



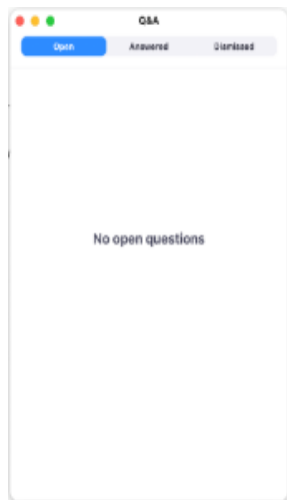
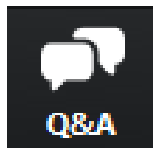
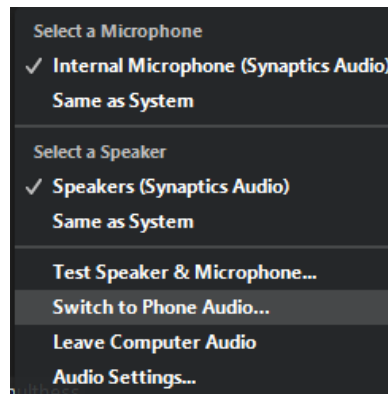
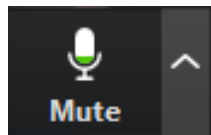
The Role of Health Data in the Post Covid-19 Era



Webinar One: The need for health data in the era of Covid-19

9 Oct 14.30-15.30 CET

If you are having problems with your connection, you can switch between phone and computer audio



We appreciate audience questions, please use the question bar in the control panel



Raquel Yotti

Director
National Health Institute Carlos III
(Spain)



Rafael Bengoa

Director of SI-Health
and former health minister of the
Basque Country (Spain)



George Hripcsak

Observational Health Data Sciences
and Informatics
(OHDSI) network



Xavier Kurz

European Medicines Agency
(EMA)



Dani Prieto-Alhambra

European Health Data and Evidence
Network
(EHDEN)



Duane Schulthess

Vital Transformation
(moderator)



Observational Health Data Sciences and Informatics (OHDSI, as “Odyssey”)

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

A multi-stakeholder, interdisciplinary, international collaborative with a coordinating center at Columbia University



OHDSI's global research community

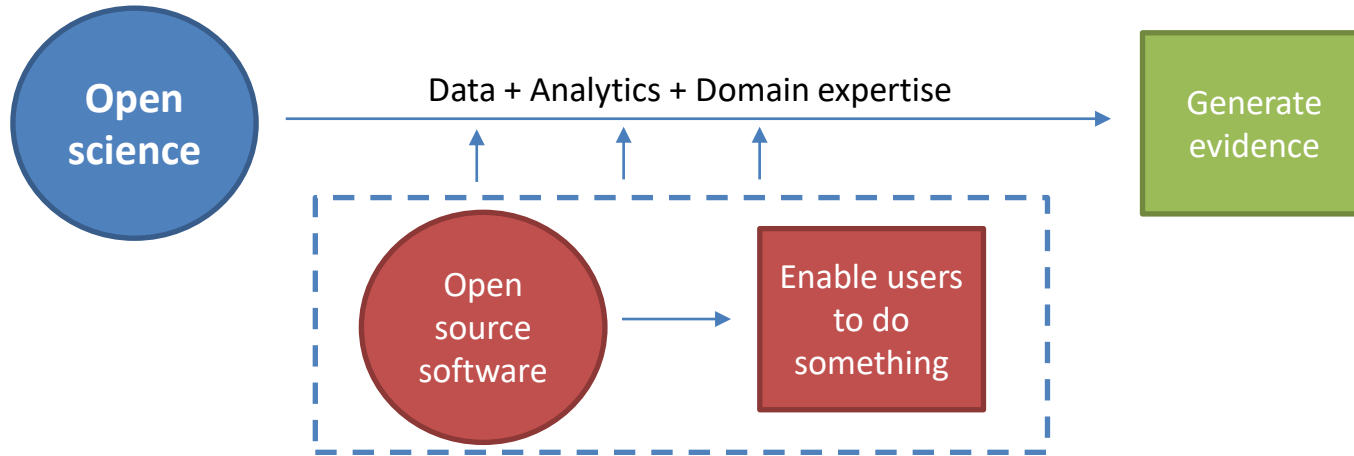


- >300 collaborators from 30 different countries
- Experts in informatics, statistics, epidemiology, clinical sciences
- Active participation from academia, government, industry, providers
- Records on about 600 million unique patients in >100 databases

<http://ohdsi.org/who-we-are/collaborators/>



Open Science

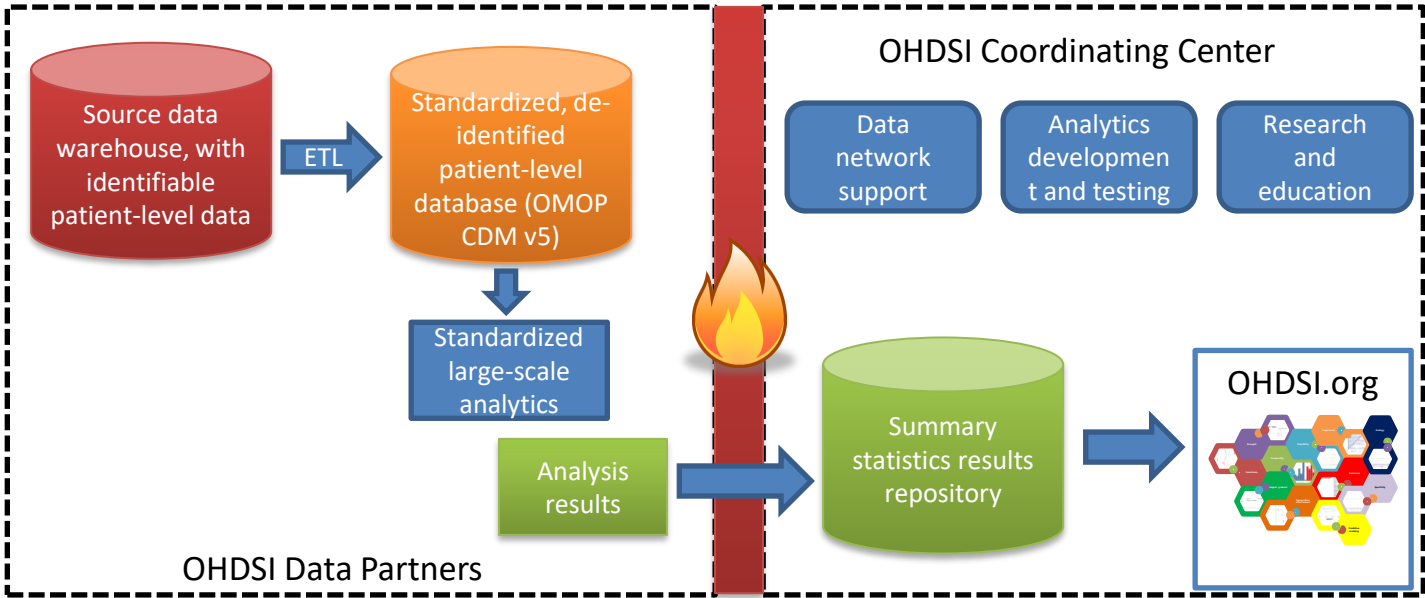


Standardized, transparent workflows





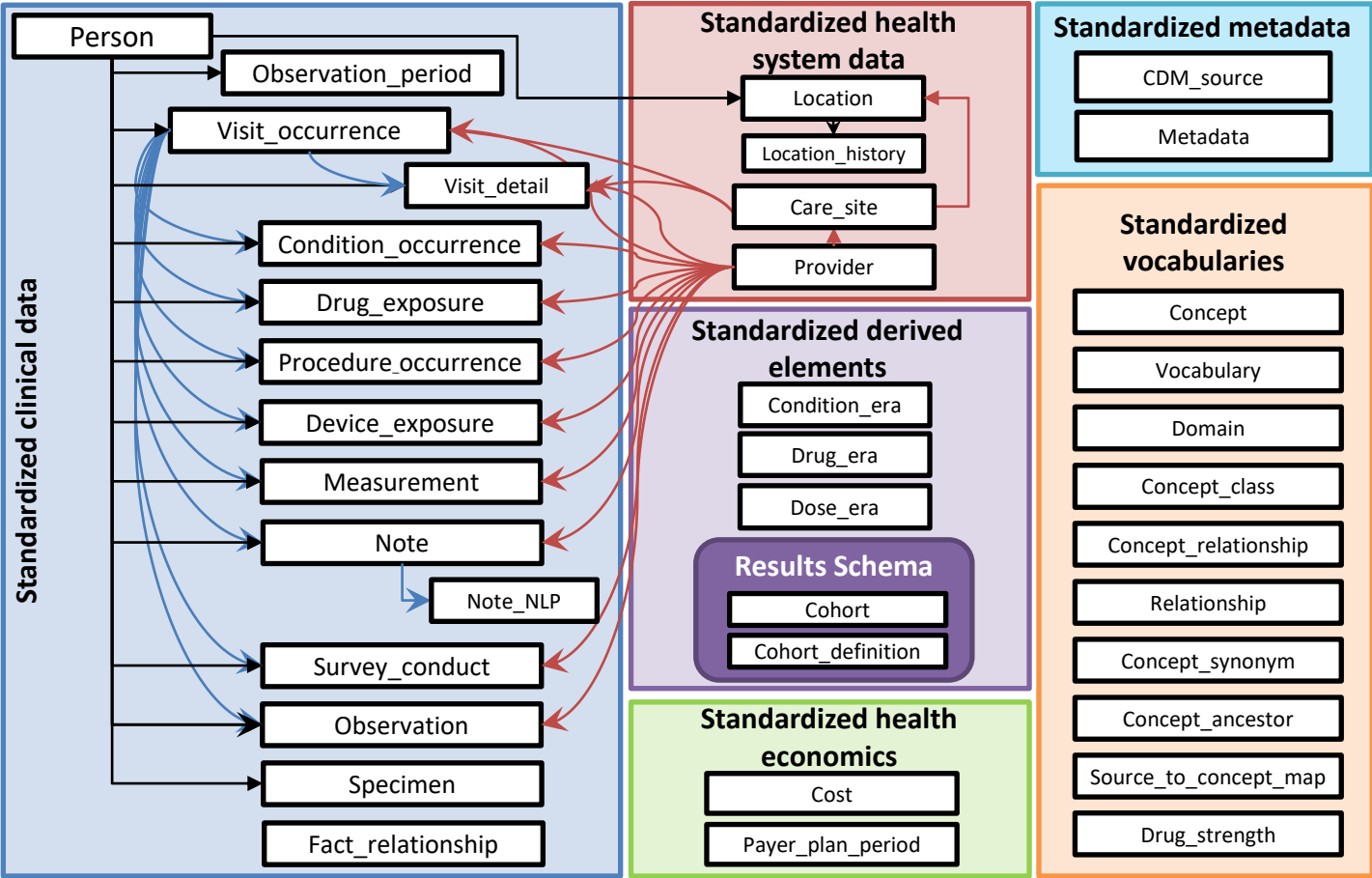
How OHDSI Works





Deep information model

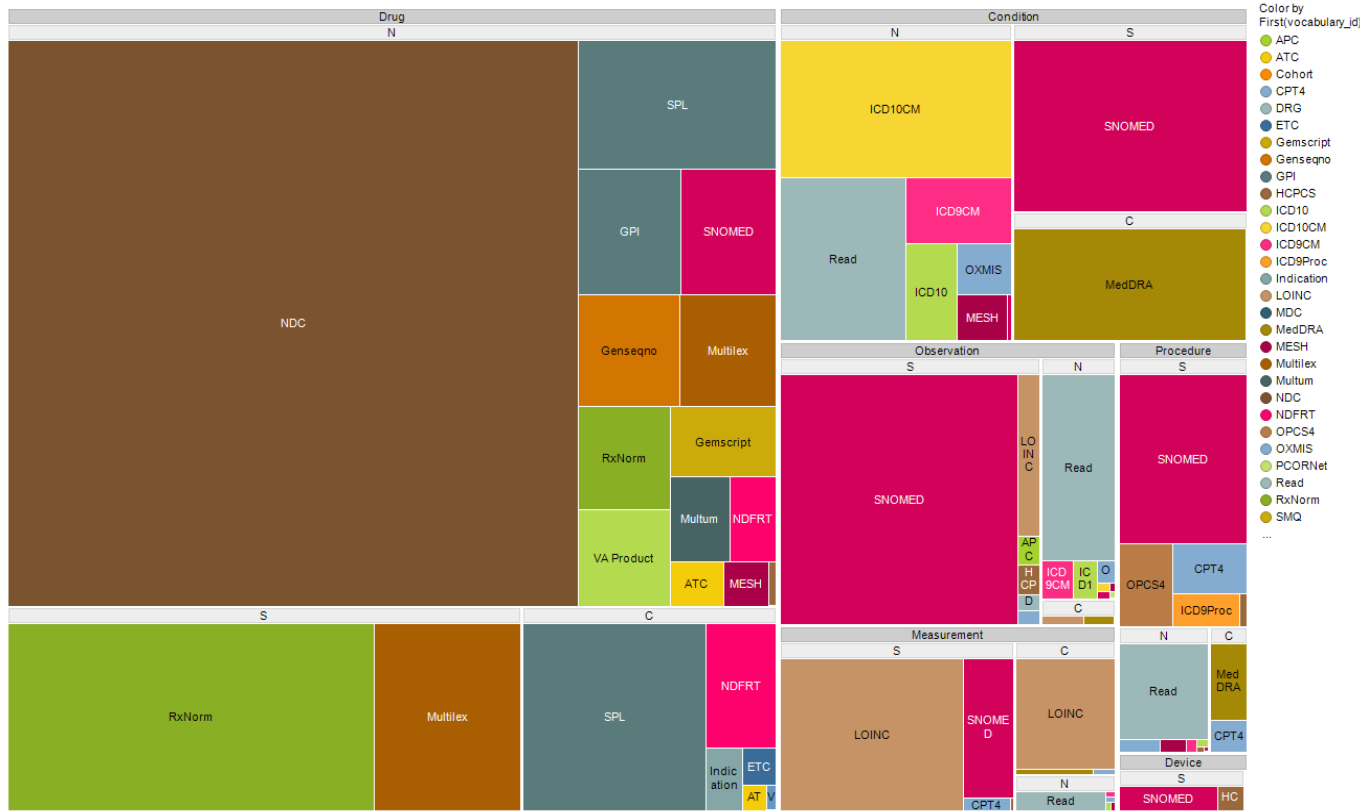
OMOP CDM Version 6 (current 5.3.1)





Extensive vocabularies

Breakdown of OHDSI concepts by domain, standard class, and vocabulary





ACHILLES Heel Data Curation

Data Quality Dashboard

Data Quality Messages	
Search: <input type="text"/>	
Show / hide columns	
Message Type	Message
ERROR	101-Number of persons by age, with age at first observation period; should not have age < 0, (n=848)
ERROR	103 - Distribution of age at first observation period (count = 1); min value should not be negative
ERROR	114-Number of persons with observation period before year-of-birth; count (n=851) should not be > 0
ERROR	206 - Distribution of age by visit_concept_id (count = 7); min value should not be negative
ERROR	301-Number of providers by specialty concept_id; 224 concepts in data are not in correct vocabulary (Specialty)
ERROR	400-Number of persons with at least one condition occurrence, by condition_concept_id; 115 concepts in data are not in correct vocabulary (SNOMED)
ERROR	406 - Distribution of age by condition_concept_id (count = 753); min value should not be negative



What is the quality of the current evidence from observational analyses?

ORIGINAL CONTRIBUTION

JAMA

Exposure to Oral Bisphosphonates and Risk of Esophageal Cancer

Chris R. Cardwell, PhD

Christian C. Abnet, PhD

Marie M. Cantwell, PhD

Liam J. Murray, MD

BISPHOSPHONATES INHIBIT OSTEOCLAST-MEDIATED BONE RESORPTION

Context Use of oral bisphosphonates has increased dramatically and elsewhere. Esophagitis is a known adverse effect of bisphosphonates, and recent reports suggest a link between bisphosphonate use and esophageal cancer, but this has not been robustly investigated.

Objective To investigate the association between bisphosphonate use and esophageal cancer.

Design, Setting, and Participants Data were extracted from the UK General Practice Research Database (GPRD), a large, longitudinal, primary care database covering the entire United Kingdom.

August 2010: “Among patients in the UK General Practice Research Database, the use of oral bisphosphonates was not significantly associated with incident esophageal or gastric cancer”

been found on biopsy in patients with bisphosphonate-related esophagitis, and follow-up endoscopies have shown that abnormalities remain after the esophagitis heals.⁹ Reflux esophagitis is an established risk factor for esophageal cancer through the Barrett pathway.¹⁰ It is not known whether bisphosphonate-related esophagitis can also increase esophageal cancer risk. However, the US Food and Drug Administration recently reported 23 cases of esophageal cancer (between 1995 and 2008) in patients using the bisphosphonate alendronate and a further 31 cases in patients taking bisphosphonates to treat

person-years of risk in both the bisphosphonate and control groups were 1000 person-years of risk, respectively. The risk of esophageal and gastric cancer combined between the bisphosphonate use (adjusted hazard ratio, 0.96 [95% confidence interval, 0.77-1.49]). There also was no difference in risk of esophageal cancer by duration of bisphosphonate intake.

Conclusion Among patients in the UK General Practice Research Database, the use of oral bisphosphonates was not significantly associated with incident esophageal or gastric cancer.

JAMA. 2010;304(6):657-663

Large studies with appropriate comparison groups, adequate follow-up, robust characterization of bisphosphonate use, and prospective

BMJ

RESEARCH

Oral bisphosphonates and risk of cancer of oesophagus, stomach, and colorectum: case-control analysis within a UK primary care cohort

Jane Green, clinical epidemiologist,¹ Gabriela Czanner, statistician,¹ Gillian Reeves, statistical epidemiologist,¹ Joanna Watson, epidemiologist,¹ Lesley Wise, manager, Pharmacoepidemiology Research and Intelligence Unit,² Valerie Beral, professor of cancer epidemiology¹

ABSTRACT

Objective To examine the hypothesis that risk of oesophageal, but not of gastric or colorectal, cancer is increased in users of oral bisphosphonates.

Design Nested case-control analysis within a primary care cohort of about 6 million people in the UK, with prospectively recorded information on prescribing of bisphosphonates.

Setting UK General Practice Research Database cohort. **Participants** Men and women aged 40 years or over—2954 with oesophageal cancer, 2018 with gastric cancer, and 10 641 with colorectal cancer, diagnosed in 1995-2005; five controls per case matched for age, sex, general practice, and observation time.

Main outcome measures Relative risks for incident invasive cancers of the oesophagus, stomach, and colorectum, adjusted for smoking, alcohol, and body mass index.

Conclusions The risk of oesophageal cancer increased with 10 or more prescriptions for oral bisphosphonates and with prescriptions over about a five year period. In Europe and North America, the incidence of oesophageal cancer at age 60-79 is typically 1 per 1000 population over five years, and this is estimated to increase to about 2 per 1000 with five years' use of oral bisphosphonates.

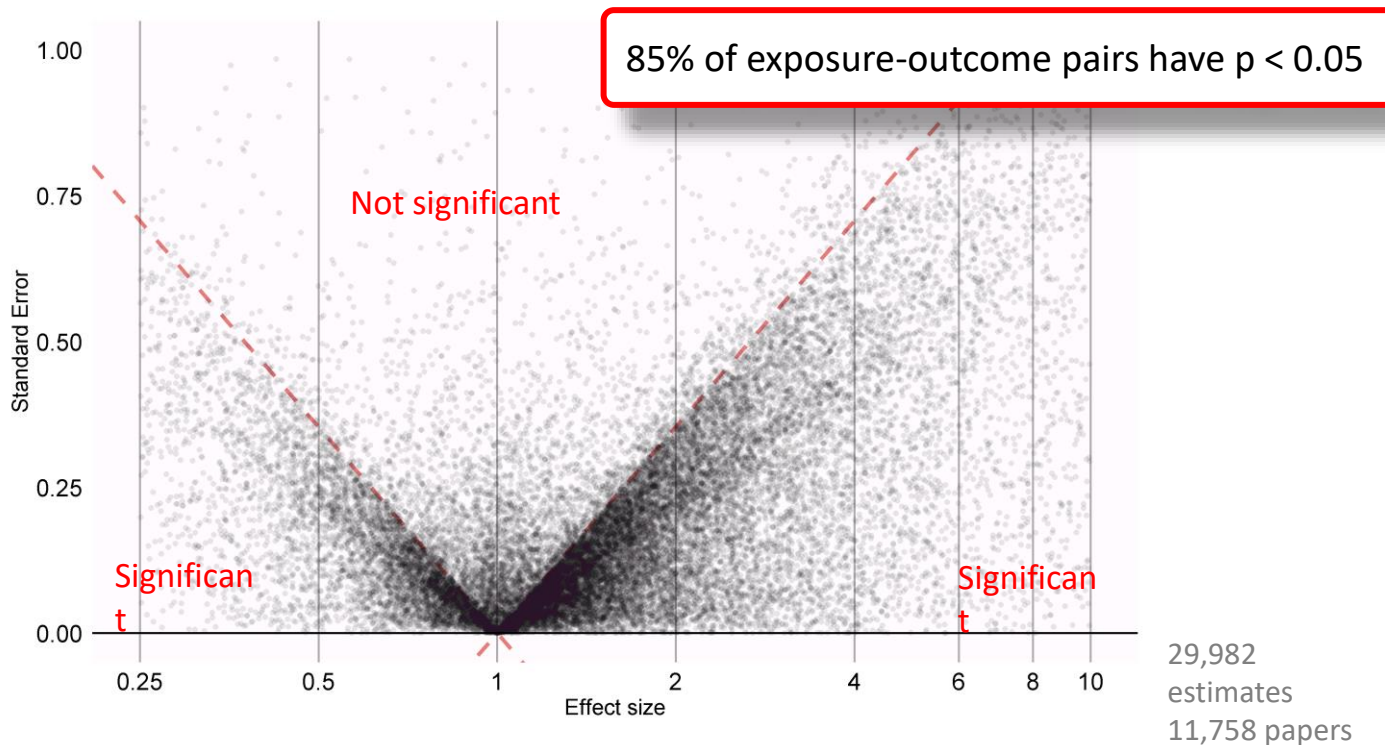
INTRODUCTION

Adverse gastrointestinal effects are common among people who take oral bisphosphonates for the prevention and treatment of osteoporosis; they range from dyspepsia, nausea, and abdominal pain to erosive oesophagitis and oesophageal ulcers.¹ Recent case reports have suggested a possible increase in the risk of oesophageal cancer with use of such bisphosphonate preparations.² We report here on the relation between prospectively recorded prescribing information for

Sept 2010: “In this large nested case-control study within a UK cohort [General Practice Research Database], we found a significantly increased risk of oesophageal cancer in people with previous prescriptions for oral bisphosphonates”



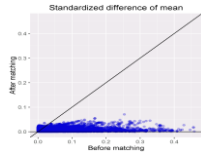
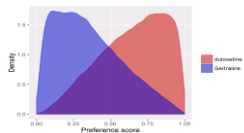
Observational research results in literature



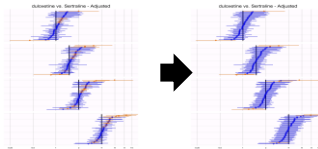
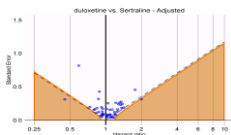


Addressing reproducibility

1. Propensity score adjustment with large-scale covariate set: measured confounding (and some unmeasured?)



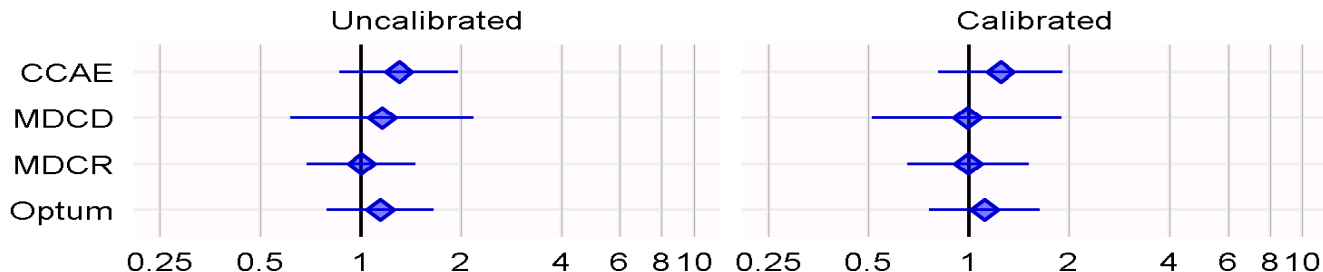
2. Confidence interval calibration using negative controls: unmeasured confounding





Addressing reproducibility

3. Multiple databases, locations, practice types



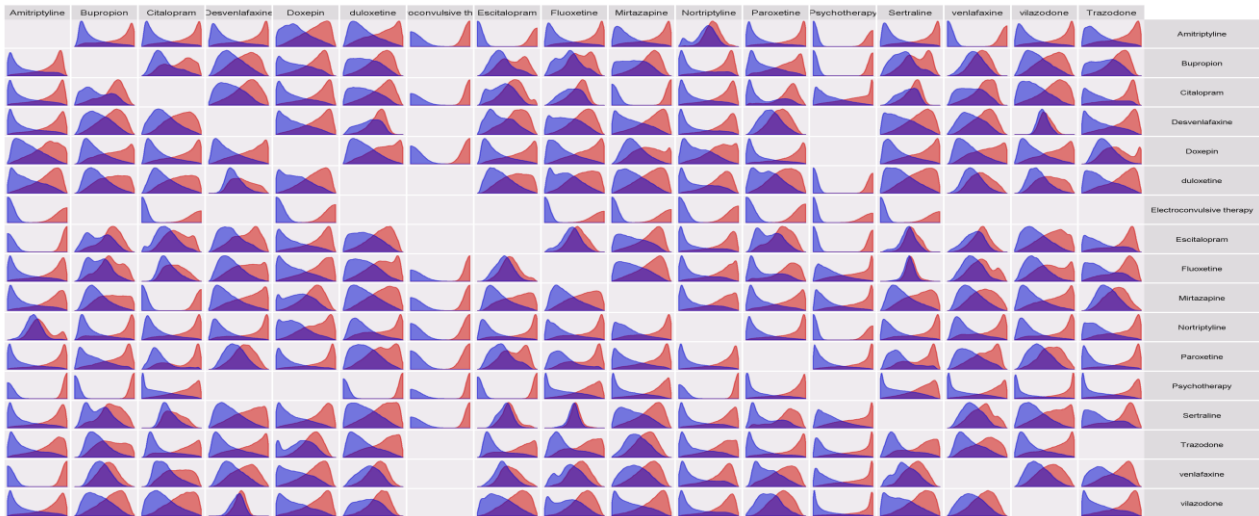
4. Publish all hypotheses, code, parameters, runs

ORL 1000



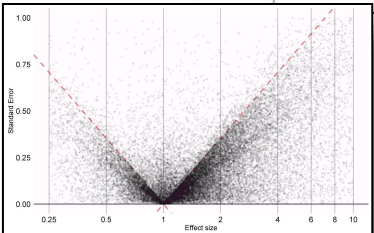
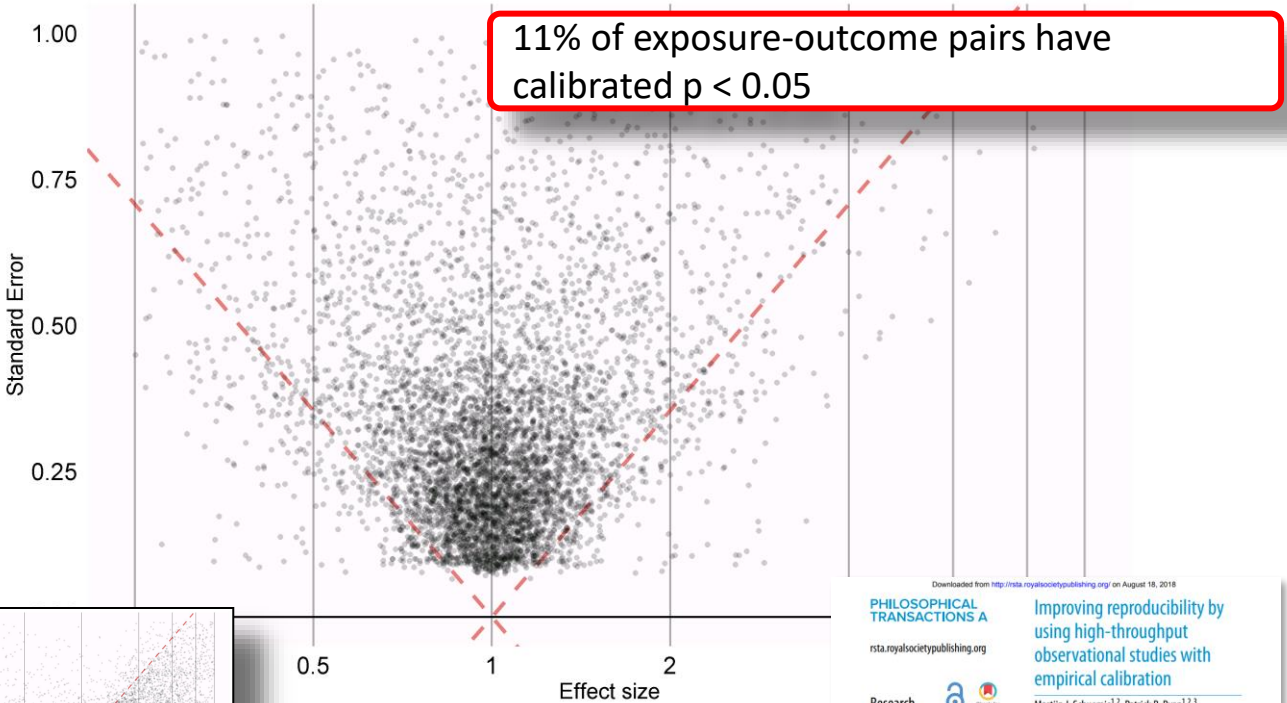
Addressing reproducibility

5. Carry out on aligned hypotheses at **scale**





Estimates are in line with expectations



Downloaded from <http://rsta.royalsocietypublishing.org/> on August 18, 2018

**PHILOSOPHICAL
TRANSACTIONS A**

rsta.royalsocietypublishing.org

Research

Cite this article: Schuemie MJ, Ryan PB, Hripcsak G, Madigan D, Suchard MA. 2018 Improving reproducibility by using high-throughput observational studies with empirical calibration. *Phil. Trans. R. Soc. A* **376**: 20170056.
<http://dx.doi.org/10.1098/rsta.2017.0056>

Accepted: 8 May 2018

Improving reproducibility by using high-throughput observational studies with empirical calibration

Martijn J. Schuemie^{1,2}, Patrick B. Ryan^{1,2,3}, George Hripcsak^{1,3,4}, David Madigan^{1,5} and Marc A. Suchard^{1,6,7,8}

¹Observational Health Data Sciences and Informatics (OHDSI), New York, NY 10012, USA
²Epidemiology Analytics, Janssen Research and Development, Titusville, NJ 08560, USA
³Department of Biomedical Informatics, Columbia University Medical Center, New York, NY 10033, USA



What's in a guideline?

Clinical Practice Guideline: Executive Summary

2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: Executive Summary

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

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56 pages
containing
106
recommendations

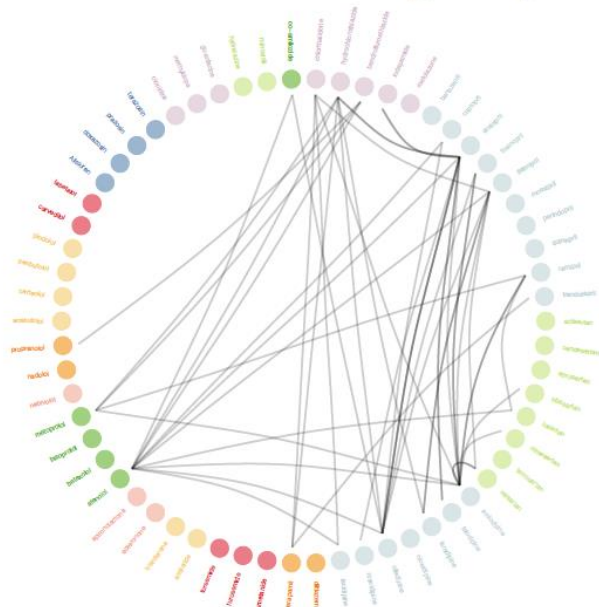
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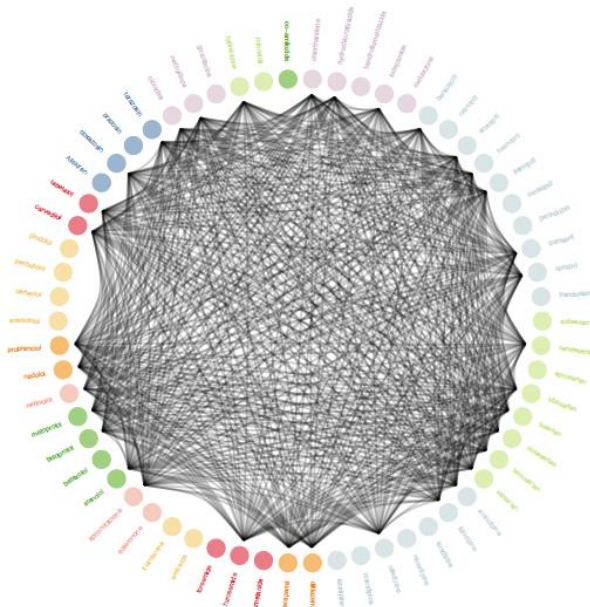


LEGEND knowledge base for hypertension

Head-to-head HTN drug comparisons



- Trials: 40
- $N = 102 - [1148] - 33K$



- Comparisons: 10,278
- $N = 3502 - [212K] - 1.9M$



Clinical lessons for hypertension

LEGEND evidence is concordant with RCTs:

- Where RCT results exist, but many unanswered questions remains
- More outcomes, comparisons, data sources

Not all 1st-line agents are equivalent:

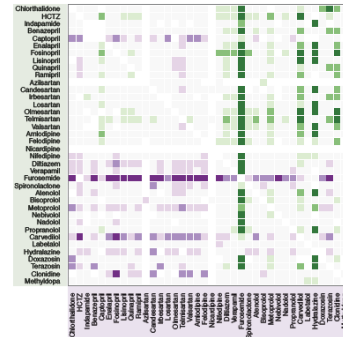
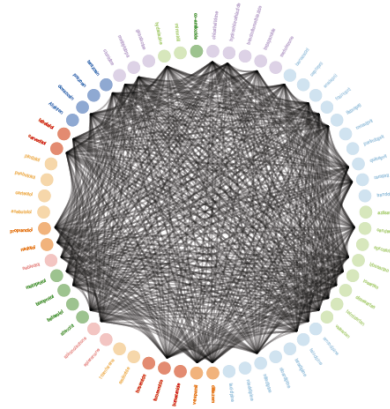
- ↓ BBs, TZDs > ACEIs

Combo-therapy initiation:

- ↓ evidence that combo-therapy is better
- Evidence of ↑ safety risk

DCP trial prediction:

- CTD vs. HCTZ – no efficacy difference





How to create a collaborative open science initiative in the setting of fierce academic and commercial competition?

Generating evidence in top journals

THE LANCET

Volume 384 • November 10/11 • Pages 1279-1878 • November 10-21, 2015

www.thelancet.com



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

Marc A. Suchard^{a,b,c,d}, Martijn J. Schuemie^{e,f,g}, Harlan M. Krumholz^h, Seng Chan Youⁱ, Rujun Chen^j, Nicole Pratt^k, Christian G. Reich^l, Jon Duke^m, David Madiganⁿ, George Hripcsak^o, Patrick B. Ryan^p

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

PNAS

Characterizing treatment pathways at scale using the OHDSI network

George Hripcsak^{a,b,c,d}, Patrick B. Ryan^{e,f}, Jon D. Duke^{g,h}, Nigam H. Shah^{i,j}, Rae Woong Park^{k,l}, Vojtech Huser^{m,n}, Marc A. Suchard^{o,p,q}, Martijn J. Schuemie^{r,s,t}, Frank J. DeFalco^{u,v}, Adler Perotte^{w,x}, Juan M. Banda^{y,z}, Christian G. Reich^{aa}, Lisa M. Schilling^{ab}, Michael E. Matheny^{ac}, Daniela Meeker^{ad}, Nicole Pratt^{ae}, and David Madigan^{af}

^aDepartment of Biomedical Informatics, Columbia University Medical Center, New York, NY 10032; ^bMedical Informatics Services, NewYork-Presbyterian Hospital, New York, NY 10032; ^cObservational Health Data Sciences and Informatics, New York, NY 10032; ^dEpidemiology Analytics, Janssen Research and Development, Titusville, NJ 08560; ^eCenter for Biomedical Informatics, Regenstrief Institute, Indianapolis, IN 46202; ^fCenter for Biomedical Informatics Research, Stanford University, CA 94305; ^gDepartment of Biomedical Informatics, Ajou University School of Medicine, Suwon, South Korea, 443-380; ^hLister Hill National Center for Biomedical Communications (National Library of Medicine), National Institutes of Health, Bethesda, MD 20894; ⁱDepartment of

Research

JAMA Internal Medicine | Original Investigation

Comparison of Cardiovascular and Safety Outcomes of Chlorthalidone vs Hydrochlorothiazide to Treat Hypertension

George Hripcsak^a, MD, Marc A. Suchard^b, MD, PhD, Steven Shea^c, MD, Rujun Chen^d, MD, Seng Chan You^e, MD, Nicole Pratt^f, PhD, David Madigan^g, PhD, Harlan M. Krumholz^h, MD, SM, Patrick B. Ryanⁱ, PhD, Martijn J. Schuemie^j, PhD

IMPORTANCE: Chlorthalidone is currently recommended as the preferred thiazide diuretic to treat hypertension, but no trials have directly compared risks and benefits.

[Supplemental content](#)

PHILOSOPHICAL
TRANSACTIONS A

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Research



Cite this article: Schuemie MJ, Ryan PB, Hripcsak G, Madigan D, Suchard MA. 2018 Improving reproducibility by using high-throughput observational studies with empirical calibration. *Phil. Trans. R. Soc. A* 376: 20180123.

Improving reproducibility by using high-throughput observational studies with empirical calibration

Martijn J. Schuemie^{1,2}, Patrick B. Ryan^{1,2,3}, George Hripcsak^{3,4}, David Madigan^{1,5} and Marc A. Suchard^{1,6,7,8}

¹Observational Health Data Sciences and Informatics (OHDSI), New York, NY 10032, USA



Book of OHDSI





Join the journey

<http://ohdsi.org>

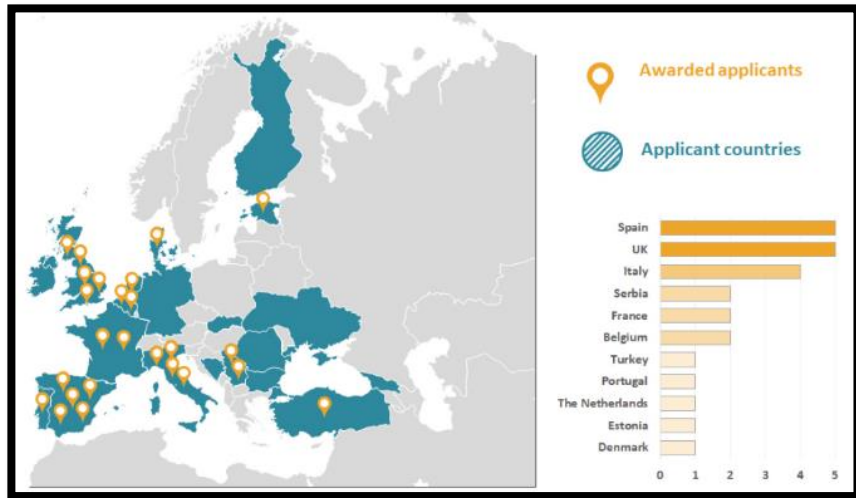
- Annual Symposium
 - October 18-21, 2020
 - Virtual this year
 - Plenary, tutorials, collaborator showcase, two-day study-a-thon
-



Harnessing EHDEN for accelerated study design and research

Dani Prieto-Alhambra, MD PhD
Prof of Pharmaco-epidemiology
Oxford University

- In April EHDEN launched a call to any institution in Europe holding relevant COVID-19 data to apply in order to contribute to research collaboration
- 75 applicants, **25 grants awarded**

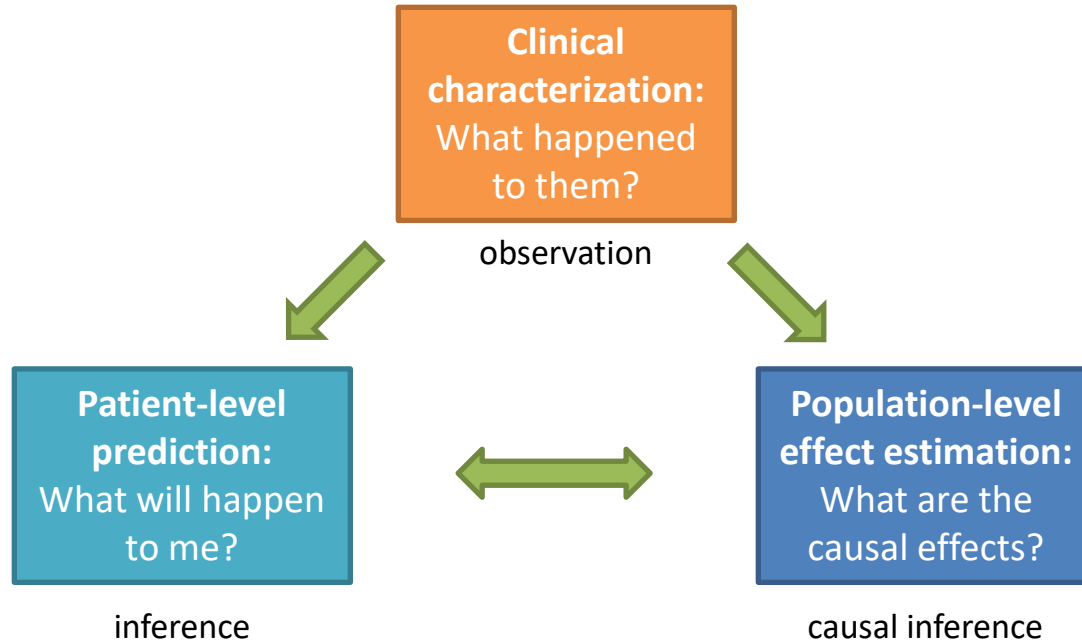


- **Highlights:**

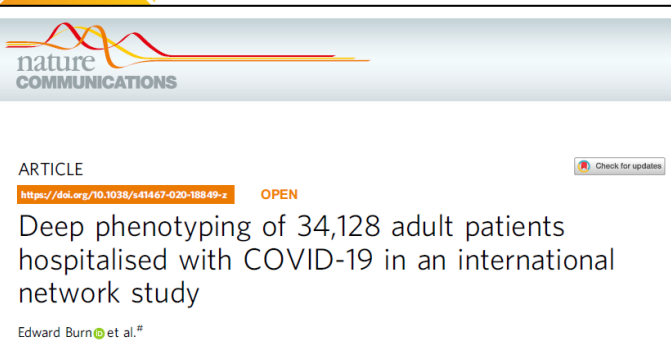
- **Health Data Hub** – medical records for the *entire French population*, millions of active patients, >>70K COVID diagnoses made
- **UK Biobank** – *large longitudinal research study* of 500K participants from England, Scotland, and Wales, has >1,000 positive COVID19 cases
- **Istanbul University Faculty of Medicine** – 2.5M patients, 1.5M active patients, more than 7K COVID19 patients seen, *work done at this data partner would be applicable for the whole country*



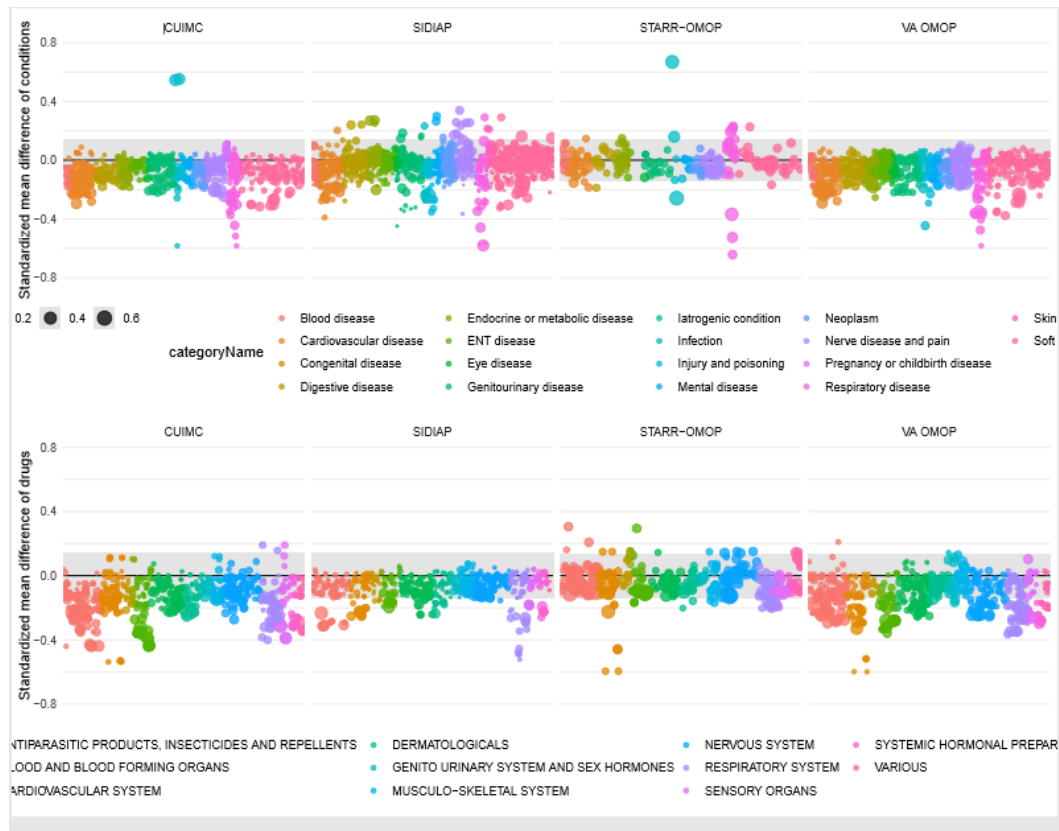
How can these data help inform the COVID response?



Characterisation: COVID is no flu



- COVID is no flu
- Healthier
- Less drug usage
- Exceptions obesity, diabetes, OA





- HCQ drug safety analyses completed within 2 weeks, informed EMA regulatory warnings.

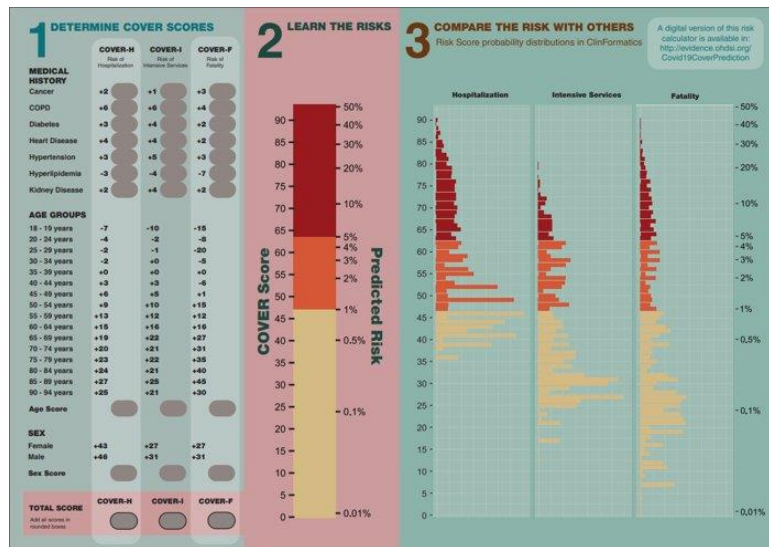




PREDICTION

COVER: COVID risk prediction

- Developed and externally validated COVER scores that quantify risks
- Used (as mentioned by ‘consellera de salut’) to measure the impact of new outbreaks in Catalonia (Spain)



3. Indicadors

- El Pla es basa en la mesura de **10 indicadors principals** que permeten una fotografia acurada de la realitat epidèmica a Catalunya.



- En la interpretació dels indicadors s'aplicaran **factors de correcció** com: índex socioeconòmic complex, envelliment de la població o la densitat poblacional.

/Salut

Generalitat de Catalunya

6



The need for health data in the era of Covid-19

“A Spanish perspective”

Dr. Raquel Yotti

Director General

National Institute of Health Carlos III

October 9th 2020

1. Need for GENERATING DATA

Urgent

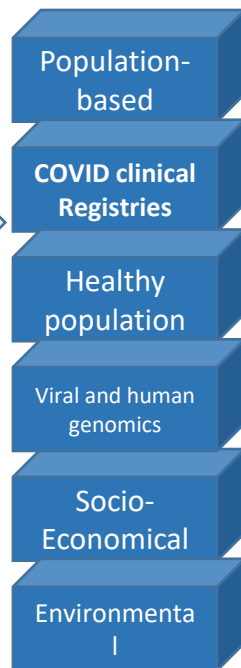
Clinical and public health questions:

- Treatment efficacy
- Severity Prediction
- Alert Parameters
- Vaccination Strategies
- Long-term sequels
- Mental health
- Surveillance and seroprevalence
- Others...

Generating & Registering

2. Need for INTEGRATING and SHARING DATA

COHORTS and real-world health data



Challenges and opportunities

Extraction & Homogenization

- Patient data
- Epidemiological data
- Imaging
- Biomarkers
- Genomics and omics
- Virological data

 **COVID-19 Data Portal**

Spanish Covid database

Analysis

3. Need for USING DATA

- Research
- Innovation and clinical transference
- Public health policies
- Design and implementation of healthcare and public health actions

ISCI research call (24 M€)
March 2020
COVID-FUND

ISCI registry creation
May 2020

Spanish Seroepidemiological Study: Science, Public health & Coordination

Prevalence of SARS-CoV-2 in Spain (ENE-COVID): a nationwide, population-based seroepidemiological study

Marina Pollán, Beatriz Pérez-Gómez, Roberto Pastor-Banrius, Jesús Oteo, Miguel A Hernán, Mayte Pérez-Olmeda, Jose I. Sanmartín, Aurora Fernández-García, Israel Cruz, Nerea Fernández de Larrea, Marta Molina, Francisco Rodríguez-Cabrer, Mariano Martín, Paloma Merino-Amador, Jose León Paniagua, Juan F Muñoz-Montalvo, Faustino Blanco, Raquel Yotti, on behalf of the ENE-COVID Study Group*

Summary

Background Spain is one of the European countries most affected by the COVID-19 pandemic. Serological surveys are a valuable tool to assess the extent of the epidemic, given the existence of asymptomatic cases and little access to diagnostic tests. This nationwide population-based study aims to estimate the seroprevalence of SARS-CoV-2 infection in Spain at national and regional level.

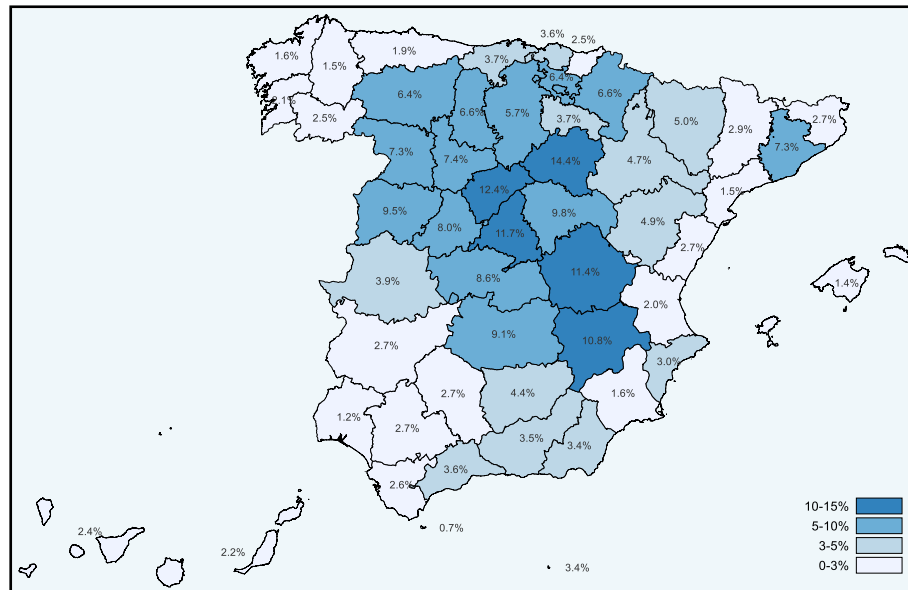
Methods 35883 households were selected from municipal rolls using two-stage random sampling stratified by province and municipality size, with all residents invited to participate. From April 27 to May 11, 2020, 61 075 participants (75.1% of all contacted individuals within selected households) answered a questionnaire on history of symptoms compatible with COVID-19 and risk factors, received a point-of-care antibody test, and, if agreed, donated a blood sample for additional testing with a chemiluminescent microparticle immunoassay. Prevalences of IgG antibodies were adjusted using sampling weights and post-stratification to allow for differences in non-response rates based on age group, sex, and census-tract income. Using results for both tests, we calculated a seroprevalence range maximising either specificity (positive for both tests) or sensitivity (positive for either test).

Findings Seroprevalence was 5.0% (95% CI 4.7–5.4) by the point-of-care test and 4.6% (4.3–5.0) by immunoassay, with a specificity–sensitivity range of 3.7% (3.3–4.0; both tests positive) to 6.2% (5.8–6.6; either test positive), with no differences by sex and lower seroprevalence in children younger than 10 years (<3.1% by the point-of-care test). There was substantial geographical variability, with higher prevalence around Madrid (>10%) and lower in coastal areas (<3%). Seroprevalence among 195 participants with positive PCR more than 14 days before the study visit ranged from 8.7–6% (81–192.1; both tests positive) to 91.8% (86.3–95.3; either test positive). In 7273 individuals with anosmia or at least three symptoms, seroprevalence ranged from 15.3% (13.8–16.8) to 19.3% (17.7–21.0). Around a third of seropositive participants were asymptomatic, ranging from 21.9% (19.1–24.9) to 35.8% (33.1–38.5). Only 19.5% (16.3–23.2) of symptomatic participants who were seropositive by both the point-of-care test and immunoassay reported a previous PCR test.

Interpretation The majority of the Spanish population is seronegative to SARS-CoV-2 infection, even in hotspot areas. Most PCR-confirmed cases have detectable antibodies, but a substantial proportion of people with symptoms compatible with COVID-19 did not have a PCR test and at least a third of infections determined by serology were asymptomatic. These results emphasise the need for maintaining public health measures to avoid a new epidemic wave.

Funding Spanish Ministry of Health, Institute of Health Carlos III, and Spanish National Health System.

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- 68.296 participants (longitudinal data in 3 rounds)
- 165.176 serum samples

EUROPEAN HEALTH DATA & EVIDENCE NETWORK

The Need for Health Data in the Era of Covid-19

Rafael Bengoa

The Institute for Health and Strategy
(SI-Health)
Bilbao (Spain)



FRAGMENTATION AND INEQUALITIES HAVE BEEN DEADLY

Social Services

Home Care

Primary Care Team

Family



Cardiologist

Nurse

Rehabilitator

Traumatologist

Administration

Different Health Systems were Reconfiguring Health Care Towards...

- A PROACTIVE AND PREVENTATIVE MODEL
- BETTER INTEGRATION WITH SOCIAL CARE
- BETTER CHRONIC CONDITIONS MANAGEMENT
- A GREATER FOCUS ON QUALITY
- MORE VOICE TO PATIENTS AND EMPOWERMENT
- POPULATION HEALTH MANAGEMENT
- TACKLING INEQUALITIES
- AN EXPANDED USE OF INFORMATION AND COMMUNICATION TECHNOLOGY
- OUTCOME BASED PAYMENT MODELS TO ENCOURAGE VALUE VERSUS ACTIVITY



Covid has reinforced
the need for
integration and
population focus

65 % deaths in LTC !!!!

¿ COVID AS AN ENABLER OF INTEGRATION ?

DURING PANDEMIC

- **VERY RAPID SERVICE SHIFTS**
- **RAPID SHARED SCIENTIFIC KNOW HOW**
- **SILOS BROKE DOWN**
- **DIGITAL HEALTH EXPANSION**
- **EXAMPLES OF CARE INTEGRATION VIA REMOTE MONITORING**
- **RAPID CHANGES IN HUMAN RESOURCES MANAGEMENT**
-

A PUSH TOWARDS POPULATION HEALTH



IMPLIES MORE PROACTIVITY AND OUTREACH TOWARDS COMMUNITY
AND HOME CARE MODELS



REQUIRES PERSON CENTRED SERVICES AND TECHNOLOGY (ALARMS ETC)



REQUIRES A SHIFT TO **DATA-DRIVEN** AND **REMOTE** MODELS OF CARE

PLAN YOUR POPULATION : RISK STRATIFICATION OF 5000 PEOPLE WITH DEMENTIA

Estratificación del riesgo

1er Nivel (1%) 50 pacientes

- Muchos problemas de comportamiento, deterioro funcional grave, recursos mínimos, comorbilidades.
- Admisiones frecuentes en urgencias y hospitalizaciones.

2do Nivel (2-5%) 199 pacientes

- Frecuentes problemas de comportamiento, deterioro funcional, recursos mínimos, comorbilidades.
- Admisiones múltiples en urgencias y hospitalizaciones.

3er Nivel (6-20%) 746 pacientes

- Muchos tienen problemas de comportamiento y/o deterioro funcional grave, comorbilidades.

4to Nivel (21-60%) 1990 pacientes

- Demencia leve.
- Conseguir atención médica de rutina.

5to Nivel (61-100%) 1990 pacientes

- Demencia leve.
- Conseguir atención médica de rutina.

Plan de Cuidados de la demencia

1er Nivel (1%) 50 pacientes

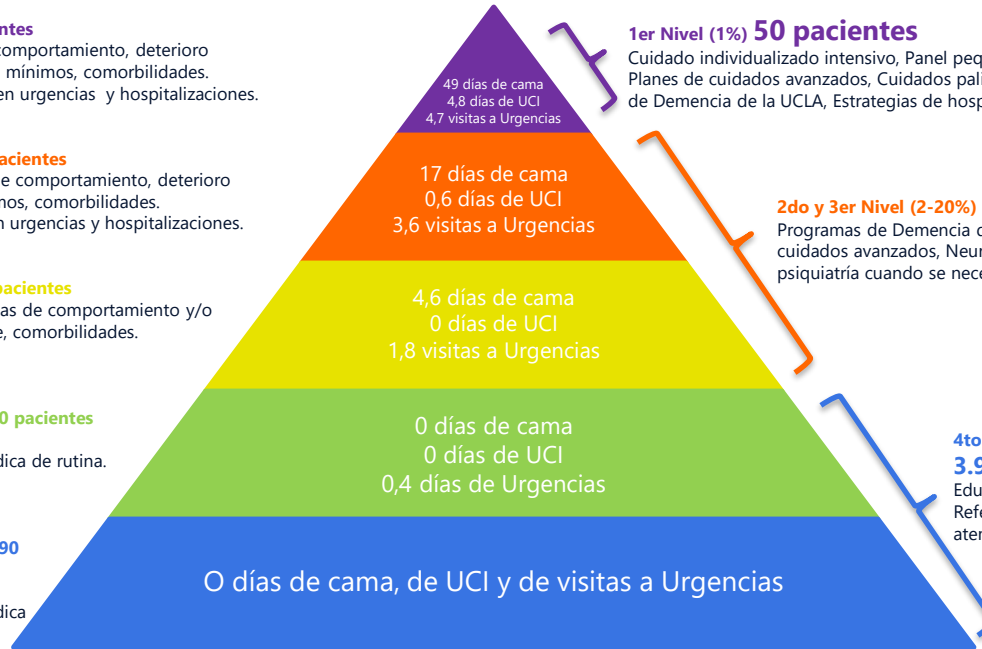
Cuidado individualizado intensivo, Panel pequeño de AP, Planes de cuidados avanzados, Cuidados paliativos, Programas de Demencia de la UCLA, Estrategias de hospital.

2do y 3er Nivel (2-20%) 945 pacientes

Programas de Demencia de la UCLA, Planes de cuidados avanzados, Neurología, Consultas de psiquiatría cuando se necesiten.

4to y 5to Nivel (21-100%) 3.980 pacientes

Educación a los cuidadores, Referencia y seguimiento y atención habitual.



SI-HEALTH
INSTITUTE FOR HEALTH
& STRATEGY

Fuente: "How A Population-Based Approach Can Improve Dementia Care,"
Health Affairs Blog, May 8, 2019. DOI: 10.1377/hblog20190506.543619

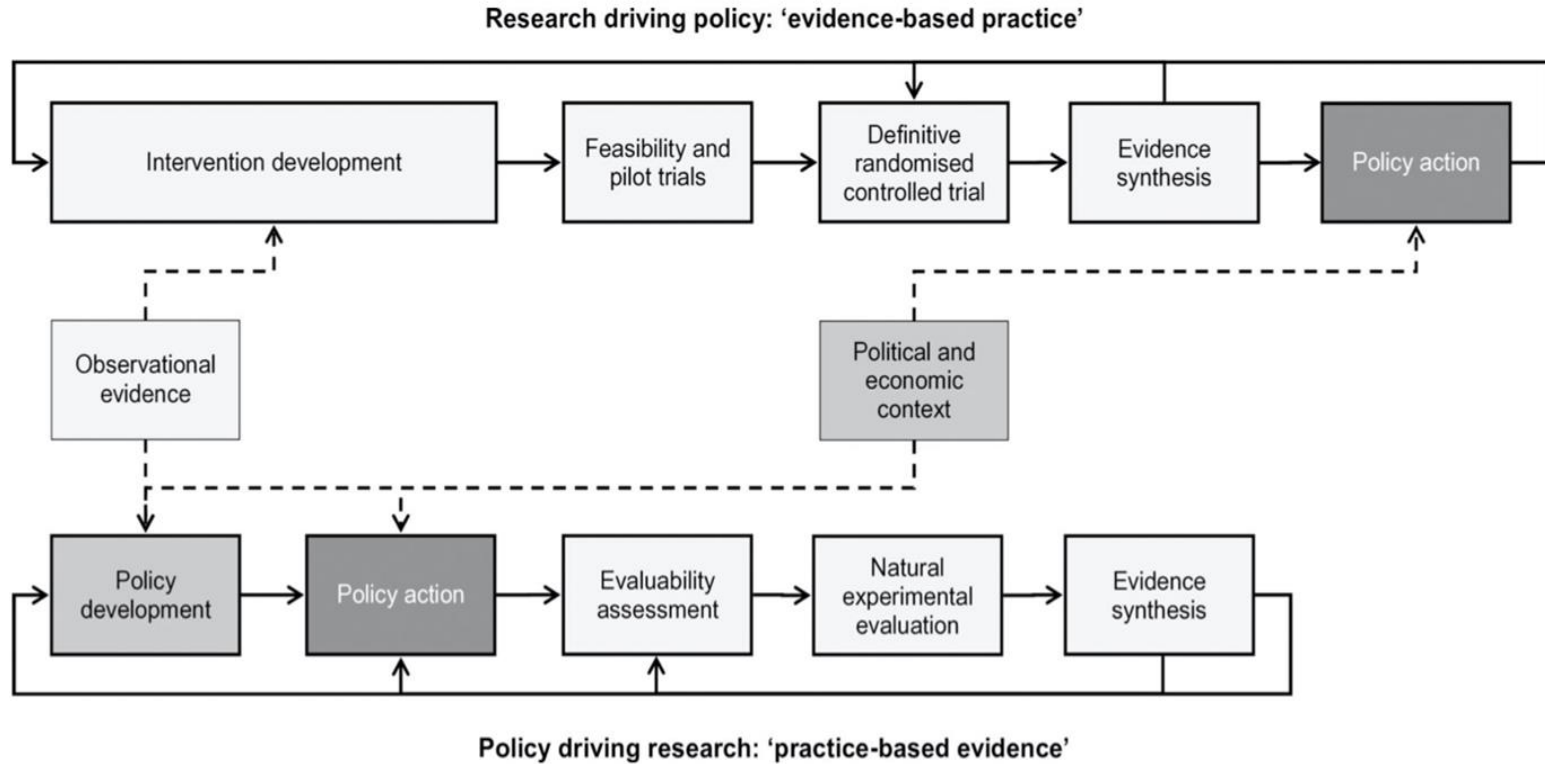
FRAGMENTED CARE “ SYSTEM” = SILOED DATA

A SYSTEM IS ABOUT COLECTING DATA AND INORMATION

SPAIN MOVING FORARD BUT INTEROPERABILITY STILL UNACCOMPLISHED

NO INTEROPERABILITY = NO INTEGRATION OF CARE

NEEDS PLANNING ; WILL NOT BE RESOLVED BY MARKET





EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EHDEN - Webinar 1

The need for health data in the era of COVID-19



Field of pharmacoepidemiology is mature and RWE used for decades for safety evaluations of medicinal products

Use for efficacy/effectiveness is debated

Frequent question received from drug manufacturers, CROs, researchers:

In which situations are observational health data acceptable by regulators for the benefit-risk evaluation of medicinal products in authorisation procedure?

Typical responses:

- Case-by-case basis
- Health data may be supportive but may not replace RCTs. Regulators open to observational evidence where, in exceptional circumstances, clinical trials are unethical or unfeasible
- Considerations given to effect size, unmet medical need and endpoints
- Recommendation to apply for Scientific advice



What should be criteria for acceptability of observational evidence?

Evidence should be:

- **adequate** (e.g. precision of effect, adequate range of characteristics of population covered, length of follow-up,..)
- **derived from real-data sources of demonstrated good quality**
- **accurate** (verification)
- **valid** (internal and external validity) – best epidemiological and statistical methods
- **consistent** (across countries/data sources) - or differences can be explained
- **replicable** (need for transparency)
- **timely**

Can we learn from experience ?

ON-GOING: Review of observational evidence submitted in MAAs and type II variations/line extensions, 2018 and 2019

Started in August 2020 by Data Analytics workstream, EMA

Objective : Identification, classification and characterisation of observational evidence submitted in new MAAs, type II variations and line extensions with change of indications/new indications (exclusion of generics, informed consent and multiple applications of same product)

Methods:

- Identification of all submissions; manual review of CHMP AR and risk management plans
- Inclusion/exclusion criteria in definition of observational evidence
- Extraction of information on any observational evidence submitted, a.o: objective, main/supportive, data sources, design, methods, RMP category, sample size, ...

Number of products included: **311**, 158 new MAA, 153 type II variations/line extension for change of indication or new indication



Preliminary observations

- Majority of observational evidence submitted relate to planned studies in the risk management plan
- High attention given to:
 - Quality of data sources and of data elements
 - Use of best practice in epidemiology and statistics
- In some cases, selection and information bias, small sample sizes, poor data quality, issues of confounding and data analysis and other limitations of observational evidence seem to be insurmountable obstacles for use of observational evidence for efficacy/effectiveness.

Any questions?



Further information

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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Raquel Yotti

Director

National Health Institute Carlos III
(Spain)



Rafael Bengoa

Director of SI-Health

and former health minister of the
Basque Country (Spain)



George Hripcsak

Observational Health Data Sciences
and Informatics
(OHDSI) network



Xavier Kurz

European Medicines Agency
(EMA)



Dani Prieto-Alhambra

European Health Data and Evidence
Network
(EHDEN)



Duane Schulthess

Vital Transformation
(moderator)