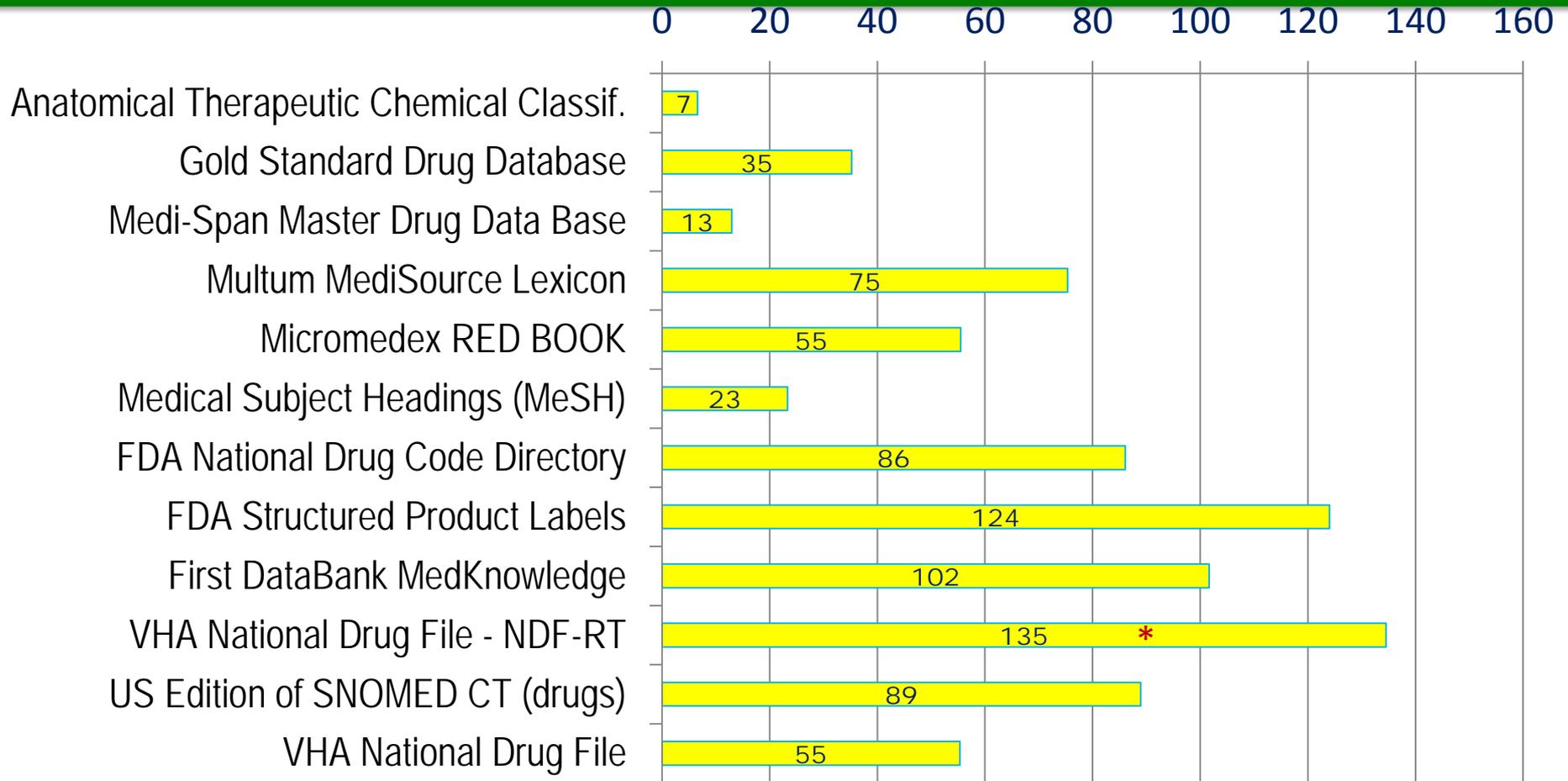


U.S. National Library of Medicine

Interoperability among drug vocabularies

- Exchange of information requires standardized names
 - Ordering drugs
 - Checking interactions
 - Inventory management
- No standard naming conventions for drugs
- Integrating drug vocabularies
- Unique identifiers for drugs
- Specify relations among drug entities

Source vocabularies in RxNorm



(terms in thousands, as of May 2015)

Normalization Lexical level

Name	Code	Source
WARFARIN (COUMADIN) NA 1MG TAB	4005203	VANDF
warfarin 1 mg oral tablet	3617	MMSL
WARFARIN NA 1MG TAB,UD	4014039	VANDF
WARFARIN NA 1MG TAB,UD [VA Product]	N0000161787	NDFRT
WARFARIN SODIUM 1 mg ORAL TABLET	14198	NDDF
WARFARIN SODIUM 1 mg ORAL TABLET	60429-784	MTHSPL
Warfarin Sodium 1 MG Oral Tablet	104045	MMX
WARFARIN SODIUM 1 mg ORAL TABLET	63629-4017	MTHSPL
WARFARIN SODIUM 1 mg ORAL TABLET [Warfarin Sodium]	53808-0985	MTHSPL
Warfarin Sodium 1 MILLIGRAM In 1 TABLET ORAL TABLET	15330-100	MTHSPL
WARFARIN SODIUM 1.09 MG ORAL TABLET	281572	MTHFDA
Warfarin Sodium 1mg Oral tablet	933	GS
Warfarin sodium 1mg tablet (product)	319733000	SNOMEDCT_US
Warfarin Sodium Tab 1 MG	6749	MDDB
Warfarin Sodium, 1 mg oral tablet	3617	MMSL
WARFARIN SODIUM@1 mg@ORAL@TABLET	14198	NDDF
[...]		



Warfarin Sodium 1 MG Oral Tablet (855288)

Normalized form

Strength

1 MG

Ingredient

Warfarin Sodium

Dose form

Oral Tablet

Strength

Warfarin Sodium 1 MG (855287)

Ingredient

Clinical drug form

Clinical drug component

Ingredient

Dose form

Warfarin Oral Tablet (374319)

Strength

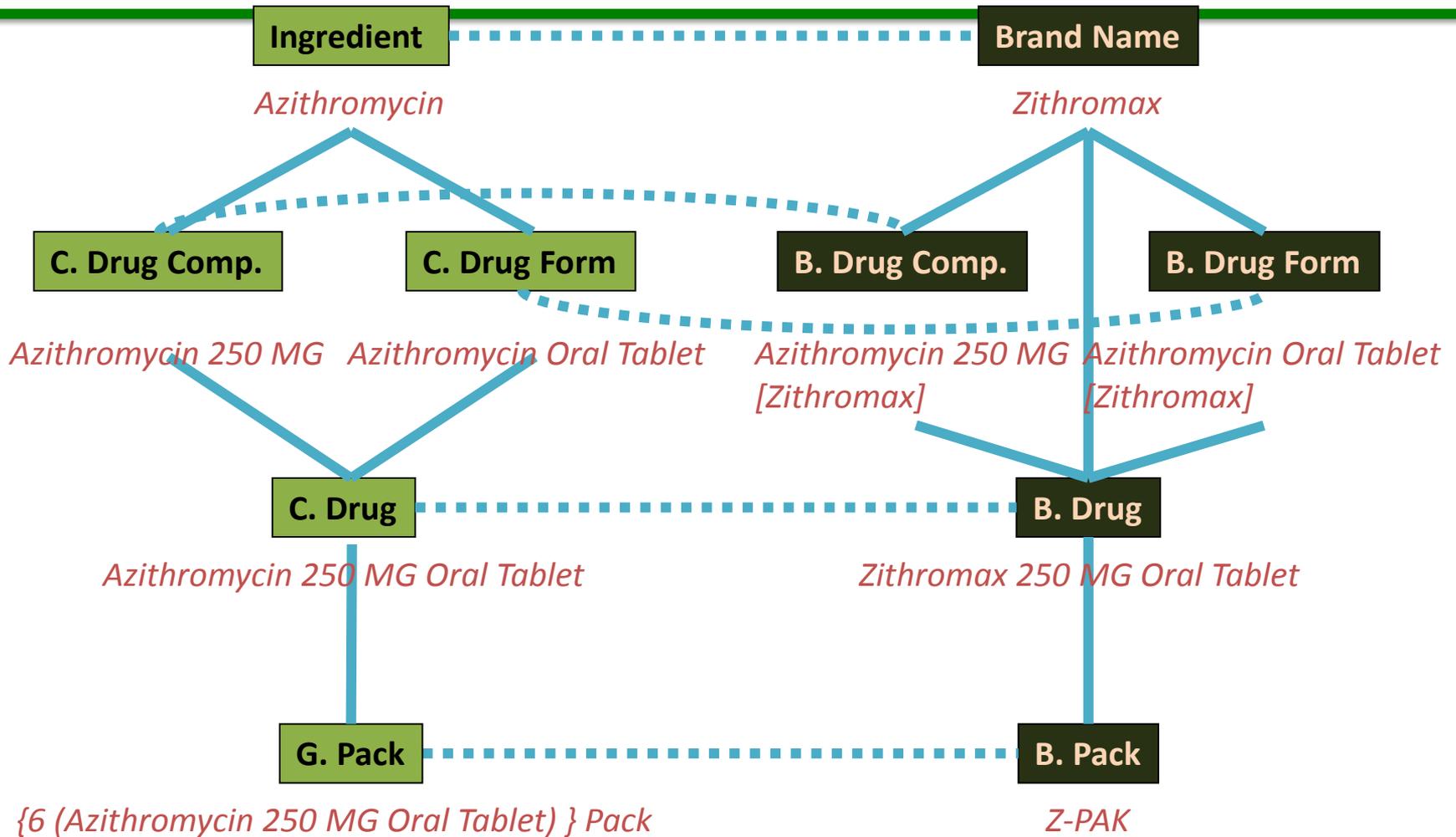
Warfarin Sodium 1 MG Oral Tablet (855288)

Ingredient

Dose form

Clinical drug

Relations among drug entities



Example Mapping NDCs to ATC drug classes

- NDCs are attached to a clinical drug (SCD) or a branded drug (SBD)
- Branded drugs are mapped to clinical drugs
- Clinical drugs are linked to their ingredient
- Many drug classification systems link classes to ingredient-level drugs (e.g., ATC, NDF-RT, EPC, MeSH pharmacologic action)

A **ALIMENTARY TRACT AND METABOLISM**

A02 **DRUGS FOR ACID RELATED DISORDERS**

A02B **DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)**

A02BC **Proton pump inhibitors**

ATC code	Name	DDD	U	Adm.R	Note
A02BC05	<u>esomeprazole</u>	30	mg	O	
		30	mg	P	

Esomeprazole (283742)

Esomeprazole (A02BC05)

Esomeprazole 40 MG Delayed Release Oral Capsule (606730)

Esomeprazole 40 MG Delayed Release Oral Capsule [Nexium] (606731)

00186504031

186-5040-31



NDC 0186-5040-31

Nexium[®]
(esomeprazole magnesium)

30 Delayed-Release Capsules

40 mg*

Rx only

Dispense the accompanying Medication Guide to each patient.

AstraZeneca

*Each delayed-release capsule contains 40 mg esomeprazole. Keep container tightly closed. Store at 25°C (77°F); excursions permitted to 15–30°C (59–86°F). [See USP Controlled Room Temperature]. USUAL ADULT DOSAGE: See package insert. NEXIUM and the color purple as applied to the capsule are registered trademarks of the AstraZeneca group. © AstraZeneca 2012 Mfd. for: AstraZeneca LP, Wilmington, DE 19850 By: Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Whitehouse Station, NJ 08889, USA Product of France

Lot

3 0186-5040-31 7

30 | No. 5040

0000000000

RxNav

RxNav is a browser for several drug information sources, including RxNorm, RxTerms and NDF-RT. RxNav finds drugs in RxNorm from the names and codes in its constituent vocabularies.



Launch RxNav

11/08 10/08/2008 10/08/2008 10/08/2008
 11/08 10/08/2008 10/08/2008 10/08/2008
 11/08 10/08/2008 10/08/2008 10/08/2008

Property	Image 1	Image 2	Image 3
imgsrc			
Atc Date	10-03-2008	10-07-2007	10-19-2012
Manufacturer	Interec Elizabeth LLC	Watson Laboratories, Inc.	Teva Pharmaceuticals USA, Inc.
Substance	100000	100000	100000
NDC	100000-0100-01	100000-0100-01	100000-0100-01
Brand	100000	100000	100000
Box	10	10	10
Control	100000	100000	100000
Image	100000	100000	100000
ImageType	100000	100000	100000

For more information about this image, please visit [RxNav](#) and [NDC](#).



RxNav

APIs

RxMix

RxClass

<http://rxnav.nlm.nih.gov/>

News

Statistics

RxNav brand names

Recent brand names added

Afterpill Invokamet

RxClass NEW

The [RxClass](#) Browser is a web application for exploring and navigating through the class hierarchies to find the RxNorm drug members associated with each class.

RxClass allows users to search by class name or identifier to find the RxNorm drug members or, conversely, search by RxNorm drug name or identifier to find the classes that the RxNorm drug is a member of. [Details](#)

NDF-RT Drug Interactions

Interactions to be removed from NDF-RT

The NDF-RT data provider has announced that the drug interactions will be removed from the data set in the **September** release. There is currently no replacement for this interactions data.

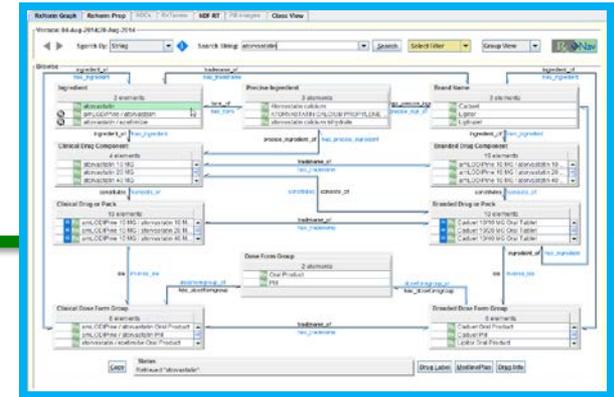
Functions to be deprecated by this change:

`findDrugInteractions` (REST: `/interaction/nui`)

`findInteractionsFromList` (REST: `/interaction?nuis`)

RxNav

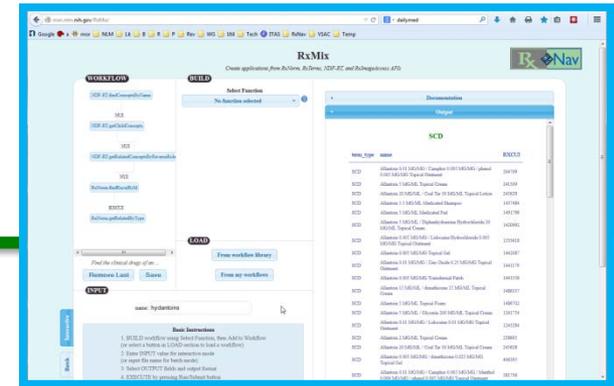
- Drug-centric browser
 - RxNorm
 - Prescribable subset
 - RxTerms
 - NDF-RT
 - Pill images
- Supports navigation to the rich RxNorm and NDF-RT graphs
- Links to other drug resources
 - DailyMed, MedlinePlus, NLM Drug Information Portal
- Drug-centric “class view”
- Leverages the drug APIs



APIs

- Expose the content of RxNorm, RxTerms and NDF-RT
 - Logical structure, not storage format
 - Up-to-date information (weekly updates of RxNorm)
 - Additional features
 - Normalized and approximate matching
 - Drug-drug interactions checking (from DrugBank)
 - Link to drug classes (from ATC, DailyMed, MeSH, NDF-RT)
 - Optimized graph traversal (pre-computed)
- For use in applications
 - Web services
 - SOAP, REST (XML, JSON)
 - Independent of any programming language

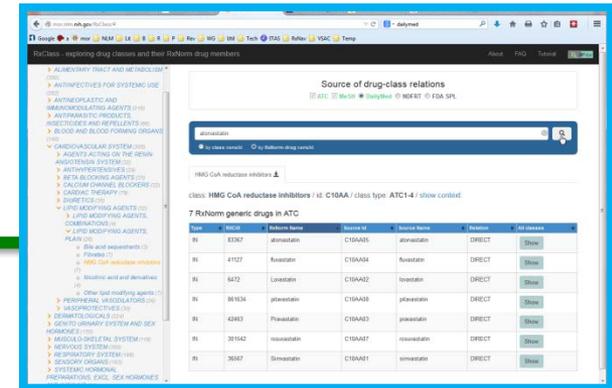
RxMix



- Graphical interface to the drug APIs
 - RxNorm, NDF-RT, RxTerms, RxImageAccess
- Handles interoperability between functions
- Helps users compose complex queries
 - *Find all the NDC codes for a given allergy class (e.g., barbiturates)*
- Supports batch execution

RxClass

- Class-centric browser for RxNorm drugs
 - ATC
 - MeSH (Pharmacologic actions)
 - NDF-RT (Mechanism of action, Physiologic effect, Chemical structure)
 - DailyMed (FDA classes)
- Supports search by drug or by class
- Features
 - Display and navigation
 - All the drugs for a class
 - All the classes for a drug
 - Compute similarity among drug classes (based on shared drug members)
- Leverages the class API
- Responsive design



Example of the value of Interoperable data for clinical research:

A Pilot Study of the Incidence of Exposure to Drugs for which Pre-emptive Pharmacogenomic Testing Is Available

Richard D. Boyce¹

Kathrin Blagec²

Matthias Samwald²

¹Department of Biomedical Informatics, University of Pittsburgh

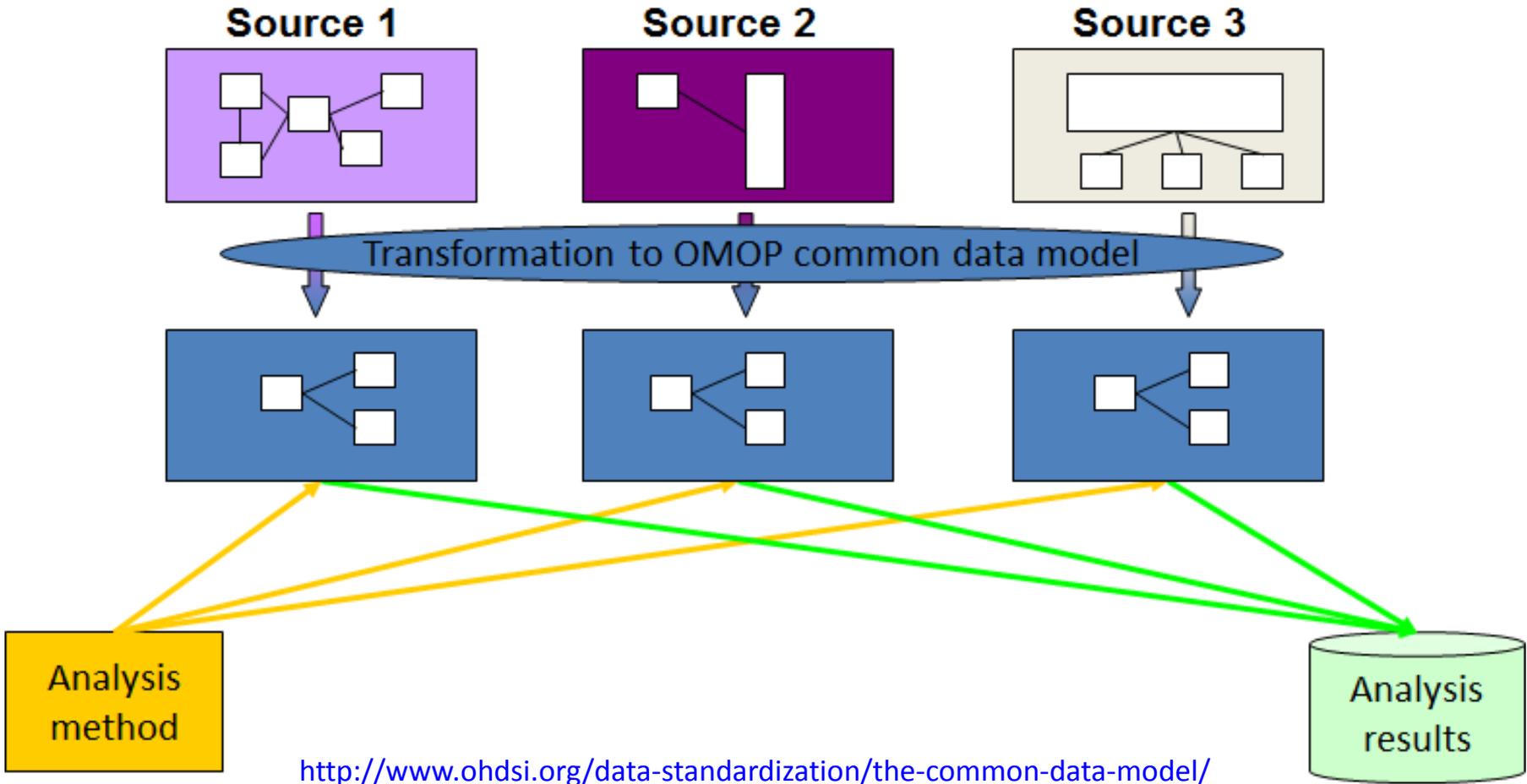
²Section for Medical Expert and Knowledge-Based Systems Medical University of Vienna

May 19th, 2015

“Common Data Models” and Interoperability

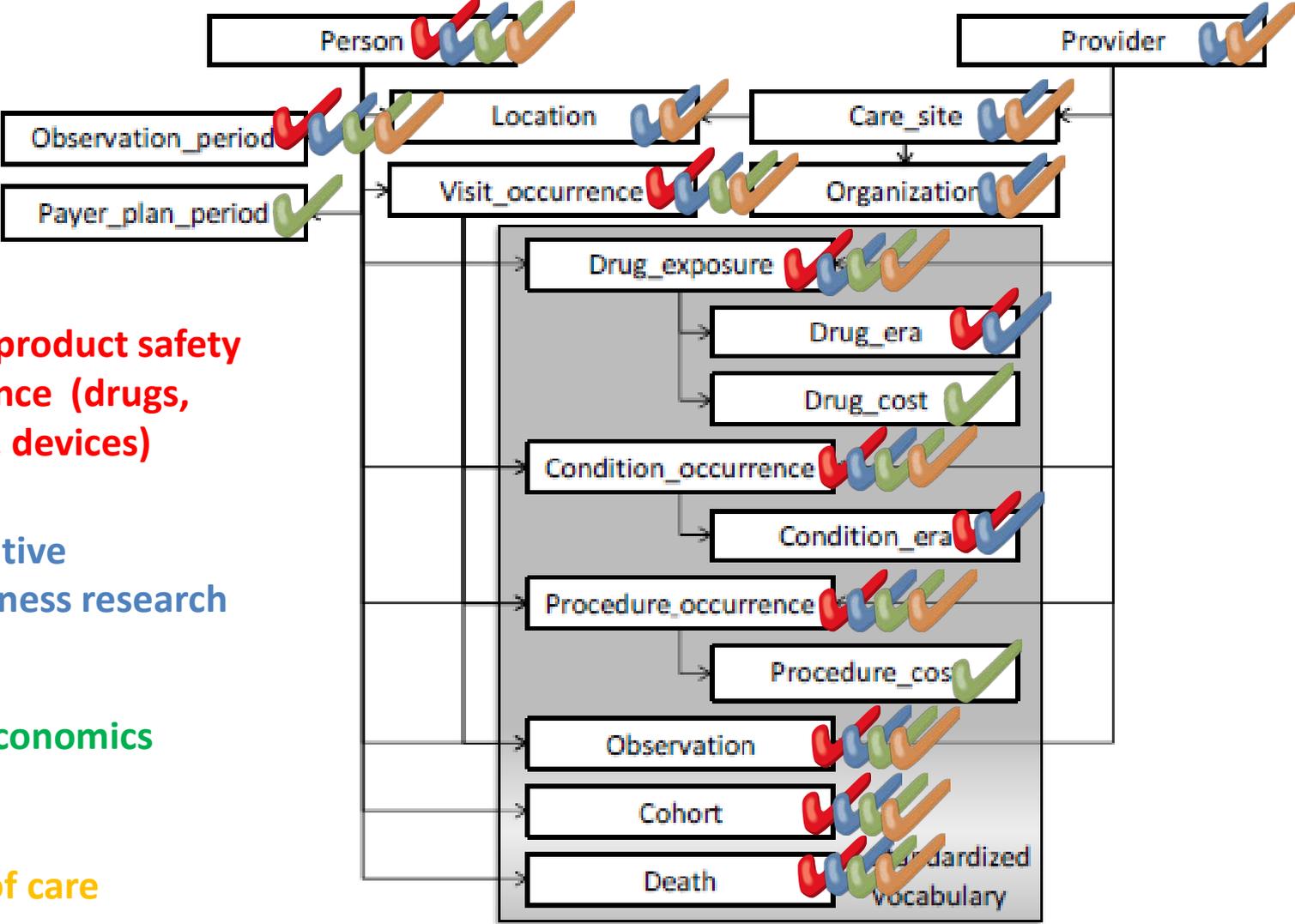
- What is a “Common Data Model” (CDM)
 - “A **common data model** allows for the systematic analysis of disparate observational databases. The concept behind this approach is to **transform** data contained within disparate databases **into a common format** (data model), and then perform systematic analyses using a library of standard analytic routines that have been written based on the common format.” - <http://www.ohdsi.org/data-standardization/the-common-data-model/>

Going from multiple databases to one



<http://www.ohdsi.org/data-standardization/the-common-data-model/>

One data model, multiple use cases



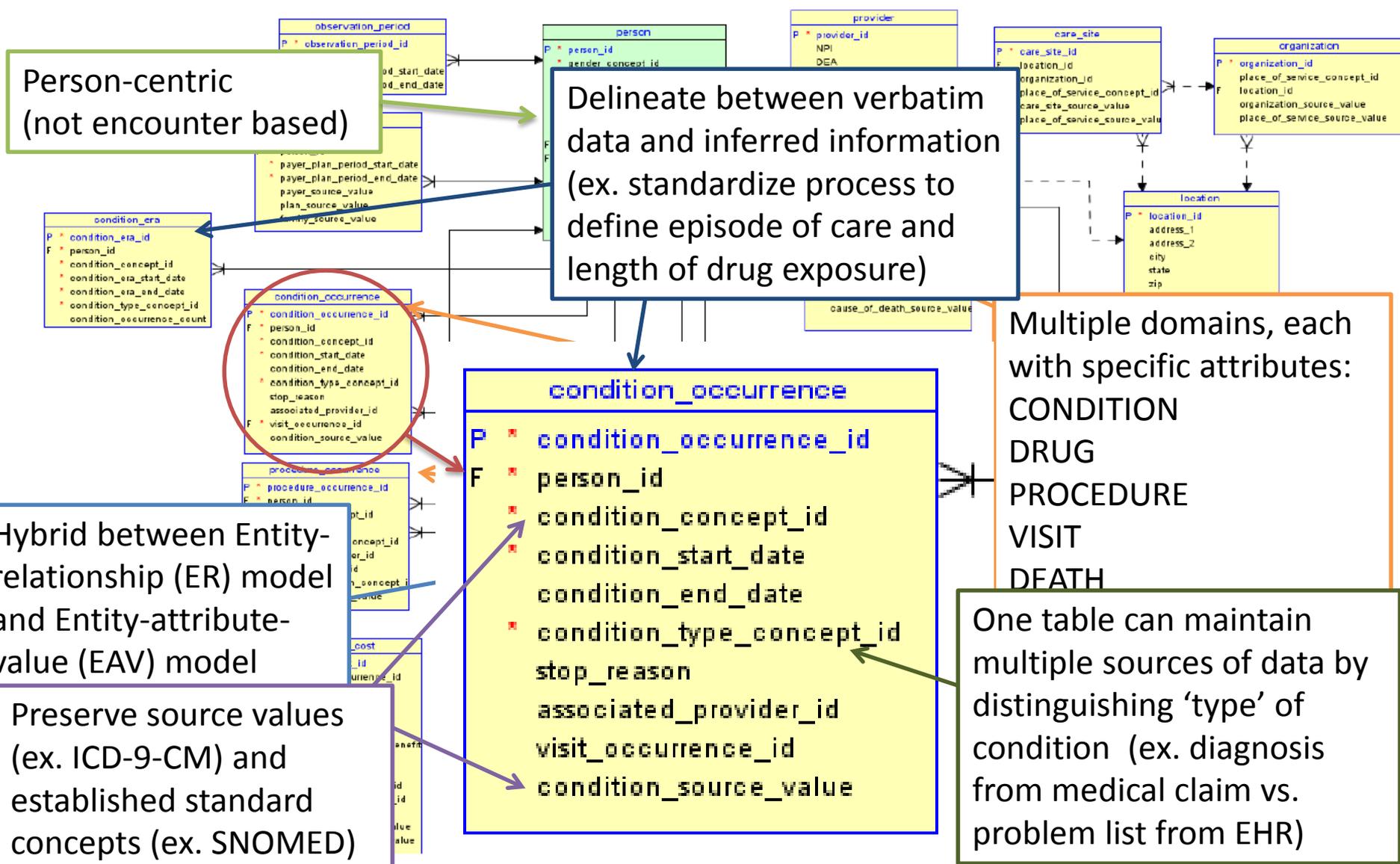
✓ **Medical product safety surveillance (drugs, vaccines, devices)**

✓ **Comparative effectiveness research**

✓ **Health economics**

✓ **Quality of care**

Key concepts within OMOP CDM v4



A recent study that used a CDM

- Objectives
 - Derive data on incident use of drugs for which there are clinical pharmacogenomics recommendations (PGx drugs)
 - E.g., warfarin, clopidogrel, abacavir, etc.
 - <http://www.fda.gov/drugs/scienceresearch/researchareas/pharmacogenetics/ucm083378.htm>
- Value proposition
 - The data could be combined with data on ADR risk and costs
 - **Enabling cost-effectiveness/cost-benefit analyses** to justify pre-emptive pharmacogenomics testing by large healthcare organisations or payers

Methods – PGx drugs

- Compiled list of PGx drugs
 - i.e., drugs with clinical pharmacogenomic guidelines
 - Two sources
 - The Clinical Pharmacogenomics Implementation Consortium (CPIC)
 - The Dutch Pharmacogenetics Working Group (DPWG)

Methods - Study design

- Cross-sectional study of drug utilization across each dataset
- Inclusion criteria
 - Time window: 1/1/2009 – 12/31/2012
 - Incident prescriptions (no prescriptions of the drug prior to 1/1/2009)
- Exclusion criteria
 - Topical preparations of PGx drugs

Methods - Data sources

- **Three** administrative claims datasets from Truven MarketScan®
 - Commercial Claims and Encounters (CCAE) Database
 - privately-insured population, >100 million patients, 2003 to 2013
 - Truven MarketScan® Multi-state Medicaid
 - > 15 million Medicaid enrollees, 2002 to 2012
 - Truven MarketScan® Medicare Supplemental Beneficiaries
 - > 8 million US retirees with Medicare supplemental insurance, 2003 to 2013

Methods - Data sources 2

- The datasets were access through a virtual “Research Lab”
 - Provided by the Innovation in Medical Evidence Development and Surveillance (IMEDS) Program
 - <http://www.reaganudall.org/our-work/safety-and-better-evidence/imes-program/>
 - OMOP Common Data Model and Standard Vocabulary Version 4

Querying all three datasets

- The CDM and standard vocabulary made it possible to write a single set of queries that worked for all three datasets...
- ...and would work for any other dataset that was also converted

Example CDM query

Data from all three datasets was loaded into tables with the same names and format

Drug concept relationships from RxNorm allow us to get ALL clinical drugs that contain the ingredients identified by these concept ids

```
DRUG_EXPOSURE.person_id AS exposed_person_id,  
CONCEPT_ANCESTOR.ancestor_concept_id as substance_id  
FROM CONCEPT_ANCESTOR, CONCEPT_RELATIONSHIP, PERSON
```

```
DRUG_EXPOSURE.DRUG_CONCEPT_ID = CONCEPT_ANCESTOR.ancestor_concept_id
```

```
AND CONCEPT_ANCESTOR.ancestor_concept_id IN (190240, ...)
```

```
--dosage form concept
```

```
AND CONCEPT_RELATIONSHIP.relationship_ID = 4
```

```
AND DRUG_EXPOSURE.DRUG_CONCEPT_ID = CONCEPT_RELATIONSHIP.concept_id_1
```

```
--concept ids for topical dosage forms
```

```
AND CONCEPT_RELATIONSHIP.concept_id_2 NOT IN (19082224,19082228,19082227, ...)
```

```
AND DRUG_EXPOSURE.DRUG_EXPOSURE_START_DATE >= DATE '2009-01-01'
```

```
AND DRUG_EXPOSURE.DRUG_EXPOSURE_START_DATE <= DATE '2012-12-31'
```

```
AND DRUG_EXPOSURE.person_id = PERSON.person_id
```

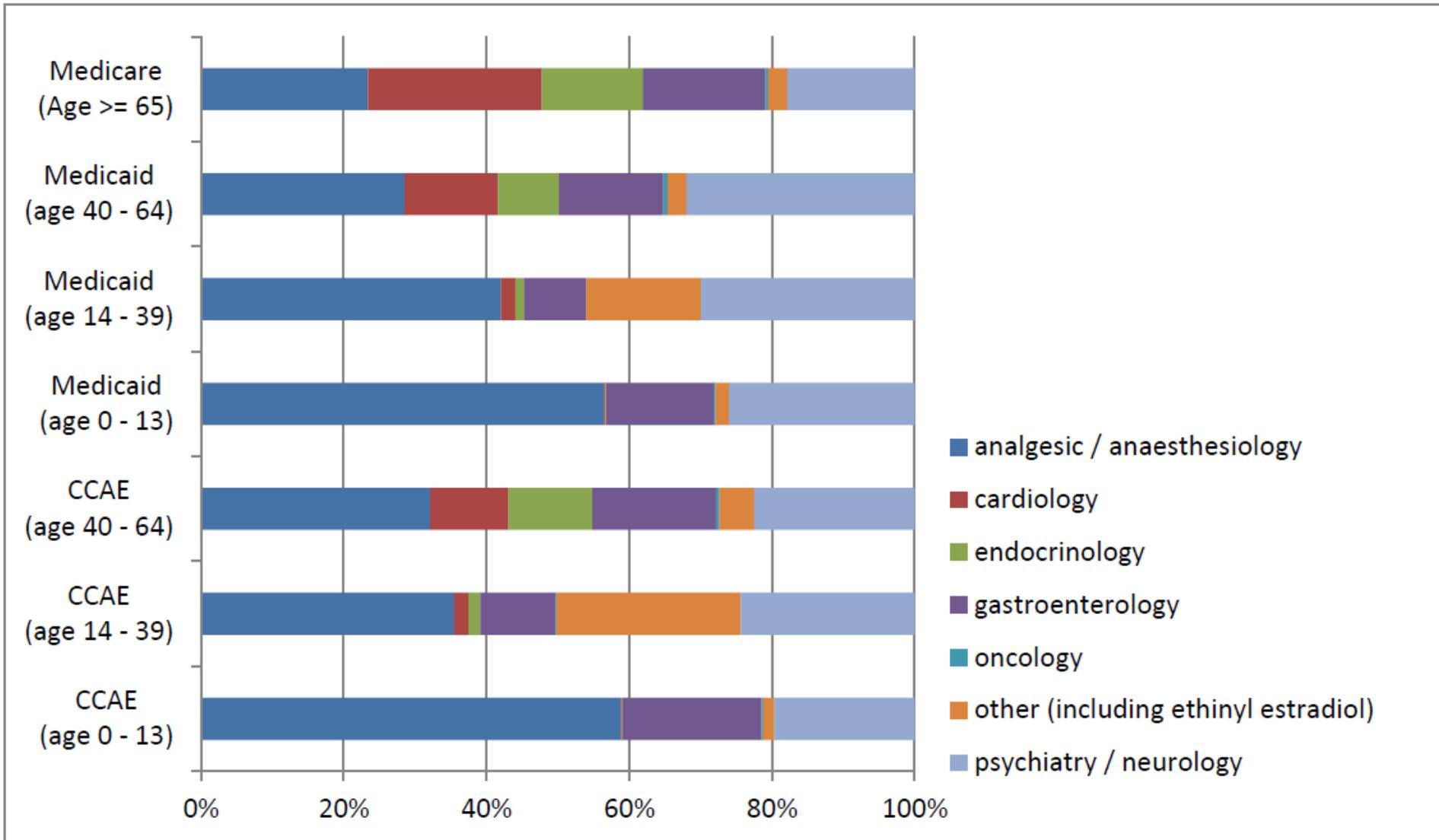
Drug "dose form" concept relationships from RxNorm are used to exclude all clinical drugs that are administered in topical form

Results

- 89 635 500 patient records
 - 55.3% associated with female patients
- Patients receiving two or more PGx drugs

Age	CCAE	Medicaid	Medicare
0-13	0.77%	1.40%	N/A
14-39	9.94%	14.71%	N/A
40-64	13.70%	32.20%	N/A
>=65	N/A	N/A	26.80%

Results



Future work that leverages the CDM

- A new research protocol to extend the study across a “research network”
 - Multiple sites that have health data loaded into the CDM and who are interested in collaboration
- The Observational Health Data Sciences and Informatics collaborative research network
 - <http://purl.org/net/drug-interaction-knowledge-base/OHDSI-PGx-incidence-protocol>

Learn more about interoperability for clinical research

- Observational Health Data Sciences and Informatics (OHDSI) collaborative: <http://www.ohdsi.org/>
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- Informatics for Integrating Biology and the Bedside (i2b2) <https://www.i2b2.org/>
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Discussion
