Preparing Electronic Medical Record Data for Pharmaco-epidemiologic Research: Essential Data Validation

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Background

- Electronic medical records (EMRs) contain far more data useful for research than administrative health records
  - Demographics, medication administrations (as opposed to dispensations), vitals, labs, social situation, risk behaviours, etc.
- Epic has exploded in popularity in Canada becoming the 2nd most common hospital EMR since its first installation in 2017
  - St. Joseph's Healthcare Hamilton (SJHH) was the first Canadian academic adult hospital to install Epic
  - Leading EMR vendor in the United States
  - Highly structured EMR with > 18,000 tables but no guide or roadmap to demonstrate which tables or fields contain which data
    - Considered proprietary information

Ehrenstein et al., 2019;
PennDnA, n.d.;
St. Joseph's Healthcare Hamilton, n.d.;
Witowski, 2024

Background

- EMR data not collected or stored primarily for research
  - High quality, accessible, and organized data are important for any resulting analysis (*garbage in, garbage out*)
- Data must be validated to assess quality and accuracy
- Few studies assess the validity of EMR data
  - Canadian Primary Care Sentinel Surveillance Network (CPCSSN) – chronic conditions in their database
  - Hospital EMRs – completeness of problem list, cancer treatment and progression
  - Epic specifically – algorithms to identify diagnoses
- International scan of research-intensive institutions did not reveal any readily usable data validation metrics
  - SickKids, Stanford, and Harvard were creating research repositories with EMR data

Botsis et al., 2010;
Breeyear et al., 2024;
Williamson et al., 2014*;*
Wright et al., 2015

Objectives

1. Create an entity relationship diagram for the Epic EMR for key general research themes
   - Using SJHH Epic-Dovetale data – 6 years' worth of data
   - Demographics, providers, exposures, outcomes, comorbidities, diagnostics, timing, decision support, etc.
2. Validate EMR data for these key themes relevant to pharmacoepidemiologic research
   - Ongoing project on whether QT-prolonging (QTP) medications are/are not associated with major adverse cardiac events (MACE)
     - Aim to develop clinical prediction rule on who will have MACE while taking QTP medication(s)

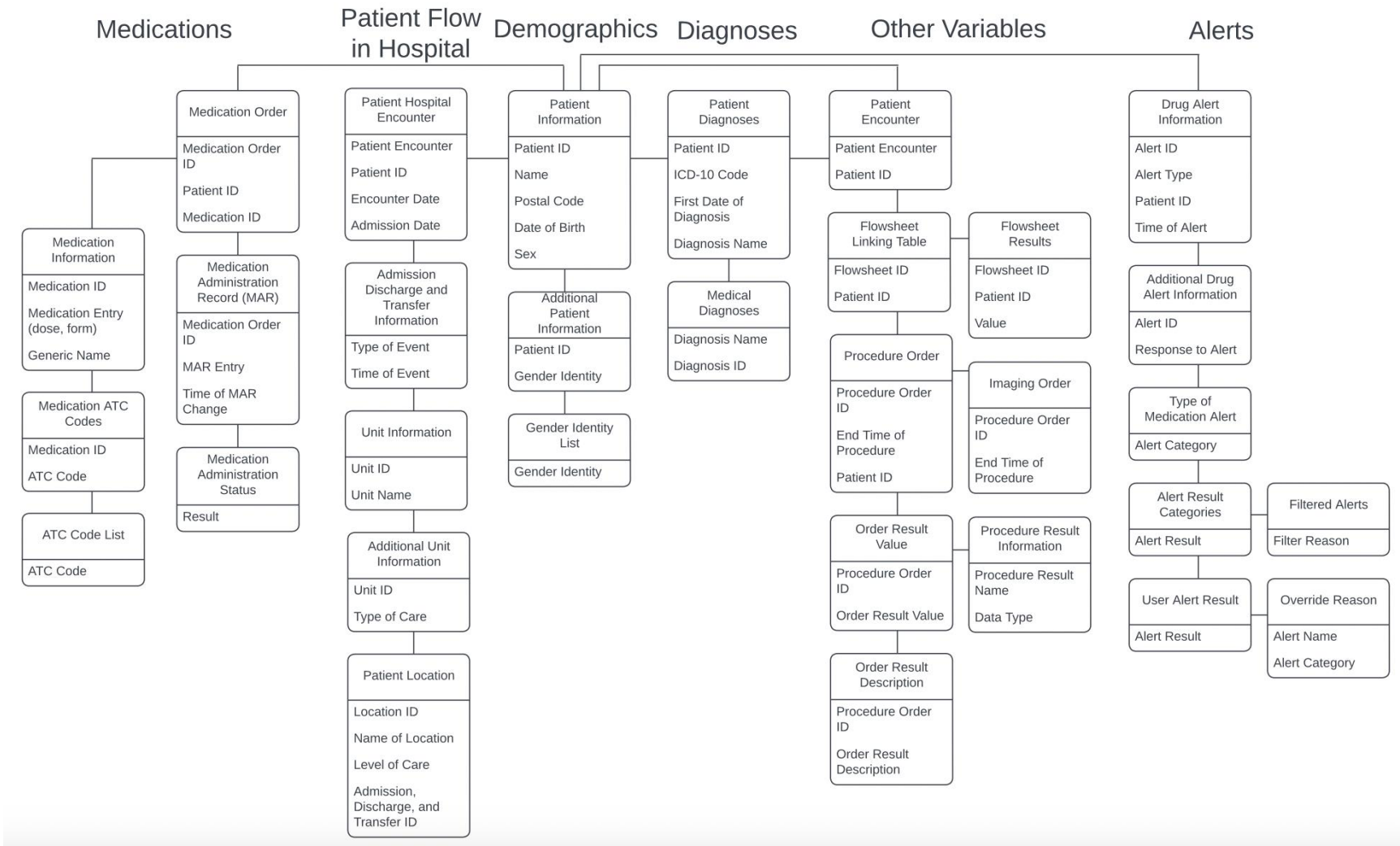
Methods

- Team of clinical pharmacologists, CMIO, medicine specialists, pharmacists, research data analysts, data scientists, informatics specialists, methodologists
- Data extracted from Epic Clarity database
- Relevant tables were found via the Epic Data Handbook, trial-and-error
- Data validated for completeness and correctness
  - Manual validation using chart review with random selection of cases
  - Computational validation comparing Epic-Dovetale to CIHI DAD data, Epic-Dovetale to Slicer Dicer

Methods

- All patients aged 18 years or older admitted to SJHH from December 2, 2017 to March 24, 2023 (N=70,079)
- CIHI DAD data available as a 'gold standard' for diagnoses if validated poorly
- Validation statistics
  - Correctness (agreement)
  - Diagnostic accuracy (positive predictive value (PPV), negative predictive value (NPV), sensitivity (Sn), specificity (Sp))

Results: Entity Relationship Diagram



- Only **31 of 20,764** tables in Epic-Dovetale required

Results: Validation Examples

1. Demographics
   - Computational validation of 70,079 unique patients from Epic-Dovetale vs 70,170 from SlicerDicer (**>99%** agreement); Age at admission vs CIHI - 9,472 patients (**100%** agreement)
   - Manual validation of sex and gender - 131 patients (**100%** agreement)
2. Exposures (ATC code + generic medication name)
   - 50,487 patients took a 'known' QTP medication
   - Manual validation of 335 charts - Diagnostic accuracy**: PPV 100%, NPV 95%, Sn 95%, Sp 100%**
3. MACE Outcomes (death, ventricular arrhythmia including Torsade de Pointes, non-fatal cardiac arrest, syncope)
   - Manual validation of 335 CIHI charts - Diagnostic accuracy**: PPV 93%, NPV 98%, Sn 99%, Sp 81%**

Results: Validation Examples (2)

4. Lab Values (potassium, magnesium, calcium, troponin)
   - Manual validation of 736 lab results for 50 patients (**100%** agreement)
5. EKGs: QTc and rhythm
   - Manual validation of 53 EKGs for 38 patients (**100%** agreement)
6. Comorbidities (diabetes, hypertension, heart failure)
   - Computational validation vs CIHI agreement - 519/560 (**93%**), 418/513 (**81%**), and 106/152 (**70%**), respectively
7. Timestamping
   - Computational validation of date of admission vs CIHI - 9,958/10,065 admissions (**>99%** agreement)
8. Alerts
   - 850,672 medication-related alerts **shown** to providers in 2023
     - **98% overridden**

Discussion

- The lack of an official entity relationship diagram wastes time, potentially creates errors
- Very small percentage of data tables needed for research
- Data from CIHI will be required for now for some fields
  - MACE outcomes (diagnoses) are not stored discretely in Epic-Dovetale unless added to medical history or the problem list
  - Natural language processing may help
- Common data models such as OMOP or i2b2 required for collaborative research across different EMRs
  - Epic has its own COSMOS network with 274 million patients