April Olympians #1 / Perseus ETL Tool

OHDSI Community Call
April 2, 2024 • 11 am ET

Upcoming Community Calls

Date	Topic
April 2	April Olympians Preview | Presentation: ETL Technical Considerations
April 9	April Olympians Update | Presentation: Vocabulary for ETL
April 16	April Olympians Update | Presentation: Tools to Evaluate ETL
April 23	April Olympians Update | Presentation: Themis & CDM Process Overview
April 30	April Olympians Update | Presentation: What We Achieved & How You Can Use It

Three Stages of The Journey

Where Have We Been?

Where Are We Now?

Where Are We Going?

OHDSI Shoutouts!

Congratulations to the team of **Kipyo Kim, Ji-Eun Kim, Jae Ho Kim, Seong Hee Ahn, Chai Young Jung, Seun Deuk Hwang, Seoung Woo Lee and Joon Ho Song** on the publication of **Real-world evidence of constipation and laxative use in the Korean population with chronic kidney disease from a common data model** in *Scientific Reports*.

scientific reports

Check for updates

OPEN

Real-world evidence of constipation and laxative use in the Korean population with chronic kidney disease from a common data model

Kipyo Kim[1,4], Ji-Eun Kim[1,4], Jae Ho Kim[1], Seong Hee Ahn[2], Chai Young Jung[3], Seun Deuk Hwang[1], Seoung Woo Lee[1] & Joon Ho Song[1]✉

Constipation is a highly prevalent gastrointestinal disorder in patients with chronic kidney disease (CKD). However, our understanding of its epidemiology and management in CKD is limited. We aimed to explore real-world data on constipation and laxative use in patients with CKD in a nationwide population-based cohort from the Korean Health Insurance Review and Assessment-National Patient Sample database. This study analyzed retrospective health claims data in Korea from 2012 to 2017 that were transformed into the Observational Medical Outcomes Partnership Common Data Model. The pooled proportion of constipation diagnoses was 30.5% in all patients with CKD and 15.9%, 16.5%, 17.4%, 29.9%, and 43.3% in patients with CKD stages 1–5, respectively, suggesting a higher prevalence in advanced CKD. Patients receiving peritoneal dialysis or hemodialysis had the highest prevalence of constipation, while transplant recipients showed a prevalence comparable to that of patients with early CKD. Patients with CKD had a significantly higher risk of constipation than age- and sex-matched non-CKD individuals (range of odds ratio [OR]:1.66–1.90). Laxative prescribing patterns differed by CKD severity. Osmotic agents were prescribed in more than half of patients with advanced CKD, while magnesium salts and bulking agents were prescribed less frequently. The CKD patients with constipation were more likely to be prescribed constipation-inducing medications, including antipsychotic and neurological medications. Our findings provide real-world constipation and laxative prescription status in the Korean CKD population, revealing a significantly higher risk of constipation and different laxative prescribing patterns in patients with CKD.

OHDSI Shoutouts!

Congratulations to the team of Cindy Cai, Akihiko Nishimura, Mary Bowring, Erik Westlund, Diep Tran, Jia Ng, Paul Nagy, Michael Cook, Jody-Ann McLeggon, Scott DuVall, Michael Matheny, Asieh Golozar, Anna Ostropolets, Evan Minty, Priya Desai, Fan Bu, Brian Toy, Michelle Hribar, Thomas Falconer, Linying Zhang, Laurence Lawrence-Archer, Michael Boland, Kerry Goetz, Nathan Hall, Azza Shoaibi, Jenna Reps, Anthony Sena, Clair Blacketer, Joel Swerdel, Kenar Jhaveri, Edward Lee, Zachary Gilbert, Scott Zeger, Deidra Crews, Marc Suchard, George Hripcsak, and Patrick Ryan on the publication of **Similar risk of kidney failure among patients with blinding diseases who receive ranibizumab, aflibercept, and bevacizumab: an OHDSI Network Study** in *Ophthalmology Retina.*

ELSEVIER

Ophthalmology Retina

Available online 20 March 2024

In Press, Journal Pre-proof What's this?

Similar risk of kidney failure among patients with blinding diseases who receive ranibizumab, aflibercept, and bevacizumab: an OHDSI Network Study

Cindy X. Cai MD, MS, Akihiko Nishimura PhD, Mary G. Bowring MPH, Erik Westlund PhD, Diep Tran MSc, Jia H. Ng MD, MSCE, Paul Nagy PhD, Michael Cook BS, Jody-Ann McLeggon MPH, Scott L. DuVall PhD, Michael E. Matheny MD, MS, MPH, Asieh Golozar PhD, Anna Ostropolets MD, PhD, Evan Minty MD MSc, Priya Desai MS, Fan Bu PhD, Brian Toy MD, Michelle Hribar PhD, Thomas Falconer MS, Linying Zhang PhD...Patrick B. Ryan PhD

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Abstract

Objective or Purpose

A) To characterize the incidence of kidney failure associated with intravitreal anti-vascular endothelial growth factor (VEGF) exposure, and B) compare the risk of kidney failure in patients treated with ranibizumab, aflibercept, or bevacizumab.

OHDSI Shoutouts!

Congratulations to the team of **Joshua Ide, Azza Shoaibi, Kerstin Wagner, Rachel Weinstein, Kathleen E. Boyle and Andrew Myers** on the publication of **Patterns of Comorbidities and Prescribing and Dispensing of Non-steroidal Anti-inflammatory Drugs (NSAIDs) Among Patients with Osteoarthritis in the USA: Real-World Study** in *Drugs & Aging*.

Drugs & Aging
https://doi.org/10.1007/s40266-024-01108-x

ORIGINAL RESEARCH ARTICLE

Patterns of Comorbidities and Prescribing and Dispensing of Non-steroidal Anti-inflammatory Drugs (NSAIDs) Among Patients with Osteoarthritis in the USA: Real-World Study

Joshua Ide[1] · Azza Shoaibi[2] · Kerstin Wagner[1] · Rachel Weinstein[2] · Kathleen E. Boyle[4] · Andrew Myers[3]

Accepted: 7 February 2024

Abstract

Background Osteoarthritis (OA) is a major cause of chronic pain. Non-steroidal anti-inflammatory drugs (NSAIDs) are analgesics commonly used for musculoskeletal pain; however, NSAIDs can increase the risk of certain adverse events, such as gastrointestinal bleeding, edema, heart failure, and hypertension.

Objective The objective of this study was to characterize existing comorbidities among patients with OA. For patients with OA with and without a coexisting medical condition of interest (CMCOI), we estimated the prevalence of prescribing and dispensing NSAIDs pre-OA and post-OA diagnosis.

Methods Data from three large administrative claims databases were used to construct an OA retrospective cohort. Databases leveraged were IBM MarketScan Medicare Supplemental Database (MDCR), IBM MarketScan Commercial Database (CCAE), and Optum's de-identified Clinformatics® Data Mart Database (Optum CDM). The OA study population was defined to be those patients who had an OA diagnosis from an inpatient or outpatient visit with at least 365 days of prior observation time in the database during January 2000 through May 2021. Asthma, cardiovascular disorders, renal impairment, and gastrointestinal bleeding risks were the CMCOI of interest. Patients with OA were then classified as having or not having evidence of a CMCOI. For both groups, NSAID dispensing patterns pre-OA and post-OA diagnosis were identified. Descriptive analysis was performed within the Observational Health Data Sciences and Informatics framework.

Results In each database, the proportion of the OA population with at least one CMCOI was nearly 50% or more (48.0% CCAE; 74.4% MDCR; 68.6% Optum CDM). Cardiovascular disease was the most commonly observed CMCOI in each database, and in two databases, nearly one in four patients with OA had two or more CMCOI (23.2% MDCR; 22.6% Optum CDM). Among the OA population with CMCOI, NSAID utilization post-OA diagnosis ranged from 33.0 to 46.2%. Following diagnosis of OA, an increase in the prescribing and dispensing of NSAIDs was observed in all databases, regardless of patient CMCOI presence.

Conclusions This study provides real-world evidence of the pattern of prescribing and dispensing of NSAIDs among patients with OA with and without CMCOI, which indicates that at least half of patients with OA in the USA have a coexisting condition. These conditions may increase the risk of side effects commonly associated with NSAIDs. Yet, at least 32% of these patients were prescribed and dispensed NSAIDs. These data support the importance of shared decision making between healthcare professionals and patients when considering NSAIDs for the treatment of OA in patients with NSAID-relevant coexisting medical conditions.

OHDSI Shoutouts!

Congratulations to the team of **Jens Weidner, Ingmar Glauche, Ulf Manuwald, Ivana Kern, Ines Reinecke, Franziska Bathelt, Makan Amin, Fan Dong, Ulrike Rothe, and Joachim Kugler** on the publication of **Correlation of Socioeconomic and Environmental Factors With Incidence of Crohn Disease in Children and Adolescents: Systematic Review and Meta-Regression** in *JMR Public Health and Surveillance*.

JMIR PUBLIC HEALTH AND SURVEILLANCE Weidner et al

Review

Correlation of Socioeconomic and Environmental Factors With Incidence of Crohn Disease in Children and Adolescents: Systematic Review and Meta-Regression

Jens Weidner[1], MPH; Ingmar Glauche[1*], PD, Dr rer med; Ulf Manuwald[2*], Prof Dr; Ivana Kern[3*], Dr rer medic; Ines Reinecke[1*], Dr rer medic; Franziska Bathelt[1,4*], Dr rer nat; Makan Amin[3,5*]; Fan Dong[3*], MPH; Ulrike Rothe[6*], Prof Dr Med; Joachim Kugler[3*], Prof Dr Med

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[2]Faculty of Applied Social Sciences, University of Applied Sciences (FHD), Dresden, Germany
[3]Institute and Policlinic for Occupational and Social Medicine, Department of Health Sciences/Public Health, Medical Faculty Carl Gustav Carus, TU Dresden, Dresden, Germany
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Abstract

Background: The worldwide incidence of Crohn disease (CD) in childhood and adolescence has an increasing trend, with significant differences between different geographic regions and individual countries. This includes an increase in the incidence of CD in countries and geographic regions where CD was not previously prevalent. In response to the increasing incidence, the pediatric care landscape is facing growing challenges.

Objective: This systematic review and meta-analysis were undertaken to comprehensively delineate the incidence rates of CD in pediatric populations across different countries and to explore potential influencing factors.

OHDSI Shoutouts!

Congratulations to the team of **Valerie van Baalen, Eva-Maria Didden, Daniel Rosenberg, Kristina Bardenheuer, Michel van Speybroeck, and Monika Brand** on the publication of **Increase transparency and reproducibility of real-world evidence in rare diseases through disease-specific Federated Data Networks** in *Pharmacoepidemiology & Drug Safety.*

Received: 30 November 2023 | Revised: 3 March 2024 | Accepted: 4 March 2024
DOI: 10.1002/pds.5778

ORIGINAL ARTICLE

WILEY

Increase transparency and reproducibility of real-world evidence in rare diseases through disease-specific Federated Data Networks

Valerie van Baalen[1] | Eva-Maria Didden[1] | Daniel Rosenberg[1] | Kristina Bardenheuer[2] | Michel van Speybroeck[3] | Monika Brand[1]

[1]Global Epidemiology, Office of the Chief Medical Officer, Johnson & Johnson, Basel, Switzerland
[2]Health Economics, Market Access and Reimbursement, EMEA Real-World Evidence and Value-based Health Care, Johnson & Johnson, Neuss, Germany
[3]Data Science, IT EMEA, Johnson & Johnson Technology, Beerse, Belgium

Correspondence
Valerie van Baalen, Global Epidemiology, Office of the Chief Medical Officer, Johnson & Johnson, Basel, Switzerland.
Email: vgazimzi@its.jnj.com

Funding information
Johnson and Johnson

Abstract

Purpose: In rare diseases, real-world evidence (RWE) generation is often restricted due to small patient numbers and global geographic distribution. A federated data network (FDN) approach brings together multiple data sources harmonized for collaboration to increase the power of observational research. In this paper, we review how to increase reproducibility and transparency of RWE studies in rare diseases through disease-specific FDNs.

Method: To be successful, a multiple stakeholder scientific FDN collaboration requires a strong governance model in place. In such a model, each database owner remains in full control regarding the use of and access to patient-level data and is responsible for data privacy, ethical, and legal compliance. Provided that all this is well documented and good database descriptions are in place, such a governance model results in increased transparency, while reproducibility is achieved through data curation and harmonization, and distributed analytical methods.

Results: Leveraging the OHDSI community set of methods and tools, two rare disease-specific FDNs are discussed in more detail. For multiple myeloma, HONEUR—the Haematology Outcomes Network in Europe—has built a strong community among the data partners dedicated to scientific exchange and research. To advance scientific knowledge in pulmonary hypertension (PH) an FDN, called PHederation, was established to form a partnership of research institutions with PH databases coming from diverse origins.

Congratulations Dr. Yang

Congratulations to **Dr. Cynthia Yang** on successfully defended her PhD dissertation last week at Erasmus MC: ***Best Practices for the Development of Clinical Prediction Models using Observational Health Data.***

Three Stages of The Journey

Where Have We Been?

Where Are We Now?

Where Are We Going?

Upcoming Workgroup Calls

Date	Time (ET)	Meeting
Tuesday	12 pm	CDM Vocabulary Subgroup
Wednesday	8 am	Psychiatry
Wednesday	7 pm	Medical Imaging
Thursday	9 am	Medical Devices
Thursday	9:30 am	Themis
Thursday	11 am	Industry
Thursday	12 pm	Methods Research
Thursday	1 pm	OMOP CDM Oncology WG- Vocabulary/Development Subgroup
Thursday	7 pm	Dentistry
Friday	10 am	GIS-Geographic Information System
Friday	11:30 am	Steering Group
Monday	9 am	Vaccine Vocabulary
Monday	10 am	Healthcare Systems Interest Group
Monday	11 am	Early-Stage Researchers
Monday	4 pm	Eyecare & Vision Research
Tuesday	9 am	OMOP CDM Oncology WG- Genomic Subgroup

Next CBER BEST Seminar: Apr. 17

2021 Titan Award honoree **Yong Chen** will lead the next CBER BEST Seminar on Wednesday, April 17 (11 am-12 pm).

Topic: Real-World Effectiveness of BNT162b2 Against Infection and Severe Diseases in Children and Adolescents: causal inference under misclassification in treatment status.

April Newsletter is Available

OHDSI

On The Journey (April 2024)

The Winter 2024 Standardized Vocabularies release has several exciting new updates, which were detailed in a recent community call. The CDM and Themis teams are leading an April collaborative event focused on CDM and THEMIS conventions and documentation. Registration for the 2024 Global Symposium is scheduled to open later this month. We review all of that and more in the latest OHDSI newsletter. #JoinTheJourney

Videocast: Vocabularies, CDM, April Olympians

In the latest edition of On The Journey, Patrick Ryan and Craig Sachson reflect on the latest standardized vocabularies release and its impact on OHDSI research, a recent discussion on CDMs and the value of OMOP, and the upcoming April Olympians activities being led by the CDM and Themis workgroups. *(click 'View this email in your browser' if video does not appear)*

Community Updates

Where Have We Been?

• OHDSI standardized vocabularies allow organization & standardization of medical terms to be used across various clinical domains of the OMOP CDM for observational research. Beginning in 2023, the OHDSI vocabulary team makes two major releases annually, including domain changes, newly added concepts, standard concept changes, changes of concept mapping, and more. The most recent release was shared in late February, and it included updates in 12 groupings, which you can read about here.

• OHDSI collaborators have published more than 600 studies related to the OMOP CDM and/or OHDSI tools or methods, including nine last month. During our March 26 community call, five lead authors presented their studies. You can find both the March publications and the five presentations later in this newsletter.

Where Are We Now?

• **Clair Blacketer and Melanie Philofsky** are leading a collab-a-thon this month called "April Olympians," which will focus on CDM and THEMIS conventions and documentation. More details, including five specific goals, are included later in this newsletter. If you are interested, please join the CDM workgroup or fill out this sign-up sheet.

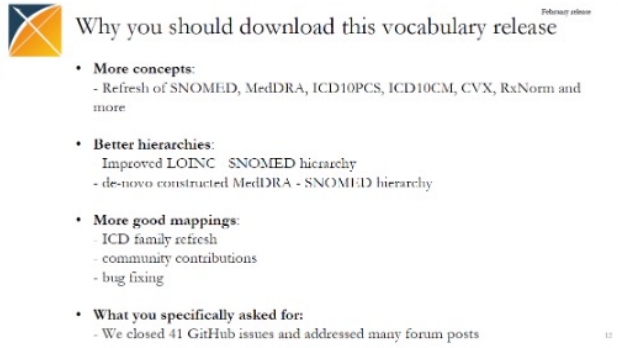
• The CBER BEST Initiative Seminar Series returns Wednesday, April 17 (11 am - 12 pm ET) as 2021 Titan Award honoree **Yong Chen** presents his research on "Real-World Effectiveness of BNT162b2 Against Infection and Severe Diseases in Children and Adolescents: causal inference under misclassification in treatment status." This series is open to anybody: Calendar invite to CBER BEST Seminar.

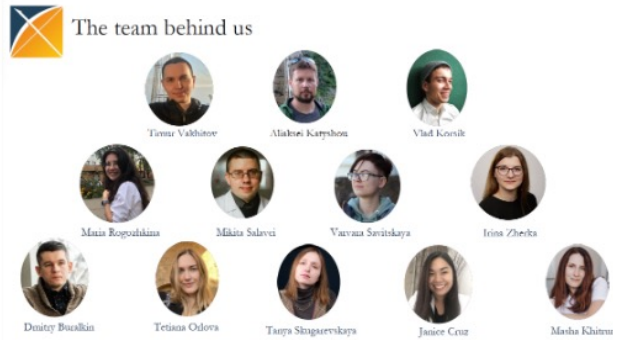
• The third annual **OHDSI DevCon** will be held virtually on Friday, April 26, from 9 am-3 pm ET. Join leaders from our Open-Source Community for a day to both welcome and inform both new and veteran developers within the OHDSI Community.

Where Are We Now?

• The 2024 OHDSI Global Symposium will be held Oct. 22-24 at the Hyatt Regency Hotel in New Brunswick, NJ. The tentative symposium format will feature tutorials on Oct. 22, plenaries and the collaborator showcase on Oct.

Winter 2024 OHDSI Standardized Vocabularies Release Announced





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March Publications

Liu S, Golozar A, Buesgens N, McLeggon JA, Black A, Nagy P. A framework for understanding an open scientific community using automated harvesting of public artifacts. JAMIA Open. 2024 Feb 29;7(1):ooae017. doi: 10.1093/jamiaopen/ooae017. PMID: 38425704; PMCID: PMC10903973.

Marcou Q, Berti-Equille L, Novelli N. Creating a computer assisted ICD coding system: Performance metric choice and use of the ICD hierarchy. J Biomed Inform. 2024 Mar 1;152:104617. doi: 10.1016/j.jbi.2024.104617. Epub ahead of print. PMID: 38432534.

Chai Y, Man KKC, Luo H, Torre CO, Wing YK, Hayes JF, Osborn DPJ, Chang WC, Lin X, Yin C, Chan EW, Lam ICH, Fortin S, Kern DM, Lee DY, Park RW, Jang JW, Li J, Seager S, Lau WCY, Wong ICK. Incidence of mental health diagnoses during the COVID-19 pandemic: a multinational network study. Epidemiol Psychiatr Sci. 2024 Mar 4;33:e9. doi: 10.1017/S2045796024000088. PMID: 38433286; PMCID: PMC10940053.

Haug M, Oja M, Pajusalu M, Mooses K, Reisberg S, Vilo J, Giménez AF, Falconer T, Danilović A, Maljkovic F, Dawoud D, Kolde R. Markov modeling for cost-effectiveness using federated health data network. J Am Med Inform Assoc. 2024 Mar 12:ocae044. doi: 10.1093/jamia/ocae044. Epub ahead of print. PMID: 38472144.

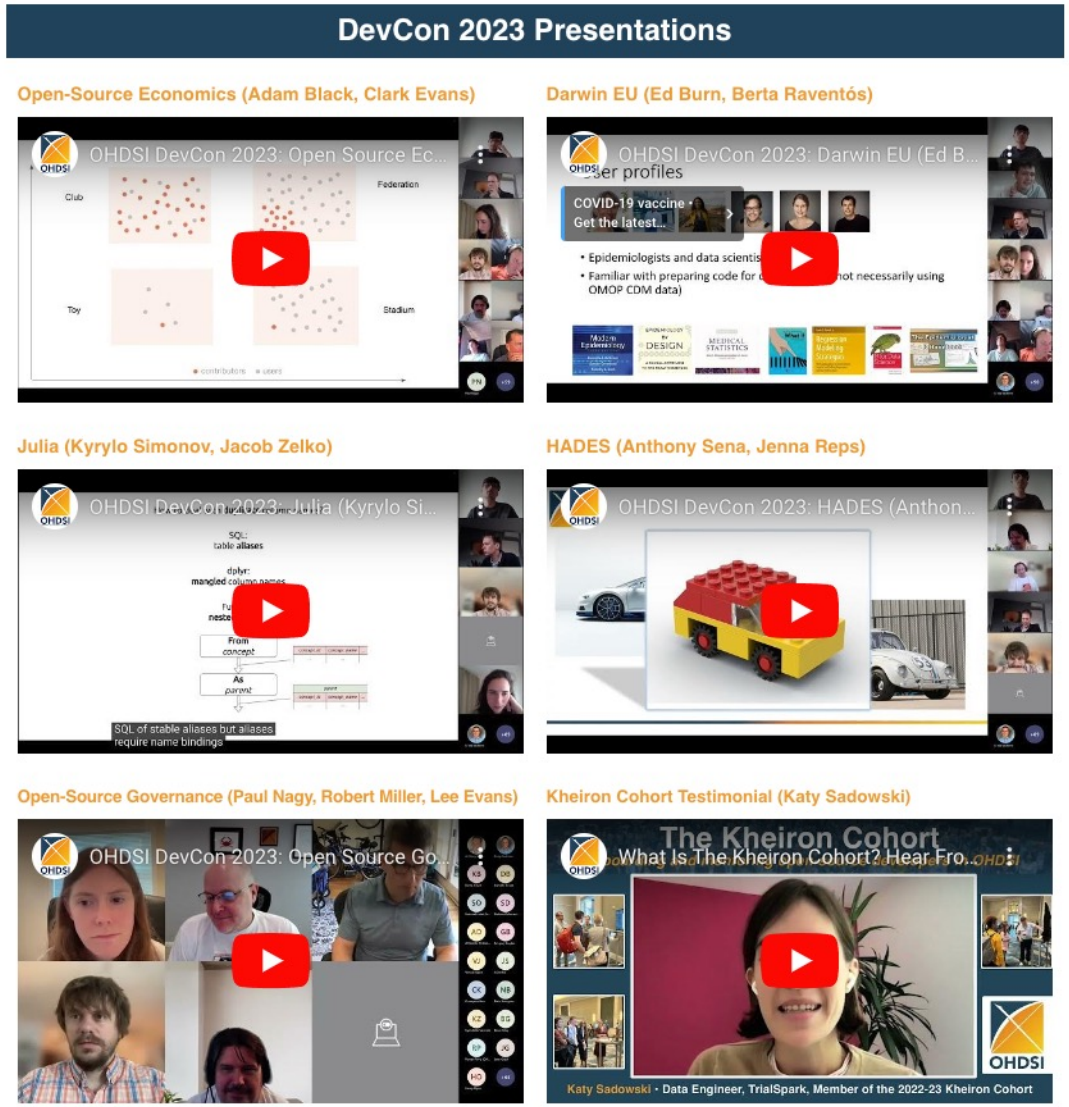
Kim K, Kim JE, Kim JH, Ahn SH, Jung CY, Hwang SD, Lee SW, Song JH. Real-world evidence of constipation and laxative use in the Korean population with chronic kidney disease from a common data model. Sci Rep. 2024 Mar 19;14(1):6610. doi: 10.1038/s41598-024-57382-7. PMID: 38503885; PMCID: PMC10951406.

Mortier P, Amigo F, Bhargav M, Conde S, Ferrer M, Flygare O, Kizilaslan B, Latorre Moreno L, Leis A, Mayer MA, Pérez-Sola V, Portillo-Van Diest A, Ramírez-Anguita JM, Sanz F, Vilagut G, Alonso J, Mehlum L, Arensman E, Bjureberg J, Pastor M, Qin P. Developing a clinical decision support system software prototype that assists in the management of patients with self-harm in the emergency department: protocol of the PERMANENS project. BMC Psychiatry. 2024 Mar 20;24(1):220. doi: 10.1186/s12888-024-05659-6. PMID: 38509500; PMCID: PMC10956300.

DevCon 2024: April 26, 9 am-3 pm ET

The third annual **OHDSI DevCon** will be held virtually on Friday, April 26, from 9 am-3 pm ET.

Join leaders from our Open-Source Community for a day to both welcome and inform both new and veteran developers within the OHDSI Community.



OHDSI Global Symposium

The **2024 OHDSI Global Symposium** will be held Oct. 22-24 at the Hyatt Regency Hotel in New Brunswick, NJ.

Tentative symposium format:

Oct. 22 – tutorials

Oct. 23 – plenaries, collaborator showcase

Oct. 24 – workgroup activities

OHDSI Europe Symposium

Registration is now OPEN for the **2024 OHDSI Europe Symposium**, which will be held June 1-3 in Rotterdam, Netherlands.

June 1 – tutorial/workshop
June 2 – tutorial/workshop
June 3 – main conference

ohdsi-europe.org

#OHDSISocialShowcase This Week

MONDAY

Integrating clinical and laboratory research data using the OMOP CDM

(Edward A. Frankenberger, Chun Yang, Vamsidhar Reddy Meda Venkata, Alyssa Goodson)

Integrating clinical and laboratory research data using the OMOP CDM

PRESENTER: Edward Frankenberger

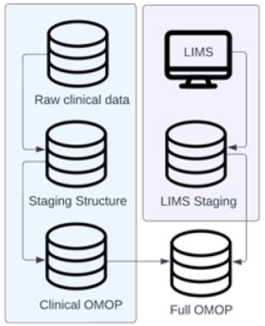
INTRO

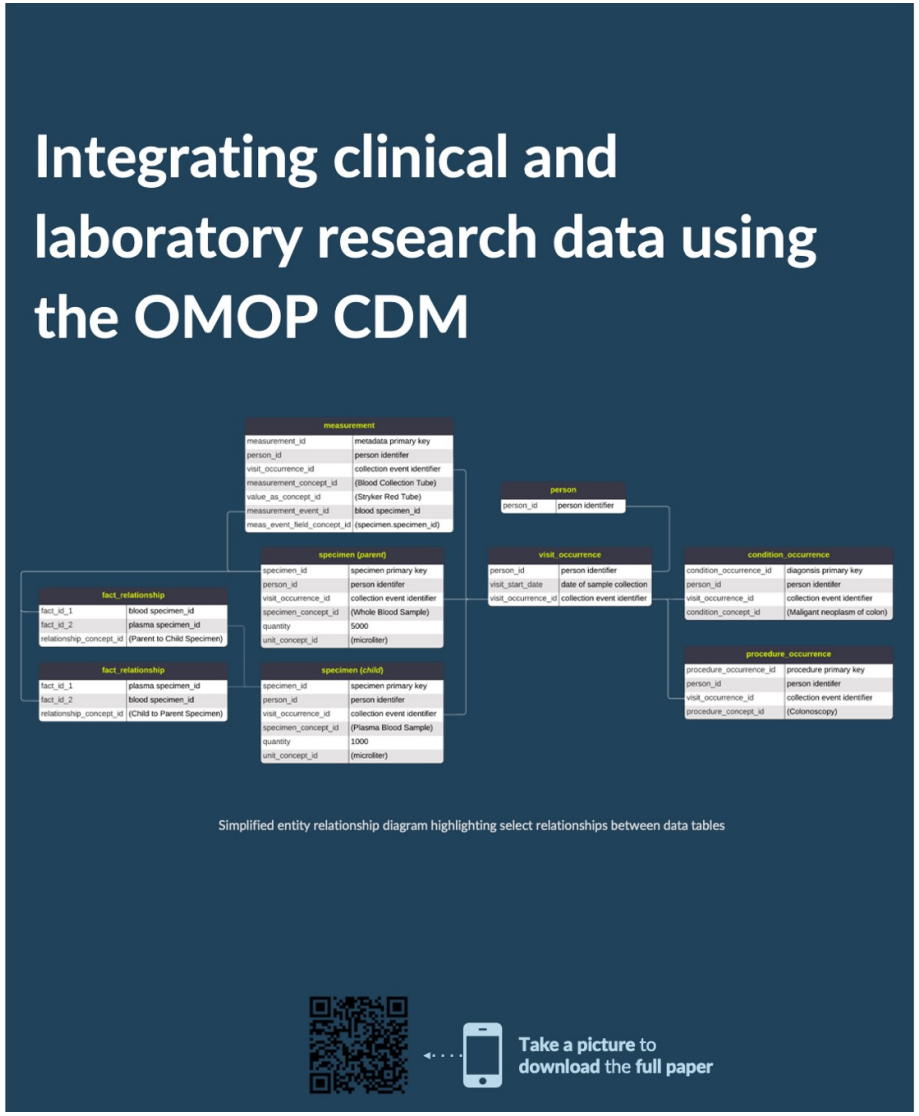
- Biopharmaticial researchers need information about samples, and the patients from whom their samples are sourced, to generate results
- Clinical data about patients, information about their samples, and research data are collected by different groups and reside in a variety of locations and formats
- The OMOP CDM can be used to integrate these disparate sources of data

METHODS

INGESTION

- Clinical data is separated from biospecimen data, imported into a database, and ETL'ed to OMOP
- Specimen metadata (volume, collection tube type, etc.) and research results are documented in lab information management software (LIMS)
- A subset of LIMS is copied to a consistent staging database, against which a secondary ETL is executed to add data to an existing OMOP instance





DATA MODEL

- Study data collection events modeled in visit_occurrence
- Biological samples modeled as specimen records
- Foreign key reference to visit_occurrence added to specimen
- Bi-directional hierarchical relationships between specimens modeled in fact_relationship
- Specimen metadata and results stored in measurement table and linked via measurement_event_id

DATA CONTENT

- Custom concepts required for study-specific clinical data, biospecimen metadata and relationships
- Patient-reported medical history *not* mapped to Observation domain
- type_concept_id used to preserve data provenance
- Single day observation periods required for some patients based on study design

RESULTS

- Established single repository of information with minimal customization to CDM structure

Data Element	Count
Specimen entities	371,108
Specimen relationships	47,379
Specimen metadata	1,052,453
Clinical facts	86,531

Edward Frankenberger, Chun Yang, Vamsidhar Reddy Meda Venkata, Alyssa Goodson

#OHDSISocialShowcase This Week

TUESDAY

A new route of administration hierarchy derived from dose forms supporting standardised drug dose calculations

(Theresa Burkard, Artem Gorbachev, Kim Lopez-Güell, Daniel Prieto-Alhambra, Martí Català, Christian Reich)

This **new route of administration hierarchy,** derived from and linked to dose forms of drugs will **enable the use of route information in standardised analytics.**

A new route of administration hierarchy derived from dose forms supporting standardised drug dose calculations

Background: Few observational databases provide route of administration records. In addition, the current route vocabulary (365 available routes), which was adopted from sources with different use cases in mind, proved insufficient to make clinically relevant categories for dose estimation and to our knowledge have largely been ignored in analytical use cases. The current system also provides no hierarchical relationships between different routes.

Results: We created a route of administration hierarchy with "systemic", "local", "other" (undefinable through dose form), and "has no dose form" as top classifiers. Subclassifications and their hierarchy are shown in Figure 1.
Some examples are listed in Table 1, where we can see the new route categorisation per dose form.

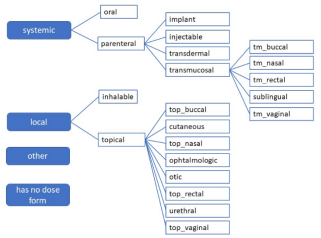


Figure 1. Suggested names and hierarchy of new route vocabulary

Table 1. Examples of suggested categorisation among the 214 existing dose form

Dose form concept id	Dose form concept name	Assigned route
19103220	12 hour Extended Release Capsule	oral
19124968	Drug Implant	implant
46234466	Auto-Injector	injectable
1856271	Intrauterine System	parenteral
19082049	16 Hour Transdermal Patch	transdermal
40164192	Buccal Film	tm_buccal
35604877	Nasal Powder	tm_nasal
19082627	Enema	tm_rectal
40220762	Sublingual Powder	sublingual

The frequency and proportion of unique drug concept ids per newly suggested routes in CPRD GOLD and CPRD AURUM are depicted in Table 2.

Table 2. Most frequent unique drug concept ids in the drug strength table of CPRD GOLD and CPRD AURUM that would be linked to the newly suggested route

Route	CPRD GOLD unique drug concept ids, n (%)	CPRD AURUM unique drug concept ids, n (%)
oral	906'064 (48.9%)	929'935 (48.7%)
injectable	365'685 (19.7%)	378'184 (19.8%)
has no dose form	261'108 (14.1%)	272'888 (14.3%)
topical - cutaneous	171'165 (9.2%)	174'156 (9.1%)
topical - ophtalmologic	42'344 (2.3%)	43'260 (2.3%)
inhalable	28'121 (1.5%)	29'297 (1.5%)
transdermal	13'752 (0.7%)	14'050 (0.7%)
topical - vaginal	11'917 (0.6%)	12'258 (0.6%)

Methods: We obtained all existing dose forms from ATHENA (searching for "Drug" domain, "dose form" concept class, "valid" flag and "RxNorm Extension" and "RxNorm" vocabularies). Based upon their name and looking at the actual drugs linked to them, we suggest a route for each dose form. TB (pharmacist) and AG (medical doctor) did this review independently and met for a consensus meeting with CR (medical doctor and vocabulary expert) in which also the level, hierarchies, categories, and names of routes were defined.

Limitation: Most dose forms can be unambiguously assigned to a route of administration, but there are exceptions where we had to make a choice. Our review had a focus on systemic administrations because they are more relevant for dose estimations – topical administration faces surface tissue and dosing is therefore less stringent.

Theresa Burkard[1], Artem Gorbachev[2], Kim Lopez-Güell[1], Daniel Prieto-Alhambra[1,3], Martí Català[1], Christian Reich[3]

[1] Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK
[2] Odysseus Inc
[3] Department of Medical Informatics, Erasmus University Medical Center, Rotterdam, The Netherlands

#OHDSISocialShowcase This Week

WEDNESDAY

Bayesian Evidence Synthesis with Bias Correction

(Louisa H. Smith, Fan Bu, Akihiko Nishimura, Kristin Kostka, Jody-Ann McLeggon, Patrick B. Ryan, George Hripcsak, David Madigan, Marc A. Suchard)

Bayesian Evidence Synthesis with Bias Correction

PRESENTER: **Louisa** Smith

Are there more adverse events than we'd expect post-vaccination?

An example using the historical comparator design

Let's say you count y_{i0} events at site i.

Historical data suggests you should have seen y_{i0}^* events over the same amount of time.

You can estimate a rate ratio comparing the two time periods using the model

$$y_{i0} \sim \text{Poisson}\left(\exp\left(\theta_{i0}\right) \times y_{i0}^*\right)$$

where a log rate ratio (θ_{i0}) of 0 indicates no difference in the event rate compared to the historical expectation.

Data on 2017-2018 flu vaccines from EUMAEUS

Data source	Events (y_{i0})	Expected events (y_{i0}^*)	Rate ratio ($\exp(\widehat{\theta}_{i0})$)
CCAE	1478	1159.0	1.28 (1.21, 1.34)
MDCD	727	711.2	1.02 (0.95, 1.10)
MDCR	98	91.8	1.07 (0.87, 1.30)
Optum	1280	991.8	1.29 (1.22, 1.36)
OptumEHR	962	501.4	1.92 (1.80, 2.04)

It looks like there's an effect of vaccination at most of the sites.

But wait! These events are animal bite wounds. Those rate ratios seem a bit large. Maybe there's some bias we need to deal with?

Let's assume we can decompose the observable log rate ratio into the sum of the true causal effect and the bias:

$$\tilde{\theta}_{i0} = \theta_{i0} + \beta_{i0}$$

If there are events y_{ij} that we are sure can't be caused by vaccination (negative control outcomes) but which are subject to the same bias distribution, we can assume that

$$y_{ij} \sim \text{Poisson}\left(\exp\left(0 + \beta_{ij}\right) \times y_{ij}^*\right)$$

Let's also assume the bias—for the event of interest and the negative control outcomes—at this particular site arises from a distribution, say,

$$\beta_{ij} \sim \text{Normal}\left(\delta_i, \gamma_i\right)$$

Then we can use the event rates for the negative control outcomes to estimate a distribution for β_{i0}, and therefore a distribution for θ_{i0}.

Now all that's left to do is combine data across sites!

We can do so while allowing for heterogeneity in the true effect across sites, such that:

$$\theta_{i0} \sim \text{Normal}\left(\mu, \tau\right)$$

as well as in the average bias across sites:

$$\beta_{ij} \sim \text{Normal}\left(\lambda, \eta\right)$$

We can fit this model—and similar models with different likelihoods—with the Bayesian statistical software Stan using the work-in-progress R package *BBAMA*: https://github.com/roux-ohdsi/BBAMA.

Then, once we've fit the model, we can draw inference directly from the posterior distribution of θ_{i0} or any other parameter!

A recipe for evidence: Start with a **Bayesian hierarchical model.** Add data from a **network study.** Remove bias using **negative control outcomes**.

Point your camera to see the **R package**

Key References

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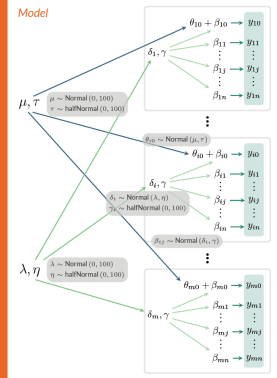
Model



$i = 1, \ldots, m$ indexes site

$j = 1, \ldots, n$ indexes negative control outcomes

y_{i0} is the data for the outcome of interest at site i

θ_{i0} is the true effect on the outcome of interest at site i

y_{ij} is the data for the outcome of interest at site i

β_{i0} is the bias to remove to identify the effect of interest

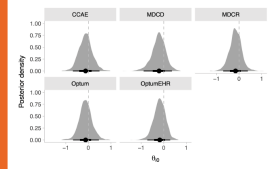
β_{ij} is the bias of negative control outcome j at site i

μ is the mean of the distribution of the overall effect across sites and τ is its variance

δ_i the mean bias at site i and γ its variance

λ is the mean bias across sites and η its variance

Site-specific posterior densities from example



Louisa H. Smith, Fan Bu, Akihiko Nishimura, Kristin Kostka, JodyAnn McLeggon, Patrick B. Ryan, George Hripcsak, David Madigan, Marc A. Suchard

OHDSI

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Observational Health Data Sciences and Informatics Center

#OHDSISocialShowcase This Week

THURSDAY

Save Our Sisyphus Challenge: Lessons learned from Strategus execution on the OHDSI Network

(Anthony G. Sena, Jenna Reps, Chungsoo Kim, Jack Brewster, Adam Black, Linying Zhang, Michael Cook, Phan Thanh Phuc, Scott L. DuVall, Marc A. Suchard)

Save Our Sisyphus (SOS) Challenge: Lessons learned from Strategus execution on the OHDSI Evidence Network

PRESENTER: **Anthony G. Sena**

INTRODUCTION:

- The OHDSI SOS challenge provided tutorials to the community on the process of leading or participating in an OHDSI network study.
- These tutorials used two network studies to illustrate the network study process: 1) Intravitreal anti-VEGF and kidney failure risk (Anti-VEGF) and 2) fluoroquinolone and aortic aneurysm risk (FQ).

METHODS

- The SOS challenge made use of the **Strategus** R package which aims to provide the software infrastructure for running the OHDSI HADES analytical packages
- Two tutorials on network execution of the SOS studies were presented to the OHDSI Community on May 2nd, 2023. These tutorials guided OHDSI community members through the steps of locating the study analysis specification and how to run the code to execute the study, including the Strategus package.

RESULTS

- Eleven (11) sites executed the two (2) studies across twenty-nine (29) databases.
- Each site had different technical challenges that were shared during "office hours" calls and provided many lessons learned for using Strategus for running network studies in the OHDSI network.

The **Strategus R package** was used to execute **2 SOS OHDSI Network Studies** at **11 sites** across **29 databases.**

OHDSI Data Partner	Study (Number of Databases)	
	Anti-VEGF (12)	FQ (17)
Ajou University Medical Center	-	2
Columbia University Medical Center	1	1
IQVIA	-	5
Janssen R&D	6	6
Johns Hopkins University	1	-
Northeastern University	1	-
Stanford University	1	-
Taipei Medical University	-	1
University of Southern California	1	-
Department of Veterans Affairs	1	1
Yonsei University College of Medicine	-	1

OHDSI

Jenna Reps, Chungsoo Kim, Jack Brewster, Adam Black, Linying Zhang, Thomas Falconer, George Hripcsak, Cindy X. Cai, Michael Cook, Phan Thanh Phuc, Jason C. Hsu, Phung-Anh Nguyen, Muhammad Solihuddin Muhtar, Brian Toy, Zachary Gilbert, Xiaoyu Lin, Jing Li, Sarah Seager, Yeonjae Han, Seng Chan You, Scott L. DuVall, Marc A. Suchard

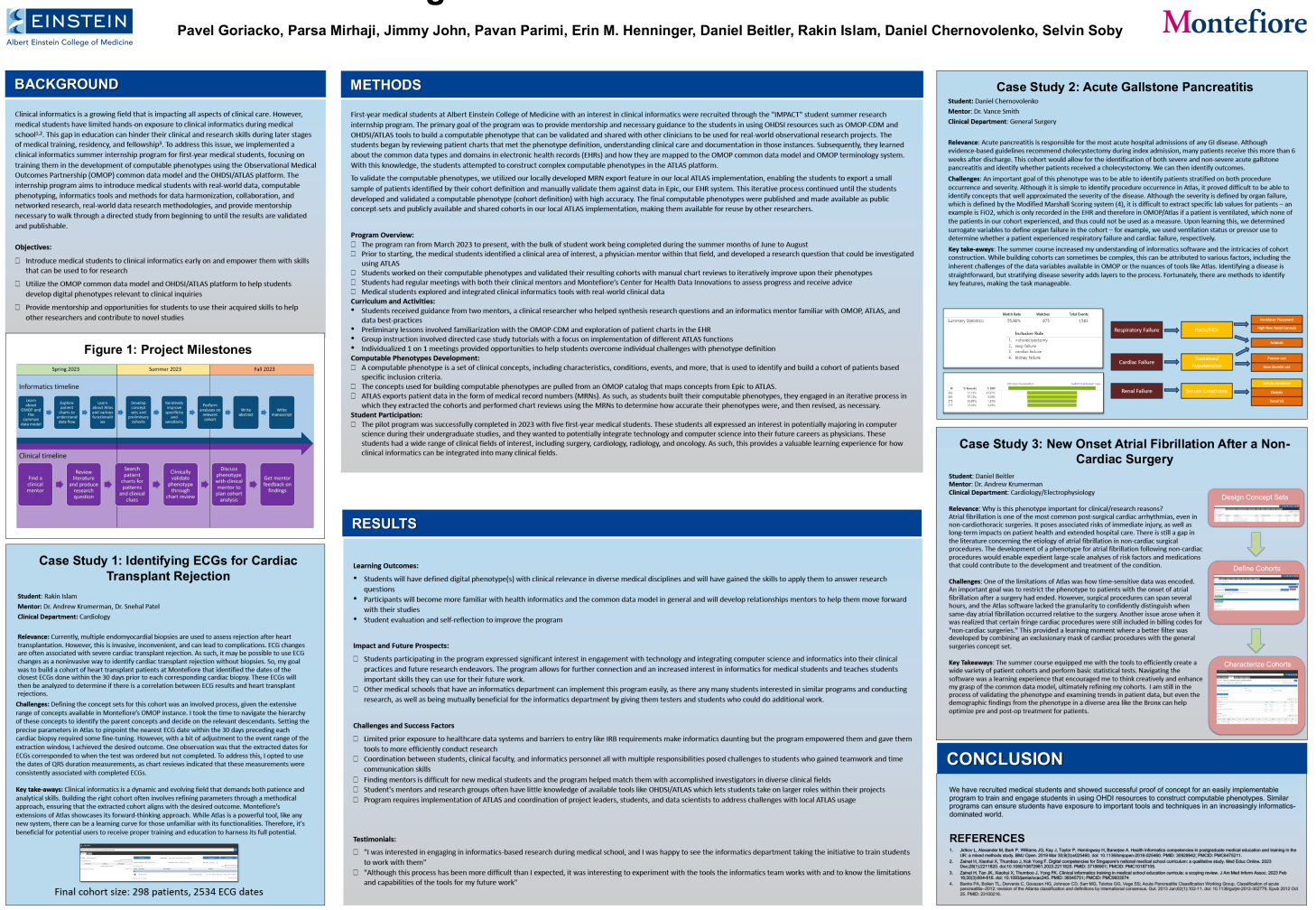
Take a picture to **download** the **full paper**

#OHDSISocialShowcase This Week

FRIDAY

Incorporating Real-World Data Research in Training First-Year Medical Students Using OHDSI OMOP and Atlas tools

(Pavel Goriacko, Parsa Mirhaji, Jimmy John, Pavan Parimi, Erin M. Henninger, Daniel Beiter, Rakin Islam, Daniel Chernovolenko, Selvin Soby)



Incorporating Real-World Data Research in Training First-Year Medical Students Using OHDSI OMOP and ATLAS Tools

EINSTEIN Albert Einstein College of Medicine

Pavel Goriacko, Parsa Mirhaji, Jimmy John, Pavan Parimi, Erin M. Henninger, Daniel Beitler, Rakin Islam, Daniel Chernovolenko, Selvin Soby

Montefiore

BACKGROUND

Clinical informatics is a growing field that is impacting all aspects of clinical care. However, medical students have limited hands-on exposure to clinical informatics during medical school[1,2]. This gap in education can hinder their clinical and research skills during later stages of medical training, residency, and fellowship[3]. To address this issue, we implemented a clinical informatics summer internship program for first-year medical students, focusing on training them in the development of computable phenotypes using the Observational Medical Outcomes Partnership (OMOP) common data model and the OHDSI/ATLAS platform. The internship program aims to introduce medical students with real-world data, computable phenotyping, informatics tools and methods for data harmonization, collaboration, and networked research, real-world data research methodologies, and provide mentorship necessary to walk through a directed study from beginning to until the results are validated and publishable.

Objectives:

- Introduce medical students to clinical informatics early on and empower them with skills that can be used to for research
- Utilize the OMOP common data model and OHDSI/ATLAS platform to help students develop digital phenotypes relevant to clinical inquiries
- Provide mentorship and opportunities for students to use their acquired skills to help other researchers and contribute to novel studies

Figure 1: Project Milestones

Case Study 1: Identifying ECGs for Cardiac Transplant Rejection

Student: Rakin Islam
Mentor: Dr. Andrew Krumerman, Dr. Snehal Patel
Clinical Department: Cardiology

Relevance: Currently, multiple endomyocardial biopsies are used to assess rejection after heart transplantation. However, this is invasive, inconvenient, and can lead to complications. ECG changes are often associated with severe cardiac transplant rejection. As such, it may be possible to use ECG changes as a noninvasive way to identify cardiac transplant rejection without biopsies. So, my goal was to build a cohort of heart transplant patients at Montefiore that identified the dates of the closest ECGs done within the 30 days prior to each corresponding cardiac biopsy. These ECGs will then be analyzed to determine if there is a correlation between ECG results and heart transplant rejections.

Challenges: Defining the concept sets for this cohort was an involved process, given the extensive range of concepts available in Montefiore's OMOP instance. I took the time to navigate the hierarchy of these concepts to identify the parent concepts and decide on the relevant descendants. Setting the precise parameters in Atlas to pinpoint the nearest ECG date within the 30 days preceding each cardiac biopsy required some fine-tuning. However, with a bit of adjustment to the event range of the extraction window, I achieved the desired outcome. One observation was that the extracted dates for ECGs corresponded to when the test was ordered but not completed. To address this, I opted to use the dates of QRS duration measurements, as chart reviews indicated that these measurements were consistently associated with completed ECGs.

Key take-aways: Clinical informatics is a dynamic and evolving field that demands both patience and analytical skills. Building the right cohort often involves refining parameters through a methodical approach, ensuring that the extracted cohort aligns with the desired outcome. Montefiore's extensions of Atlas showcases its forward-thinking approach. While Atlas is a powerful tool, like any new system, there can be a learning curve for those unfamiliar with its functionalities. Therefore, it's beneficial for potential users to receive proper training and education to harness its full potential.

Final cohort size: 298 patients, 2534 ECG dates

METHODS

First-year medical students at Albert Einstein College of Medicine with an interest in clinical informatics were recruited through the "IMPACT" student summer research internship program. The primary goal of the program was to provide mentorship and necessary guidance to the students in using OHDSI resources such as OMOP-CDM and OHDSI/ATLAS tools to build a computable phenotype that can be validated and shared with other clinicians to be used for real-world observational research projects. The students began by reviewing patient charts that met the phenotype definition, understanding clinical care and documentation in those instances. Subsequently, they learned about the common data types and domains in electronic health records (EHRs) and how they are mapped to the OMOP common data model and OMOP terminology system. With this knowledge, the students attempted to construct complex computable phenotypes in the ATLAS platform.

To validate the computable phenotypes, we utilized our locally developed MRN export feature in our local ATLAS implementation, enabling the students to export a small sample of patients identified by their cohort definition and manually validate them against data in Epic, our EHR system. This iterative process continued until the students developed and validated a computable phenotype (cohort definition) with high accuracy. The final computable phenotypes were published and made available as public concept-sets and publicly available and shared cohorts in our local ATLAS implementation, making them available for reuse by other researchers.

Program Overview:

- The program ran from March 2023 to present, with the bulk of student work being completed during the summer months of June to August
- Prior to starting, the medical students identified a clinical area of interest, a physician-mentor within that field, and developed a research question that could be investigated using ATLAS
- Students worked on their computable phenotypes and validated their resulting cohorts with manual chart reviews to iteratively improve upon their phenotypes
- Students had regular meetings with both their clinical mentors and Montefiore's Center for Health Data Innovations to assess progress and receive advice
- Medical students explored and integrated clinical informatics tools with real-world clinical data

Curriculum and Activities:

- Students received guidance from two mentors, a clinical researcher who helped synthesis research questions and an informatics mentor familiar with OMOP, ATLAS, and data best-practices
- Preliminary lessons involved familiarization with the OMOP-CDM and exploration of patient charts in the EHR
- Group instruction involved directed case study tutorials with a focus on implementation of different ATLAS functions
- Individualized 1 on 1 meetings provided opportunities to help students overcome individual challenges with phenotype definition

Computable Phenotypes Development:

- A computable phenotype is a set of clinical concepts, including characteristics, conditions, events, and more, that is used to identify and build a cohort of patients based specific inclusion criteria.
- The concepts used for building computable phenotypes are pulled from an OMOP catalog that maps concepts from Epic to ATLAS.
- ATLAS exports patient data in the form of medical record numbers (MRNs). As such, as students built their computable phenotypes, they engaged in an iterative process in which they extracted the cohorts and performed chart reviews using the MRNs to determine how accurate their phenotypes were, and then revised, as necessary.

Student Participation:

- The pilot program was successfully completed in 2023 with five first-year medical students. These students all expressed an interest in potentially majoring in computer science during their undergraduate studies, and they wanted to potentially integrate technology and computer science into their future careers as physicians. These students had a wide range of clinical fields of interest, including surgery, cardiology, radiology, and oncology. As such, this provides a valuable learning experience for how clinical informatics can be integrated into many clinical fields.

RESULTS

Learning Outcomes:

- Students will have defined digital phenotype(s) with clinical relevance in diverse medical disciplines and will have gained the skills to apply them to answer research questions
- Participants will become more familiar with health informatics and the common data model in general and will develop relationships mentors to help them move forward with their studies
- Student evaluation and self-reflection to improve the program

Impact and Future Prospects:

- Students participating in the program expressed significant interest in engagement with technology and integrating computer science and informatics into their clinical practices and future research endeavors. The program allows for further connection and an increased interest in informatics for medical students and teaches students important skills they can use for their future work.
- Other medical schools that have an informatics department can implement this program easily, as there any many students interested in similar programs and conducting research, as well as being mutually beneficial for the informatics department by giving them testers and students who could do additional work.

Challenges and Success Factors

- Limited prior exposure to healthcare data systems and barriers to entry like IRB requirements make informatics daunting but the program empowered them and gave them tools to more efficiently conduct research
- Coordination between students, clinical faculty, and informatics personnel all with multiple responsibilities posed challenges to students who gained teamwork and time communication skills
- Finding mentors is difficult for new medical students and the program helped match them with accomplished investigators in diverse clinical fields
- Student's mentors and research groups often have little knowledge of available tools like OHDSI/ATLAS which lets students take on larger roles within their projects
- Program requires implementation of ATLAS and coordination of project leaders, students, and data scientists to address challenges with local ATLAS usage

Testimonials:

- "I was interested in engaging in informatics-based research during medical school, and I was happy to see the informatics department taking the initiative to train students to work with them"
- "Although this process has been more difficult than I expected, it was interesting to experiment with the tools the informatics team works with and to know the limitations and capabilities of the tools for my future work"

Case Study 2: Acute Gallstone Pancreatitis

Student: Daniel Chernovolenko
Mentor: Dr. Vance Smith
Clinical Department: General Surgery

Relevance: Acute pancreatitis is responsible for the most acute hospital admissions of any GI disease. Although evidence-based guidelines recommend cholecystectomy during index admission, many patients receive this more than 6 weeks after discharge. This cohort would allow for the identification of both severe and non-severe acute gallstone pancreatitis and identify whether patients received a cholecystectomy. We can then identify outcomes.

Challenges: An important goal of this phenotype was to be able to identify patients stratified on both procedure occurrence and severity. Although it is simple to identify procedure occurrence in Atlas, it proved difficult to be able to identify concepts that well approximated the severity of the disease. Although the severity is defined by organ failure, which is defined by the Modified Marshall Scoring system (4), it is difficult to extract specific lab values for patients – an example is FiO2, which is only recorded in the EHR and therefore in OMOP/Atlas if a patient is ventilated, which none of the patients in our cohort experienced, and thus could not be used as a measure. Upon learning this, we determined surrogate variables to define organ failure in the cohort – for example, we used ventilation status or pressor use to determine whether a patient experienced respiratory failure and cardiac failure, respectively.

Key take-aways: The summer course increased my understanding of informatics software and the intricacies of cohort construction. While building cohorts can sometimes be complex, this can be attributed to various factors, including the inherent challenges of the data variables available in OMOP or the nuances of tools like Atlas. Identifying a disease is straightforward, but stratifying disease severity adds layers to the process. Fortunately, there are methods to identify key features, making the task manageable.

Case Study 3: New Onset Atrial Fibrillation After a Non-Cardiac Surgery

Student: Daniel Beitler
Mentor: Dr. Andrew Krumerman
Clinical Department: Cardiology/Electrophysiology

Relevance: Why is this phenotype important for clinical/research reasons?
Atrial fibrillation is one of the most common post-surgical cardiac arrhythmias, even in non-cardiothoracic surgeries. It poses associated risks of immediate injury, as well as long-term impacts on patient health and extended hospital care. There is still a gap in the literature concerning the etiology of atrial fibrillation in non-cardiac surgical procedures. The development of a phenotype for atrial fibrillation following non-cardiac procedures would enable expedient large-scale analyses of risk factors and medications that could contribute to the development and treatment of the condition.

Challenges: One of the limitations of Atlas was how time-sensitive data was encoded. An important goal was to restrict the phenotype to patients with the onset of atrial fibrillation after a surgery had ended. However, surgical procedures can span several hours, and the Atlas software lacked the granularity to confidently distinguish when same-day atrial fibrillation occurred relative to the surgery. Another issue arose when it was realized that certain fringe cardiac procedures were still included in billing codes for "non-cardiac surgeries." This provided a learning moment where a better filter was developed by combining an exclusionary mask of cardiac procedures with the general surgeries concept set.

Key Takeaways: The summer course equipped me with the tools to efficiently create a wide variety of patient cohorts and perform basic statistical tests. Navigating the software was a learning experience that encouraged me to think creatively and enhance my grasp of the common data model, ultimately refining my cohorts. I am still in the process of validating the phenotype and examining trends in patient data, but even the demographic findings from the phenotype in a diverse area like the Bronx can help optimize pre and post-op treatment for patients.

CONCLUSION

We have recruited medical students and showed successful proof of concept for an easily implementable program to train and engage students in using OHDI resources to construct computable phenotypes. Similar programs can ensure students have exposure to important tools and techniques in an increasingly informatics-dominated world.

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Opening: Biomedical Informatics Data Scientist at Stanford

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The Biomedical Informatics Data Scientist will partner with researchers and clinicians to enable effective and efficient use of data and resources available via Stanford's research clinical data repository (STARR) including the Electronic Health Records in the OMOP Common Data Model, radiology and cardiology imaging data and associated metadata, and new data types as they get integrated along with their databases and respective cohort query tools and interfaces e.g., OHDSI ATLAS. This individual will enable researchers to maximize their understanding, interpretation and use of these clinical and research tools for more informed and productive research, clinical trials, patient care and quality outcome projects.

Clean, extract, transform and analyze various kinds of clinical data to create analysis-ready datasets that follow the FAIR (Findable, Accessible, Interoperable and Re-usable) principles. Partner with researchers and clinicians to enable effective and efficient use of Stanford Clinical data and resources for the advancement of research and the educational mission.

(I²DB)

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Opening: Epidemiology UX/Web Design Intern at J&J

Career Programs

Epidemiology UX/Web Design Intern

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SUB FUNCTION	Non-LDP Intern/Co-Op
LOCATION	Raritan, New Jersey, United States
DATE POSTED	Jan 19 2024
REQUISITION NUMBER	2406163977W

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Janssen Research & Development, L.L.C., a division of Johnson & Johnson's Family of Companies is recruiting for Epidemiology UX/Web Design Intern. This position is a member of the Observational Health Data Analytics (OHDA) team. OHDA's mission is to improve the lives individuals and quality of healthcare by efficiently generating real-world evidence from the world's observational health data, transparently disseminating evidence-based insights to real-world decision-makers, and objectively advancing the science and technology behind reliab

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Responsibilities:

Collaborate with researchers and data scientists to understand project requirements and translate them into OHDSI-compatible solutions. Work with databases, ensuring data integrity and optimization for OHDSI-related queries and analyses. Perform data analyses in OHDSI-related tools like ATLAS. Customize and extend OHDSI tools and applications to meet specific project needs. Collaborate with cross-functional teams to troubleshoot and resolve technical issues related to OHDSI implementations. Stay informed about OHDSI community updates, best practices, and emerging trends in observational health data research. Contribute to the development and documentation of data standards and conventions within the OHDSI community.

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Where Are We Going?

Any other announcements of upcoming work, events, deadlines, etc?

Three Stages of The Journey

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Where Are We Now?

Where Are We Going?

The weekly OHDSI community call is held every Tuesday at 11 am ET.

Everybody is invited!

Links are sent out weekly and available at: ohdsi.org/community-calls