Open Science for Observational Research: Lessons from the OHDSI Collaborative

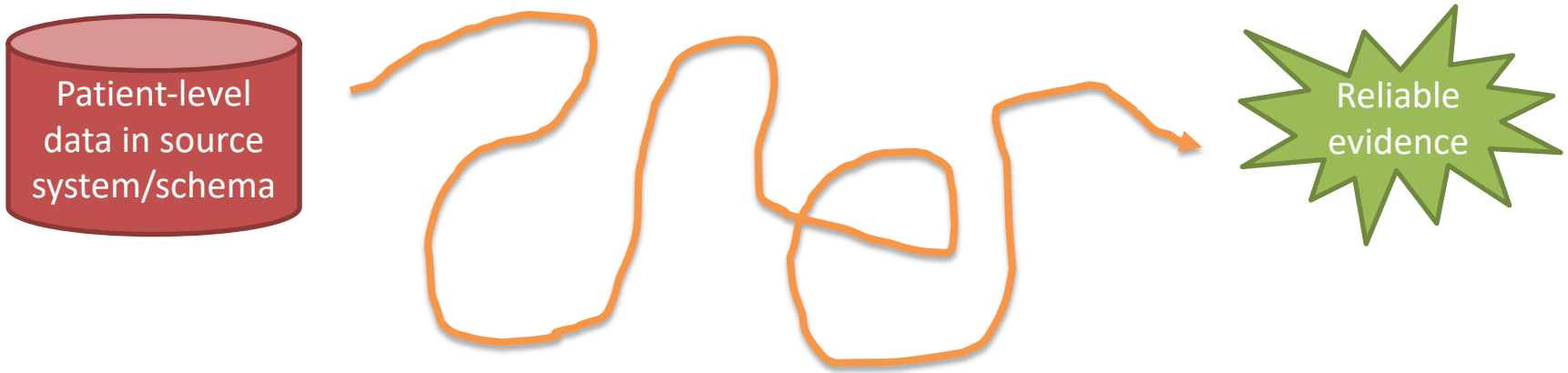
Patrick Ryan, PhD

Vice President, Observational Health Data Analytics, Janssen Research and Development

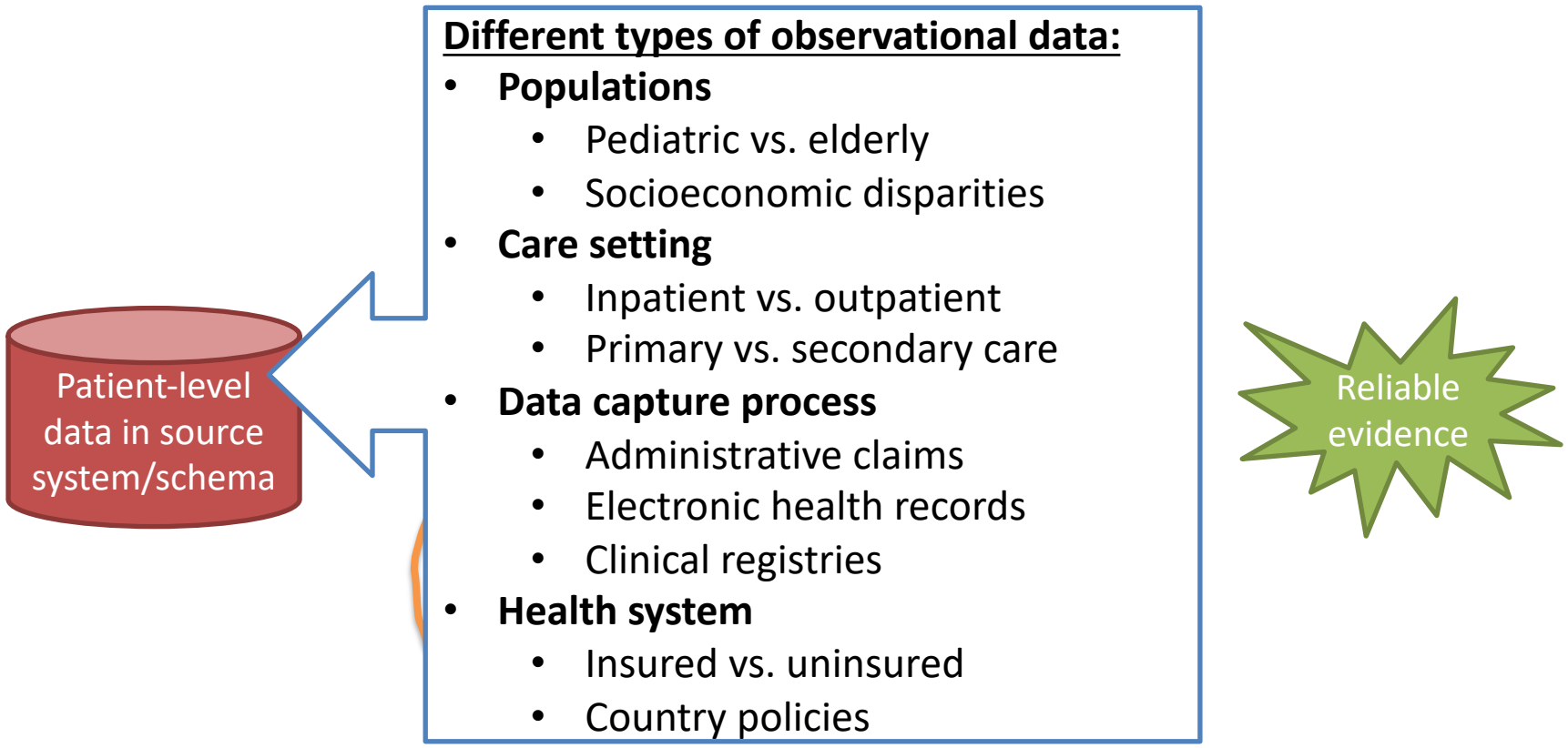
Assistant Professor, Adjunct, Department of Biomedical Informatics, Columbia University Medical Center

on behalf of the OHDSI community

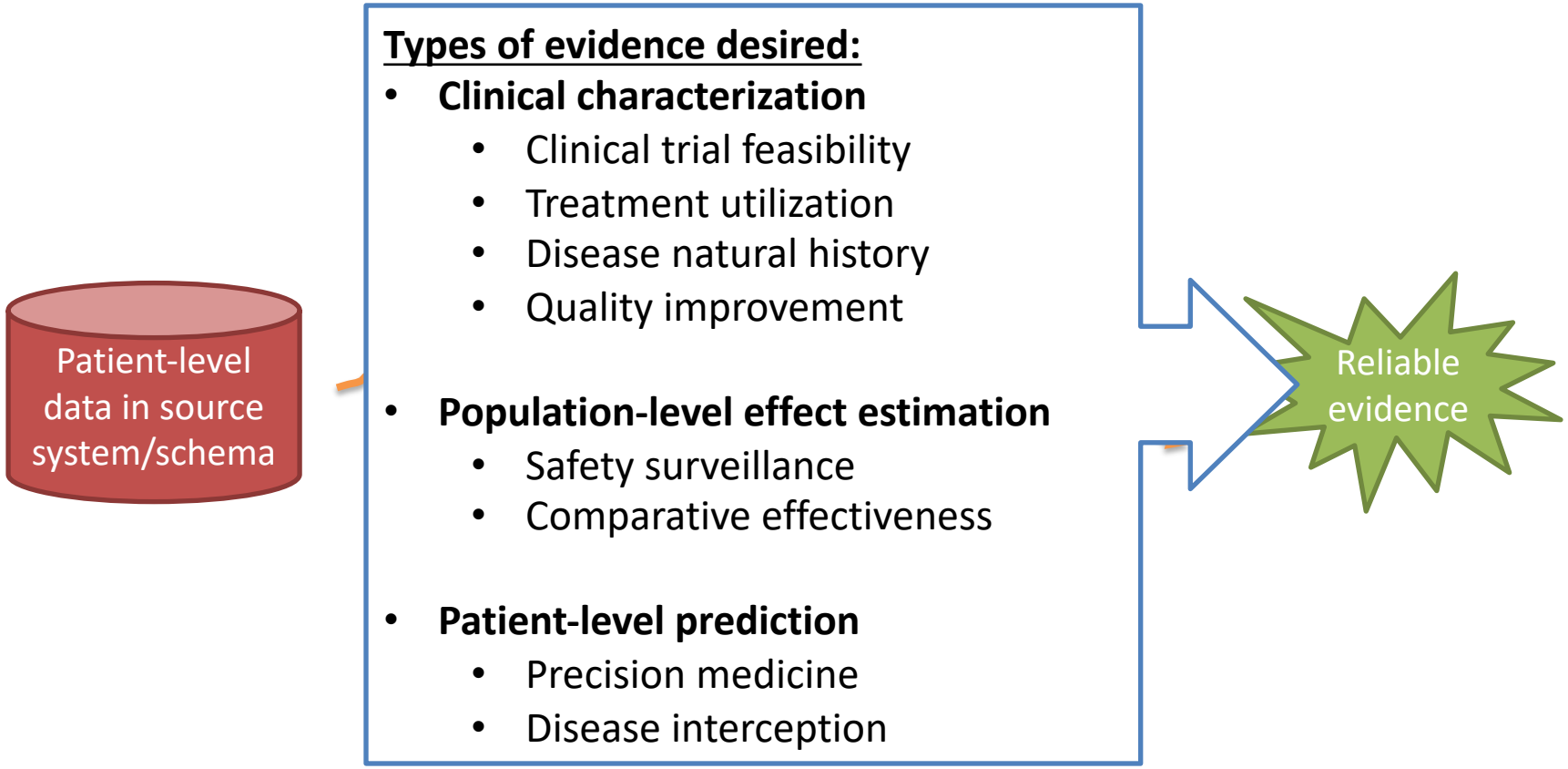
The journey to real-world evidence



The journey to real-world evidence



The journey to real-world evidence



Desired attributes for reliable evidence

Desired attribute	Question	Researcher	Data	Analysis		Result
Repeatable	Identical	Identical	Identical	Identical	=	Identical
Reproducible	Identical	Different	Identical	Identical	=	Identical
Replicable	Identical	Same or different	Similar	Identical	=	Similar
Generalizable	Identical	Same or different	Different	Identical	=	Similar
Robust	Identical	Same or different	Same or different	Different	=	Similar
Calibrated	Similar (controls)	Identical	Identical	Identical	=	Statistically consistent

OHDSI's mission

To improve health by empowering a community to collaboratively generate the evidence that promotes better health decisions and better care

OHDSI community

We're all in this journey together…

OHDSI's community engagement

- Active community online discussion: forums.ohdsi.org
  - **>2,770** distinct users have made **>18,700** posts on **>3,250** topics
  - Implementers, Developers, Researchers, CDM Builders, Vocabulary users, OHDSI in Korea, OHDSI in China, OHDSI in Europe
- Weekly community web conferences for all collaborators to share their research ideas and progress
- >25 workgroups for solving shared problems of interest
  - ex: Common Data Model, Population-level Estimation, Patient-level Prediction, Phenotype, NLP, GIS, Oncology, Women of OHDSI
- Quarterly tutorials in OHDSI tools and best practices, taught by OHDSI collaborators for OHDSI collaborators
- OHDSI Symposiums held annually in North America, Europe and Asia to provide the community face-to-face opportunities to showcase research collaborations
- Follow us on Twitter @OHDSI and LinkedIn

OHDSI is

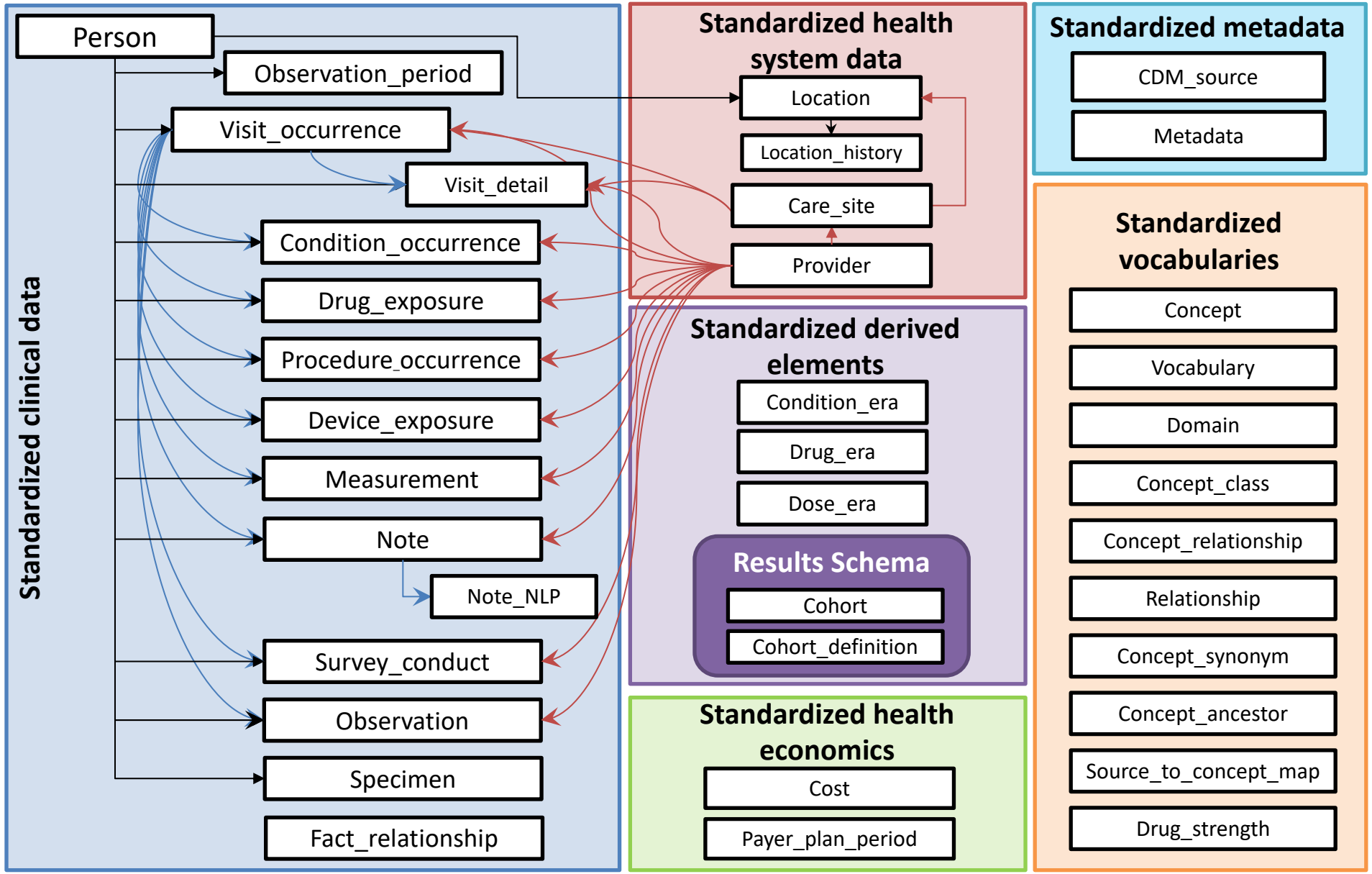
an international data network

Data across the OHDSI community

- 152 entries on 2019 OHDSI data network inventory
- 133 different databases with patient-level data from various perspectives:
  - Electronic health records, administrative claims, hospital systems, clinical registries, health surveys, biobanks
- Data in 18 different countries, with >369 million patient records from outside US

All using one open community data standard:
OMOP Common Data Model

Open community data standard: OMOP CDM v6



OHDSI's standardized vocabularies

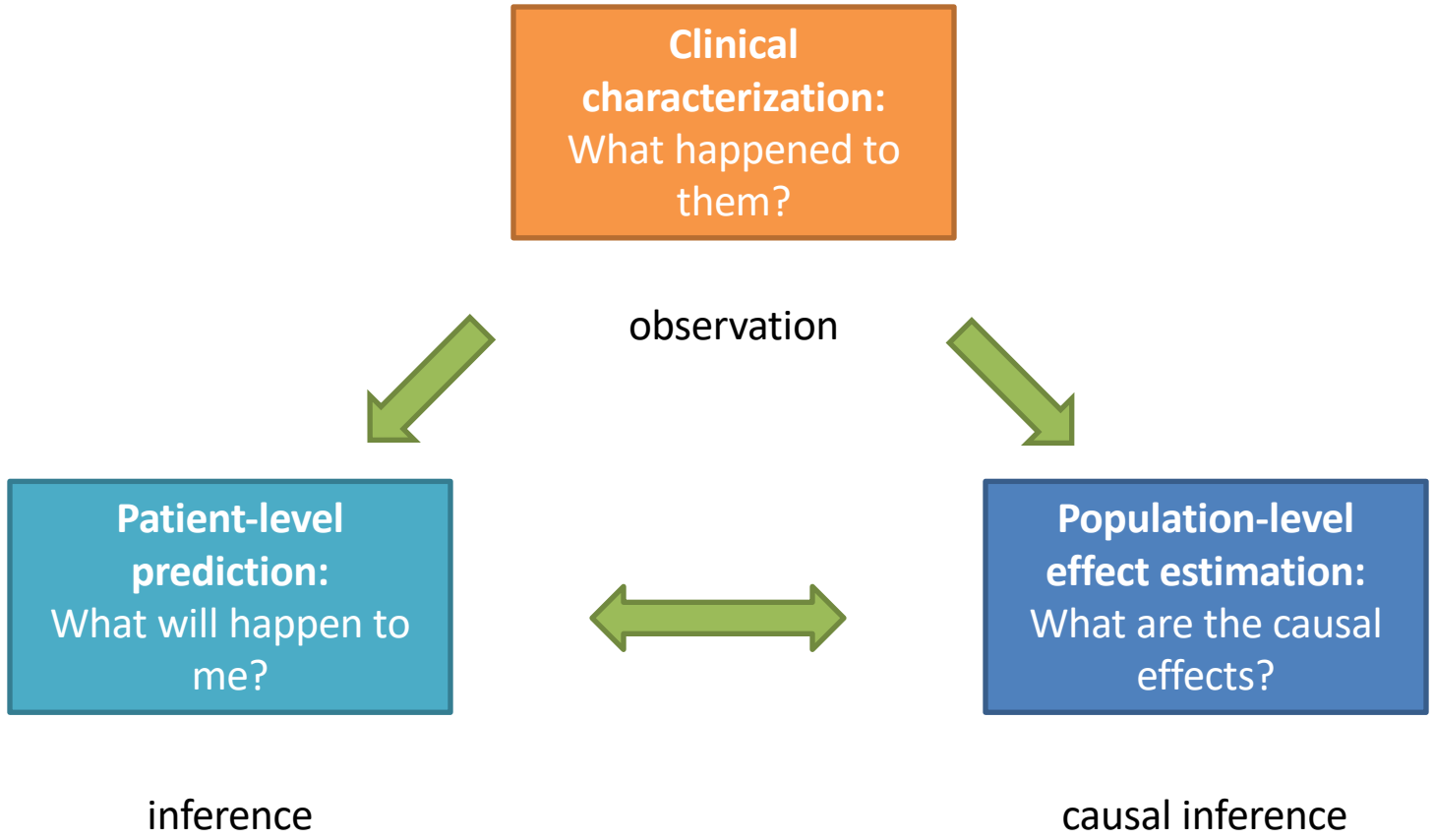
- >130 Vocabularies across 40 domains
  - MU3 standards: SNOMED, RxNorm, LOINC
  - Disparate sources: ICD9CM, ICD10(CM), Read, NDC, Gemscript, CPT4, HCPCS…
- >7.4 million concepts
  - >3.0 million standard concepts
  - >3.8 million source codes
  - >511,000 classification concepts
- >45 million concept relationships
- >74 million ancestral relationships

OHDSI is advancing science

What is OHDSI's strategy to deliver reliable evidence?

- **Methodological research**
  - Develop new approaches to observational data analysis
  - Evaluate the performance of new and existing methods
  - Establish empirically-based scientific best practices
- **Open-source analytics development**
  - Design tools for data transformation and standardization
  - Implement statistical methods for large-scale analytics
  - Build interactive visualization for evidence exploration
- **Clinical evidence generation**
  - Identify clinically-relevant questions that require real-world evidence
  - Execute research studies by applying scientific best practices through open-source tools across the OHDSI international data network
  - Promote open-science strategies for transparent study design and evidence dissemination

Complementary evidence to inform the patient journey



Analytic use case	Type	Structure
Clinical characterization	**Disease Natural History**	Amongst patients who are diagnosed with **<insert your favorite disease>**, what are the patient's characteristics from their medical history?
	Treatment utilization	Amongst patients who have **<insert your favorite disease>**, which treatments were patients exposed to amongst **<list of treatments for disease>** and in which sequence?
	Outcome incidence	Amongst patients who are new users of **<insert your favorite drug>,** how many patients experienced **<insert your favorite known adverse event from the drug profile>** within **<time horizon following exposure start>**?
Population-level effect estimation	**Safety surveillance**	Does exposure to **<insert your favorite drug>** increase the risk of experiencing **<insert an adverse event>** within **<time horizon following exposure start>**?
	Comparative effectiveness	Does exposure to **<insert your favorite drug>** have a different risk of experiencing **<insert any outcome (safety or benefit) >** within **<time horizon following exposure start>**, relative to **<insert your comparator treatment>**?
Patient level prediction	**Disease onset and progression**	Amongst patients who are diagnosed with **<insert your favorite disease>**, which patients will go on to have **<another disease or related complication>** within **<time horizon from diagnosis>**?
	Treatment response	Amongst patients who are new users of **<insert your favorite chronically-used drug>**, which patients will **<insert desired effect>** in **<time window>**?
	Treatment safety	Amongst patients who are new users of **<insert your favorite drug>,** which patients will experience **<insert your favorite known adverse event from the drug profile>** within **<time horizon following exposure start>**?

OHDSI is
a community

Case Western Reserve University : OHDSI face-to-face documentation-a-thon

OHDSI China Symposium 2019

The Journey From Data to Evidence OHDSI Europe 2019

- A platform to stimulate community building: 250 participants from **27** countries
- OHDSI Europe in action: 35 posters, 8 software demos
- Educate and train the community: 5 full day tutorials

www.ohdsi-europe.org

Fudan University – OHDSI tutorials

OHDSI Korea – Study design datathon

OHDSI

OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

2019 OHDSI Symposium

Sept. 15-17, 2019

Bethesda North Marriott Hotel and Conference Center

OHDSI Korea

OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

OHDSI Korea Symposium

KONJIAM Resort, Gwangju, Gyeonggi-Do, Republic of Korea

Building the LHC of observational data science?

ICMJE guidelines

The ICMJE recommends that authorship be based on the following 4 criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

OHDSI in action

MEDINFO 2015: eHealth-enabled Health
I.N. Sarkar et al. (Eds.)

doi:10.3233/978-1-61499-564-7-574

Observational Health Data Sciences and Informatics (OHDSI): Opportunities for Observational Researchers

George Hripcsak[a], Jon D. Duke[b], Nigam H. Shah[c], Christian G. Reich[d], Vojtech Huser[e], Martijn J. Schuemie[f,g], Marc A. Suchard[h], Rae Woong Park[i], Ian Chi Kei Wong[f], Peter R. Rijnbeek[j], Johan van der Lei[j], Nicole Pratt[k], G. Niklas Norén[l], Yu-Chuan Li[m], Paul E. Stang[g], David Madigan[n], Patrick B. Ryan[g]

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2015:
17 authors
1 promise

OHDSI in action: Treatment Pathways

PNAS

COLLOQUIUM PAPER

Characterizing treatment pathways at scale using the OHDSI network

George Hripcsak[a,b,c,1], Patrick B. Ryan[c,d], Jon D. Duke[c,e], Nigam H. Shah[c,f], Rae Woong Park[c,g], Vojtech Huser[c,h], Marc A. Suchard[c,i,j,k], Martijn J. Schuemie[c,d], Frank J. DeFalco[c,d], Adler Perotte[a,c], Juan M. Banda[c,f], Christian G. Reich[c,l], Lisa M. Schilling[c,m], Michael E. Matheny[c,n,o], Daniella Meeker[c,p,q], Nicole Pratt[c,r], and David Madigan[c,s]

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Edited by Richard M. Shiffrin, Indiana University, Bloomington, IN, and approved April 5, 2016 (received for review June 14, 2015)

2016:
17 authors
11 data sources

OHDSI in action: Safety surveillance

BRIEF COMMUNICATION

Risk of angioedema associated with levetiracetam compared with phenytoin: Findings of the observational health data sciences and informatics research network

*†Jon D. Duke, *‡§Patrick B. Ryan, *¶Marc A. Suchard, *§George Hripcsak, *§Peng Jin, *#Christian Reich, *#Marie-Sophie Schwalm, ***††Yuriy Khoma, *‡‡Yonghui Wu, *‡‡Hua Xu, *§§Nigam H. Shah, *§§Juan M. Banda, and *‡Martijn J. Schuemie

Epilepsia, 58(8):e101–e106, 2017
doi: 10.1111/epi.13828

Dr. Jon Duke is Director of the Center for Health Analytics and Informatics at the Georgia Tech Research Institute.

SUMMARY

Recent adverse event reports have raised the question of increased angioedema risk associated with exposure to levetiracetam. To help address this question, the Observational Health Data Sciences and Informatics research network conducted a retrospective observational new-user cohort study of seizure patients exposed to levetiracetam (n = 276,665) across 10 databases. With phenytoin users (n = 74,682) a comparator group, propensity score-matching was conducted and hazard rati computed for angioedema events by per-protocol and intent-to-treat analyse Angioedema events were rare in both the levetiracetam and phenytoin groups (54 v 71 in per-protocol and 248 vs. 435 in intent-to-treat). No significant increase in angio dema risk with levetiracetam was seen in any individual database (hazard ratios ran ing from 0.43 to 1.31). Meta-analysis showed a summary hazard ratio of 0.72 (95 confidence interval [CI] 0.39–1.31) and 0.64 (95% CI 0.52–0.79) for the per-protoc and intent-to-treat analyses, respectively. The results suggest that levetiracetam h the same or lower risk for angioedema than phenytoin, which does not currently car a labeled warning for angioedema. Further studies are warranted to evaluate angio dema risk across all antiepileptic drugs.

KEY WORDS: Angioedema, Levetiracetam, Anticonvulsant hypersensitivity syndrome, Pharmacovigilance, Observational research, Adverse drug reactions.

2017:
13 authors
10 data sources

OHDSI in action: Comparative effectiveness

JAMA Network Open

Original Investigation | Diabetes and Endocrinology

Association of Hemoglobin A_{1c} Levels With Use of Sulfonylureas, Dipeptidyl Peptidase 4 Inhibitors, and Thiazolidinediones in Patients With Type 2 Diabetes Treated With Metformin

Analysis From the Observational Health Data Sciences and Informatics Initiative

Rohit Vashisht, PhD; Kenneth Jung, PhD; Alejandro Schuler, MS; Juan M. Banda, PhD; Rae Woong Park, MD, PhD; Sanghyung Jin, MS; Kipp W. Johnson, MD, PhD; Mark M. Shervey, PhD; Hua Xu, PhD; Yonghui Wu, PhD; Karthik Natrajan, PhD; George Hripcsak, MD, MS; Anthony Reckard, BS; Christian G. Reich, MD; James Weaver, MPH, MS; Martijn J. Schuemie, PhD; Patrick B. Ryan, PhD; Alison Callaha

2018:
22 authors
8 data sources

OHDSI in action: LEGEND-HTN

Articles

THE LANCET

Comprehensive comparative effectiveness and safety of first-line antihypertensive drug classes: a systematic, multinational, large-scale analysis

Marc A Suchard, Martijn J Schuemie, Harlan M Krumholz, Seng Chan You, RuiJun Chen, Nicole Pratt, Christian G Reich, Jon Duke, David Madigan, George Hripcsak, Patrick B Ryan

Lancet 2019; 394: 1816–26

Published Online October 24, 2019 https://doi.org/10.1016/S0140-6736(19)32317-7

See Comment page 1782

Department of Biostatistics, Fielding School of Public Health (Prof M A Suchard MD, M J Schuemie PhD), and Department of Biomathematics, David Geffen School of Medicine at UCLA (Prof M A Suchard), University of California, Los Angeles, CA, USA; Epidemiology Analytics, Janssen Research & Development, Titusville, NJ, USA (M J Schuemie, P B Ryan PhD); Department of Medicine, Yale University School of Medicine, New Haven, CA, USA

Summary

Background Uncertainty remains about the optimal monotherapy for hypertension, with current guidelines recommending any primary agent among the first-line drug classes thiazide or thiazide-like diuretics, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, dihydropyridine calcium channel blockers, and non-dihydropyridine calcium channel blockers, in the absence of comorbid indications. Randomised trials have not further refined this choice.

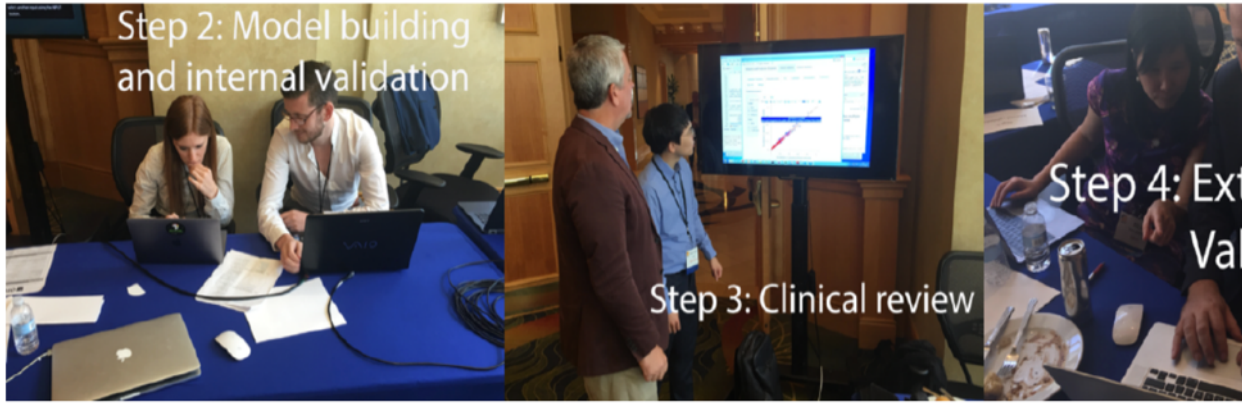
Methods We developed a comprehensive framework for real-world evidence that enables comparative effectiveness and safety evaluation across many drugs and outcomes from observational data encompassing millions of patients, while minimising inherent bias. Using this framework, we did a systematic, large-scale study under a new-user cohort design to estimate the relative risks of three primary (acute myocardial infarction, hospitalisation for heart failure, and stroke) and six secondary effectiveness and 46 safety outcomes comparing all first-line classes across a global network of six administrative claims and three electronic health record databases. The framework addressed residual confounding, publication bias, and p-hacking using large-scale propensity adjustment, a large set of control outcomes, and full disclosure of hypotheses tested.

Findings Using 4·9 million patients, we generated 22 000 calibrated, propensity-score-adjusted hazard ratios (HRs) comparing all classes and outcomes across databases. Most estimates revealed no effectiveness differences between classes; however, thiazide or thiazide-like diuretics showed better primary effectiveness than angiotensin-converting enzyme inhibitors: acute myocardial infarction (HR 0·84, 95% CI 0·75–0·95), hospitalisation for heart failure (0·83,

Oct2018→2019:
11 authors
9 sources
1.4m TCOs

OHDSI In Action:
Patient-Level Prediction Live at OHDSI'18

OHDSI
OBSERVATIONAL HEALTH DATA SCIENCES ANI
Patient-Level Prediction Team



From question to preliminary results in 1 day

PLOS ONE

RESEARCH ARTICLE

Development and validation of a prognostic model predicting symptomatic hemorrhagic transformation in acute ischemic stroke at scale in the OHDSI network

Qiong Wang[1,2,3], Jenna M. Reps[3,4], Kristin Feeney Kostka[3,5], Patrick B. Ryan[3,4,6], Yuhui Zou[7], Erica A. Voss[3,4,8], Peter R. Rijnbeek[3,8], RuiJun Chen[3,6,9], Gowtham A. Rao[3,4], Henry Morgan Stewart[3,5], Andrew E. Williams[3,10], Ross D. Williams[3,8], Mui Van Zandt[3,5], Thomas Falconer[3,6], Margarita Fernandez-Chas[3,5], Rohit Vashisht[3,11], Stephen
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Check for updates

OPEN ACCESS

Citation: Wang Q, Reps JM, Kostka KF, Rya
Zou Y, Voss EA, et al. (2020) Development a
validation of a prognostic model predicting
symptomatic hemorrhagic transformation in acute
ischemic stroke at scale in the OHDSI network.
PLoS ONE 15(1): e0226718. https://doi.org/

Oct2018→2019:
23 authors
11 data sources

OHDSI in action: Oxford study-a-thon

WE CAN DO THIS IN ONE WEEK (STUDY-A-THON)??

"To compare the risk of post-operative complications and mortality between unicompartmental *vs* total knee replacer

Monday
Group consensus on the problem
Draft cohort definitions

Tuesday
Review clinical characterisation
Draft patient-level prediction design

Wednesday
Review patient-level prediction results
Externally validate prediction model

Thursday
Draft population-lev
Review population-l

efpia OHDSI

Dec2018→2019:
26 authors
5 sources

THE LANCET Rheumatology

Articles

Opioid use, postoperative complications, and implant survival after unicompartmental versus total knee replacement: a population-based network study

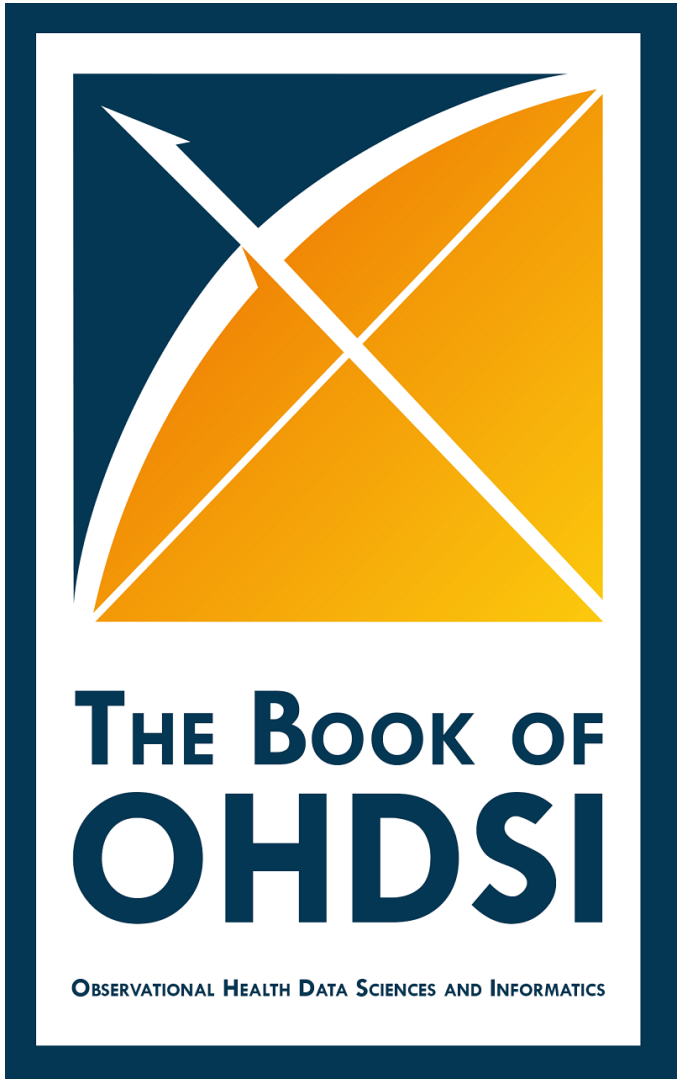
Edward Burn, James Weaver*, Daniel Morales, Albert Prats-Uribe, Antonella Delmestri, Victoria Y Strauss, Ying He, Danielle E Robinson, Rafael Pinedo-Villanueva, Spyros Kolovos, Talita Duarte-Salles, William Sproviero, Dahai Yu, Michel Van Speybroeck, Ross Williams, Luis H John, Nigel Hughes, Anthony G Sena, Ruth Costello, Belay Birlie, David Culliford, Caroline O'Leary, Henry Morgan, Theresa Burkard, Daniel Prieto-Alhambra†, Patrick Ryan†*

Summary

Background There is uncertainty around whether to use unicompartmental knee replacement (UKR) or total knee replacement (TKR) for individuals with osteoarthritis confined to a single compartment of the knee. We aimed to emulate the design of the Total or Partial Knee Arthroplasty Trial (TOPKAT) using routinely collected data to assess whether the efficacy results reported in the trial translate into effectiveness in routine practice, and to assess comparative safety.

Lancet Rheumatol 2019
Published Online
November 7, 2019
https://doi.org/10.1016/S2665-9913(19)30075-X
See Online/Comment

OHDSI in Action: Book of OHDSI



Contributors

Each chapter lists one or more chapter leads. These are the people who
the chapter. However, there are many others that have contributed to t
would like to acknowledge here:

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Anthor		
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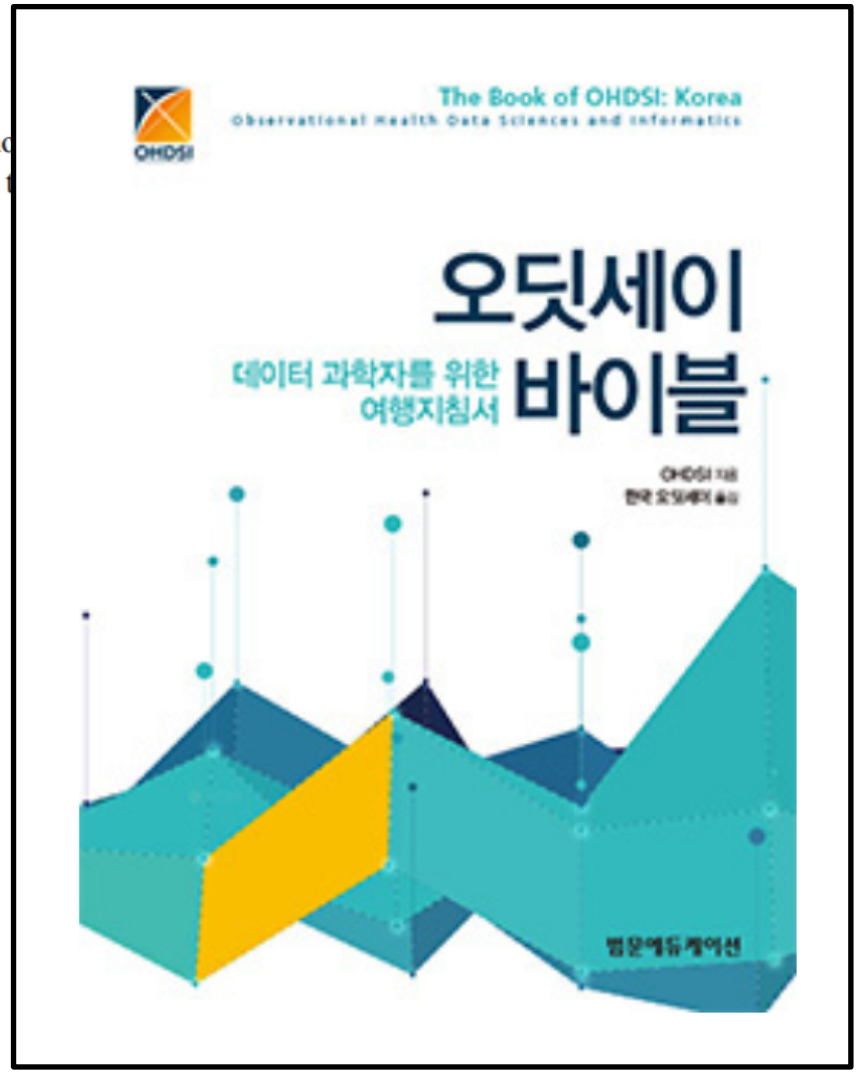
Mike Warfe	Jamie Weaver	James Wiggins
Andrew Williams	Chan You Seng	

2019:
56 contributors!



Why do we need more collaboration?

- We want to learn from as many data sources as the world as possible (replicability, generalizability, heterogeneity)
  - Each data partner contributes source data understanding and shares in interpreting their results in the context of the entire network
- Large scale evidence generation requires large scale collaboration for interpretation
  - LEGEND : One causal evidence system → Many clinical insights to inform different health decisions

Building the LHC of observational data science?

CERN Accelerating science Sign in

CERN Accelerating science Sign in Directo

CERN Accelerating science Sign in Directo

CERN Document Server

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TLAS Publication Drafts Final > Measurement of the transverse momentum distribution of Drell-Yan lepton pairs in proton-proton collisions at $\sqrt{s} = 13$ TeV with the ATLAS detector

Information | Discussion (0) | Files

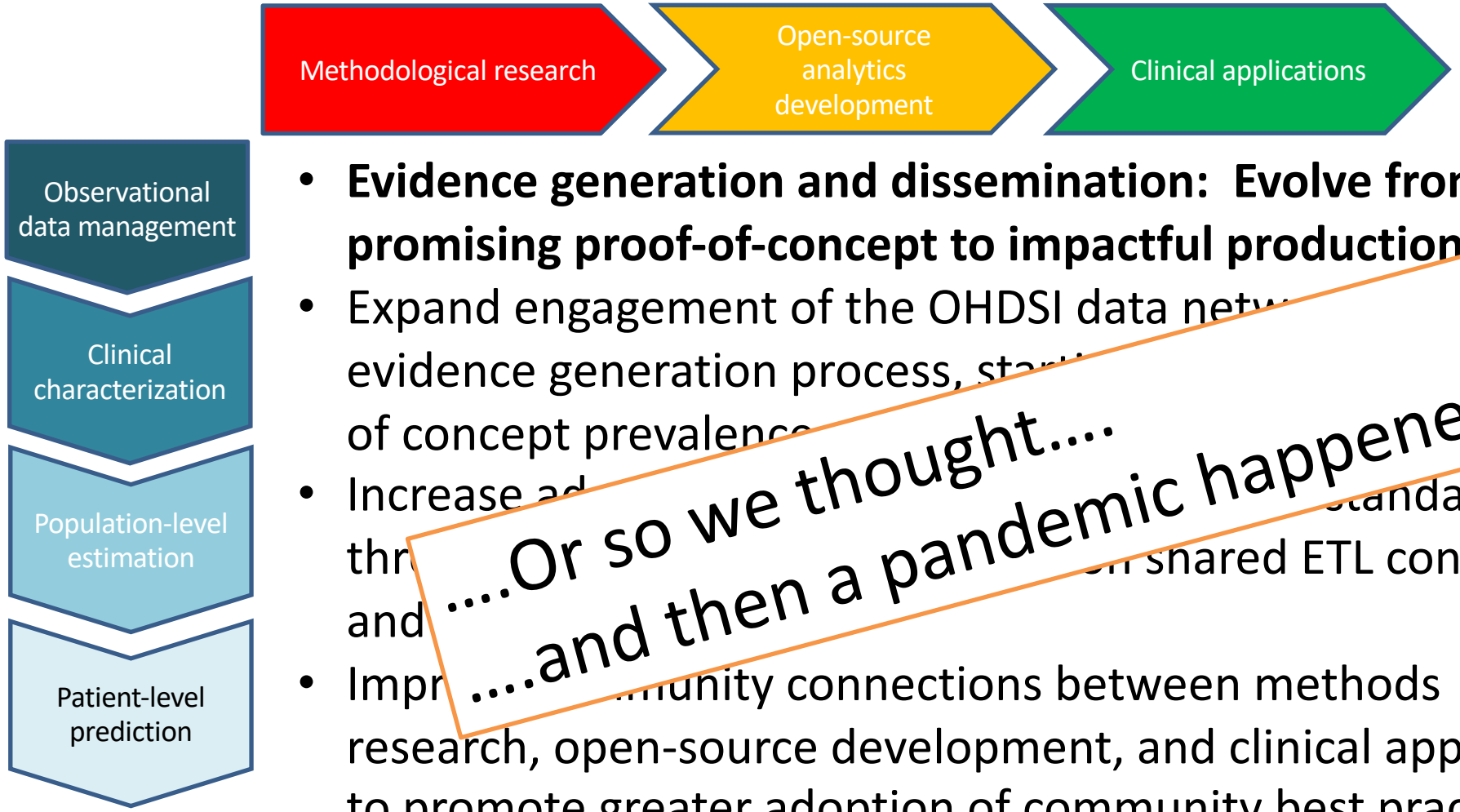
Preprint

Report number	arXiv:1912.02844 ; CERN-EP-2019-223
Title	**Measurement of the transverse momentum distribution of Drell-Yan lepton pairs in proton-proton collisions at $\sqrt{s} = 13$ TeV with the ATLAS detector**
Related	
Author(s)	ATLAS Collaboration *Show all 2948 authors*
Corporate author(s)	ATLAS Collaboration
Imprint	05 Dec 2019. - 39 p.
Note	39 pages in total, author list starting page 23, 6 figures, 4 tables, to be submitted to Eur. Phys. J. C. All figures including auxiliary figures are available at https://atlas.web.cern.ch/Atlas/GROUPS/PHYSICS/PAPERS/STDM-2018-14/
Subject category	Particle Physics - Experiment
Accelerator/Facility,	CERN LHC : ATLAS

What will be the research we do together that generates >1000 co-author papers?

- Methods research:
  - “Examining data heterogeneity across a global health network”
  - “Development and evaluation of methods for integrating causal inference design and machine learning algorithms for patient-level estimation”
- Open-source development:
  - “Implementation of a large-scale analytics ecosystem to enable evidence generation within health systems and across a global health network”
  - “Validation of a international phenotype library to define and identify disease across electronic health record systems”
- Clinical applications:
  - “Characterization of disease incidence and treatment utilization patterns across the world”
  - “Comprehensive comparative safety and effectiveness of treatments for <every disease>: an OHDSI LEGEND study”

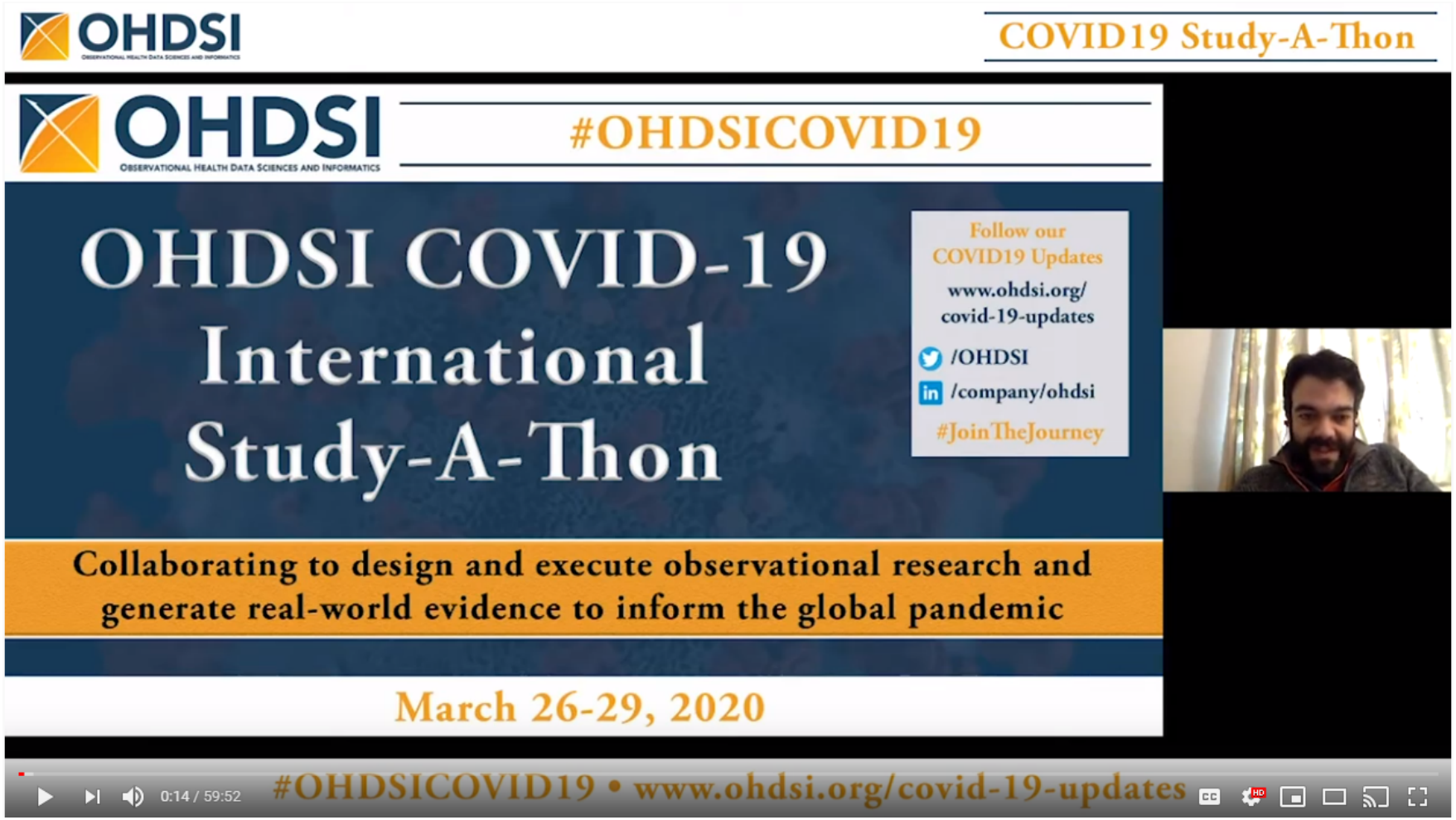
OHDSI's areas of focus: Continuing our journey in 2020…



- **Evidence generation and dissemination: Evolve from promising proof-of-concept to impactful production**
- Expand engagement of the OHDSI data netw… evidence generation process, stan… of concept prevalenc…
- Increase ad… thr… …standards and … …shared ETL conventions
- Impr… …munity connections between methods research, open-source development, and clinical applications to promote greater adoption of community best practices

….Or so we thought….
….and then a pandemic happened…

OHDSI COVID-19 Study-a-thon kickoff 26Mar2020 3amEST



https://www.ohdsi.org/covid-19-updates/

Tracking our collaboration 26Mar2020 3amET

OHDSI COVID-19 Study-a-thon Study Tracker

Analytic use case	Study	Lit Review and protocol development	Phenotype development and evaluation	Study package development	Study execution across network	Clinical review and dissemination
Characterization						
	COVID-19 positive patients					
	COVID-19 +ve subgroup analyses					
	Influenza, symptoms, and complications					
	Invasive treatments for respiratory distress					
	other questions?					
Prediction						
	1) Who presenting with flu, symptoms, or complications will be admitted to hospital?					
	2) Who sent home with symptoms will progress to require hospitalizaton?					
	3) Who admitted to hospital will require intensive care services or die?					
	other questions?					
Estimation						
	Effects of hydroxychloroquine					
	Effects of IL6 and JAK inhibitors					
	Effects of HIV protease inhibitors					
	Effects of HepC protease inhibitors					
	Effects of ACE inhibitors					
	other questions?					

To be done
Completed

Where did we end up by 29Mar2020 7pmET?

OHDSI COVID-19 Study-a-thon Study Tracker

Analytic use case	Study	Lit Review and protocol development	Phenotype development and evaluation	Study package development	Study execution across network	Clinical review and dissemination
Characterization						
	COVID-19 positive patients					
	COVID-19 +ve subgroup analyses					
	Influenza, symptoms, and complications					
	Invasive treatments for respiratory distress					
	other questions?					
Prediction						
	1) Who presenting with flu, symptoms, or complications will be admitted to hospital?					
	2) Who sent home with symptoms will progress to require hospitalizaton?					
	3) Who admitted to hospital will require intensive care services or die?					
	other questions?					
Estimation						
	Effects of hydroxychloroquine					
	Effects of IL6 and JAK inhibitors					
	Effects of HIV protease inhibitors					
	Effects of HepC protease inhibitors					
	Effects of ACE inhibitors					
	other questions?					

To be done
In progress
Results in, more to come
Completed

What have we done?

In only **88** hours, we have:

- Convened **351** participants brought together from **30** countries
- Held **12** Global Huddles, **>100** collaborator calls, **>13,000** chat messages
- Engaged **15** concurrent channels
- Reviewed **>10,000** publications
- Drafted **9** protocols
- Released **13** study packages
- Designed **355** cohort definitions
- Assembled a distributed data network with **37** partners signed on to execute studies

https://www.ohdsi.org/covid-19-updates/

3 things that we did in 4 days together that nobody had ever done before

- First large-scale international characterization of COVID hospitalized patients
- First prediction model externally validated on COVID patients to support triage to ‘flatten the curve’
- Largest study ever conducted on the safety of hydroxychloroquine

Open collaboration requires FULL transparency in every step of the research process

- Study registered in ENCEPP with full protocol posted: http://www.encepp.eu/encepp/viewResource.htm?id=34498
- Phenotype definitions and analysis specifications are both human-readable and computer-executable using ATLAS against any OMOP CDM: https://atlas.ohdsi.org/#/estimation/cca/6
- Analysis source code freely available and directly downloadable: https://github.com/ohdsi-studies/Covid19EstimationHydroxychloroquine
- Manuscript posted on Medrxiv while awaiting peer-review: https://www.medrxiv.org/content/10.1101/2020.04.08.20054551v1
- All analysis results available for public exploration through interactive R shiny application: http://evidence.ohdsi.org/Covid19EstimationHydroxychloroquine

Safety of hydroxychloroquine, alone and in combination with azithromycin, in light of rapid wide-spread use for COVID-19: a multinational, network cohort and self-controlled case series study

Jennifer C.E Lane, James Weaver, Kristin Kostka, Talita Duarte-Salles, Maria Tereza F. Abrahao, Heba Alghoul, Osaid Alser, Thamir M Alshammari, Patricia Biedermann, Edward Burn, Paula Casajust, Mitch Conover, Aedin C. Culhane, Alexander Davydov, Scott L. DuVall, Dmitry Dymshyts, Sergio Fernández Bertolín, Kristina Fišter, Jill Hardin, Laura Hester, George Hripcsak, Seamus Kent, Sajan Khosla, Spyros Kolovos, Christophe G. Lambert, Johan ver der Lei, Ajit A. Londhe, Kristine E. Lynch, Rupa Makadia, Andrea V. Margulis, Michael E. Matheny, Paras Mehta, Daniel R. Morales, Henry Morgan-Stewart, Mees Mosseveld, Danielle Newby, Fredrik Nyberg, Anna Ostropolets, Rae Woong Park, Albert Prats-Uribe, Gowtham A. Rao, Christian Reich, Jenna Reps, Peter Rijnbeek, Selva Muthu Kumaran Sathappan, Martijn Schuemie, Sarah Seager, Anthony Sena, Azza Shoaibi, Matthew Spotnitz, Marc A. Suchard, Joel Swerdel, Carmen Olga Torre, David Vizcaya, Haini Wen, Marcel de Wilde, Seng Chan You, Lin Zhang, Oleg Zhuk, Patrick Ryan, Daniel Prieto-Alhambra

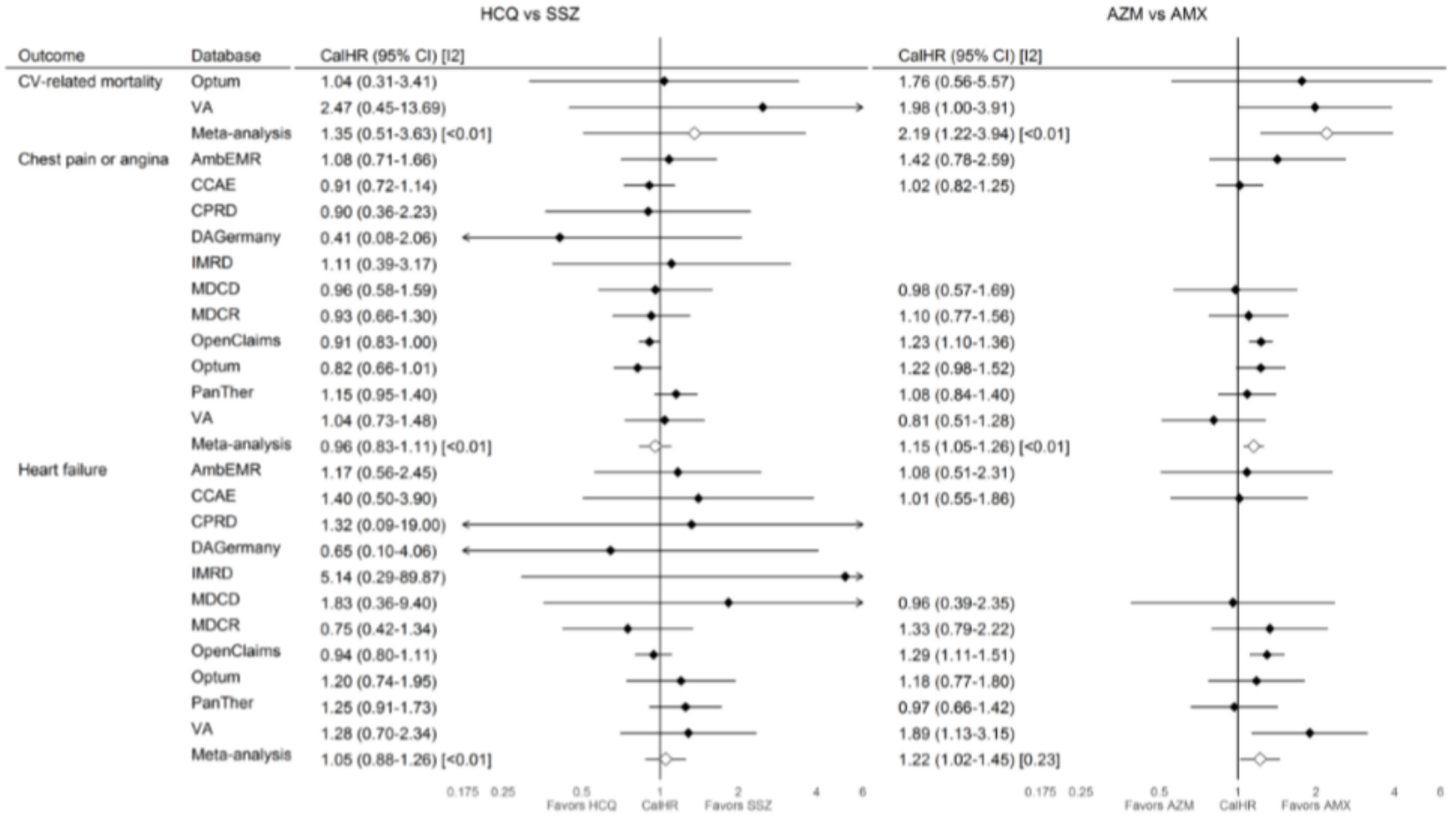
doi: https://doi.org/10.1101/2020.04.08.20054551

Methods

- New user cohort studies were conducted including 16 severe adverse events (SAEs).
- Rheumatoid arthritis patients aged 18+ and initiating hydroxychloroquine were compared to those initiating sulfasalazine and followed up over 30 days.
- Self-controlled case series (SCCS) were conducted to further establish safety in wider populations.
- Separately, SAEs associated with hydroxychloroquine - azithromycin (compared to hydroxychloroquine-amoxicillin) were studied.
- Data comprised 14 sources of claims data or electronic medical records from Germany, Japan, Netherlands, Spain, UK, and USA.
- Propensity score stratification and calibration using negative control outcomes were used to address confounding. Cox models were fitted to estimate calibrated hazard ratios (CalHRs) according to drug use.
- Estimates were pooled where $I^2<40\%$.

https://www.medrxiv.org/content/10.1101/2020.04.08.20054551v1

Figure 1. Source-specific and meta-analytic cardiovascular risk estimates for hydroxychloroquine vs sulfasalazine and azithromycin vs amoxicillin new users during 30-day follow-up



HCQ=hydroxychloroquine; SSZ=sulfasalazine; AZM=azithromycin (plus concurrent hydroxychloroquine exposure); AMX=amoxicillin (plus concurrent hydroxychloroquine exposure); CalHR=calibrated hazard ratio; CI=confidence interval; I2=estimate heterogeneity statistic. Meta-analytic estimates reported where I2<0.4. All database-specific estimates are reported in Appendix Table S7. AmbEMR=IQVIA Ambulatory EMR; CCAE=IBM Commercial Database; CPRD=Clinical Practice Research Datalink, DAGermany=IQVIA Disease Analyzer Germany; IMRD=IQVIA UK Integrated Medical Record Data; MDCD=IBM IBM Multi-state Medicaid; MDCR=IBM Medicare Supplemental Database; OpenClaims=IQVIA Open Claims; Optum=Optum Clinformatics Datamart; PanTher=Optum PanTherapeutic Electronic Health Record; VA=Veteran's Health Administration Database

https://www.medrxiv.org/content/10.1101/2020.04.08.20054551v1

Key findings*

- HCQ appears safe in short term in RA, but long-term use may be associated with increased CV mortality
- HCQ+azithromycin increases 30-day risk of heart failure and cardiovascular mortality

*under peer review

Open collaboration requires FULL transparency in every step of the research process

- Protocol and analysis source code freely available and directly downloadable: https://github.com/ohdsi-studies/Covid19HospitalizationCharacterization
- Phenotype definitions are both human-readable and computer-executable using ATLAS against any OMOP CDM: https://atlas.ohdsi.org/
- Manuscript posted on Medrxiv while awaiting peer-review: https://www.medrxiv.org/content/10.1101/2020.04.22.20074336v1
- All analysis results available for public exploration through interactive R shiny application: http://evidence.ohdsi.org/Covid19CharacterizationHospitalization/
- The study is a living evidence repository: any data partners can execute analysis and share aggregate results at any point, including updates as data accumulate

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An international characterisation of patients hospitalised with COVID-19 and a comparison with those previously hospitalised with influenza

Edward Burn, Seng Chan You, Anthony Sena, Kristin Kostka, Hamed Abedtash, Maria Tereza F. Abrahao, Amanda Alberga, Heba Alghoul, Osaid Alser, Thamir M Alshammari, Carlos Areia, Juan M Banda, Jaehyeong Cho, Aedin C Culhane, Alexander Davydov, Frank J DeFalco, Talita Duarte-Salles, Scott L DuVall, Thomas Falconer, Weihua Gao, Asieh Golozar, Jill Hardin, George Hripcsak, Vojtech Huser, Hokyun Jeon, Yonghua Jing, Chi Young Jung, Benjamin Skov Kaas-Hansen, Denys Kaduk, Seamus Kent, Yeesuk Kim, Spyros Kolovos, Jennifer Lane, Hyejin Lee, Kristine E. Lynch, Rupa Makadia, Michael E. Matheny, Paras Mehta, Daniel R. Morales, Karthik Natarajan, Fredrik Nyberg, Anna Ostropolets, Rae Woong Park, Jimyung Park, Jose D. Posada, Albert Prats-Uribe, Gowtham A. Rao, Christian Reich, Yeunsook Rho, Peter Rijnbeek, Selva Muthu Kumaran Sathappan, Lisa M. Schilling, Martijn Schuemie, Nigam H. Shah, Azza Shoaibi, Seokyoung Song, Matthew Spotnitz, Marc A. Suchard, Joel Swerdel, David Vizcaya, Salvatore Volpe, Haini Wen, Andrew E Williams, Belay B Yimer, Lin Zhang, Oleg Zhuk, Daniel Prieto-Alhambra, Patrick Ryan

doi: https://doi.org/10.1101/2020.04.22.20074336

This article is a preprint and has not been peer-reviewed [what does this mean?]. It reports new medical research that has yet to be evaluated and so should *not* be used to guide clinical practice.

Key findings*

- Rates of comorbidities and medication use are high among individuals hospitalized with COVID-19
- COVID-19 patients are more likely to be male and appear to be younger and, in the US, generally healthier than those typically admitted with influenza.

https://www.medrxiv.org/content/10.1101/2020.04.22.20074336v1

*under peer review

OHDSI COVID and Influenza Hospitalization

About
Databases
Cohort Counts
Cohort Characterization
Compare Cohort Char.

Database

- [x] CUIMC
- [x] DCMC
- [x] HIRA
- [x] STARR-OMOP
- [ ] Tufts CLARET
- [x] VA OMOP

Cohort (Target)

COVID-19 with prior obser

○ Pretty ◉ Raw ◉ Binary ○ Continuous

Show 25 entries Search:

Covariate Name	CUIMC		DCMC		HIRA		STARR-OMOP		VA OMOP	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
age group: 00-04	<1.0%									
age group: 05-09									<1.7%	
age group: 15-19	<1.0%				2.1%	0.15	<7.1%			
age group: 20-24	1.2%	0.11			11.5%	0.34	<7.1%		<1.7%	
age group: 25-29	3.5%	0.19	16.7%	0.41	13.1%	0.36	<7.1%		<1.7%	
age group: 30-34	5.4%	0.23			9.1%	0.30	7.8%	0.28	<1.7%	
age group: 35-39	5.5%	0.23	3.3%	0.19	9.7%	0.31	7.1%	0.27	2.4%	0.16
age group: 40-44	5.0%	0.22	6.7%	0.26	8.4%	0.29	13.5%	0.37	2.6%	0.16
age group: 45-49	4.0%	0.20	3.3%	0.19	8.2%	0.29	<7.1%		3.8%	0.20
age group: 50-54	8.4%	0.29	3.3%	0.19	8.4%	0.29	<7.1%		6.4%	0.25
age group: 55-59	9.6%	0.31	10.0%	0.32	7.2%	0.27	12.1%	0.35	9.2%	0.30
age group: 60-64	9.3%	0.30	23.3%	0.49	6.5%	0.26	7.8%	0.28	13.9%	0.37
age group: 65-69	10.2%	0.32	3.3%	0.19	4.5%	0.21	7.8%	0.28	12.7%	0.36
age group: 70-74	9.9%	0.32	3.3%	0.19	3.6%	0.19	7.1%	0.27	19.9%	0.45
age group: 75-79	9.1%	0.30	10.0%	0.32	3.6%	0.19	8.5%	0.29	11.1%	0.33
age group: 80-84	6.8%	0.26	13.3%	0.37	2.3%	0.15	<7.1%		5.0%	0.22
age group: 85-89	5.2%	0.23	3.3%	0.19	1.2%	0.11	<7.1%		5.9%	0.24
age group: 90-94	5.0%	0.22			0.4%	0.07			3.1%	0.18
age group: 95-99	<1.0%				<0.1%				<1.7%	
condition_era group during day -30 through 0 days relative to index: Abdominal abscess	<1.0%						<7.1%		<1.7%	
condition_era group during day -30 through 0 days relative to index: Abdominal aortic aneurysm									<1.7%	
condition_era group during day -30 through 0 days relative to index: Abdominal aortic aneurysm without rupture									<1.7%	
condition_era group during day -30 through 0 days relative to index: Abdominal aortic ectasia									<1.7%	
condition_era group during day -30 through 0 days relative to index: Abdominal distension, gaseous	<1.0%						<7.1%		<1.7%	

http://evidence.ohdsi.org/Covid19CharacterizationHospitalization/

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COVID-19 Study-A-Thon

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(other names not fully entered in registration)

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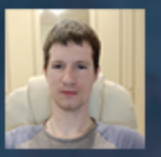

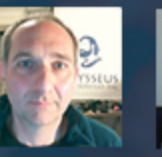
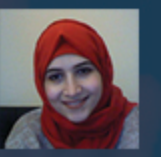

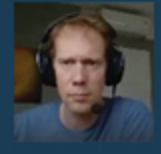


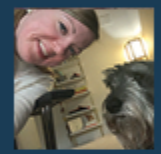
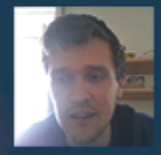

Characterizing Health Associated Risks, and Your Baseline Disease In SARS-COV-2 (CHARYBDIS)

OHDSI
OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

#OHDSICOVID19

COVID-19 Collaborators

BILL & MELINDA GATES foundation
COLUMBIA UNIVERSITY MEDICAL CENTER
CPRD
EHDEN
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HIRA
HM HOSPITALES
IQVIA
Ucla
janssen
Maine Medical Center MaineHealth
SIDIAP
Stanford MEDICINE
Tufts Medical Center
UNIVERSITY OF OXFORD
UNIVERSITY of WASHINGTON
VA U.S. Department of Veterans Affairs

Objectives: 1) Describe the baseline demographic, clinical characteristics, treatments and outcomes of interest among individuals tested for SARS-CoV-2 and/or diagnosed with COVID-19 overall and stratified by sex, age and specific comorbidities; **2)** Describe characteristics and outcomes of hospitalized influenza patients between September 2017 and April 2018 compared to the COVID-19 population.

Data Sources: OHDSI studies around COVID-19 currently leverage datasets from Asia, Europe and North America. We are actively looking for data partners to join the journey!

1 IRB / 1 Study Package = Dozens of studies & papers that will be submitted for peer review!

Study Topics: COVID-19 and …

- Asthma
- Cancer
- Cardiac Outcomes
- Chronic Kidney Disease
- COPD
- Elderly
- End-Stage Renal Disease
- Gender Differences
- Heart Disease
- Hepatitis C
- HIV infection
- Hypertension
- Immune Disorders
- Obesity
- Pediatrics
- Pregnant Women
- Testing
- Tuberculosis
- Type 2 Diabetes

… And more!

OHDSI research into COVID-19 has generated many studies, including two currently in the peer-review process. Our baseline characterization of hospitalized COVID-19 patients is available on MedRxiv.


An international characterisation of patients hospitalised with COVID-19 and a comparison with those previously hospitalised with influenza

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This article is a preprint and has not been certified by peer review [what does this mean?]. It reports new medical research that has yet to be evaluated and so should not be used to guide clinical practice.

Abstract Info/History Metrics Preview PDF

Abstract

Background To better understand the profile of individuals with severe coronavirus disease 2019 (COVID-19), we characterised individuals hospitalised with COVID-19 and compared them to individuals previously hospitalised with influenza. Methods We report the characteristics (demographics, prior conditions and medication use) of patients hospitalised with COVID-19 between December 2019 and April 2020 in the US (Columbia University Irving Medical Center [CUIMC], STAnford Medicine Research data Repository [STARR-OMOP], and the Department of Veterans Affairs [VA OMOP]) and Health Insurance Review & Assessment [HIRA] of South Korea. Patients hospitalised with COVID-19 were compared with patients previously hospitalised with influenza in 2014-19. Results 6,806 (US: 1,634, South Korea: 5,172) individuals hospitalised with COVID-19 were included. Patients in the US were majority male (VA OMOP: 94%, STARR-OMOP: 57%, CUIMC: 52%), but were majority female in HIRA (56%). Age profiles varied across data sources. Prevalence of asthma ranged from 7% to 14%,

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Posted April 25, 2020.

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COVID-19 SARS-CoV-2 preprints from medRxiv and bioRxiv

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www.ohdsi.org/Covid-19-Updates

Project SCYLLA

SARS-Cov-2 Large-scale Longitudinal Analyses

OHDSI
Observational Health Data Sciences and Informatics
#OHDSICOVID19

COVID-19 Collaborators

Bill & Melinda Gates foundation
Columbia University Medical Center
CPRD
EHDEN
Erasmus MC
HIRA
HM Hospitales
IQVIA
Ucla
janssen
Johnson & Johnson
Maine Medical Center
MaineHealth
SIDIAP
Stanford Medicine
Tufts Medical Center
University of Oxford
University of Washington
VA U.S. Department of Veterans Affairs

Objective: The aim of this study is to assess the comparative safety and effectiveness of all emerging drug therapies used in COVID-19 treatments …

… administered during hospitalization and prior to intensive services.
… administered during hospitalization after initiating intensive services.
… administered after COVID-19 positive testing and prior to hospitalization.

Methods: Apply a comparative cohort design, comparing alternative treatments amongst 1) drugs with in vitro activity on SARS-COV-2 virus, and 2) drugs used as adjuvant therapy for COVID-19 disease. Building off *OHDSI LEGEND* framework, all treatment comparisons will be systematically evaluated for a large range of safety and effectiveness outcomes.

Data Setting: Analyses will be run across data partners in the OHDSI network across Asia, Europe and North America, using EHR and claims data from primary and secondary care.

Any researchers with data in OMOP CDM are encouraged to collaborate.

Treatments to be Evaluated

- Hydroxychloroquine
- Hydroxychloroquine + azithromycin (or alternative antibiotics)
- HIV Protease inhibitors
  - lopinavir/ritonavir
- Interferon beta
- Favipiravir
- Remdesivir
- Ivermectin
- Oseltamivir
- Ribavirin
- Ivermectin
- Corticosteroids
- IL6 inhibitors
  - Tocilizumab
  - Sarilumab
  - Siltuximab
- Anakinra
- JAK inhibitors
  - Baricitinib
  - Tofacitinib
- Bevacizumab

… and many others

The Project SCYLLA protocol, along with our COVID-19 preprints (MedRxiv) and all updates on related work can be found at **www.ohdsi.org/Covid-19-Updates**.

Join the journey!

ohdsi.org

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