



‘Phenotype Phebruary’ Introduction

OHDSI Community Call
Feb. 1, 2022 • 11 am ET



Future OHDSI Community Calls

Date	Topic
Feb. 1	Introduction to Phenotype Phebruary
Feb. 8	Phenotype Phebruary Report, Workgroup Updates (Healthcare Systems, Open Source Community)
Feb. 15	Phenotype Phebruary Report, Workgroup Updates (CDM, Data Quality, Medical Imaging)
Feb. 22	Phenotype Phebruary Report #3, Workgroup Updates (ATLAS/WebAPI, Education)
Mar. 1	Breakout Sessions (Characterization, Estimation, Prediction)
Mar. 8	CDM Workshop (Part 1)
Mar. 15	CDM Workshop (Part 2)
Mar. 22	OHDSI Vocabulary Journey
Mar. 29	Reproducibility



Future OHDSI Community Calls

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February 8 OHDSI Community Call



Open Source Community Workgroup Update

Adam Black



Healthcare Systems Interest Group Update

Melanie Philofsky



Phenotype Phebruary Update #1

Patrick Ryan



Three Stages of The Journey

Where Have We Been?

Where Are We Now?

Where Are We Going?





OHDSI Shoutouts!



Congratulations to the team of **Ross D. Williams, Aniek F. Markus, Cynthia Yang, Talita Duarte-Salles, Scott L. DuVall, Thomas Falconer, Jitendra Jonnagaddala, Chungsoo Kim, Yeunsook Rho, Andrew E. Williams, Amanda Alberga Machado, Min Ho An, María Aragón, Carlos Areia, Edward Burn, Young Hwa Choi, Iannis Drakos, Maria Tereza Fernandes Abrahão, Sergio Fernández-Bertolín, George Hripcsak, Benjamin Skov Kaas-Hansen, Prasanna L. Kandukuri, Jan A. Kors, Kristin Kostka, Siaw-Teng Liaw, Kristine E. Lynch, Gerardo Machnicki, Michael E. Matheny, Daniel Morales, Fredrik Nyberg, Rae Woong Park, Albert Prats-Urbe, Nicole Pratt, Gowtham Rao, Christian G. Reich, Marcela Rivera, Tom Seinen, Azza Shoaibi, Matthew E. Spotnitz, Ewout W. Steyerberg, Marc A. Suchard, Seng Chan You, Lin Zhang, Lili Zhou, Patrick B. Ryan, Daniel Prieto-Alhambra, Jenna M. Reps and Peter R. Rijnbeek** on the publication of **“Seek COVER: using a disease proxy to rapidly develop and validate a personalized risk calculator for COVID-19 outcomes in an international network”** in BMC Medical Research Methodology.

 **BMC** Part of Springer Nature

BMC Medical Research Methodology

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Seek COVER: using a disease proxy to rapidly develop and validate a personalized risk calculator for COVID-19 outcomes in an international network

[Ross D. Williams, Aniek F. Markus, ... Peter R. Rijnbeek](#)  [+ Show authors](#)

[BMC Medical Research Methodology](#) **22**, Article number: 35 (2022) | [Cite this article](#)

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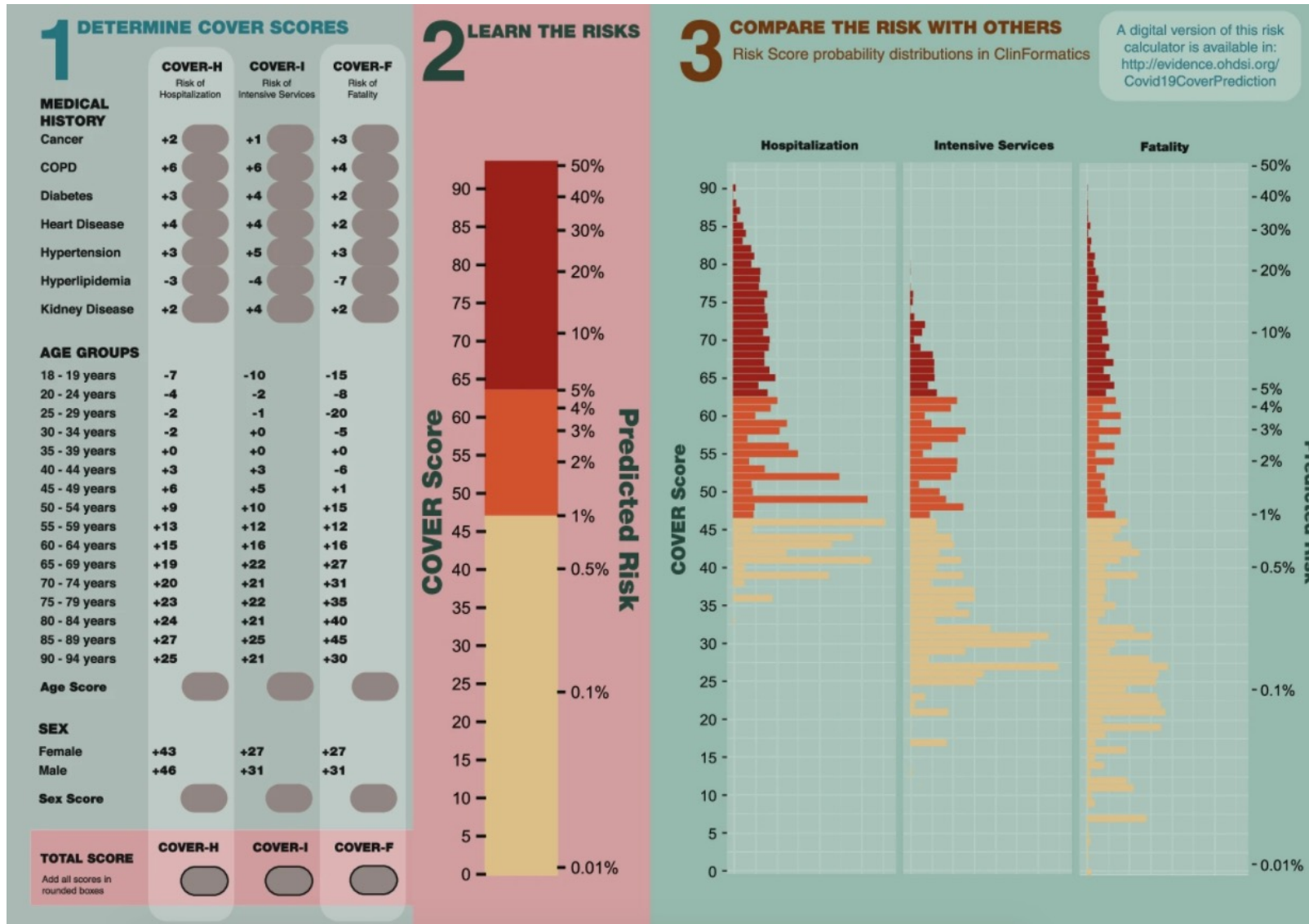
Abstract

Background

We investigated whether we could use influenza data to develop prediction models for COVID-19 to increase the speed at which prediction models can reliably be developed and validated early in a pandemic. We developed COVID-19 Estimated Risk (COVER) scores that quantify a patient's risk of hospital admission with pneumonia (COVER-H), hospitalization with pneumonia requiring intensive services or death (COVER-I), or fatality (COVER-F) in the 30-days following COVID-19 diagnosis using historical data from patients with influenza or flu-like symptoms and tested this in COVID-19 patients.



OHDSI Shoutouts!





OHDSI Shoutouts!



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OHDSI Shoutouts!



Congratulations to the team of **Seung-Hwa Lee, Jungchan Park, Rae Woong Park, Seo Jeong Shin, Jinseob Kim, Ji Dong Sung, Dae Jung Kim, and Kwangmo Yang** on the publication of **“Renin-Angiotensin-Aldosterone System Inhibitors and Risk of Cancer: A Population-Based Cohort Study Using a Common Data Model”** in *Diagnostics*.



diagnostics



Article

Renin-Angiotensin-Aldosterone System Inhibitors and Risk of Cancer: A Population-Based Cohort Study Using a Common Data Model

Seung-Hwa Lee ^{1,2,†}, Jungchan Park ^{3,4,†}, Rae Woong Park ^{4,†}, Seo Jeong Shin ^{4,†}, Jinseob Kim ⁵, Ji Dong Sung ¹, Dae Jung Kim ⁶ and Kwangmo Yang ^{4,7,*}

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 - ³ Department of Anesthesiology and Pain Medicine, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul 06351, Korea; j83.park@samsung.com
 - ⁴ Department of Biomedical Sciences, Ajou University Graduate School of Medicine, Suwon 16499, Korea; rwpark99@gmail.com (R.W.P.); lucid900921@naver.com (S.J.S.)
 - ⁵ Department of Epidemiology, School of Public Health, Seoul National University, Seoul 03080, Korea; jinseob2kim@gmail.com
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 - ⁷ Center for Health Promotion, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul 06351, Korea
- * Correspondence: kmhi.yang@samsung.com; Tel./Fax: +82-2-3410
† These authors contributed equally to this work.



Citation: Lee, S.-H.; Park, J.; Park, R.W.; Shin, S.J.; Kim, J.; Sung, J.D.; Kim, D.J.; Yang, K. Renin-Angiotensin-Aldosterone System Inhibitors and Risk of Cancer: A Population-Based Cohort Study Using a Common Data Model. *Diagnostics* **2022**, *12*, 263. <https://doi.org/10.3390/diagnostics12020263>

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Abstract: Studies have reported conflicting results on the association between the use of renin-angiotensin-aldosterone system (RAAS) inhibitors and cancer development. We compared the incidence of cancer between patients using RAAS inhibitors and other antihypertensive drugs. This retrospective observational cohort study used data from seven hospitals in Korea that were converted for use in the Observational Medical Outcomes Partnership Common Data Model. A total of 166,071 patients on antihypertensive therapy across the databases of the seven hospitals were divided into two groups according to the use of RAAS inhibitors. The primary outcome was the occurrence of cancer. A total of 166,071 patients across the databases of the seven hospitals was included in the final analysis; 26,650 (16%) were in the RAAS inhibitors group and 139,421 (84%) in the other antihypertensive drugs group. The meta-analysis of the whole cohort showed a lower incidence of cancer occurrence in the RAAS inhibitor group (9.90 vs. 13.28 per 1000 person years; HR, 0.81; 95% confidence interval [CI], 0.75–0.88). After propensity-score matching, the RAAS inhibitor group consistently showed a lower incidence of cancer (9.90 vs. 13.28 per 1000 person years; HR, 0.86; 95% CI, 0.81–0.91). The patients using RAAS inhibitors showed a lower incidence of cancer compared with those using other antihypertensive drugs. These findings support the association between the use of RAAS inhibitors and cancer occurrence.


Keywords: renin-angiotensin-aldosterone system inhibitors; cancer occurrence



OHDSI Shoutouts!



< All teams



OHDSI

General

OHDSI coordinating center administration

OHDSI Meme-a-thon


OHDSI Viz Challenge July2021 Health Equity

OHDSI Viz Challenge March2021 COVID


Teams Best Practices and Guidance

Teams Technical support

Wins



Wins Posts Files Wiki +



Kristin Kostka 1/28 11:40 AM Edited


Big WIN for OHDSI CHARYBDIS Team!

After a year and many rejections, we are happy to report the OHDSI CHARYBDIS general paper (aka our paper that talks about the overarching framework of large scale characterization for baseline risk of SARS-CoV-2) was ACCEPTED by Clinical Epidemiology (Dove Press).

We are SO grateful for the entire team's tenacity in pushing this ahead!

See more

Reply




Kristin Kostka 1/28 11:35 AM

ANNOUNCING: The Weekly Wins Channel!

You might be wondering, why is there a new channel here on the OHDSI General area? Well, a few of us were talking about how to share good news in the community. Sometimes we can announce things on workgroup calls. Sometimes we can have a minute or two to shout out in the OHDSI Community Calls. But why not create an asynchronous space to share our wins? 😊

Enter this channel. Please share your good news ("Wins!"). These can be OHDSI-specific (e.g. a successful event, a paper is submitted, a paper is accepted, a big presentation goes well, etc) or Professional development related. We simply want to share in the good news with you and celebrate the successes of our amazing global community!

See less



Kristin Kostka 1/28 11:43 AM Edited


Suggested on how to use this channel:

Start a New Conversation:

See more

Reply

Today



Kristin Kostka 10:00 AM


Congrats to SEEK COVER!

Aniek Markus Ross Williams Peter Rijnbeek et al have published the SEEK COVER manuscript from the 2020 OHDSI COVID-19 Studyathon: <https://bmcmedresmethodol.biomedcentral.com/articles/10.1186/s12874-022-01505-z>

Congrats!!!!


Medical

New conversation

 @OHDSI

www.ohdsi.org

#JoinTheJourney

 ohdsi



OHDSI Shoutouts!



Any shoutouts from the community? Please share and help promote and celebrate OHDSI work!

Have a study published? Please send to sachson@ohdsi.org so we can share during this call and on our social channels.
Let's work together to promote the collaborative work happening in OHDSI!





Three Stages of The Journey

Where Have We Been?

Where Are We Now?

Where Are We Going?





Upcoming Workgroup Calls



Date	Time (ET)	Meeting
Wednesday	2 am	Patient-Level Prediction/Population-Level Estimation (Eastern Hemi)
Wednesday	9 am	ATLAS/WebAPI
Wednesday	10 am	FHIR and OMOP Data Quality Measurements Subgroup (Zoom)
Wednesday	4 pm	FHIR and OMOP Data Model Harmonization Subgroup (Zoom)
Thursday	8 am	Psychiatry
Thursday	12 pm	Patient-Level Prediction/Population-Level Estimation (Western Hemi)
Thursday	12 pm	FHIR and OMOP Oncology Subgroup
Thursday	3 pm	FHIR and OMOP Terminologies Subgroup (Zoom)
Friday	10:30 am	Clinical Trials
Monday	10 am	GIS-Geographic Information System
Tuesday	9 am	OMOP CDM Oncology Genomic Subgroup

www.ohdsi.org/upcoming-working-group-calls



Get Access To Different Teams/WGs/Chapters

OHDSI
OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

Who We Are ▾ OHDSI Updates & News ▾ Standards Software Tools OHDSI Studies ▾ Book of OHDSI ▾ Resources ▾ New To OHDSI? ▾

EHDEN Academy ▾ This Week In OHDSI/Community Calls ▾ Events/Collaborations ▾ Workgroups ▾ How To Join MStTeams & Workgroups ▾

NEW: Our Journey – Where The OHDSI Community Has Been, And Where We Are Going 2022 Europe Letters ▾

Welcome to OHDSI

The Observational Health Data Sciences and Informatics (or OHDSI, pronounced "Odyssey") program is a multi-stakeholder, interdisciplinary collaborative to bring out the value of health data through large-scale analytics. All our solutions are open-source.

OHDSI has established an international network of researchers and observational health databases with a central coordinating center based at Columbia University.

2021 OHDSI Symposium

The 2021 OHDSI Global Symposium featured plenary presentations on OHDSI's Impact on the COVID-19 Pandemic, as well as on the Journey to Reliable Evidence. The main days included the State of the Community Presentation, the Collaborator Showcase, and a memorable Closing Ceremony that focused on OHDSI's work through the perspective of a patient.

There were also a pair of full-day activities, including the first OHDSI Reproducibility...

5. Select the workgroups you want to join (you can refer to the WIKI for work group objectives www.ohdsi.org/web/wiki/doku.php?id=projects:overview)

- ☐ ATLAS
- ☐ Clinical Trials
- ☐ Common Data Model
- ☐ Data Quality Dashboard Development
- ☐ Early-stage Researchers
- ☐ Education Work Group
- ☐ FHIR and OMOP
- ☐ Geographic Information System (GIS)
- ☐ HADES Health Analytics Data-to-Evidence Suite
- ☐ Healthcare Systems Interest Group (formerly EHR)
- ☐ Health Equity
- ☐ Latin America
- ☐ Medical Devices
- ☐ Medical Imaging
- ☐ Natural Language Processing
- ☐ OHDSI APAC
- ☐ OHDSI APAC Steering Committee
- ☐ OHDSI Steering Committee
- ☐ Oncology
- ☐ Open-source Community
- ☐ Phenotype Development and Evaluation
- ☐ Population-Level Effect Estimation / Patient-Level Prediction

- ☐ Psychiatry
- ☐ Registry (formerly UK Biobank)
- ☐ Surgery and Perioperative Medicine
- ☐ Vaccine Evidence
- ☐ Vaccine Vocabulary


6. Select the chapter(s) you want to join

- ☐ Africa
- ☐ Australia
- ☐ China
- ☐ Europe
- ☐ Japan
- ☐ Korea
- ☐ Singapore
- ☐ Taiwan

7. Select the studies you want to join

- ☐ HERA-Health Equity Research Assessment
- ☐ PIONEER for Prostate Cancer (study-a-thon ended)
- ☐ SCYLLA (SARS-Cov-2 Large-scale Longitudinal Analyses)

Get Access To Different Teams/WGs/Chapters



General Posts Files **Join Work groups, Chapters, and Studies** Meet

OHDSI MTeams Work groups, Chapters, and Studies Registration

OHDSI is using MTeams to further encourage active collaboration within the community. Within the OHDSI organization, there are separate teams for work groups, chapters, and studies, as well as OHDSI community activities (such as the OHDSI2020 Symposium). All teams are open to all collaborators. Below please indicate which Team you would like to join and the OHDSI coordinating center team will grant access.

* Required

1. First and Last Name *

Enter your answer

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New Workgroups Page on OHDSI.org



OHDSI Workgroups

OHDSI's central mission is to improve health by empowering a community to collaboratively generate the evidence that promotes better health decisions and better care. We work towards that goal in the areas of data standards, methodological research, open-source analytics development, and clinical applications.

Our workgroups present opportunities for all community members to find a home for their talents and passions, and make meaningful contributions. We are always looking for new collaborators. Learn more about these workgroups by checking out this page. Any workgroup that provided a community call update is highlighted in the top section.

See an area where you want to contribute? Please Join The Journey!

Join Our Workgroup Efforts!

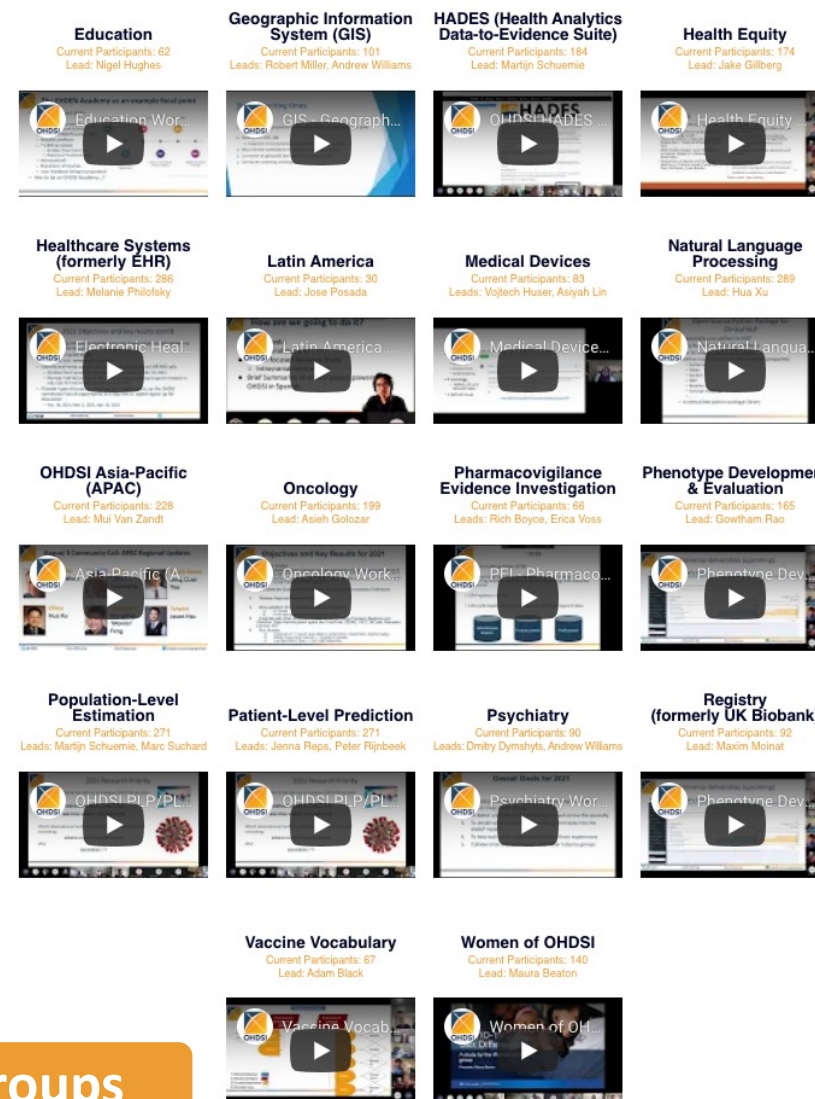
Form To Join Workgroups In MStems

Weekly Workgroup Meeting Schedule

Get To Know The OHDSI Workgroups



ohdsi.org/ohdsi-workgroups





Jan. 27 APAC Call: CDM Workshop

CDM



APAC Workshop
26 January 2022

— Jan. 27, 2022 - CDM Workshop

Jan. 27 APAC Community Call: CDM Workshop

[Workshop Q&A](#) | [Meeting Slides](#)

Video Presentation

OHDSI APAC Community Call 20220127

Interests & Questions

Category 1

1. What's the updates and challenges so far?
2. Tips for ETL conventions? Personal hints?
3. Where to start learning about ETL?
4. What kind of level of statistical or program skills requirement for CDM?

Watch on YouTube

Watch later Share

4

1. What's the updates and challenges so far?
 - a. We recently released CDM v5.4 (<http://ohdsi.github.io/CommonDataModel/cdm54.html>). So far there have been many challenges but the main one we have been struggling with is how fast to update the CDM. We want to be responsive to the needs of the community but with an understanding that any change we make to the model has huge impacts down the line.
2. Tips for ETL conventions? Personal hints?
 - a. Keep it as simple as possible at first. Many people want to use complex logic to make their data fit the model but I have found that the simplest approach is usually best because it makes it easier to error check later.
3. Where to start learning about ETL?
 - a. The EHDEN academy is a great place to start! <https://academy.ehden.eu/>
4. What kind of level of statistical or program skills requirement for CDM?
 - a. This one depends on what you are planning to do. If you are responsible for developing the ETL you need strong SQL skills or a good understanding of the database management system you will be using for the conversion. If you are the one designing the ETL then only some SQL skills will be enough. If you plan on designing studies using existing R packages then strong R skills are required. However, if you plan on only running studies or packages then you only need some R skills, you don't need to be an expert.
5. Is there any best practices for CDM mapping for pediatric survey questions?
 - a. I am not sure about pediatric surveys but, in general, I usually use the OBSERVATION table for survey questions. You can set the

ohdsi.org/apac



New Dates For The 2022 European Symposium



 **EUROPEAN OHDSI SYMPOSIUM**
Symposium: June 24th
Workshops: 25-26th

“All aboard!”
New Date!!

We'll meet again for
one journey ahead

Organised by:

Erasmus MC
University Medical Center Rotterdam

Health
Data
Science

www.ohdsi-europe.org/symposium-2022



#OHDSISocialShowcase This Week



Securing OHDSI on AWS for HIPAA and Research Data Management Compliance

Michael Lubke¹, Tapati Mazumdar¹, Murat Sincan, M.D.^{1*}, Catherine Hajek, M.D.^{1*}

¹. Sanford Imaginetics, Sioux Falls, South Dakota

*. Equally Contributed

Abstract

Requirements for HIPAA and research protocol compliance should be at the core of a healthcare organization's implementation practices when storing and analyzing healthcare data in the cloud. Every utilized service must be thoroughly vetted to ensure security best practices and data access permissions are being established properly. This process results in a secure environment where organizations can embrace utilizing the cloud for performing analysis on observational health data.

Background

With cloud services and cloud storage adoption becoming more widespread in the healthcare industry, the need for securing these environments and the health data within is of utmost importance. The OHDSI on AWS project provides an enterprise-level solution for enabling advanced analytics and outcome prediction on this observational health data with the ultimate goal of improving population and individual health. With this project comes the need for developing customized cloud solutions to process various research study data files, and for that reason it is important that every step of the data processing conforms to HIPAA requirements as well as the data management policies outlined in each research study protocol. Enforcing strict security measures in the cloud environment is not only performed to mitigate the financial risks associated with noncompliance, but it is also done to implement additional layers of security with the purpose of preventing the patient health data from being compromised in a data breach.

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Methods

The default OHDSI on AWS environment was analyzed and the following were identified as areas needing additional security:

- Restrict access to OHDSI instance to the Sanford trusted network
- Ensure all health data is encrypted at rest and in-transit
- Restrict access to study data to applicable persons and systems outlined in research data management plan

A site-to-site VPN solution was implemented that creates a tunnel between the on-premises trusted network at Sanford Health and the Virtual Private Cloud (VPC) on AWS. This combined with leveraging the AWS Certificate Manager to handle the generation and application of SSL certificates on the OHDSI on AWS environment enforce HIPAA compliance requirements by ensuring that the communication between all system components within the VPC are encrypted in-transit.

Data access policies were configured for each AWS S3 bucket restricting accessing the data to individual members of each research study. Furthermore, in order to meet HIPAA requirements, all S3 buckets are encrypted at-rest. Policies were created for AWS System Roles that allow the components of the custom OMOP CDM ETL pipeline to decrypt the contents of the S3 buckets. The transformed research data is then inserted directly into the corresponding study schema on Amazon Redshift via a JDBC connection, which ensures that the data is once again encrypted in-transit.

Results

Figure 1 illustrates the site-to-site VPN solution that was established between the AWS VPC and a routing device at the Sanford data center. This configuration resulted in the default public-facing applications in the OHDSI on AWS environment stack (Atlas, RStudio, Jupyter) being accessible via the Sanford trusted network only.

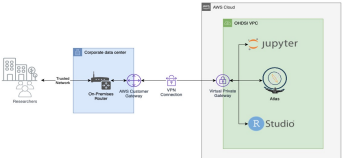


Figure 1: Site-to-Site VPN

Results

Figure 2 shows the final state of the ETL pipeline after establishing data access permissions per HIPAA and data management policy requirements. The steps are summarized as follows:

- The research study honest broker uploads de-identified study data into an access-managed AWS S3 bucket, accessible only to those listed in the study's data management policy.
- New data event triggers the lambda function, which first decrypts the contents of the bucket, then stores the resulting processed data into a subsequent encrypted access-managed S3 bucket.
- AWS Glue Crawler automatically decrypts the processed data files and stores the contents in an AWS Glue Data Catalog
- AWS Glue ETL scripts conform the data into the OMOP CDM and insert the records directly into the corresponding study's schema in Amazon Redshift via an encrypted JDBC connection.

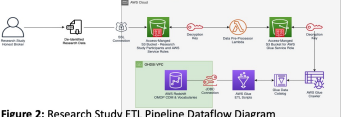


Figure 2: Research Study ETL Pipeline Dataflow Diagram

Conclusions

It is imperative that every interaction with patient health data hosted in a cloud environment is thoroughly analyzed to ensure that HIPAA and research study compliance requirements are met. Each component added to the cloud environment must be carefully implemented to ensure that the health data is secured regardless of where it exists. This process can be daunting to undertake when an entire data processing pipeline has already been established without initially giving any thought to access controls and encryption practices. For that reason, employing best practices in accordance with HIPAA and data management compliance requirements at the onset of development can provide a safeguard for the cloud environment as well as the data stored within.

References:

1. AWS Site-to-Site User Guide [Internet]. Amazon Web Services; 2011 Sep 29 [updated 2020 Oct 29; cited 2021 Jun 16]. Available from: <https://docs.aws.amazon.com/site-to-site/latest/vpc-vpn/vpn.html>
2. Architecting for HIPAA Security and Compliance on Amazon Web Services: AWS Whitepaper [Internet]. Amazon Web Services; 2016 Oct [updated 2020 Oct 29; cited 2021 Jun 16]. Available from: https://d1.awsstatic.com/whitepapers/compliance/AWS_HIPAA_Compliance_Whitepaper.pdf
3. Guidance on HIPAA & Cloud Computing [Internet]. U.S. Department of Health and Human Services [Updated 2020 Nov 24; cited 2021 Jun 16]. Available from: <https://www.hhs.gov/hipaa/for-professionals/special-topics/health-information-technology/cloud-computing/index.html>

Securing OHDSI on AWS for HIPAA and Research Data Management Compliance

MONDAY

Author: Michael Lubke, Tapati Mazumdar, Murat Sincan, Catherine Hajek



#OHDSISocialShowcase This Week

Identification of treatment intent from the actual time-to-treatment distribution in prostate cancer patients

PRESENTER: Asieh Golozar

PROBLEM

- Conservative management aims to reduce over-treatment of patients with prostate cancer.
- At time of diagnosis a decision must be made: conservative management or immediate treatment.
- It is an important task of clinical research to inform this decision.
- Observational research could provide such research.
- Unfortunately, the decision is rarely captured in observational data.
- It might be feasible to infer what the decision might have been by checking whether or not there was immediate treatment.
- However, there is no obvious or generally accepted cut-off time after which a treatment can be designated "deferred".
- A data driven approach might help distinguish between patients with the two choice.

OBJECTIVE

- To empirically identify the two distinct populations immediate from deferred from the data, and to determine the optimal cut-off, minimizing misclassification of the patients and potential selection bias.

METHODS

Data

- IQVIA Ambulatory EHR (EHR)
- IQVIA Hospital Charge Data Master (charge data)
- IQVIA Oncology EHR (EHR)
- IQVIA Open Claims (unadjudicated claims)
- IQVIA PharMetrics Plus (adjudicated claims)

Schematic Study Design



- Fitting time to treatment initiation data to finite mixture models via EM
- Bayesian information criterion (BIC) to select the best model
- Maximum likelihood estimation (MLE) used to estimate parameters of the selected distribution

Inclusion criteria:

- >18 years old
- Male
- No history of PCa or PCa-related condition one year prior
- Prostate biopsy +/- 30 days of the first PCa diagnosis
- No ADT or other hormone therapies one year prior

Table 1. Median days (IQR) Time to treatment initiation and follow-up in the participating databases.

Participating Databases	N	Time to Treatment Initiation	Follow-up time
IQVIA Ambulatory EHR	9791	31 (10, 33)	980 (951, 1000)
IQVIA Hospital Charge	1676	73 (71, 75)	793 (772, 773)
IQVIA Oncology EHR	219	14 (10, 18)	308 (291, 457)
IQVIA Open Claims	632285	55 (55, 55)	1889 (1885, 1894)
IQVIA PharMetrics Plus	110317	61 (60, 63)	950 (944, 955)

Identification of treatment intent from observational data is context-dependent and challenging. Potential for substantial degree of patient misclassification



Take a picture to download the full paper

RESULTS

- 912,789 newly diagnosed prostate cancer patients across a network of claims and EHR data were included in the study (Table 1)
- A bimodal two-parameter Weibull distribution fitted the data better than a unimodal one (Figure 2)
- The distribution of the two populations shows substantial overlap across the participating databases (Figure 2)

Figure 1. Fitted unimodal (green) and bimodal (blue) Weibull distributions together with the observed data red.

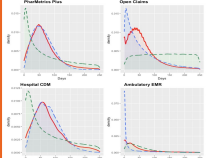
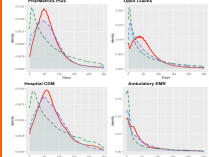


Figure 2. Empirical depiction of the two patient populations. Green and blue density plots represent the two distinct putative patient populations.



- Prostate cancer patients seem to be composed of two populations with different time to treatment characteristics, as expected from the treatment guidelines.
- The parameters of the optimal fitted models are in line with expectations:
 - 49-76 days for the putative "immediate" group
 - 295-1067 days for the "deferred" group,
 - a proportion with a dominant "immediate" group in the claims versus a 50/50 distribution in the ambulatory setting.

Table 2. EM estimated parameters for the TTT distribution.

		Component 1	Component 2
PharMetrics Plus	Proportions	0.8	0.2
	Mean	63	30
	Shape	1.9	0.6
Open Claims	Proportions	0.9	0.1
	Mean	68	1068
	Shape	0.9	1.1
Ambulatory EHR	Proportions	0.5	0.5
	Mean	1025	49
	Shape	0.2	1.9
Hospital Charge	Proportions	0.7	0.3
	Mean	77	316
	Shape	1.9	0.6

Asieh Golozar, Christian Reich

Regeneron Pharmaceuticals, NY USA, Paul
World Solutions IQVIA



TUESDAY

Identification of treatment intent from the actual time-to-treatment distribution in prostate cancer patients
Authors: Asieh Golozar, Christian Reich



#OHDSISocialShowcase This Week



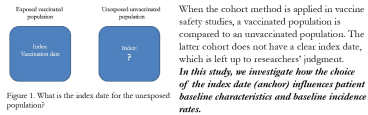
The concept of anchoring in vaccine safety studies and its influence on baseline patient characteristics and study estimates

Anna Ostropolets¹, Xintong Li², Rupa Makadia³, Gowtham Rao³, Peter R. Rijnbeek⁴, Talita Duarte-Salles⁵, Anthony G. Sena^{3,4}, Azza Shaoibi², Marc A. Suchard^{6,7}, Patrick B. Ryan^{1,3}, Daniel Prieto-Alhambra², George Hripcsak^{1,8}



Background

The cohort method is one of the most common methods in comparative effectiveness and safety studies. In a cohort study, we compare rates of events during time-at-risk in target and comparator groups. Such rates are, therefore, dependent on the choice of starting point for time-at-risk on, as we call it, anchoring. Choice of anchoring may influence both the rates of observed outcomes and baseline patient characteristics, which are subsequently used in propensity score models or outcome models.



Methods

We investigated the influence of anchoring unvaccinated population on incidence rates of 15 adverse events occurring during different time-at-risk windows (A). Additionally, we investigated its impact on baseline patient characteristics in unvaccinated and vaccinated populations (B).

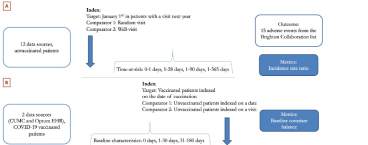


Figure 2. Two study designs used in this study. A – Background incidence rate evaluation and B – baseline characteristics assessment.

For the first study, we modified the study design described in the paper by Li et al. (2021). Briefly, we used 12 data sources to study incidence rates of 15 adverse events of special interest in unvaccinated population in 2017–2020 in a number of time-at-risk intervals. We calculated incidence rate ratios (IRR) of incidence rates in two pairs of cohorts with different index dates (“anchors”): a visit and a well visit, defined as a visit associated with preventive visit CPT4 codes. In the second study, we compared baseline characteristics of patients vaccinated with COVID-19 and unvaccinated patients in CUMC and Optum EHR. The latter were anchored on a) a date matched to the index date of one of the target group, b) a visit matched to the index date of one of the target group. Additionally, each target and comparator groups were matched on age and sex.

Results

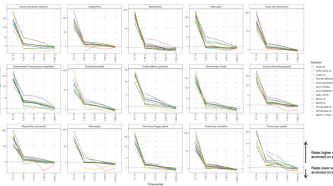


Figure 3. Incidence rate ratio of outcomes when entering the cohort on a random visit versus entering on January 1st in patients with a visit in the next year, time-at-risk 0-1 day, 1-28 days, 1-42 days, 1-90 days and 1-365 days.

Influence of anchoring on baseline characteristics

When looking at the baseline characteristics, unvaccinated population had more events (measurements, conditions, procedures, observations) on day 0 than vaccinated population regardless of the anchoring event (Figure 4). Similarly, the effect attenuated with increased lookback window but was still present. Vaccinated patients had fewer lab tests (such as body weight, blood pressure or respiratory rate), co-morbidities (diabetes, hyperlipidemia, dyspnea etc) and visits on day 0 when compared to a random date or a random visit in unvaccinated population. In patients vaccinated with an influenza vaccine (not shown here) compared to patients not vaccinated with influenza vaccine the opposite trend was observed: the former had more lab tests and co-morbidities on day 0 than unvaccinated patients.

Influence of anchoring on the background incidence rates

Incidence rates of all adverse events across all data sources and all conditions were highly sensitive to the choice of anchoring. For a short time-at-risk (0-1 day) anchoring on a visit was associated with up to a 100-fold increase in incidence when compared to anchoring on January 1st (pooled IRR 26.8 (95% CI 21.9-32.8)). Acute conditions such as amphetamine were impacted the most (pooled IRR 47.4 (95% CI 32.8-69.1)). The effect was attenuated for longer times at risk (Figure 3) but was still present. For example, for 1-28 days window, pooled IRR was 1.4 (95% CI 1.3-1.5). We observed similar trends for anchoring on a well visit with the pooled IRR of 1.21 (95% CI 1.11-1.31). Overall, anchoring on a well visit was associated with higher incidence rates with several conditions (such as Bell's palsy or narcolepsy) being highly sensitive.

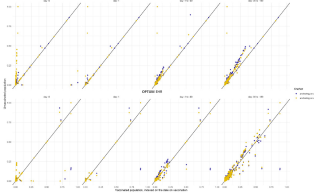


Figure 4. Comparison of baseline characteristics in unvaccinated versus COVID-19 vaccinated patients in CUMC and Optum EHR. Each dot represents one covariate, blue – unvaccinated patients anchored on a date, yellow – unvaccinated patients anchored on a visit.

Conclusions

1. Anchoring influences both baseline patient characteristics and incidence rates of conditions observed after the index date.
2. It is crucial to select an anchoring that represents the target index date best based on the knowledge of the target (e.g. vaccination settings) or empirical comparison of multiple options.
3. Balance on visit on day 0 should be assessed in any cohort study.

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The concept of anchoring in observational study design and its influence

Authors: Anna Ostropolets, Talita Duarte-Salles, Xintong Li, Rupa Makadia, Daniel Prieto-Alhambra, Gowtham Rao, Peter R. Rijnbeek, Martijn Schuemie, Anthony G. Sena, Azza Shaoibi, Marc A. Suchard, Patrick B. Ryan, George Hripcsak

WEDNESDAY



#OHDSISocialShowcase This Week



Summarising current evidence for the PIONEER study-a-thon: Systematic Literature Review of prostate cancer patients managed with watchful waiting

Authors: Peter-Paul Willemse, Katharina Beyer, Muhammed Imran Omar, Ronald Herrera, Megan Molnar, Isabella Greco, Riccardo Campi, Samuel Fatoba, Bertrand De Meulder; Susan Evans, Nazanin Zounemat Kermani, Sebastiaan Remmers, Christian Reich, Shilpa Ratwani, Asieh Golozar, Robert Snijder, Mauro Gacci, Ariel Achtman, Nigel Hughes, Peter Rijnbeek, Emma Smith; Carl Steinbeirer, Mieke Van Hemelrijck; Anders Bjartell, James N'dow, Alex Asiimwe, Monique Roobol, Giorgio Gandaglia

Introduction

- Prostate cancer (PCa) affects more than 2 million men in Europe.
- Clinical management of PCa is challenging and involves difficult trade-offs, especially when one should consider not to treat the disease.
- 'Watchful Waiting' (WW) is recommended when local treatment of prostate cancer would not increase the survival of the patient, with the aim of avoiding treatment-related side effects and is a management option for men with low-risk PCa who have a limited life expectancy and for whom curative treatment at the time of progression is not deemed to be beneficial.
- The need for long term outcomes in patients managed with WW makes this topic a good subject for the new Real World Evidence approaches pioneered by OHDSI and EHDSN.
- We therefore conducted a study-a-thon to look at the long term outcomes of prostate cancer managed with WW.
- A study-a-thon is a focused event in which a large-scale study, which traditionally takes many months to complete, is executed and completed in a few days.
- Here, we report on the systematic literature review which was needed to guide the study-a-thon.

Methods

- We conducted a systematic review of all literature published between 1980 and 2021 reporting on adult men (>18 years of age) who were managed with WW to provide the evidence for the study-a-thon question: "What are the long term outcomes of prostate cancer patients undergoing non-interventive management (i.e. WW) and what is the impact of comorbidities and life expectancy?"
- We searched for RCT's, non-randomized comparative studies and case cohort studies. All type of reviews were scrutinised for potential papers on WW.
- We extracted: author, year, title, link, country, data source, study design, sample size, target cohort definition, intervention, outcomes, aims and gaps in the literature to ultimately guide the study-a-thon.

Results

- We systematically reviewed 14,996 articles during the months before the study-a-thon.
- After abstract and full text screening, 47 articles were included (see Figure 1).

Results (continued)

- 12 papers reported clinical trials.
- The age range of included patients was 40-88 years, most of the studies used <75 years as the cut off age.
- Research gaps in the literature were identified e.g. cost effectiveness, better description of the differences in the sup-groups characteristics, better understanding of patient experience on WW, longer follow up.
- The main limitations in the studies identified were small sample sizes and under use of terminology (Active Surveillance vs Watchful Waiting).
- As part of the preparation for the study-a-thon, our multidisciplinary group (urologists, patients, epidemiologists and data scientists) translated the identified evidence into data requirements to develop the patient cohorts.

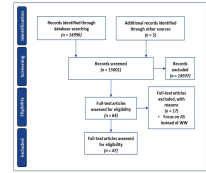
Conclusion

- A systematic review is the key to gather all known available information before starting a study-a-thon.
- The presented work supported research groups in the process of developing a protocol for this study-a-thon.
- A systematic review is key to collect data on information gaps in the available evidence for prostate cancer management.
- The systematic review outcomes can be used to develop cohort definitions, a selection can be used for study-a-thon outcomes and sets a standard for a multidisciplinary group to communicate in 'one language'.
- The outcomes of the systematic review enables the use of different skill sets in which Real World Evidence projects lead to meaningful conclusions.

Background


PIONEER's goal is to ensure the optimal care for all European men diagnosed with PCa by unlocking the potential of big data.

The goal of EHDSN is to make the large-scale analysis of health data in Europe a reality. The project aims to do this by building a federated data network of allowing access to the data of 100 million EU citizens standardised to a common data model.



Study-a-thon overview

- 4 data sources
- 400 participants
- 27 practitioners
- 20 countries
- 3 time zones
- 3 patient cohorts
- 40 practitioners
- 27 practitioners
- 20 countries
- 3 time zones
- 4 packages built
- 4 federated analysis tools
- 3 time zones available
- 2 months of preparation



PIONEER is funded through the IMI2 Joint Undertaking and is listed under grant agreement No. 777492. EHDSN is funded through the IMI2 Joint Undertaking and is listed under grant agreement No. 806968. The IMI2 receives support from the European Union's Horizon 2020 research and innovation programme and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

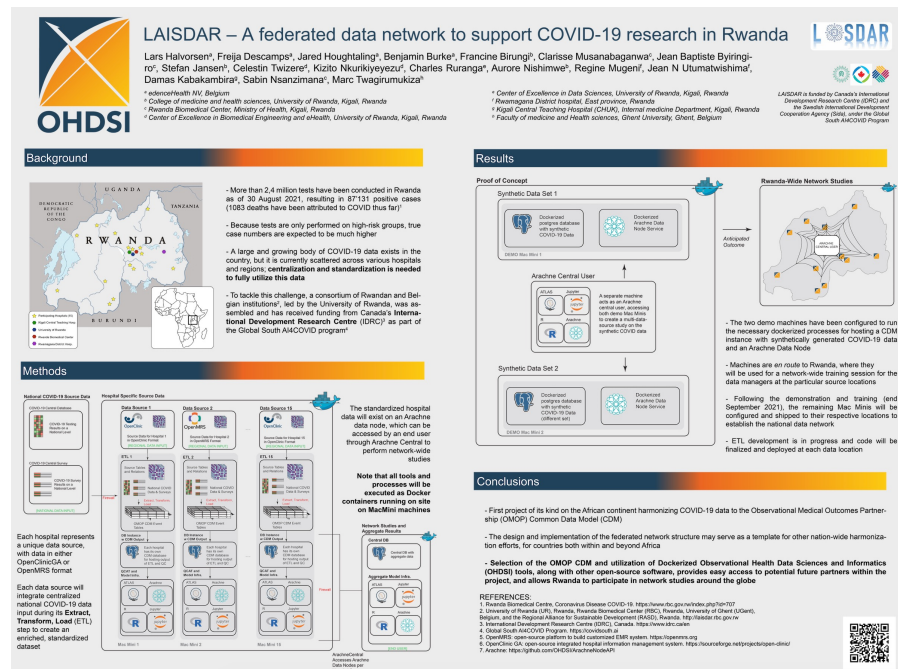
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THURSDAY



#OHDSISocialShowcase This Week



FRIDAY

LAISDAR - A federated data network to support COVID-19 research in Rwanda
Authors: Lars Halvorsen, Freija Descamps, Jared Houghtaling, Benjamin Burke, Francine Birungi, Clarisse Musanabaganwa, Jean Baptiste Byiringiro, Stefan Jansen, Celestin Twizere, Kizito Nkurikiyeyezu, Charles Ruranga, Aurore Nishimwe, Regina Mugeni, Jean N Utumatwishima, Damas Kabakambira, Sabin Nsanzimana, Marc Twagirimukiza



Where Are We Going?

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





Welcome To OHDSI Newcomers

Are there any people new to the OHDSI community call who would like to introduce themselves?

**Please raise your hand,
and we will call on three people.**



Three Stages of The Journey

Where Have We Been?

Where Are We Now?

Where Are We Going?

