Gold or Lead? Adjudicating Differences between CDM Data and Chart Reviews

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Background

PEDSnet is a network of children's hospitals in the US which standardize electronic health record (EHR) data into an OMOP Common Data Model (CDM)[1]. Each PEDSnet site executes a quarterly extract, transform, load (ETL) process transforming EHR data into the CDM. Though the PEDSnet database is a HIPAA-limited dataset void of direct patient identifiers, the network has the capability to retrieve medical record numbers through an honest broker process to facilitate review of patient medical charts.

Chart review has long been used as a gold standard for retrospective studies or cohort validation. [2, 3, 4, 5] While its format is not conducive to efficient large-scale analyses and is often prohibitively expensive to conduct, its interface can provide a clear understanding of patient clinical stories captured in structured and unstructured fields. PEDSnet has conducted 10 studies which included both a chart review and CDM component. The chart review intent included a constellation of purposes such as gathering information not captured in structured data, validating CDM data, or providing ease of access to information. We systematically reviewed two case studies, analyzing records where CDM data would have produced different results from analysis of chart review data, to classify types of discordance, identify strengths of each data source, and propose guidelines for leveraging the strengths of chart review and of CDM data.

Methods

The two cases reviewed include a clinical trial and a safety surveillance study. For the clinical trial, the CDM facilitated recruitment and the chart review validated eligibility criteria. For the safety surveillance study, patients administered a medication were identified in the CDM and chart review supplemented information about adverse events. For each of the studies, chart review data was collected through a case report form (CRF) in REDCap.[6] The PEDSnet study team performed checks on the CRF data for internal consistency (e.g. alignment of sensible dates) and validation (e.g. comparison with related CDM data). In cases of discordance, the team followed one of the following processes to determine the source of truth:

- Contact chart reviewer for additional review of medical record
- Contact ETL analyst for investigation into mappings or source data
- Conduct additional review of CDM data (i.e. source values and other columns not initially queried)
- Review more up-to-date version of CDM

Each instance of discordance was recorded along with metadata such as domain impacted, process for discovering the source of truth, outcome of the investigation, and whether the database or chart reviewer was ultimately deemed correct.

Results

Between the two studies systematically reviewed, 138 instances of discordance were described. We classified discordance based on three common themes: incorrectness, missingness, and mistranslation.

The chart reviewer was incorrect in 63 instances and the database in 69 instances. In 6 instances, the chart review and CDM held different values, but neither were incorrect. Frequencies and examples of the three common themes of discordance are summarized in Table 1.

Theme	Incorrect Source	Number of Instances	Example
Incorrect	CDM	49	**ETL error**: Incorrect mapping of dose units **Source data error**: Inpatient drug administration time entered incorrectly into Epic. Chart reviewer noticed that administration time was prior to the medication order time
Incorrect	Chart reviewer	24	**Typo:** Erroneous entry of diagnosis date in CRF **Source data error:** Physician mis-typed diagnosis in notes which was then transcribed by chart reviewer
Missing	CDM	15	**Latency**: Patient admitted during ETL cycle, causing lack of visit_end_date **Non-standard capture**: death_date reflects date of organ donation. Chart reviewer found actual date patient was declared dead within physician notes
Missing	Chart reviewer	9	**Oversight**: Chart reviewer did not search the medical history field for a diagnosis
Mistranslation	CDM	5	**Logic lapse**: Patient was transferred to another inpatient unit with a new visit_occurrence, which the CDM query had not taken into account
Mistranslation	Chart reviewer	30	**Logic lapse**: Chart reviewer searched for diagnoses "within" (<=) 6 months instead of "at least" (>) 6 months prior to an anchor event **Question misalignment**: Diagnosis was on the patient's Problem List, which chart reviewer had not considered a true diagnosis

Table 1. Summary and examples of common themes of CDM and chart review discordance

Incorrectness: We classified erroneous values in the CRF, EHR, or CDM as incorrect. Data entry errors into the CRF were the most frequent cause of incorrect chart review data. Erroneous entry by a clinician into the EHR which were then either transcribed by the chart reviewer or transformed into the CDM contributed to both incorrect chart review and CDM data. When the CDM contained an incorrect value that accurately reflected error in the source system, the chart reviewer had an easier ability to supplement with context from unstructured fields or by comparison with nearby events to determine incorrectness. The most frequent cause of intrinsically incorrect CDM data were ETL errors. All ETL errors stemmed from two sources: one causing a mis-mapping of a unit and another causing an order of magnitude difference of a medication dose administered. While the source ETL errors were few, an error of this type has potential to impact a high number of records.

Missingness: We classified instances where the chart reviewer overlooked information in the EHR or where data were not present in the CDM as missing. We found that chart reviewers miss diagnosis, drug, or other clinical events frequently by not exhaustively searching all potential places where the information may be stored in the EHR. A clinical fact can be present in the EHR but missing from analytic results from the CDM if information is not mapped to a standard concept, is not captured by the logic of a query against the CDM, or is more recent than the latency introduced by the ETL process.

Mistranslation: We commonly detected errors in logic by the chart reviewer or analyst writing code, as well as misinterpretation of clinical information. Chart reviewers may impose clinical judgment when

reviewing a patient's chart or follow a line of reasoning to arrive at the response. For example, a chart reviewer provided a date of discharge from a rehabilitation unit rather than discharge from an inpatient unit (which the study required) because the reviewer reasoned that the clinical encounter persisted through rehabilitation. The chart reviewer was also more likely to err in implementation of logic (e.g. computing time frame around an anchor event) whereas the database query could be written to apply a definition uniformly across all patient records without imposing human judgment.

Conclusions

Careful consideration should be made when specifying data elements captured via manual review of the EHR and from the CDM. Since each introduces potential error, applying data quality checks and comparing values between both sources is critical. Though chart review can provide a clearer snapshot of the overall patient experience across domains at one time, due to the financial and time investment of chart review in addition to human error which increases as the chart reviewer fatigues, the design of the chart review should be targeted and limited to capture a low volume of information. The CDM is particularly valuable for applying a common rule or definition across a cohort in an efficient manner and representing data that are scattered throughout the EHR. Leveraging the utility of both sources can help to ensure accuracy and efficiency when conducting studies.

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