Creating a Common Data Model for Comparative Effectiveness with the Observational Medical Outcomes Partnership

F. FitzHenry[1,2]; F.S. Resnic[3]; S.L. Robbins[3]; J. Denton[1,4]; L. Nookala[1,4]; D. Meeker[5]; L. Ohno-Machado[6]; M.E. Matheny[1,2,4,7]

[1]Tennessee Valley Healthcare System, Veterans Affairs Medical Center, Nashville, TN; [2]Department of Biomedical Informatics; Vanderbilt University, Nashville, TN; [3]Division of Cardiology, Brigham and Women's Hospital, Boston, MA; [4]Division of General Internal Medicine and Public Health, Vanderbilt University, Nashville, TN;[5]Department of Health, RAND Corporation, Santa Monica, CA; [6]Division of Biomedical Informatics, University of California, San Diego, CA;[7]Department of Biostatistics, Vanderbilt University, Nashville, TN

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Summary
Background: Adoption of a common data model across health systems is a key infrastructure requirement to allow large scale distributed comparative effectiveness analyses. There are a growing number of common data models (CDM), such as Mini-Sentinel, and the Observational Medical Outcomes Partnership (OMOP) CDMs.
Objective: In this case study, we describe the challenges and opportunities of a study specific use of the OMOP CDM by two health systems and describe three comparative effectiveness use cases developed from the CDM.
Methods: The project transformed two health system databases (using crosswalks provided) into the OMOP CDM. Cohorts were developed from the transformed CDMs for three comparative effectiveness use case examples. Administrative/billing, demographic, order history, medication, and laboratory were included in the CDM transformation and cohort development rules.
Results: Record counts per person month are presented for the eligible cohorts, highlighting differences between the civilian and federal datasets, e.g. the federal data set had more outpatient visits per person month (6.44 vs. 2.05 per person month). The count of medications per person month reflected the fact that one system's medications were extracted from orders while the other system had pharmacy fills and medication administration records. The federal system also had a higher prevalence of the conditions in all three use cases. Both systems required manual coding of some types of data to convert to the CDM.
Conclusion: The data transformation to the CDM was time consuming and resources required were substantial, beyond requirements for collecting native source data. The need to manually code subsets of data limited the conversion. However, once the native data was converted to the CDM, both systems were then able to use the same queries to identify cohorts. Thus, the CDM minimized the effort to develop cohorts and analyze the results across the sites.

Correspondence to:
Fern FitzHenry, RN, MM, PhD
Department of Biomedical Informatics
Eighth Floor, Suite 800
2525 West End Avenue
Nashville, TN
Tel.: 615 343–6316
Fax: 615 322–0502
Email: fern.fitzhenry@vanderbilt.edu

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1. Introduction

Worldwide, the business of healthcare research and quality improvement is increasingly focused on "big data" [1–3]. Evidence of the transformation is that observational outcomes from electronic health record (EHR) systems are increasingly important in comparative effectiveness analyses [4, 5].

Administrative claims databases have long been used (and criticized) for secondary analysis in research [6, 7]. However, the increasing adoption of EHRs as part of the Meaningful Use incentive program along with the availability of Medicare Part-D databases for outpatient prescription drug claims is spurring renewed interest in observational comparative effectiveness studies using secondary datasets [8, 9]. EHRs may become the focus of clinical effectiveness as informatics tools prove effective at divining knowledge and wisdom [10–12]. Big data research will certainly be lower cost than clinical trials, estimated between a low of $60 to $31 million to a high of $100 to $67 million for phase II or phase III trials, respectively [13]. The FDA has demonstrated its capability to research drug safety questions with its Mini-Sentinel System, a distributed electronic health data safety monitoring system [14, 15].

Adoption of a common data model (CDM) across health care systems is a key infrastructure requirement to allowing large scale distributed comparative effectiveness research [16]. Without a CDM, the investment in developing algorithms to identify cases and perform analyses is not transferrable to other organizations. Differences in data models and phenotyping algorithms across organizations may have contributed to the significant variance in results across sites seen in a recent review of rofecoxib [17].

2. Objective

To provide a case report of the challenges of moving a federal and civilian health system into a CDM [18], the Observational Medical Outcomes Partnership (OMOP) with three comparative effectiveness use cases. Systematic differences between data sources are highlighted in the context of the cohort selection.

3. Methods

The two health systems participating in the study were a community system, Partners Healthcare in Massachusetts (Partners), and a federal system, the Veterans Affairs (VA) MidSouth Healthcare Network (VISN9).

Partners, the larger of the two systems with twelve acute care hospitals, was ahead of many hospitals in mandating use of electronic systems in 2007 [19]. Partners harvested their systems to create a de-identified research patient data repository used for this study.

The federal system, MidSouth Healthcare Network (VISN9), included six hospital systems in Tennessee, Kentucky, and West Virginia. VISN9, as is true of the VA healthcare system overall, was an early adopter of electronic records. Although electronic charts were used exclusively at the VA, documentation received from outsourced fee based care was sometimes incomplete or not machine readable.

The OMOP CDM (Version 4) used in this study, selected after a syntactic and semantic interoperability review described elsewhere [20], was developed by a consortium of groups including PhRMA, the FDA, and the Foundation of the National Institutes of Health [21]. The OMOP CDM transforms observational data, both administrative and clinical, standardizing the content and format of the data allowing the use of common queries and analysis tools. The OMOP model included tools for extraction, loading, and transformation (ETL) to vocabularies described elsewhere [21–23]. The electronic data used in this study included administrative billing data and extended to laboratory results, physician orders, pharmacy dispensing, and medication administration. The OMOP data were demographics, visits, procedures, observations, medications, conditions, and death.

Cohort Development: Cohorts were developed for three comparative effectiveness use cases comparing emerging cardiac drug therapies to treatment standards, e.g. warfarin and dabigatran among patients with (1) atrial fibrillation, and (2) venous thromboembolism and clopidogrel and prasugrel among (3) patients with drug eluting stents. All patients hospitalized from January 1, 2009 to June 30, 2012 were eligible for inclusion in the clinical use cases. The VA performed the OMOP ETL process on all hospitalized patients during the study period and Partners conducted an ETL on all hospitalized patients meeting the first inclusion/exclusion step (►Figure 1). The project used standard sequel query language (SQL) using concepts from the CDM to develop the cohort according to inclusion and exclusion criteria described in ►Figure 1.

4. Results

►Table 1 presents a summary description of the two organizations in the study, and ►Table 2 presents a summary of the data record counts for the eligible population. We used percent of records loaded from the source to the CDM as a measure of data quality as have other studies [22–25]. The eligible population at the VA and Partners system differed not only in funding sources but also in representation of females (3% vs. 45%, respectively). The Partners health system was larger than VISN9. The higher ratio of inpatient to outpatient visits at Partners may reflect its tertiary-care model vs. the VA's comprehensive care model. There were some differences in billing datasets such as the lack of Ambulatory Patient Classification coding at the VA.

The biggest difference in record counts between the two sites was in the number of visits per person month – the VA had more than three times as many visits as Partners (6.44 vs. 2.05 per person month, respectively). There was a greater prevalence of outpatient vs. inpatient visits in the VA when compared with Partners. However, the VA also used "visits" to document professional services and mental health services in inpatient stays as required by VHA Directive 2009–002, Patient Care Data Capture [26]. For example, for a VA inpatient with a 28 day stay, the patient could have an average of 7 visits per day including group therapy, chaplain, pulmonary therapy, and the nursing unit. The ratio of deaths per person month was also higher at the VA (0.005 vs. 0.003), a possible reflection of more comorbidities [27].

The larger number of visits at the VA may account in part for a larger count of diagnoses at the VA vs. Partners (6.81 vs. 4.05 per person month, respectively). The only source data for conditions in both systems was ICD-9-CM codes. The OMOP common vocabulary for conditions, SNOMED-CT, did not cover all ICD-9-CM codes (88.6%) [21]. For example, all of the five digit codes for '453.7-Chronic venous embolism and thrombosis of other specified vessels' were unavailable in SNOMED-CT. These critical codes were custom added to the data at higher less-specific SNOMED-CT concept levels so they could appear in outcomes (►Table 3).

Medication and laboratory data sources were loaded for only a subset of the source data because manual coding was required at Partners for medications and at the VA for laboratory tests. ►Table 2 reflects this limited subset. Again VA had a higher count than Partners (2.04 vs. 1.45 per person month, respectively).

The count of drugs per person month was three times as high at the VA when compared to Partners (0.44 vs. 0.13 per person month, respectively). This higher count must also reflect the higher number of drug records in the VA resulting from the use of medication administration records for inpatients and fill records for outpatients while Partners used only physician orders for medications. Observation records were limited to laboratory test results.

►Table 3 presents a summary of key challenges encountered in implementing the common data model, some of which are being addressed in subsequent releases of the CDM. The VA had a higher prevalence of the conditions in all three use cases (►Table 4, ►Figure 2)

5. Discussion

Sample sizes and generalizability of findings can be increased by including multiple healthcare delivery systems, but researchers must assure that the data are standardized. In our initiative, the adopted CDM, OMOP, was successful in allowing the case finding and outcome rules to be developed once and applied with minimal adaptation across sites, but required substantial resources to map local data into the underlying CDM. The process highlighted significant heterogeneity between healthcare systems.

The algorithm logic for each of the cohort selection processes noted above were developed by a single team and deployed across both healthcare systems. The same logic could be applied across other OMOP installations with no additional development cost, underscoring the scalability in the use of CDMs. Developing the logic for the 2nd and 3rd use case was also more efficient than for the 1st use case. The use cases also reinforced the need for large data sets to pursue comparative effectiveness studies, as the volume of eligible patients declined rapidly when inclusion and exclusion criteria were applied. However, cohort selection rigor is essential in improving the strength of findings disseminated from observational data sources, as all observational cohort data suffer from confounding and bias. One of the noted limitations of a similar study done by the Mini-Sentinel initiative (although a comparative risk vs. comparative effectiveness assessment) was their reliance on only administrative data, lack of adjustment for confounders, and less rigorous inclusion and exclusion criteria [28–32]. These issues can impact study results, as biases and limitations of data sources can be associated with 20–40% of outcome results moving from a statistically positive association to a negative association depending on the database [33].

There were a number of systematic differences noted in the data collected within Partners and the VISN9 VA healthcare systems. The VA population in general is older, poorer, may have disabilities as part of military service, and have more comorbidities compared with civilians [34]. Previous studies of prevalence for the conditions were higher than both organizations in the study (►Table 4), possibly because of the stringent exclusion criteria we applied [35–37]. Although the two organizations harmonized on drug ingredient, formulation and type/reliability (medication administration/prescription fills vs. orders) of exposure differed. Observed medication administration would be the most reliable, prescription refills next most reliable and orders least reliable [38]. Partners used drug orders where 12.6% of ordered doses may be omitted, 31% of prescriptions may not be filled, and adherence to dose taking ranges from 43–78% even in clinical trials [39].

In the literature, an estimated 9.3% of drugs were typed in as free text [40], combination drugs were frequently represented in structured data as only one of the two drug classes in the combination [41], and only 55.8 to 69.2% of NDC codes were mapped to a vocabulary although these drugs accounted for 93.9 to 95.1% of the drugs in common use [25]. Our work adds to the literature by describing a use case where the loss of even a small number of codes can affect the detection of adverse outcomes, e. g. we could have potentially lost 75% of VTE cases had we not custom mapped the ICD-9 pulmonary embolism codes absent in the standard CDM crosswalk.

Whether or not the patient continues care within the healthcare system administering the electronic records influences whether adverse outcomes will be captured. We deployed criteria for determining patient enrollment or connection to the participating sites using clinical visits relative to the study index date, which may reduce the case volume available for analysis but was more rigorous than previous studies using insurance enrollment data. Research indicates that 13–17% of patients change health plans/providers over 1–2 year periods [42–44]. Persons aged 55–65, blacks, Hispanics and those in fair or poor health would be less likely to change plans so will be more likely to be represented in cohort data [42]. In two of the clinical use cases, the VA system had a higher rate of patient retention, very possibly because of the coverage benefits that would persist with moves or changes in employment [27, 45]. VA patients were largely male, older with poorer health, more medical conditions, more physician visits, and more admissions, matching most of Cunningham et. al [42] criteria for patients less likely to change plans [27]. For these reasons, intra- and inter-healthcare system data quality assessments broadly across data domains and deeply within clinical use cases are necessary to understand the data.

The data transformation to OMOP was time consuming as reported by others [22, 23]. In our study, the ETL team first executed the VA data load over six person months and then performed the Partners load in 1–2 person months. This suggests using an ETL team allowed gains in efficiency as the knowledge and programming was partially transferrable regardless of the source data. At other sites, the authors estimated transformation (full vs. partial data as in current study) and loading processes to require four people over a six month period with conversion to OMOP concept codes and then loads running 4–11 days [22]. The conversion of 466 group practices from native data to OMOP took two person years [23]. This is consistent with expert panelists' estimates of costs of data standardization [46].

6. Conclusion

Use of data within a CDM across multiple USA healthcare systems requires an understanding of the differences between the source data in the healthcare systems. Understanding the strengths and limitations of CDMs is useful, as there are a number of large initiatives promoting CDM development and implementation, such as the European Medicines Agency's post authorization safety studies, FDA's Mini-Sentinel/MDEpiNet, and the PCORnet [14, 47, 48].

Clinical Relevance Statement

It is feasible to develop and implement a common data model from electronic health record data sources. Early comparison of effectiveness in common data models could better inform the adoption recommendations for emerging therapies. The organization's adoption of standard codes (like National Drug Codes) across care locations increases the percent of data that could be made available in a CDM.

Note: Preliminary data from this paper was used in a poster presented at the American Medical Informatics Association 2012 Annual Symposium.

Conflicts of Interest

The authors declare that they have no conflicts of interest in the research.

Protection of Human and Animal Subjects

The study was performed in compliance with the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects. All research was conducted with the approval by the Partners and VA TVHS Institutional Review Board.

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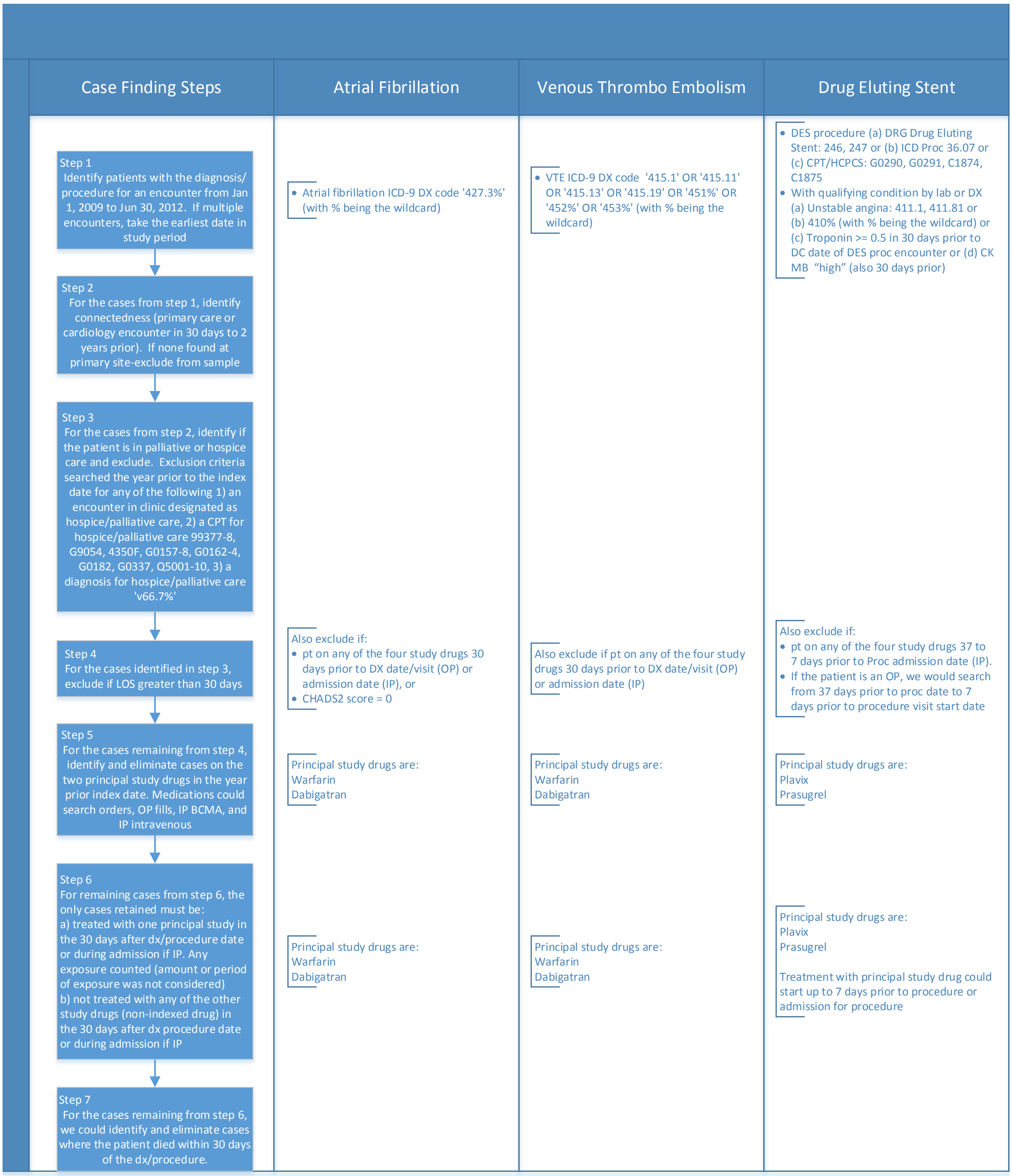

Note: All case finding criteria were operationalized into OMOP concept codes, e.g. the diagnosis code 427.31-Atrial Fibrillation translated to OMOP concept code 313217.

Fig. 1 Use case inclusion exclusion criteria

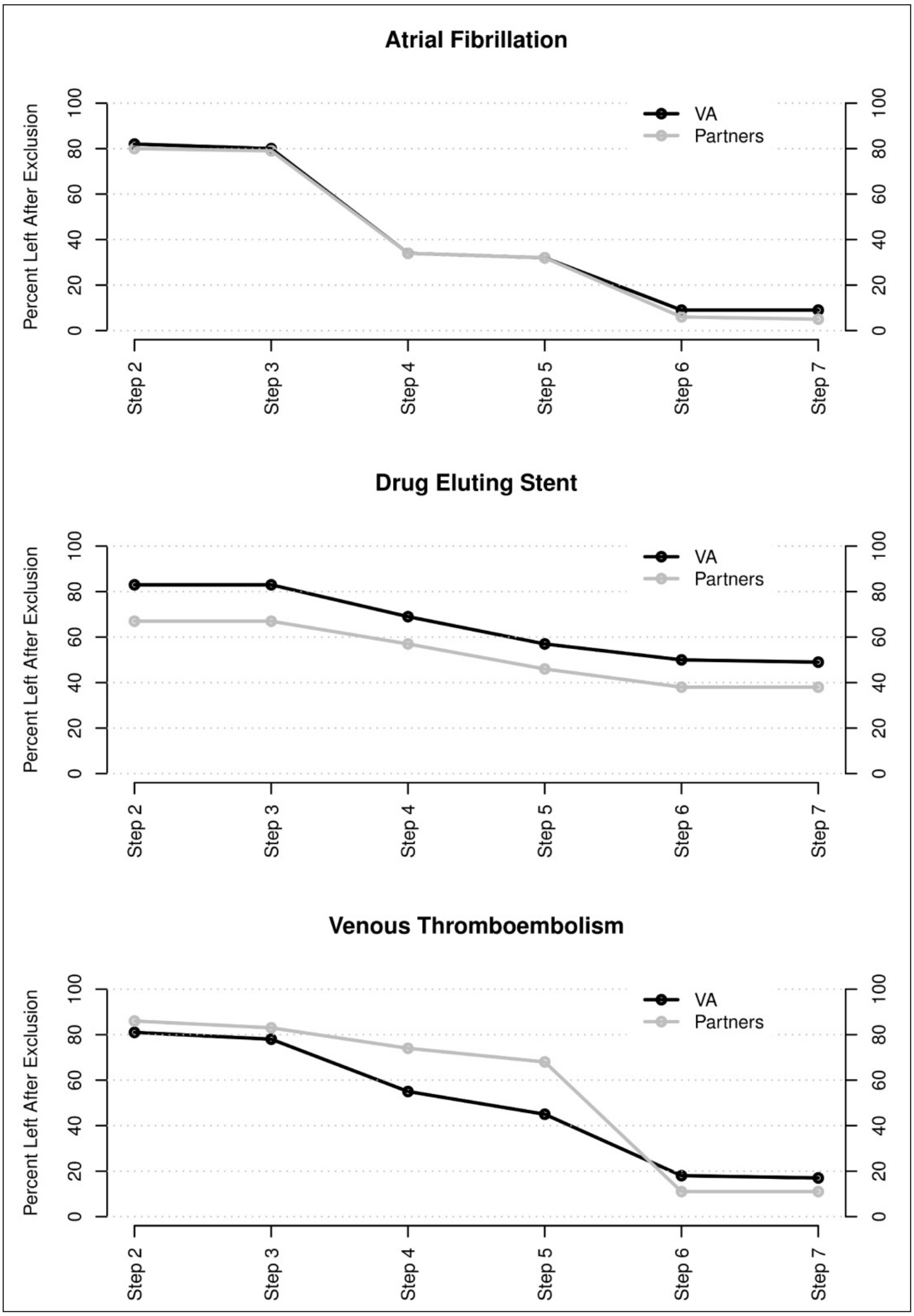

Fig. 2 Percent of cases eligible by case finding step
Note: Steps 1–7 reference the inclusion and exclusion criteria in Figure 1.

Table 1 Population and organizational characteristics

Description	VA VISN9 (6 Hospital Systems)	Partners (2 Hospital Systems)
Ownership	Federally owned budget-based costs of care	Not for profit, fee for service
Revenue-Partners/Cost-VA (billions)	$2.3	$6.1
Physicians/providers	1544	6400
Beds	1676	2700
Admissions	39987*	151000
OP Visits	3283572**	4300000
Percent electronic health record (estimate)	90–95%	Outpatient 95% Inpatient 20%
Average Age	67 Years	66 Years
Percent Females	3%	45%
Percent Caucasian	82%	81%
Percent African/American	14%	8%
Percent Other Unknown	4%	11%

*VA admissions do not include 34% non-VA bed days
**VA outpatient visits do not include 11% non-VA outpatient visits

Table 2 Records in OMOP Common Data Model for eligible persons

Data Category	Percent of Qualified Records for 60 Study Months		Rows per Person Month	
	VISN9 (n=21002)	Partners (n=25641)	VISN9	Partners
Drug Exposure – Subset*	99.0% (out of 556894)	94.9% (out of 215145)	0.44	0.13
Condition Exposure	100.0% (out of 8582589)	90.2% (out of 6909958)	6.81	4.05
Observations – Subset**	99.8% (out of 2579109)	100.0% (out of 2226963)	2.04	1.45
Procedures	99.8% (out of 10007359)	99.28% (out of 8011290)	7.92	5.17
Visits/encounters	100.0% (out of 8112358)	100.0% (out of 3147382)	6.44	2.05
Deaths	100.0% (out of 5909)	94.0% (out of 5344)	0.005	0.003

*Partners native drug data used multiple drug coding standards, some of which were not included in the OMOP crosswalks to RxNorm. Since the uses cases did not require dose or formulation we identified drugs with string searches for generic and trade names for only the drugs used in study and manually coded them to the OMOP coding standard for drugs (RxNorm).
**Laboratory data in observations required manual coding because many laboratory tests were profiled without the OMOP coding standard for laboratory (LOINC). For example, about 16% of Prothrombin/INR test results were missing a LOINC code.

Table 3 Challenges and opportunities in implementing the OMOP CDM

Description	VA	Partners	Lessons learned
Effort to load and transform	Over 6 person months	1–2 person months	CDM transformation probably not feasible for a single study
Memory/space requirements to load	Required partitioning the data into subsets*		Conduct feasibility assessments prior to execution of full ETL to estimate hardware requirements.
ICD-9-CM codes must map to specific SNOMED-CT codes or dropped	Rolled more specific ICD-9-CM codes to less specific SNOMED-CT codes**		Custom mapping minimized dropped codes
Diagnosis must connect to "visits"	Diagnosis with just dates and no „visit" were dropped	Within CDM parameters	Missing or mis-formatted data affects data limitations
Visits within "visits"	Selected the longest visit that included the diagnosis of interest	Within CDM parameters	Missing data affects data limitations and required standardization in rules
Start dates and end dates required for visits regardless of type of encounter	Populate the same date to both start and end date		Missing data affects data limitations for clinic encounters.
DRGs only profiled in "costs"	Populated the DRGs of interest for identifying drug eluting stent procedures	Also would have missed some cases but most drug eluting stents did have ICD-9-CM procedure codes	Custom mapping of DRG's required to identify procedures
Abnormal flag for laboratory results	Missing flag field		Required custom field to hold the flag
CDM needed quantity field for procedures (needed especially the bleeding outcome, e.g. transfusions)	Took the quantity field used for CPT/HCPCS coding and populated custom field		Required custom field to hold the quantity
Manual coding of some data	Had LOINC codes but some missing, e.g. 10% of Troponin results had no LOINC Code, 16% of INR results had no LOINC code	No single drug vocabulary was used across Partners sites. Some sites did not use a medication vocabulary that had an available cross-walk to RXNORM.	If the organization wants to participate in a CDM model, then assign a group to code data where needed. If the organization has no long term commitment to supporting codified data, then assess the feasibility of coding the data only where the use case requires it.

*Merged columns represent similar processes/findings at VA and Partners.
**The pulmonary embolism outcome used for the atrial fibrillation use case would have missed 75% of cases had the unmapped ICD-9 codes been dropped at VISN9.

Table 4 Case counts by step with prevalence

Step	Atrial Fibrillation Count				Venous Thromboembolism Count				Drug Eluting Stent Count			
	VISN9	% of Total	Partners	% of Total	VISN9	% of Total	Partners	% of Total	VISN9	% of Total	Partners	% of Total
1	14204		16427		6998		1183		1278		1720	
2	11616	82%	13124	80%	5692	81%	8725	86%	1067	83%	1160	67%
3	11350	80%	12981	79%	5445	78%	8413	83%	1062	83%	1157	67%
4	4814	34%	5529	34%	3854	55%	7485	74%	886	69%	986	57%
5	4591	32%	5313	32%	3135	45%	6973	68%	732	57%	789	46%
6	1278	9%	908	6%	1246	18%	1138	11%	634	50%	660	38%
7	1248	9%	889	5%	1207	17%	1120	11%	625	49%	658	38%
Prevalence	0.011		0.001		0.011		0.001		0.006		0.001	
Comparison Prevalence	Go AS et al., 2001				White RH, 2003				Nielsen KM et al., 2007			
	0.950*				0.100				0.002			

Population VA = 109339
Population Partners = 1275000
*Go AS et al., 2001 included all atrial fibrillation vs. only newly diagnosed atrial fibrillation in this study.

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