



PRESCRIPTION ERRORS!! A PHYSICIAN'S CHALLENGE!

Surabhi Dutta

Bristol Myers Squibb

RE01 – REAL WORLD EVIDENCE – PHUSE 2023





FACTS FROM AROUND THE WORLD ON PRESCRIPTION/MEDICAL ERRORS

“Study Suggests Medical Errors Now Third Leading Cause of Death in the U.S.

Physicians advocate for changes in how deaths are reported to better reflect reality

Analyzing medical death rate data over an eight-year period, Johns Hopkins patient safety experts have calculated that more than 250,000 deaths per year are due to medical error in the U.S. Their figure, published May 3 in *The BMJ*, surpasses the U.S. Centers for Disease Control and Prevention’s (CDC’s) third leading cause of death — respiratory disease, which kills close to 150,000 people per year.”

Reference:

“*Study Suggests Medical Errors Now Third Leading Cause of Death in the U.S. - 05/03/2016.*” *Johns Hopkins Medicine, Based in Baltimore, Maryland,*

https://www.hopkinsmedicine.org/news/media/releases/study_suggests_medical_errors_now_third_leading_cause_of_death_in_the_us.

“In hospitals, errors occur in every step of medication use process starting from procuring the drug to prescribing, transcribing, dispensing, administering, and monitoring its effect.² Annually 7,000 mortalities have been reported due to medication errors.³ In India, the medication errors and medication-related problems are mainly due to irrational use of medications.^{4,5} According to a recent finding, the incidence of adverse drug events was as high as 82/1,000 prescriptions in Delhi, and the national figures report up to 5.2 million medical errors annually.^{4,5}”

Reference:

Bhutada, Anand. “*Incidence of Medication Error in Critical Care Unit of a Tertiary Care Hospital: Where Do We Stand?*” *Indian Journal of Critical Care Medicine : Peer-Reviewed, Official Publication of Indian Society of Critical Care Medicine, U.S. National Library of Medicine, Sept. 2020,*

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7584828/#:~:text=Annually%207%2C000%20mortalities%20have%20been%20reported%20due%20to%20medication%20errors.&text=In%20India%2C%20the%20medication%20errors,to%20irrational%20use%20of%20medications>.

“Globally, the cost associated with medication errors has been estimated at \$42 billion USD annually. It is projected that 5% of all patients who are admitted to a hospital experience a medication error, and that an average hospital will have one medication error every 23 hours or every 20 admissions. Medication errors result in severe patient harm, disability and even death.”

Reference:

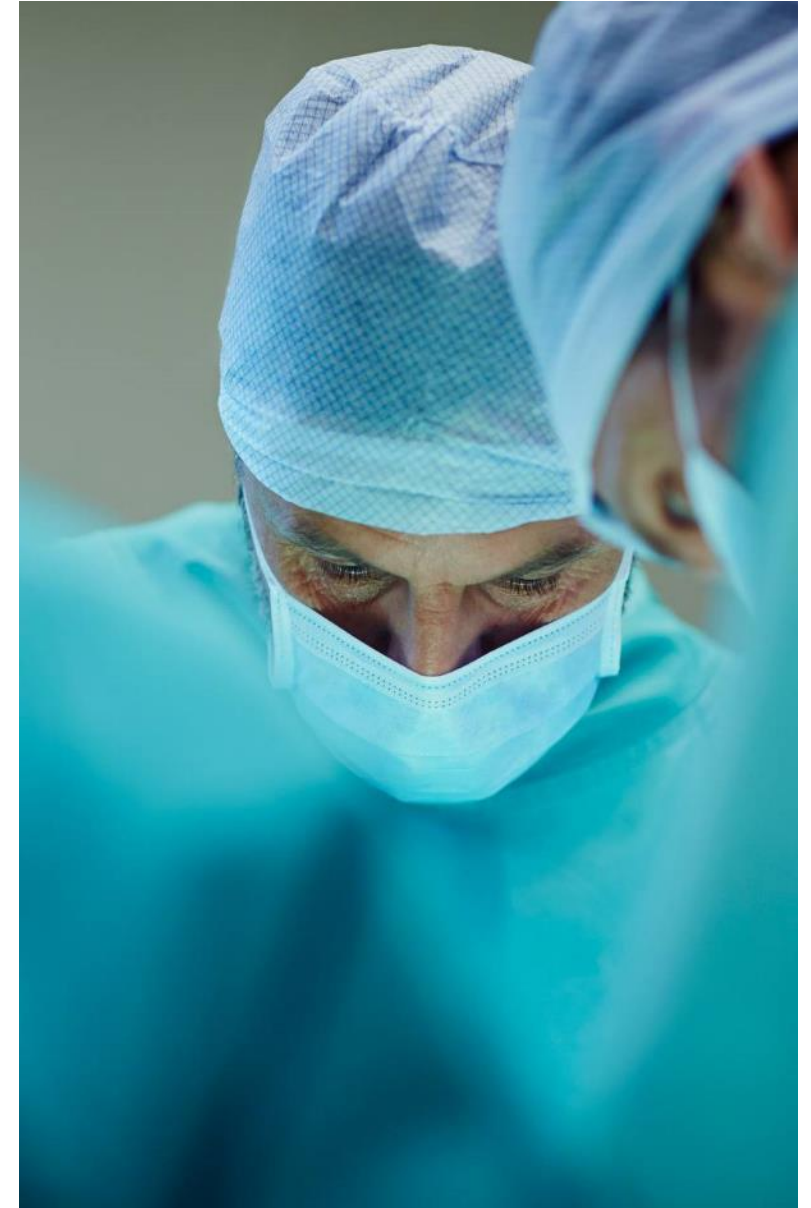
WFSA, By: and By: Sophie Harris. “*World Patient Safety Day: Medication without Harm.*” WFSA, 17 Sept. 2022, <https://wfsahq.org/news/latest-news/world-patient-safety-day-medication-without-harm/>.





1. Facts from around the world on Prescription/medical errors
2. What are Prescription/Medical Errors?
3. Reporting Prescription errors and related Adverse Events
4. FDA guidelines on Medication Errors
5. Reporting Prescription errors and related Adverse Events - MedWatch
6. Some Stats on Medication Errors
7. Pragmatic Trials and Real-World Evidence
8. Curating Real World Data to Support Clinical Decision Making
9. Applications of Real-World Data for Avoiding Prescription Errors and Ensuring Patient Safety
10. Decision Support For the Physician in the For of Curated Patient Summary?
11. Data flow in Electronic Health Records
12. MedlinePlus Connect – A Web based Decision Support Tool for Patients and Clinicians
13. Drug related side effects and interactions for a patient – Sample Reference charts
14. Endpoint Based Real World Evidence For Tracking Medication Errors And Adverse Events
15. Common Public Use API's/Vocabulary of RxNorm API
16. REST API responses from OPEN FDA, RxNorm, CDC
17. RxNav, RXCUI - A key component of RxNorm is the Concept Unique Identifier (RXCUI) – API Responses
18. RxNav API: GET ATC, DrugBank, RXCUI, SNOWMEDCT CODES for a Drug
19. Data retrieved for Ibuprofen from OpenFDA API- Normalized, filter RXCUI=5640
20. Data summary Ibuprofen from OpenFDA, RXCUI=5640, AE – PT Summary Counts, Dosage and Frequency
21. Creating Search Keys
22. Data retrieved for Ibuprofen, RXCUI=5640, DrugBank API – Normalized Data
23. Matching - Patient Medical History with reactionmedrpt from OpenFDA for drugname="Ibuprofen", and DrugBank for Drug Interaction and Description Column for Adverse Event Matching
24. NLTK :: Natural Language Toolkit– Python, Finding Association Rules
25. NLTK :: Natural Language Toolkit– Finds Close Matches with the list of Preferred Terms
26. Data Interaction search and Matches for Ibuprofen
27. Data Interaction search and Matches for Ibuprofen – Sample Matches for One Drug
28. Disease Outcomes Data – From CDC
29. Patient summary report created by joining all data sources: Patient EHR + OpenFDA + DrugBank + RxNav + CDC
30. Tools to REPORT AND measure Prescription Errors – In the US and other countries
31. Healthcare Quality Measures-Benchmarking and Dashboards
32. Summary and Acknowledgement

AGENDA



INTRODUCTION

WHAT ARE PRESCRIPTION/MEDICAL ERRORS?

“The National Coordinating Council for Medication Error Prevention and Analysis (NCC MERP) defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of a healthcare provider, patient, or consumer. ”

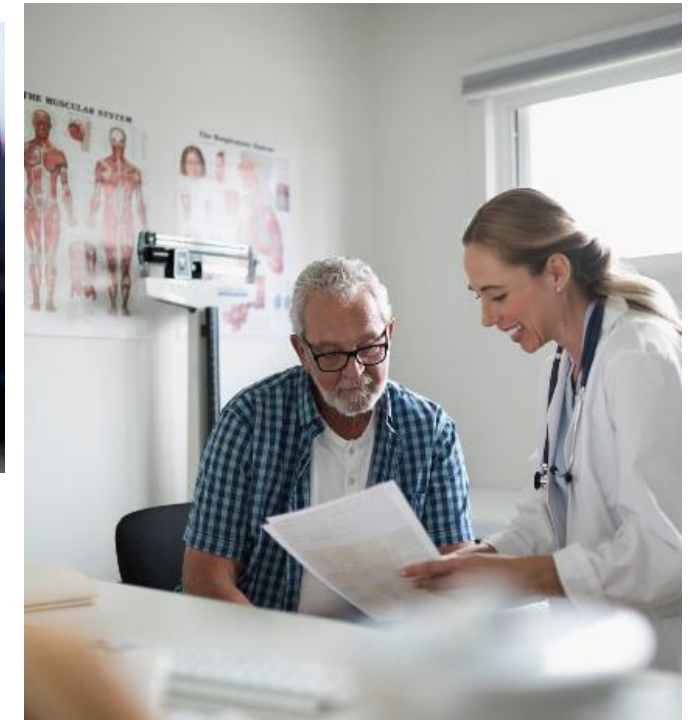
Reference: *Center for Drug Evaluation and Research. (n.d.). Medication errors related to drugs. U.S. Food and Drug Administration. <https://www.fda.gov/drugs/drug-safety-and-availability/medication-errors-related-cder-regulated-drug-products>*



TYPES OF MEDICATION ERRORS

- Prescribing
- Omission
- Wrong time
- Unauthorized drug
- Improper dose
- Wrong dose prescription/wrong dose preparation
- Administration errors include the incorrect route of administration, giving the drug to the wrong patient, extra dose, or wrong rate
- Monitoring errors such as failing to take into account patient liver and renal function, failing to document allergy or potential for drug interaction
- Compliance errors such as not following protocol or rules established for dispensing and prescribing medications
- One of the major causes of medication errors is distraction. Nearly 75% of medication errors have been attributed to this cause..”

Reference: *Medication Dispensing Errors and Prevention - NCBI Bookshelf. <https://www.ncbi.nlm.nih.gov/books/NBK519065/>.*





FDA GUIDELINES ON MEDICATION ERRORS

Along with the Center for Biologics Evaluation and Research (CBER), the Division of Medication Error Prevention and Analysis (DMEPA) and Division of Mitigation Assessment and Medication Error Surveillance (DMAMES) are two units within the FDA's Center for Drug Evaluation and Research (CDER), Office of Medication Error Prevention and Risk Management (OMEPRM). They are a multidisciplinary teams of safety analysts, responsible for monitoring and preventing medication errors related to the naming, labeling, packaging, and design for CDER-regulated drug and biological products, right from preapproval to post approval.

Reference:

Center for Drug Evaluation and Research. "Medication Errors Related to Drugs." U.S. Food and Drug Administration, FDA, <https://www.fda.gov/drugs/drug-safety-and-availability/medication-errors-related-cder-regulated-drug-products#:~:text=DMEPA%20and%20DMAMES%20have%20multidisciplinary,product's%20lifecycle%2C%20from%20preapproval%20to.>

Reporting Prescription errors and related Adverse Events - MedWatch

Begin Online Report



Health Professional
(FDA Form 3500)



Consumer/Patient
(FDA Form 3500B)

En español para el consumidor / paciente (formulario 3500B de la FDA)



Continue an incomplete report

Click here to continue filling out an incomplete report. You will need Report ID and Report Date. You will have 3 days to complete this report from the start date.

MedWatch, the FDA's medical product safety reporting program for health professionals, patients and consumers.
<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm>

The Sentinel Initiative has computer programs that analyze electronic healthcare data to answer the FDA's questions on approved medical products managed by the CDER (Center for Drug Evaluation and Research) and CBER (Center for Biologics Evaluation and Research). These computer programs use statistical methods to study relationships and patterns in medical billing information and electronic health records enabling medication errors tracking.

Reference:

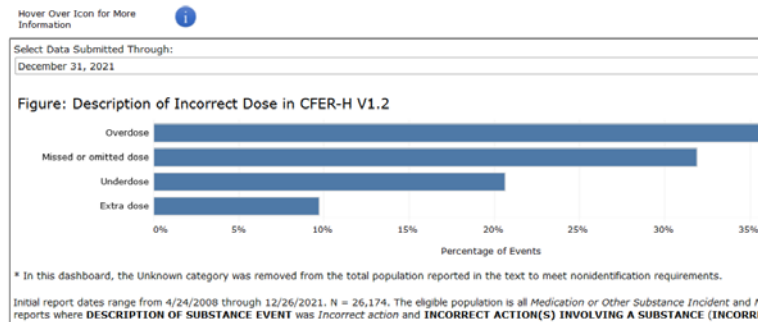
"Medication Error Pharmacovigilance and the FDA Sentinel System." Sentinel Initiative, 11 Apr. 2023, <https://www.sentinelinitiative.org/>.

Thank you for taking the time to submit a MedWatch report. If you wish to download and print a copy of your report please review the [MedWatch Voluntary Report Frequently Asked Questions](#).

SOME STATS ON MEDICATION ERRORS

Extent of Harm
Incorrect Actions
Incorrect Action by Extent of Harm
Description of Incorrect Dose
Description of Incorrect Dose by Extent of Harm
Stage Event Originated
Stage Event Originated by Extent of Harm

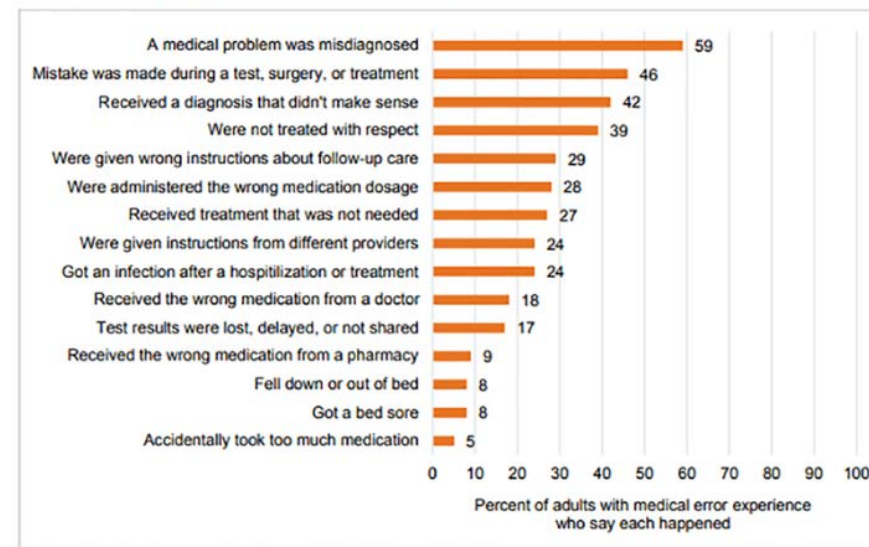
Description of Incorrect Dose



Stats - Incorrect Dosing - AHRQ

Stats – Survey NORC, University of Chicago

Six in 10 adults with medical error experience say a medical problem was misdiagnosed and 4 in 10 say they weren't treated with respect.



Question: Again, thinking about the most recent time a medical error was made in [your care/the care of someone close to you], for each of the following, please indicate whether or not it is the sort of medical error that occurred.

- “A 2013 meta-analysis found that the likelihood of a prescribing error was reduced by 48% when using CPOE compared with paper-based orders, which translates into more than 17 million medication errors prevented yearly in United States hospitals. Studies of e-prescribing systems—CPOE systems used primarily in outpatient practices that allow direct transmittal of prescriptions to pharmacies—have also found similar effectiveness at preventing outpatient prescribing errors.”

Reference:

- “Computerized Provider Order Entry Systems.” Patient Safety Network, <https://psnet.ahrq.gov/primer/computerized-provider-order-entry>.
- <https://www.fda.gov/media/161944/download>. “Medication or Other Substance Dashboard.” AHRQ, <https://www.ahrq.gov/npsd/data/dashboard/medication.html>.
- “Americans' Experiences with Medical Errors and Views on Patient Safety.” Patient Safety Network, https://www.ihl.org/about/news/Documents/IHI_NPSF_Patient_Safety_Survey_Fact_Sheets_2017.pdf.



Pragmatic Trials and Real-World Evidence

Advantages of Pragmatic Trials and Real-World Data:

Unlike Explanatory trials, Pragmatic Trials can use multiple Health Systems for wider data collection.

Pragmatic Trials are beneficial to study how a specific intervention may work in different healthcare settings using all facilities and tools available at a healthcare setting.

Some of the other advantages are: Wide Eligibility Criteria, flexible Interventions, Objective Clinical Outcome and Clinical decisions. Some of the real-world data sources are:

- Electronic Health Records
- Medical Claims data
- Product Registries
- Disease registries
- Digital Devices

Trials of Interest : National Institute of Aging (NIA)+ National Institute of Health(NIH)

Shed MEDS – a randomized controlled trial to evaluate the effects of an intervention to reduce medication use among hospitalized older adults discharged to skilled nursing facilities.



Curating Real World Data to Support Clinical Decision Making

Electronic Medical Records

Disease registry Data – Measurable Outcomes

Digital Devices Data



FDA – FAERS Data

FDA – Sentinel Initiative

National Library of Medicine – RxNav

Center for Disease Control –CDC – Chronic Disease History/ Disease Outcomes Data.

All this Information may be combined to create a Patient level 360° panoramic view



Applications of Real-World Data for Avoiding Prescription Errors and Ensuring Patient Safety

▼ SNOMED CT Concept (SNOMED RT+CTV3)

- ▶ Body structure (body structure)
- ▶ Clinical finding (finding)
- ▶ Environment or geographical location (environment / location)
- ▶ Event (event)
- ▶ Observable entity (observable entity)
- ▶ Organism (organism)
- ▶ Pharmaceutical / biologic product (product)
- ▶ Physical force (physical force)
- ▶ Physical object (physical object)
- ▶ Procedure (procedure)
- ▶ Qualifier value (qualifier value)
- ▶ Record artifact (record artifact)
- ▶ Situation with explicit context (situation)
- ▶ SNOMED CT Model Component (metadata)
- ▶ Social context (social concept)
- ▶ Special concept (special concept)
- ▶ Specimen (specimen)
- ▶ Staging and scales (staging scale)
- ▶ Substance (substance)

Electronic Health Records Data Collection

Administrative
Demographic information
Diagnosis,
Procedures
Prescription drugs,
laboratory tests,
Physiologic monitoring
data
Hospitalization
Claims

How Real-World Data May be Leveraged

To get the latest drug interaction information, Drug related Adverse events.

Drug Related Adverse Events – DrugBank

Drug Interactions Data – DrugBank

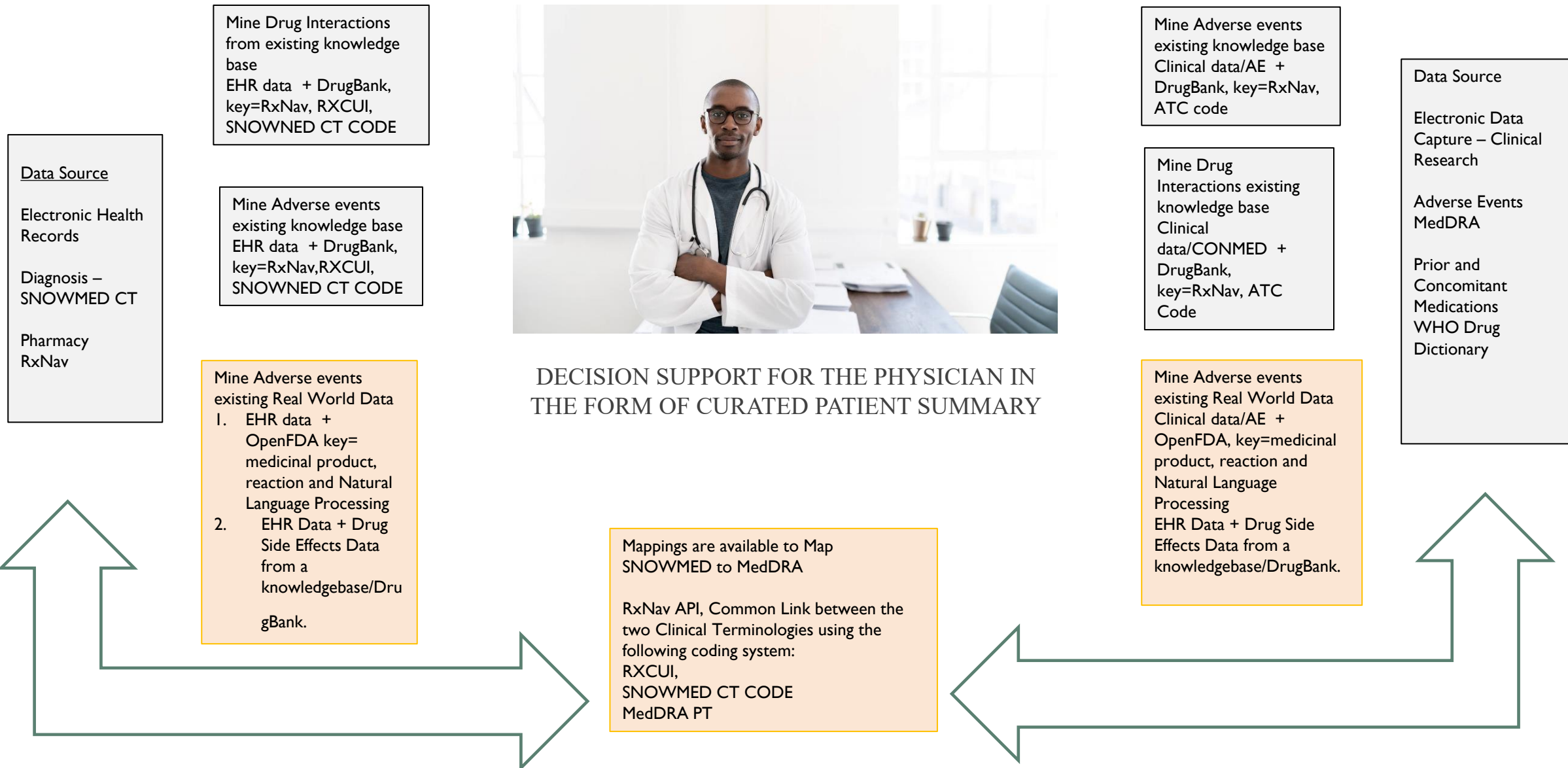
Drug Related Serious Adverse Events from OpenFDA

Clinical Trials Data Collection

Demographics
Adverse Events
Vital Signs
Exposure
Labs
Physical Exam
Concomitant Medications
PK Parameters
Inclusion Exclusion
Medical History
Disposition
Physiologic monitoring data
Hospitalization
Patient Generated data

Domains
DM
CO
CM
EX
SU
AE
DS
DE
MH
EG
IE
LB
TA

Data Standardization Common Data Model





DATA FLOW IN ELECTRONIC HEALTH RECORDS

Categories of Health IT Standards by HIMSS

Type	Function	Example Standards
Content	- Defines the structure and organization of messages and documents - Often referred to as information models or data models	CDISC, OMOP, FHIR Resources, HL7 CDA, HL7 C-CDA
Terminology	Structured vocabulary to represent concepts unambiguously	LOINC, UCUM, SNOMED, RxNorm, RadLex, MEDCIN, ICD-10, CPT, HCPC, CDC CVX and MVX, NDC, FHIR Terminology
Transport/Exchange	- Format and method of messages exchanged - How data gets from one system to another	FHIR, HL7v2, Direct, DICOM, IEEE 11073 Personal Health Devices
Privacy/Security	Protect an individual's or organization's right to determine whether, what, when, by whom and for what purpose their protected health information is collected, accessed or disclosed	SMART on FHIR, OAuth 2.0, OpenID Connect, HEART

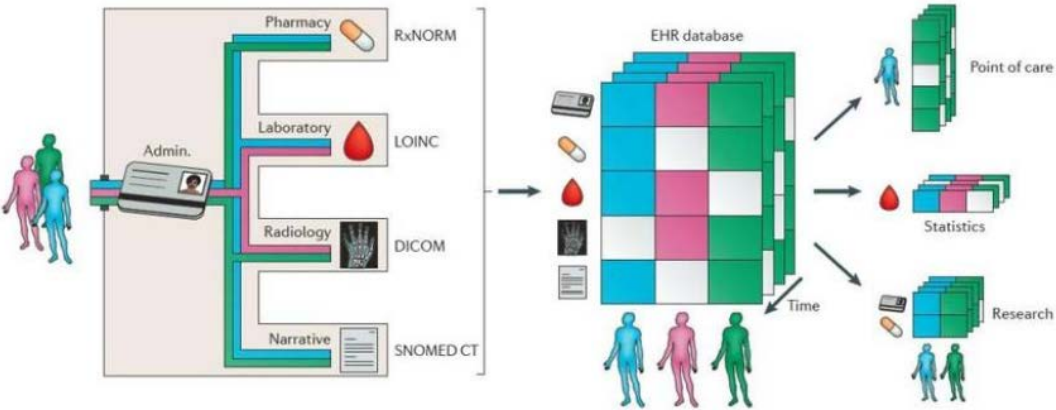
Source: [HIMSS Resource Library](#)

Reference:

- Delvaux, Nicolas, et al. "Coding Systems for Clinical Decision Support: Theoretical and Real-World Con Analysis." *JMIR Formative Research*, U.S. National Library of Medicine, 21 Oct. 2020, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7641774/table/table1/?report=objectonly>.
- Jensen, Peter B., et al. "Mining Electronic Health Records: Towards Better Research Applications and C Care." *Nature News*, Nature Publishing Group, 2 May 2012, <https://www.nature.com/articles/nrg3208>.

Overview of some clinical terminologies used in electronic health records including their domain coverage and purpose. This list is not exhaustive.

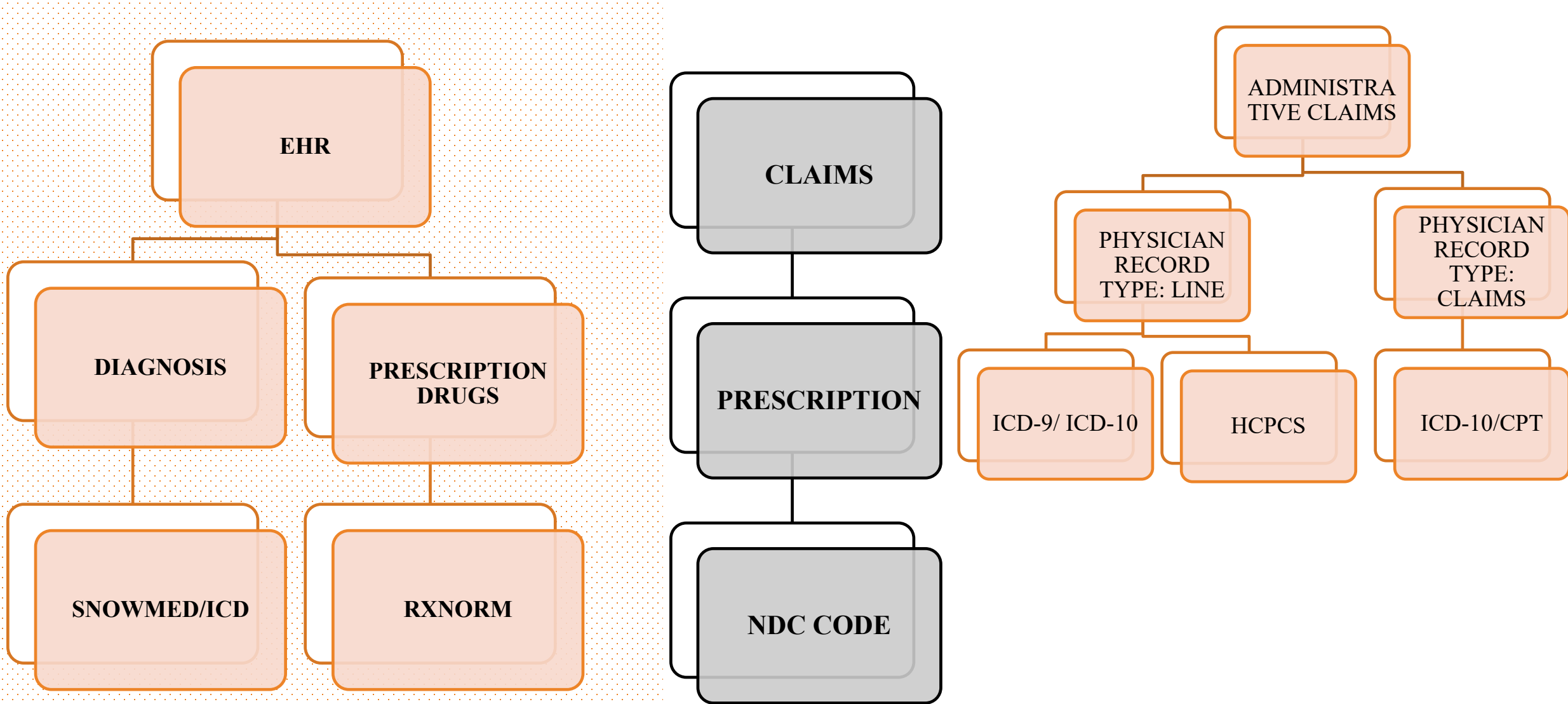
Clinical coding system	Domain coverage	Type, purpose
SNOMED CT	Multiple areas (diagnoses, allergies, symptoms, etc)	Terminology, clinical documentation
International Classification of Diseases (ICD)	Diagnoses, some procedures	Classification, reporting
Current Procedural Terminology (CPT)	Procedures	Terminology, clinical documentation
Logical Observation Identifiers Names and Codes (LOINC)	Laboratory tests	Terminology, clinical documentation
Anatomical Therapeutic Chemical (ATC)	Drugs	Classification, reporting
International Classification of Primary Care (ICPC)	Diagnoses, reasons for encounter, some procedures	Classification, reporting



Mining Electronic Health Records ((Jensen, Jensen, & Brunak, 2012))



DATA FLOW IN ELECTRONIC HEALTH RECORDS



MedlinePlus Connect – A Web based Decision Support Tool for Patients and Clinicians

Code Types	If you send:	MedlinePlus Connect responds with:
Diagnosis (problem) codes:	• ICD-9-CM • ICD-10-CM • SNOMED CT® [1]	MedlinePlus Health Topic Pages, Genetics Pages NIDDK pages, NIA pages, NCI pages, NIAMS pages
Medication Codes:	• RxCUI (RxNorm Concept Unique Identifier) • NDC (National Drug Code)	MedlinePlus Drug Pages (ASHP) MedlinePlus Supplement Pages (NMCD, NCCIH, ODS)
Laboratory Test Codes:	• LOINC® (Logical Observation Identifiers Names and Codes)	MedlinePlus Lab Test Pages
Procedure Codes:	• CPT® (Current Procedural Terminology) • SNOMED CT® [1]	MedlinePlus Health Topic Pages, Lab Test Pages

[1] MedlinePlus Connect coverage of SNOMED CT focuses on CORE Problem List Subset and their descendants.

The output is in JSON, XML , JSONP format and support Procedure, Lab Test, Problem and Medication codes.

Reference: “Medline Plus.” MedlinePlus, U.S. National Library of Medicine, <https://connect.medlineplus.gov/demo/service>.



hor.name._value	feed.author.uri._value	feed.subtitle.type	feed.subtitle._value	feed.category	feed.entry
National Library of Medicine	https://www.nlm.nih.gov	text	MedlinePlus Connect results for RXCUI 5640		<pre>{ "title": { "_value": "Ibuprofen", "type": "text", "link": [{ "href": "https://medlineplus.gov/druginfo/meds/a682159.html?utm_source=mplusconnect&utm_medium=service", "rel": "alternate" }], "id": { "_value": "tag: medlineplus.gov, 2023-01-02:/druginfo/meds/a682159.html?utm_source=mplusconnect&utm_medium=application", "type": "html", "_value": "Prescription ibuprofen is used to relieve pain, tenderness, swelling, and stiffness caused by osteoarthritis (arthritis caused by a breakdown of the lining of the joints) and rheumatoid arthritis (arthritis caused by swelling of the lining of the joints). It is also used to relieve mild to moderate pain, including menstrual pain (pain that happens before or during a menstrual period). Nonprescription ibuprofen is used to reduce fever and to relieve minor aches and pain from headaches, muscle aches, arthritis, menstrual periods, the common cold, toothaches, and backaches. Ibuprofen is in a class of medications called NSAIDs. It works by stopping the body's production of a substance that causes pain, fever, and inflammation." }, "updated": { "_value": "2023-02-01T02:54:30Z", "type": "text", "link": [{ "href": "https://medlineplus.gov/painrelievers.html?utm_source=mplusconnect&utm_medium=service", "rel": "alternate" }], "id": { "_value": "tag: medlineplus.gov, 2023-01-02:/painrelievers.html?utm_source=mplusconnect&utm_medium=application", "type": "html", "_value": "<p>Pain relievers are medicines that reduce or relieve headaches, sore muscles, arthritis, or other aches and pains. There are many different pain medicines, and each one has advantages and risks. Some types of pain respond better to certain medicines than others. Each person may also have a slightly different response to a pain reliever. </p> <p>Over-the-counter (OTC)" } } } }</pre>

MedlinePlus Connect is a portal that helps with Clinical Decision support for Physicians and easily readable information for patients, it can accept only one code per request. It is free resource by the government and Health organizations and IT providers can link patient portals and electronic health record (EHR) systems to MedlinePlus consumer health information. MedlinePlus Connect medication requests support both RXCUI and NDC Codes and connect to Electronic Health Records using web portal.



DRUG RELATED SIDE EFFECTS AND INTERACTIONS FOR A PATIENT – SAMPLE REFERENCE CHARTS

Prescription	Drug Interactions – NLM/RxNav/DrugBank	Drug Half-Life - NLM/RxNav/DrugBank	Drug related AE reported from FAERS
Fludrocortisone DrugBank Accession [RXCUI = 4452] NumberDB00687	Fludrocortisone may increase the anticoagulant activities of Warfarin.	The plasma half-life of fludrocortisone has been variably reported to be between 1-3.5 hours, though prescribing information gives an approximate half-life of 18-36 hours.	3 AE's including: Headache, Visual Impairment, Papilloedema
Warfarin DrugBank Accession [RXCUI = 11289] NumberDB00682	The metabolism of Warfarin can be decreased when combined with Ibuprofen. Ibuprofen may decrease the excretion rate of Warfarin which could result in a higher serum level.	R-warfarin is cleared more slowly than S- warfarin, at about half the rate. Label T1/2 for R-warfarin is 37-89 hours. T1/2 for S- warfarin is 21-43 hours.	35 AE's including: Haematuria, Hemorrhage, Splenomegaly, Lower gastrointestinal hemorrhage, Pulmonary arterial hypertension, Subdural haematoma
ibuprofen DrugBank Accession [RXCUI = 5640] NumberDB01050	The risk or severity of gastrointestinal irritation can be increased when Fludrocortisone is combined with Ibuprofen.	The serum half-life of ibuprofen is 1.2-2 hours. ¹⁰ In patients with a compromised liver function, the half-life can be prolonged to 3.1-3.4 hours.	64 AE's including Renal impairment, Platelet count decreased, Pulmonary hemorrhage, Vision blurred, Malaise, Stevens-Johnson syndrome
Prednisolone [RXCUI = 8638] DrugBank Accession NumberDB00860	Prednisone may increase the anticoagulant activities of Warfarin.	Prednisolone has a plasma half life of 2.1- 3.5 hours. This half life is shorter in children and longer in those with liver disease.	33 AE's including Hyperhidrosis, Grand mal convulsion, Acute graft versus host disease, Therapeutic response decreased, Local swelling, Pulmonary alveolar hemorrhage, Hypotension.



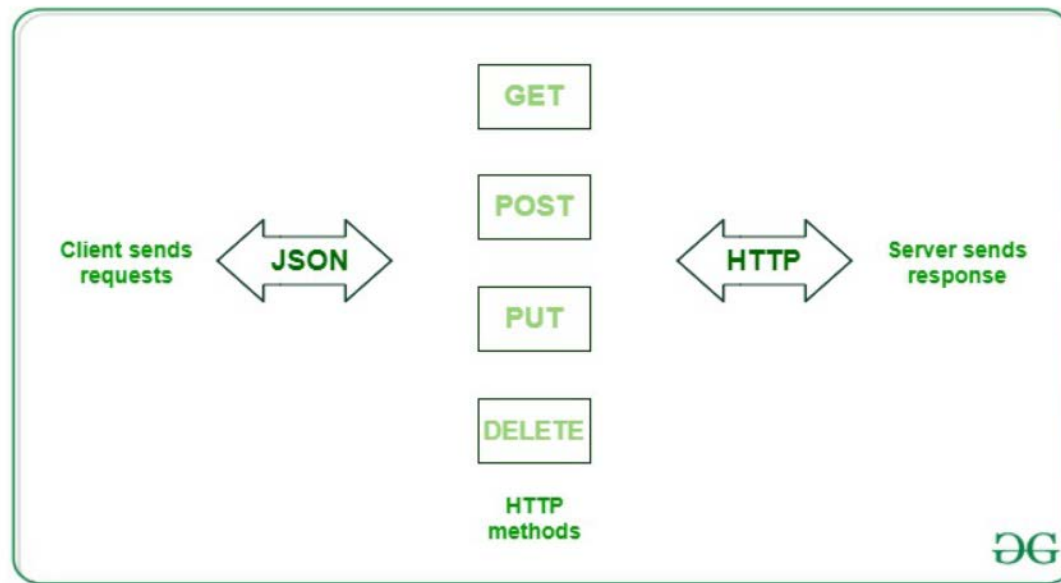
ENDPOINT BASED REAL WORLD EVIDENCE FOR TRACKING MEDICATION ERRORS AND ADVERSE EVENTS

HL7 International creates international data standards for sharing and processing information(FHIR) in a uniform and consistent manner. We will be discussing some of the very useful API's that are publicly available.

1. OpenFDA Adverse event API: access to adverse event and medication error reports created by contributions of healthcare professionals and consumers voluntarily report adverse events to the FDA and they are stored in the FDA Adverse Event Reporting System (FAERS). <https://open.fda.gov/apis/drug/event/>
2. DrugBank Clinical Drug API: That is a curation of clinical data from the USA, Canada, and European Union by a health technology institution. <https://go.DrugBank.com/>
3. The RxNorm API which is a web service-based API by the National Library of Medicine(NLM) for retrieving RXCUI based Drug Interaction, Drug Classification information from the RxNorm data set. <https://www.nlm.nih.gov/>
4. CDC's Chronic Disease Indicator API, which is a collection of chronic disease indicators, filtered by 65+ age group. <https://chronicdata.cdc.gov/Chronic-Disease-Indicators/U-S-Chronic-Disease-Indicators-Chronic-Obstructive/aqr6-8kj8>
5. MedlinePlus Connect Web Service <https://connect.medlineplus.gov/demo/service>
6. Dummy Electronic Health Record Data will be created to join with Drug Related Adverse Event and Interaction data.
7. Data will be curated and analyzed using commonly available analytical packages for data wrangling using python.

Common Public Use API's

1. RxNorm: The API retrieves data from the RxNorm vocabulary developed by the National Library of Medicine using multiple source vocabularies.
2. American Society of Health-System Pharmacists
3. OpenFDA is an open government platform for drug and medical device data.
4. OpenFDA NDC Directory API: access to the database of the National Drug Codes
5. DailyMed RESTful API: access to the structured product labeling data: NDA numbers, drug names, NDC codes, RXCUI's, SPLs, Unique Ingredient Identifiers.
6. MedlinePlus: connection to Electronic Medical Records + Patient friendly information
7. DrugBank Clinical Drug API: access to comprehensive clinical data from the USA, Canada, and European Union
8. Wolters Kluwer Health APIs
9. VigiBase, UMC - Uppsala Monitoring Centre



Vocabularies in RxNorm API

<u>ATC</u>	Anatomical Therapeutic Chemical Classification System
<u>CVX</u>	Vaccines Administered
<u>DrugBank</u>	DrugBank
<u>GS</u>	Gold Standard Drug Database
<u>MDDB</u>	Medi-Span Master Drug Data Base*
<u>MMSL</u>	Multum MediSource Lexicon
<u>MMX</u>	Micromedex RED BOOK
<u>MSH</u>	Medical Subject Headings (MeSH) [subset]
<u>MTHCMSFRF</u>	CMS Formulary Reference File [subset]
<u>MTHSPL</u>	FDA Structured Product Labels
<u>NDDF</u>	FDB MedKnowledge (formerly NDDF Plus)
<u>RXNORM</u>	RxNorm terminology normalized names and codes
<u>SNOMEDCT_US</u>	US Edition of SNOMED CT [drug information subset]**
<u>USP</u>	USP Compendial Nomenclature
<u>VANDE</u>	Veterans Health Administration National Drug File

Image Reference: "Accessing Rest API Using R Programming." *GeeksforGeeks*, GeeksforGeeks, 28 Dec. 2021, <https://www.geeksforgeeks.org/accessing-rest-api-using-r-programming/>.

REST API responses from OPEN FDA, RxNorm, CDC

```
{
  "nlmDisclaimer": "It is not the intention of NLM to provide specific medical advice, but rather to provide users with information to better understand their health and their medications. NLM urges you to consult with a qualified physician for advice about medications.",
  "interactionTypeGroup": [
    {
      "sourceDisclaimer": "DrugBank is intended for educational and scientific research purposes only and you expressly acknowledge and agree that use of DrugBank is at your sole risk. The accuracy of DrugBank information is not guaranteed and reliance on DrugBank shall be at your sole risk. DrugBank is not intended as a substitute for professional medical advice, diagnosis or treatment..[www.drugbank.ca]",
      "sourceName": "DrugBank",
      "interactionType": [
        {
          "comment": "ibuprofen (5640) is resolved to ibuprofen (5640)",
          "minConceptItem": {
            "rxcul": "5640",
            "name": "ibuprofen",
            "rxclassTree": [
              {
                "rxclassMinConceptItem": {
                  "classId": "N0000185505",
                  "className": "Cytochrome P450 Inducer",
                  "classType": "MOA"
                },
                "rxclassTree": [
                  {
                    "rxclassMinConceptItem": {
                      "classId": "N0000187064",
                      "className": "Cytochrome P450",
                      "classType": "MOA"
                    }
                  ]
                }
              ]
            }
          }
        ]
      }
    }
  ]
}
```

```
{
  "propCategory": "CODES",
  "propName": "ATC",
  "propValue": "R06AX09"
},
{
  "propCategory": "CODES",
  "propName": "DRUGBANK",
  "propValue": "DB00719"
},
{
  "propCategory": "CODES",
  "propName": "MESH",
  "propValue": "C006656"
},
{
  "propCategory": "CODES",
  "propName": "MMSL_CODE",
  "propValue": "CND60791"
}
```

Example: Interaction sources

XML: <https://rxnav.nlm.nih.gov/REST/interaction/sources>

JSON: <https://rxnav.nlm.nih.gov/REST/interaction/sources.json>

An XML result is shown below.

```
<interactiondata>
  <nlmDisclaimer>It is not the intention of NLM to provide specific medical advice, but rather to provide users with information to better understand their health and their medications. NLM urges you to consult with a qualified physician for advice about medications.</nlmDisclaimer>
  <sourceList>
    <source>DrugBank</source>
    <source>ONCHigh</source>
  </sourceList>
</interactiondata>
```

```
{
  "meta": {
    "disclaimer": "Do not rely on openFDA to make decisions. openFDA restricts your access to the API in line with our Terms of Service.",
    "terms": "https://open.fda.gov/terms/",
    "license": "https://open.fda.gov/license/",
    "last_updated": "2022-11-04",
    "results": {
      "skip": 0,
      "limit": 1,
      "total": 9123782
    }
  },
  "results": [
    {
      "safetyreportid": "5801206-7",
      "transmissiondateformat": "102",
      "transmissiondate": "20090109",
      "serious": "1",
      "seriousnessdeath": "1",
      "receiveddateformat": "102",
      "receiveddate": "20080707",
      "receiptdateformat": "102",
      "receiptdate": "20080625",
      "fulfillexpeditecriteria": "1",
      "companynumb": "JACAN16471",
      "primarysource": {
        "source": "JACAN16471"
      }
    }
  ]
}
```

```
"23088",
"7052",
"7676",
"7804"
],
"rankClassConcept": [
  {
    "similarityEntityItem": {
      "equivalenceScore": "0.5962848",
      "inclusionScore": "-1.0",
      "intersection": "4",
      "cardinality1": "4",
      "cardinality2": "6"
    },
    "drugClassConceptItem": {
      "rela": "",
      "relaSource": "ATC",
      "rxclassMinConceptItem": {
        "classId": "N02AA",
        "className": "Natural opium alkaloids",
        "classType": "ATC1-4"
      }
    }
  }
]
```

RxNav, RXCUI - A key component of RxNorm is the Concept Unique Identifier (RXCUI) – API Responses

String

prednisone

Q

prednisone [RxCUI = 8640]

RxNorm Graph

RxNorm Properties

NDC

RxTerms

Class View

Interaction View

Status

Views

Classic

Simple

Table

Filters

H

V

S

Group

Form

Links

IN/MIN

Ingredient (3)

H R S

predniSONE

M

chloramphenicol / predniSONE

M

piroxicam / predniSONE

PIN

Precise Ingredient (0)

BN

Brand Name (2)

H R S

Deltasone

H R S

Rayos

SCDC

Clinical Drug Component (0)

H R S

predniSONE 2 MG

H R S

predniSONE 2.5 MG

H R S

predniSONE 20 MG

H R S

predniSONE 5 MG

H R S

predniSONE 5 MG/ML

H R S

predniSONE 50 MG

SBDC

Branded Drug (0)

H R S

predniSONE 1 MG [Rayos]

H R S

predniSONE 2 MG [Rayos]

H R S

predniSONE 20 MG [Delta]

H R S

predniSONE 5 MG [Rayos]

ibuprofen [RxCUI = 5640]

RxNorm Graph

RxNorm Properties

NDC

RxTerms

Class View

Interaction View

Status

Views

Attributes

Codes

Names

Sources

Download

Property

Value

ATC

C01EB16

ATC

G02CC01

ATC

M01AE01

ATC

M02AA13

ATC

R02AX02

DRUGBANK

DB01050

MESH

D007052

MMSL_CODE

BN2133

MMSL_CODE

BN7027

MMSL_CODE

GNd00015

MMSL_CODE

IN4862

RxCUI

5640

SNOMEDCT

38268001

SNOMEDCT

387207008

SPL_SET_ID

00653b7c-7099-487e-9a01-e89781c21323

API: Retrieving all
CODES : ATC,
RXCUI, DrugBank,
SNOWMEDCT from
NLM's RxNav for
one or all DRUGS

A	B	C
fullName	termType	rxcul
0.005 ML dexamethasone 103.4 MG/ML Injection	SCD	2045404
0.005 ML dexamethasone 103.4 MG/ML Injection [Dexycu]	SBD	2045409
0.05 ML aflibercept 40 MG/ML Injection	SCD	1232154
0.05 ML aflibercept 40 MG/ML Injection [Eylea]	SBD	1232159
0.05 ML brolocizumab-dbl 120 MG/ML Injection	SCD	2204920
0.05 ML brolocizumab-dbl 120 MG/ML Injection [Beovu]	SBD	2204925
0.05 ML brolocizumab-dbl 120 MG/ML Prefilled Syringe	SCD	2602276
0.05 ML brolocizumab-dbl 120 MG/ML Prefilled Syringe [Beovu]	SBD	2602279
0.05 ML faricimab-svoa 120 MG/ML Injection	SCD	2591588
0.05 ML faricimab-svoa 120 MG/ML Injection [Vabysmo]	SBD	2591594
0.05 ML ranibizumab 10 MG/ML Injection	SCD	643193
0.05 ML ranibizumab 10 MG/ML Injection [Lucentis]	SBD	644301
0.05 ML ranibizumab 10 MG/ML Prefilled Syringe	SCD	1864423
0.05 ML ranibizumab 10 MG/ML Prefilled Syringe [Lucentis]	SBD	1864425
0.05 ML ranibizumab 6 MG/ML Injection	SCD	1306074
0.05 ML ranibizumab 6 MG/ML Injection [Lucentis]	SBD	1306076
0.05 ML ranibizumab 6 MG/ML Prefilled Syringe	SCD	2045501
0.05 ML ranibizumab 6 MG/ML Prefilled Syringe [Lucentis]	SBD	2045502
0.05 ML ranibizumab-eqrn 10 MG/ML Injection	SCD	2612684
0.05 ML ranibizumab-eqrn 10 MG/ML Injection [Cimerli]	SBD	2612687

Reference:

"Apis." U.S. National Library of Medicine, National Institutes of Health,
<https://lhncbc.nlm.nih.gov/RxNav/APIs/index.html>.



RxNav API: GET ATC, DrugBank, RXCUI, SNOWMEDCT CODES for a Drug

drugClassConceptItem.relaSource	drugClassConceptItem.rxclassMinConceptItem.classId	drugClassConceptItem.rxclassMinConceptItem.className	drugClassConceptItem.rxclassMinConceptItem.classType
ATC	N02AA	Natural opium alkaloids	ATC1-4
MEDRT	D009022	Morphine Derivatives	CHEM
MEDRT	D003061	Codeine	CHEM
propCategory	propName	propValue	
CODES	ATC	C01EB16	
CODES	ATC	G02CC01	
CODES	ATC	M01AE01	
CODES	ATC	M02AA13	
CODES	ATC	R02AX02	
CODES	DRUGBANK	DB01050	
CODES	MESH	D007052	
CODES	MMSL_CODE	BN2133	
CODES	MMSL_CODE	BN7027	
CODES	MMSL_CODE	GNd00015	
CODES	MMSL_CODE	IN4862	
CODES	RxCUI	5640	
CODES	SNOMEDCT	38268001	
CODES	SNOMEDCT	387207008	

The Output on left and bottom display normalized data retrieved from RxNav API for Ibuprofen(left: All Codes) and Drug Similarity Score Calculation.

Similarity Scores are pre-calculated, data is displayed after API was normalized.

GET Drug Similarity between three Drugs by RXCUI and Similarity Score, RXCUI= fludrocortisone [RXCUI = 4452]+ warfarin[RXCUI = 11289]+ oxycodone[RXCUI = 7804]+ prednisolone[RXCUI = 8638]

similarityEntity1	similarityEntity2	similarityEntity3	similarityEntity4	similarityEntity5	drugClassConceptItem.relaSource	drugClassConceptItem.rxclassMinConceptItem.classId	drugClassConceptItem.rxclassMinConceptItem.className	drugClassConceptItem.rxclassMinConceptItem.classType
0.5962848	-1.0	4	4	6		ATC	N02AA	Natural opium alkaloids ATC1-4
0.3211308	-0.45	3	4	7	has_ingredient	MEDRT	D009022	Morphine Derivatives CHEM
0.2581989	0.0	2	4	4	has_ingredient	MEDRT	D003061	Codeine CHEM



Data retrieved for Ibuprofen from OpenFDA API- Normalized, filter RXCUI=5640

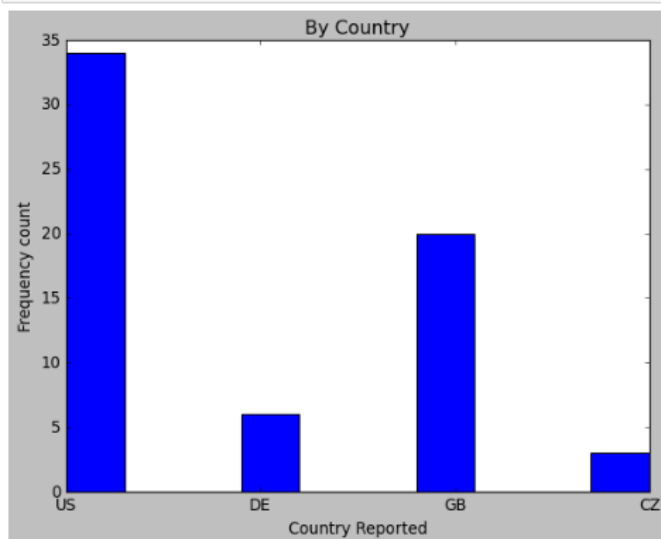
0	safetyreportversion_x	n	medicinalproduct	drugbatchnumb	drugauthorizationnumb	drugstructuredosagenumb	drugstructuredosageunit	drugdosagetext	drugadministrationro
1	safetyreportid								
2	primarysourcecountry								
3	transmissiondateformat	1	IBUPROFEN	NaN	17463	NaN	NaN	NaN	N
4	transmissiondate								
5	reporttype								
6	serious								
7	seriousnessdisabling	1	IBUPROFEN	NaN	17463	NaN	NaN	NaN	N
8	receivedateformat								
9	receivedate								
10	receiptdateformat								
11	receiptdate								
12	fulfillexpeditecriteria	2	IBUPROFEN	NaN	NaN	NaN	NaN	NaN	N
13	companynumb								
14	duplicate								
15	reportduplicate.duplicatesou	reactionmeddraversionpt	reactionmeddrapt	reactionoutcome	safetyreportversion_y	drugcharacterization	medicinalproduct	drugbatchnumb	drugauthorizati
16	reportduplicate.duplicatenum								
17	primarysource.reportercount	17.0	Dyspepsia	NaN	1	1	IBUPROFEN	NaN	
18	primarysource.qualification								
19	sender.sendertype								
20	sender.senderorganization								
21	receiver.receiveratype	17.0	Renal impairment	NaN	1	1	IBUPROFEN	NaN	
22	receiver.receiverorganizatio								
23	patient.patientonsetage								
24	patient.patientonsetageunit								
25	patient.patientsex	17.0	Cholecystectomy	1	2	2	IBUPROFEN	NaN	
26	seriousnessother								
27	occurcountry								
28	patient.patientagegroup								
		17.0	Nephrolithiasis	1	2	2	IBUPROFEN	NaN	



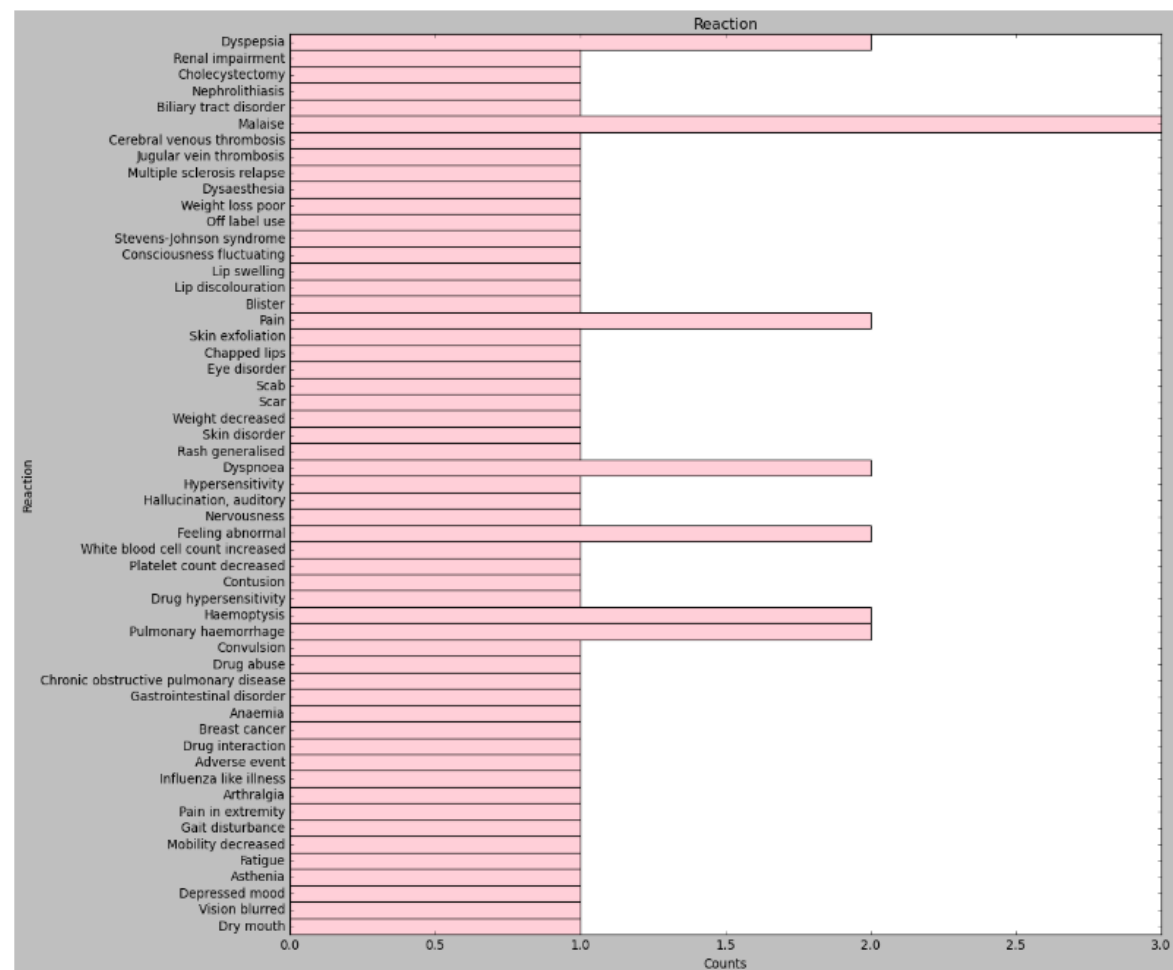
Data summary Ibuprofen from OpenFDA, RXCUI=5640, AE – PT Summary Counts, Dosage and Frequency

drugindication	BACK PAIN	NASOPHARYNGITIS	PAIN
drugdosagetext			
DAILY DOSE: 2800 MG MILLGRAM(S) EVERY TOTAL	2	0	0
UNK	0	0	3
UNK, GIVEN STANDARD DOSE OF LIQUID IBUPROFEN.	0	18	0

```
plt.show()
```

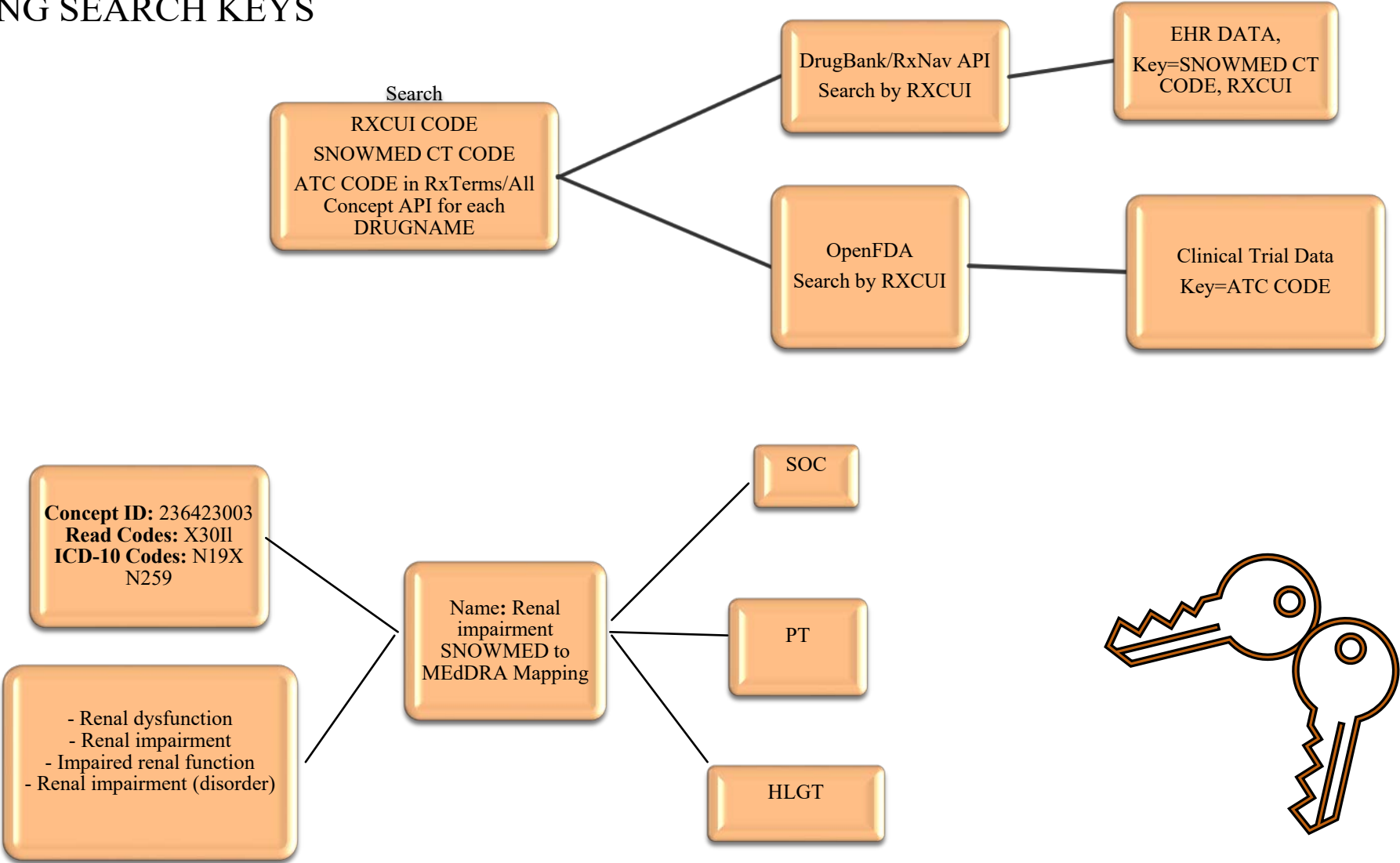


```
plt.xlabel('Counts')  
plt.ylabel('Reaction')  
Text(0, 0.5, 'Reaction')
```





CREATING SEARCH KEYS





Data retrieved for IBUPROFEN, RXCUI=5640, NLM/RxNav/DrugBank API – Normalized Data

```
df_drugbank.info()

<class 'pandas.core.frame.DataFrame'>
Int64Index: 1467 entries, 0 to 1466
Data columns (total 8 columns):
#   Column              Non-Null Count  Dtype
---  ---
0   row_num              1467 non-null  int32
1   minConceptItem.rxcui 1467 non-null  object
2   minConceptItem.name   1467 non-null  object
3   sourceConceptItem.url 1467 non-null  object
4   interactionConcept     1467 non-null  object
5   severity              1467 non-null  object
6   description           1467 non-null  object
7   sourceName            1467 non-null  object
dtypes: int32(1), object(7)
memory usage: 87.4+ KB
```

minConceptItem.rxcui	minConceptItem.name	sourceConceptItem.url	interactionConcept	severity	description	sourceName
5640	ibuprofen	https://go.drugbank.com/drugs/DB01050#interact...	{'minConceptItem': {'rxcur': '5640', 'name': ...	N/A	The risk or severity of bleeding can be increa...	DrugB
1000492	resveratrol	https://go.drugbank.com/drugs/DB02709#interact...	{'minConceptItem': {'rxcur': '5640', 'name': ...	N/A	The risk or severity of adverse effects can be...	DrugB
5640	ibuprofen	https://go.drugbank.com/drugs/DB01050#interact...	{'minConceptItem': {'rxcur': '5640', 'name': ...	N/A	The metabolism of Ibuprofen can be decreased	DrugB

```
Drugbank[["RXCUI", "Drugname", "description"]]
```

	RXCUI	Drugname	description
0	5640	ibuprofen	The risk or severity of bleeding can be increased when Ibuprofen is combined with Resveratrol.
1	1000492	resveratrol	The risk or severity of adverse effects can be increased when Ibuprofen is combined with Antipyrine.
2	5640	ibuprofen	The metabolism of Ibuprofen can be decreased when combined with Doconexent.
3	1001	antipyrine	Ibuprofen may decrease the excretion rate of Antithrombin III human which could result in a higher serum level.
4	5640	ibuprofen	The risk or severity of angioedema can be increased when Streptokinase is combined with Ibuprofen.
...	...	...	...
1462	5640	ibuprofen	The excretion of Piperacillin can be decreased when combined with Ibuprofen.
1463	322167	solifenacin	The excretion of Saxagliptin can be decreased when combined with Ibuprofen.
1464	5640	ibuprofen	The risk or severity of gastrointestinal irritation can be increased when Prednisolone phosphate is combined with Ibuprofen.
1465	32311	octylonium	The risk or severity of gastrointestinal irritation can be increased when Prednisolone acetate is combined with Ibuprofen.
1466	5640	ibuprofen	Ibuprofen may decrease the excretion rate of Fenofibric acid which could result in a higher serum level.

1467 rows × 3 columns



Matching - Patient Medical History with reactionmedrapt from OpenFDA for drugname=“Ibuprofen”, and NLM-RxNav, DrugBank for Drug Interaction and Description Column for Adverse Event Matching

Patient Name/ID	Patient Medical History	Medications	Diagnosis	Doctors Prescription	DRUGBANK_AE	
0	XXX	Haemoptysis	Streptomycin	NaN	NaN	IBUPROFEN MAY DECREASE THE EXCRETION RATE OF STREPTOMYCIN WHICH COULD RESULT IN A HIGHER SERUM LEVEL.
1	NaN	Bronchiatis	Sulfamethizole	NaN	NaN	THE METABOLISM OF IBUPROFEN CAN BE DECREASED WHEN COMBINED WITH SULFAMETHIZOLE.
2	NaN	renal impairment	Ibuprofen	NaN	NaN	IBUPROFEN MAY DECREASE THE EXCRETION RATE OF TEMAZEPAM WHICH COULD RESULT IN A HIGHER SERUM LEVEL.
3	NaN	bleeding	Benzphetamine	NaN	NaN	THE METABOLISM OF TESTOSTERONE ENANTHATE CAN BE DECREASED WHEN COMBINED WITH IBUPROFEN.
4	NaN	NaN	Temazepam	NaN	NaN	THE RISK OR SEVERITY OF HYPERTENSION CAN BE INCREASED WHEN BENZPHETAMINE IS COMBINED WITH IBUPROFEN.
				280		THE RISK OR SEVERITY OF NEPHROTOXICITY CAN BE INCREASED WHEN IBUPROFEN IS COMBINED WITH DIHYDROSTREPTOMYCIN.

MH1 = DBAE[DBAE['DRUGBANK_AE'].str.contains(pattern)]

MH1

Word Pattern Matching, rows are displayed: for Medical History and Concomitant Medications

				DRUGBANK_AE
result_Openfda_Ibuprofen				
patient.patientweight	NaN	NaN	NaN	THE RISK OR SEVERITY OF BLEEDING CAN BE INCREASED WHEN IBUPROFEN IS COMBINED WITH RESVERATROL.
seriousnessdeath	NaN	NaN	NaN	THE RISK OR SEVERITY OF BLEEDING CAN BE INCREASED WHEN IBUPROFEN IS COMBINED WITH SULFINPYRAZONE.
seriousnesscongenitalanomaly	NaN	NaN	NaN	THE METABOLISM OF TESTOSTERONE ENANTHATE CAN BE DECREASED WHEN COMBINED WITH IBUPROFEN.
authoritynumb	NaN	NaN	NaN	THE RISK OR SEVERITY OF BLEEDING CAN BE INCREASED WHEN IBUPROFEN IS COMBINED WITH TICLOPIDINE.
primarysource.literaturereference	NaN	NaN	NaN	THE RISK OR SEVERITY OF BLEEDING CAN BE INCREASED WHEN IBUPROFEN IS COMBINED WITH TRAPIDIL.
reactionmeddraversionpt	17.0	17.0	17.0	SEVERITY OF GASTROINTESTINAL BLEEDING CAN BE INCREASED WHEN TRAZODONE IS COMBINED WITH IBUPROFEN.
reactionmeddrapt	Haemoptysis	Haemoptysis	Haemoptysis	SEVERITY OF GASTROINTESTINAL BLEEDING CAN BE INCREASED WHEN TRIMIPRAMINE IS COMBINED WITH IBUPROFEN.
reactionoutcome	6	6	6	THE RISK OR SEVERITY OF BLEEDING CAN BE INCREASED WHEN IBUPROFEN IS COMBINED WITH TICAGRELOR.
safetyreportversion_y	1	1	1	THE RISK OR SEVERITY OF BLEEDING CAN BE INCREASED WHEN ZIDOVUDINE IS COMBINED WITH IBUPROFEN.
drugcharacterization	1	1	1	ERITY OF GASTROINTESTINAL BLEEDING CAN BE INCREASED WHEN IBUPROFEN IS COMBINED WITH PAMIDRONIC ACID.
medicinalproduct	IBUPROFEN	IBUPROFEN	IBUPROFEN	ERITY OF GASTROINTESTINAL BLEEDING CAN BE INCREASED WHEN IBUPROFEN IS COMBINED WITH PAMIDRONIC ACID.
drugbatchnumb	NaN	NaN	NaN	ERITY OF GASTROINTESTINAL BLEEDING CAN BE INCREASED WHEN IBUPROFEN IS COMBINED WITH TILUDRONIC ACID.
drugauthorizationnumb	070045	070045	070045	ERITY OF GASTROINTESTINAL BLEEDING CAN BE INCREASED WHEN IBUPROFEN IS COMBINED WITH TILUDRONIC ACID.
drugstructuredosagenumb	400	NaN	NaN	



NLTK :: Natural Language Toolkit– Python, Finding Association Rules

Below is a mapping of MedDRA PT Code and SNOWMED CT CODE

MedDRA Code	PT Name	SOC Name	SNOWMED CT Code	Code System Preferred Concept Name	RWE_AE	RWE_DI
10077512	End stage renal disease	Renal and urinary disorders				The risk or severity of renal failure, hyperkalemia, and hypertension can be increased when Ibuprofen is combined with Triamterene.
10078987	Foetal renal impairment	Renal and urinary disorders				
10063544	Renal embolism	Renal and urinary disorders				The risk or severity of renal failure and hypertension can be increased when Ibuprofen is combined with Cyclosporine.
10038435	Renal failure	Renal and urinary disorders				The risk or severity of renal failure, hyperkalemia, and hypertension can be increased when Ibuprofen is combined with Moexipril.
10038447	Renal failure neonatal	Renal and urinary disorders				The risk or severity of hypertension can be increased when Ibuprofen is combined with Theodrenaline.
10038460	Renal haemorrhage	Renal and urinary disorders				The risk or severity of renal failure, hyperkalemia, and hypertension can be increased when Olmesartan is combined with Ibuprofen.
10062854	Renal hydrocele	Renal and urinary disorders				The risk or severity of renal failure and hypertension can be increased when Ibuprofen is combined with Aliskiren.
10062237	Renal impairment	Renal and urinary disorders	236423003	Renal impairment (disorder)	Renal impairment	The risk or severity of renal failure, hyperkalemia, and hypertension can be increased when Azilsartan medoxomil is combined with Ibuprofen.
10049776	Renal impairment neonatal	Renal and urinary disorders				The risk or severity of renal failure, hyperkalemia, and hypertension can be increased when Ibuprofen is

"DYSPEPSIA', 'NAN', 'CHOLECYSTECTOMY', 'NEPHROLITHIASIS', 'BILIARY TRACT DISORDER', 'MALAISE', 'CEREBRAL VENOUS THROMBOSIS', 'JUGULAR VEIN THROMBOSIS', 'MULTIPLE SCLEROSIS RELAPSE', 'DYSAESTHESIA', 'WEIGHT LOSS POOR', 'OFF LABEL USE', 'STEVENS-JOHNSON SYNDROME', 'CONSCIOUSNESS FLUCTUATING', 'LIP SWELLING', 'LIP DISCOLOURATION', 'BLISTER', 'PAIN', 'SKIN EXFOLIATION', 'CHAPPED LIPS', 'EYE DISORDER', 'SCAB', 'SCAR', 'WEIGHT DECREASED', 'SKIN DISORDER', 'RASH GENERALISED', 'DYSPNOEA', 'RENAL IMPAIRMENT', 'MALAISE', 'HALLUCINATION, AUDITORY', 'NERVOUSNESS', 'FEELING ABNORMAL', 'MALAISE', 'PAIN', 'FEELING ABNORMAL', 'WHITE BLOOD CELL COUNT INCREASED', 'PLATELET COUNT DECREASED', 'CONTUSION', 'DRUG HYPERSENSITIVITY', 'HAEMOPTYSIS', 'HAEMOPTYSIS', 'PULMONARY HAEMORRHAGE', 'PULMONARY HAEMORRHAGE', 'CONVULSION', 'DRUG ABUSE', 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE', 'DYSPNOEA', 'GASTROINTESTINAL DISORDER', 'DYSPEPSIA', 'ANAEMIA', 'BREAST CANCER', 'DRUG INTERACTION', 'ADVERSE EVENT', 'INFLUENZA LIKE ILLNESS', 'ARTHRALGIA', 'PAIN IN EXTREMITY', 'GAIT DISTURBANCE', 'MOBILITY DECREASED', 'FATIGUE', 'ASTHENIA', 'DEPRESSED MOOD', 'VISION BLURRED', 'DRY MOUTH', 'END STAGE RENAL DISEASE', 'FOETAL RENAL IMPAIRMENT', 'IMMUNE-MEDIATED RENAL DISORDER', 'MALIGNANT RENAL HYPERTENSION', 'PANCREATORENAL SYNDROME', 'POSTRENAL FAILURE', 'PRERENAL FAILURE', 'PULMONARY RENAL SYNDROME', 'RENAL AMYLOIDOSIS', 'RENAL ARTERIOSCLEROSIS', 'RENAL ARTERITIS', 'RENAL ARTERY ARTERIOSCLEROSIS', 'RENAL ARTERY DISSECTION', 'RENAL ARTERY FIBROMUSCULAR DYSPLASIA', 'RENAL ARTERY HYPERPLASIA', 'RENAL ARTERY OCCLUSION', 'RENAL ARTERY STENOSIS', 'RENAL ARTERY THROMBOSIS', 'RENAL ATROPHY', 'RENAL CORTICAL NECROSIS', 'RENAL CYST HAEMORRHAGE', 'RENAL CYST RUPTURED', 'RENAL EMBOLISM', 'RENAL FAILURE', 'RENAL FAILURE NEONATAL', 'RENAL HAEMORRHAGE', 'RENAL HYDROCELE', 'RENAL IMPAIRMENT', 'RENAL IMPAIRMENT NEONATAL', 'RENAL INFARCT', 'RENAL INJURY', 'RENAL ISCHAEMIA', 'RENAL NECROSIS', 'RENAL PAPILLARY NECROSIS', 'RENAL PELVIC ECTASIA', 'RENAL PHOSPHATIDOSTATICS', 'RENAL SALT-LOSING SYNDROME', 'RENAL TUBULAR ACIDOSIS', 'RE

1. Figure on the left display's mappings between PT NAME, SOC NAME, SNOWMED CT CODE, Concept Name
2. Figure below: Is a Word List of All Preferred Terms in OpenFDA for text matching with a Physicians summary note.
3. Take Sample Text from Patient Records for Physicians Summary/Medications List – search for AE Terms.



NLTK :: Natural Language Toolkit– Python, Finding Association Rules

```
text.head()
```

	text	filtered_text	filtered_text_rem_pronouns_conjunction_preposition_interjection	removed_stopwords
0	Chief Complaint (CC)\n\nThe CC or presenting problem is reported by the patient. This can be a symptom, condition, previous diagnosis or another short statement that describes why the patient is presenting today. The CC is similar to the title of a paper, allowing the reader to get a sense of what the rest of the document will entail.\n\nExamples: chest pain, decreased appetite, shortness of breath. However, a patient may have multiple CC's, and their first complaint may not be the most significant one. Thus, physicians should encourage patients to state all of their problems, while paying attention to detail to discover the most compelling problem. Identifying the main problem must occur to perform effective and efficient diagnosis	Chief Complaint (CC) CC presenting problem is reported patient . can be symptom , condition , previous diagnosis short statement describes why patient is presenting today . CC is similar to title paper , allowing reader to get sense rest document will entail . Examples : chest pain , decreased appetite , shortness breath . However , patient may have multiple CC ' s , first complaint may not be most significant one . Thus , physicians should encourage patients to state all of their problems , paying attention to detail to discover most compelling problem . Identifying main problem must occur to perform effective efficient diagnosis	Chief Complaint (CC) CC presenting problem is reported patient . can be symptom , condition , previous diagnosis short statement describes why patient is presenting today . CC is similar to title paper , allowing reader to get sense rest document will entail . Examples : chest pain , decreased appetite , shortness breath . However , patient may have multiple CC ' s , first complaint may not be most significant one . Thus , physicians should encourage patients to state problems , paying attention to detail to discover most compelling problem . Identifying main problem must occur to perform effective efficient diagnosis	Chief Complaint (CC) CC presenting problem reported patient . symptom , condition , previous diagnosis short statement describes patient presenting today . CC similar title paper , allowing reader get sense rest document entail . Examples : chest pain , decreased appetite , shortness breath . However , patient may multiple CC ' , first complaint may significant one . Thus , physicians encourage patients state problems , paying attention detail discover compelling problem . Identifying main problem must occur perform effective efficient diagnosis
1	History of Present Illness (HPI)\n\nThe HPI begins with a simple one line opening statement including the patient's age, sex and reason for the visit.\n\nExample: 47-year old female presenting with abdominal pain, renal impairment	History Present Illness (HPI) HPI begins simple one line opening statement including patient ' s age , sex reason visit . Example : 47-year old female presenting abdominal pain , renal	History Present Illness (HPI) HPI begins simple one line opening statement including patient ' s age , sex reason visit . Example : 47-year old female presenting abdominal pain , renal impairment	History Present Illness (HPI) HPI begins simple one line opening statement including patient ' s age , sex reason visit . Example : 47-year old female presenting abdominal pain , renal impairment

Summary notes, have been cleaned by removing Pronouns, Conjunctions, Prepositions, Interjections

Removed all Stopwords, to get the words we need to parse through.

Notes Reference: *Soap Notes - StatPearls - NCBI Bookshelf*.
<https://www.ncbi.nlm.nih.gov/books/NBK482263/>.

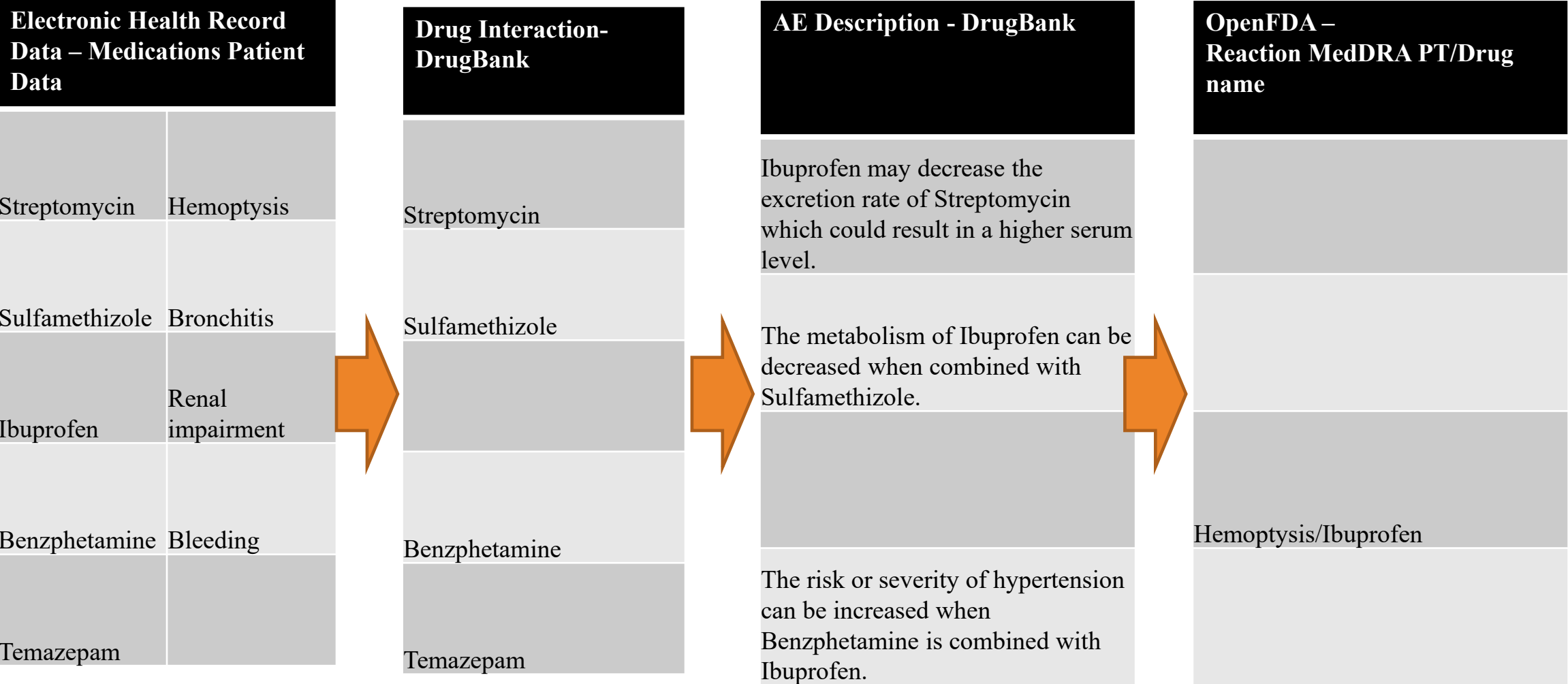


NLTK :: Natural Language Toolkit– Finds Close Matches with the list of Preferred Terms

text	CHIEF COMPLAINT (CC) THE CC OR PRESENTING PROBLEM IS REPORTED BY THE PATIENT. THIS CAN BE A SYMPTOM, CONDITION, PREVIOUS DIAGNOSIS OR ANOTHER SHORT STATEMENT THAT DESCRIBES WHY THE PATIENT IS PRESENTING TODAY. THE CC IS SIMILAR TO THE TITLE OF A PAPER, ALLOWING THE READER TO GET A SENSE OF WHAT THE REST OF THE DOCUMENT WILL ENTAIL. EXAMPLES: CHEST PAIN, DECREASED APPETITE, SHORTNESS OF BREATH. HOWEVER, A PATIENT MAY HAVE MULTIPLE CC'S, AND THEIR FIRST COMPLAINT MAY NOT BE THE MOST SIGNIFICANT ONE. THUS, PHYSICIANS SHOULD ENCOURAGE PATIENTS TO STATE ALL OF THEIR PROBLEMS, WHILE PAYING ATTENTION TO DETAIL TO DISCOVER THE MOST COMPELLING PROBLEM. IDENTIFYING THE MAIN PROBLEM MUST OCCUR TO PERFORM EFFECTIVE AND EFFICIENT DIAGNOSIS	HISTORY OF PRESENT ILLNESS (HPI) THE HPI BEGINS WITH A SIMPLE ONE LINE OPENING STATEMENT INCLUDING THE PATIENT'S AGE, SEX AND REASON FOR THE VISIT. EXAMPLE: 47-YEAR OLD FEMALE PRESENTING WITH ABDOMINAL PAIN, RENAL IMPAIRMENT
removed_stopwords	CHIEF COMPLAINT (CC) CC PRESENTING PROBLEM REPORTED PATIENT . SYMPTOM , CONDITION , PREVIOUS DIAGNOSIS SHORT STATEMENT DESCRIBES PATIENT PRESENTING TODAY . CC SIMILAR TITLE PAPER , ALLOWING READER GET SENSE REST DOCUMENT ENTAIL . EXAMPLES : CHEST PAIN , DECREASED APPETITE , SHORTNESS BREATH . HOWEVER , PATIENT MAY MULTIPLE CC ' , FIRST COMPLAINT MAY SIGNIFICANT ONE . THUS , PHYSICIANS ENCOURAGE PATIENTS STATE PROBLEMS , PAYING ATTENTION DETAIL DISCOVER COMPELLING PROBLEM . IDENTIFYING MAIN PROBLEM MUST OCCUR PERFORM EFFECTIVE EFFICIENT DIAGNOSIS	HISTORY PRESENT ILLNESS (HPI) HPI BEGINS SIMPLE ONE LINE OPENING STATEMENT INCLUDING PATIENT 'S AGE , SEX REASON VISIT . EXAMPLE : 47-YEAR OLD FEMALE PRESENTING ABDOMINAL PAIN , RENAL IMPAIRMENT
PAIN	TRUE	TRUE
RENAL IMPAIRMENT	FALSE	TRUE



Data Interaction search and Matches for Ibuprofen – Sample Matches for One Drug





DISEASE OUTCOMES DATA – FROM CDC

Chronic Disease Indicators provide an overview of Disease Outcomes by Patient demographic information based on given Patient Demographic Parameters

CDC Data: CMS Claims Data: Hospitalization for chronic obstructive pulmonary disease as any diagnosis among Medicare-eligible persons aged ≥ 65 years

stratification1	American Indian or Alaska Native	Asian or Pacific Islander	Black, non-Hispanic	Female	Hispanic	Male	Overall	White, non-Hispanic	Total
locationdesc									
Alabama	10	20	17	14	18	16	18	19	132
Alaska	17	15	10	19	8	17	16	10	112
Arkansas	16	15	15	19	18	17	18	18	136
Total	43	50	42	52	44	50	52	47	380



Patient summary report created by joining all data sources: Patient EHR + OpenFDA + DrugBank + RxNav + CDC

Patient Summary						
Patient EHR Data						
Patient Name/ID	Medical History	Medications	Diagnosis	Race/Ethnicity	Gender	Age
AA00--XXX	Haemoptysis	Streptomycin	Pulmonary disease	Black, non-Hispanic	Male	70
	Bronchiatis	Sulfamethizole				
	renal impairment	Ibuprofen				
	bleeding	Benzphetamine				
		Temazepam				
Patient Medications + DrugBank - Drug Interactions						
RXCUI	10109	10179	1422			
Drugname	streptomycin	sulfamethizole	benzphetamine			
description	The metabolism of Ibuprofen can be decreased when combined with Sulfamethoxazole.	The risk or severity of adverse effects can be increased when Ibuprofen is combined with Azapropazone.	The risk or severity of bleeding can be increased when			
severity	N/A	N/A	N/A			
sourceConceptItem.url	https://go.drugbank.com/drugs/DB00576#interactions		https://go.drugbank.com/drugs/DB00865#interactions			
Patient Medical History + OpenFDA Reaaction medDRA PT						
Open_FDA_reactionmedd	Haemoptysis	Haemoptysis				
openfda.pharm_class_cs	['Anti-Inflammatory Agents, N']	['Anti-Inflammatory Agents, Non-Steroidal [CS]']				
openfda.pharm_class_epc	['Nonsteroidal Anti-inflammatory Drug [EPC]']	['Nonsteroidal Anti-inflammatory Drug [EPC]']				
DrugBank - Drug Related Adverse events - DrugBank						
RXCUI	Drugname	description	sourceConceptItem.url			



DrugBank - Drug Related Adverse events - DrugBank						
RXCUI	Drugname	description	sourceConceptItem.url			
5640	ibuprofen	The risk or severity of bleeding can be increased	https://go.drugbank.com/drugs/DB01050#interactions			
5640	ibuprofen	The risk or severity of bleeding can be increased	https://go.drugbank.com/drugs/DB01050#interactions			
10324	tamoxifen	The risk or severity of bleeding can be increased	https://go.drugbank.com/drugs/DB00675#interactions			
10378	testolactone	The risk or severity of bleeding can be increased	https://go.drugbank.com/drugs/DB00894#interactions			
5640	ibuprofen	The risk or severity of gastrointestinal bleeding c	https://go.drugbank.com/drugs/DB01050#interactions			
1043	apomorphine	The risk or severity of gastrointestinal bleeding c	https://go.drugbank.com/drugs/DB00714#interactions			
5640	ibuprofen	The risk or severity of bleeding can be increased	https://go.drugbank.com/drugs/DB01050#interactions			
10600	timolol	The risk or severity of bleeding can be increased	https://go.drugbank.com/drugs/DB00373#interactions			
10627	tobramycin	The risk or severity of gastrointestinal bleeding c	https://go.drugbank.com/drugs/DB00684#interactions			
5640	ibuprofen	The risk or severity of gastrointestinal bleeding c	https://go.drugbank.com/drugs/DB01050#interactions			
10635	tolbutamide	The risk or severity of gastrointestinal bleeding c	https://go.drugbank.com/drugs/DB01124#interactions			
108118	mometasone	The risk or severity of bleeding can be increased	https://go.drugbank.com/drugs/DB00764#interactions			
10827	trimethadione	The risk or severity of bleeding can be increased	https://go.drugbank.com/drugs/DB00347#interactions			
Open FDA - Related Adverse Events - API						
primarysourcecountry	DE	DE				
receivedate	20140312	20140312				
receiptdateformat	102	102				
receiptdate	20140312	20140312				
fulfillexpeditecriteria	1	1				
companynumb	DE-MYLANLABS-2014S10	DE-MYLANLABS-2014S1004723				
duplicate	1	1				
reportduplicate.duplicate	MYLAN	MYLAN				
reportduplicate.duplicate	DE-MYLANLABS-2014S10	DE-MYLANLABS-2014S1004723				



Patient Overall Summary Report

Note: Once All Data sources are retrieved, custom visualizations may be prepared as needed.

For this presentation we have prepared a Patient report for the Physician.



Microsoft Excel
Worksheet

primarysource.reporterco	DE	DE
primarysource.qualificati	3	3
sender.sendertype	2	2
sender.senderorganization	FDA-Public Use	FDA-Public Use
receiver.receivertype	6	6
receiver.receiverorganizat	FDA	FDA
patient.patientonsetage	18	18
patient.patientonsetageun	801	801
patient.patientsex	1	1
seriousnessother		
occurcountry	DE	DE
seriousnesshospitalization	1	1
reactionmeddraversionpt	17.0	17.0
reactionmeddrapt_x	Haemoptysis	Haemoptysis
reactionoutcome	6	6
safetyreportversion_y	1	1
drugcharacterization	1	1

openfda.route	['ORAL']	['ORAL']						
openfda.substance_name	['IBUPROFEN', 'IBUPROFEN SODIUM']	['IBUPROFEN', 'IBUPROFEN SODIUM']						
openfda.rxcui	['310965', '310964', '197803']	['310965', '310964', '197803', '201126', '204442', '197805', '197806', '197807', '206905', '206913', '206917', '206878', '310963', '544393', '731533', '153008', '854762', '792242', '792243']						
openfda.pharm_class_mo	['Cyclooxygenase Inhibitors']	['Cyclooxygenase Inhibitors [MoA]']						
openfda.pharm_class_cs	['Anti-Inflammatory Agents, Non-Steroidal [CS]']	['Anti-Inflammatory Agents, Non-Steroidal [CS]']						
openfda.pharm_class_epc	['Nonsteroidal Anti-inflammatory Drug [EPC]']	['Nonsteroidal Anti-inflammatory Drug [EPC]']						
actiondrug	1	1						
drugdosageform								
activesubstance.activesubstance								
drugenddateformat	102							
drugenddate	20140125							
safetyreportversion	1	1						

CDC Data: CMS Claims Data: Hospitalization for chronic obstructive pulmonary disease as any diagnosis among Medicare-eligible persons aged >= 65 years								
American Indian or Alaska	Asian or Pacific Islander	Black, non-Hispanic	Female	Hispanic	Male	Overall	White, non-Hispanic	Total
10	20	17	14	18	16	18	19	132
17	15	10	19	8	17	16	10	112
16	15	15	19	18	17	18	18	136
43	50	42	52	44	50	52	47	380



TOOLS TO REPORT/MEASURE PRESCRIPTION ERRORS

- FDA Adverse Event Reporting System (FAERS)
- [ConsumerMedSafety.org](#)
- [Institute for Safe Medication Practices \(ISMP\).](#)
- [AARP\(link is external\)](#)
- [Agency for Healthcare Research and Quality - HCUP\(link is external\)](#)
- [American Hospital Association\(link is external\)](#)
- [Sentinel Initiative](#)
- [American Society of Health System Pharmacists\(link is external\)](#)
- [Be MedWise\(link is external\)](#)
- [Food and Drug Administration – MedWatch Program\(link is external\)](#)
- [Institute for Safe Medication Practices\(link is external\)](#)
- [The Joint Commission \(link is external\)](#)
- [Medicine Safety\(link is external\)](#)
- [National Patient Safety Foundation\(link is external\)](#)
- [SeniorCarePharmacist.com\(link is external\)](#)

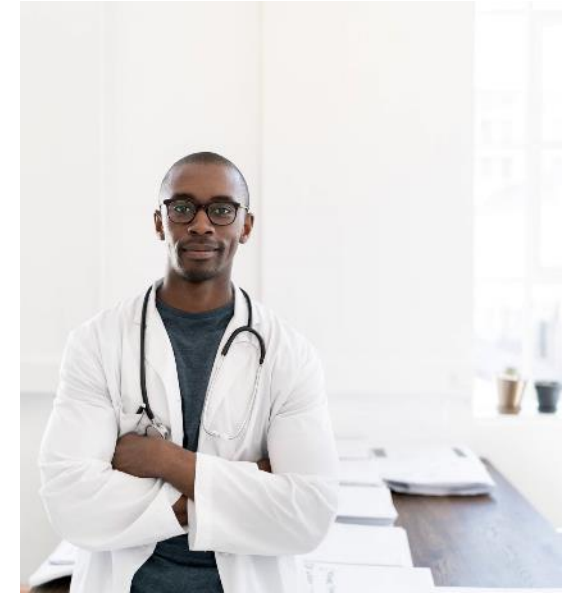
Links:

1. <https://www.fda.gov/drugs/quick-tips-buying-medicines-over-internet/besafex-your-source-online-pharmacy-information>
2. <https://www.consumermedsafety.org/>
3. <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>
4. <https://vaers.hhs.gov/reportevent.html>
5. <https://www.nccmerp.org/consumer-information>
6. <https://www.ima-india.org/ima/>
7. https://apps.who.int/iris/bitstream/handle/10665/137036/9789241507943_eng.pdf
8. <https://www.sentinelinitiative.org/>
9. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HVBP/Hospital-Value-Based-Purchasing>

HEALTHCARE QUALITY MEASURES AND BENCHMARKING

- Benchmarking – the process of comparing performance to standards
- Hospital Value Based Purchasing Programs (HVBP) : Total Performance Score (TPS) that is used to determine an incentive payment added to Medicare inpatient payments for participating hospitals.
- HCUPnet is a free, on-line query system based on data from the Healthcare Cost and Utilization Project (HCUP):
- National Quality Forum (NQF):
<https://www.qualityforum.org/Home.aspx>
- Medicare Quality Measures: <https://www.aafp.org/family-physician/practice-and-career/managing-your-practice/quality-measures.html>
- Hospital Compare: <https://hospitalcompare.io/>
- Bridges to Excellence: <https://www.cms.org/articles/bridges-to-excellence>
- Leapfrog Group: <https://www.leapfroggroup.org/ratings-reports>
- HealthGrades: <https://www.healthgrades.com/>
- HEDIS: <https://www.ncqa.org/hedis/>





SUMMARY ACKNOWLEDGEMENT

In the effort to reduce clinical and prescription errors care providers, clinicians or researchers may use several tools in their arsenal. The first and foremost being effective decision support systems that enable efficient access to accurate correlated data necessary for critical decision making in dispensing patient care. With the advent of digital health , real world data, new knowledge may be combined with existing knowledge ensuring patient safety, reduced cost of care and positive clinical outcomes. I am thankful to my guides and reviewers for all their support.

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ACRONYMS:

API	Application Programming Interface
CDER	Center for Drug Evaluation and Research
CBER	Center for Biologics Evaluation and Research
HL7, FHIR	Health Level Seven International, Fast Healthcare Interoperability Resources
NLM	National Library of Medicine
AHRQ	Agency for Health Care Research and Quality
NCC MERP	National Coordinating Council for Medication Error Reporting and Prevention
CMS	Centers for Medicare and Medicaid Services
ICD-9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification
ICD-10-CM	International Classification of Diseases, Tenth Revision, Clinical Modification
NDC	National Drug Code
CPT	Current Procedural Terminology (CPT®)
RxNAV, RXCUI	RxNorm browser RxNav, A normalized naming system for generic and branded drugs, RXCUI is RxNorm concept unique identifier
SNOWMED	Systematized Nomenclature of Medicine Clinical Terms
MedDRA	Medical Dictionary for Regulatory Activities (MedDRA®)
LOINC	Logical Observation Identifiers Names and Codes
DMEPA	Division of Medication Error Prevention and Analysis
DMAMES	Division of Mitigation Assessment and Medication Error Surveillance
OMEPRM	Office of Medication Error Prevention and Risk Management



THANK YOU



- Surabhi Dutta
- Senior Manager
- Clinical Data Reporting & Analytics
- Bristol Myers Squibb
- Surabhi.dutta@bms.com