



Catalyzing a Global Pandemic Response: The OHDSI COVID Study-A-Thon and EHDEN Data Partner Call

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Prof of Pharmaco-epidemiology
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AGENDA

- What's in this for us?
- The EHDEN-OHDSI COVID-19 collaboration
- Unravelling COVID19: the devil, in the detail...
- A MUST DO: learning from the past...



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Not Only Data...

Home / News & Opinion

WHO Halts Hydroxychloroquine Testing Over Safety Concerns

A paper published in *The Lancet* reported that hospitalized COVID-19 patients taking the drug had a higher risk of death, although some researchers have raised questions about the data.



Catherine Offord
May 27, 2020



Update (June 18): The World Health Organization announced yesterday that it was dropping hydroxychloroquine from the Solidarity trial after new data suggest the drug is ineffective as a COVID-19 treatment or prophylaxis. A study published June

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#datasaveslives

But poor practice can harm

Science Contents ▾ News ▾ Careers ▾ Journals ▾




Two papers relying on hospital records of COVID-19 patients have been retracted because the company that purportedly analyzed the raw data won't allow their validity to be independently validated. AP PHOTO/MANU FERNANDEZ

Two elite medical journals retract coronavirus papers over data integrity questions

By Charles Piller, Kelly Servick | Jun. 4, 2020 , 5:30 PM

Science Contents ▾ News ▾ Careers ▾ Journals ▾



E. PETERSEN/SCIENCE

Who's to blame? These three scientists are at the heart of the Surgisphere COVID-19 scandal

By Charles Piller | Jun. 8, 2020 , 7:00 PM

Science's COVID-19 reporting is supported by the Pulitzer Center.

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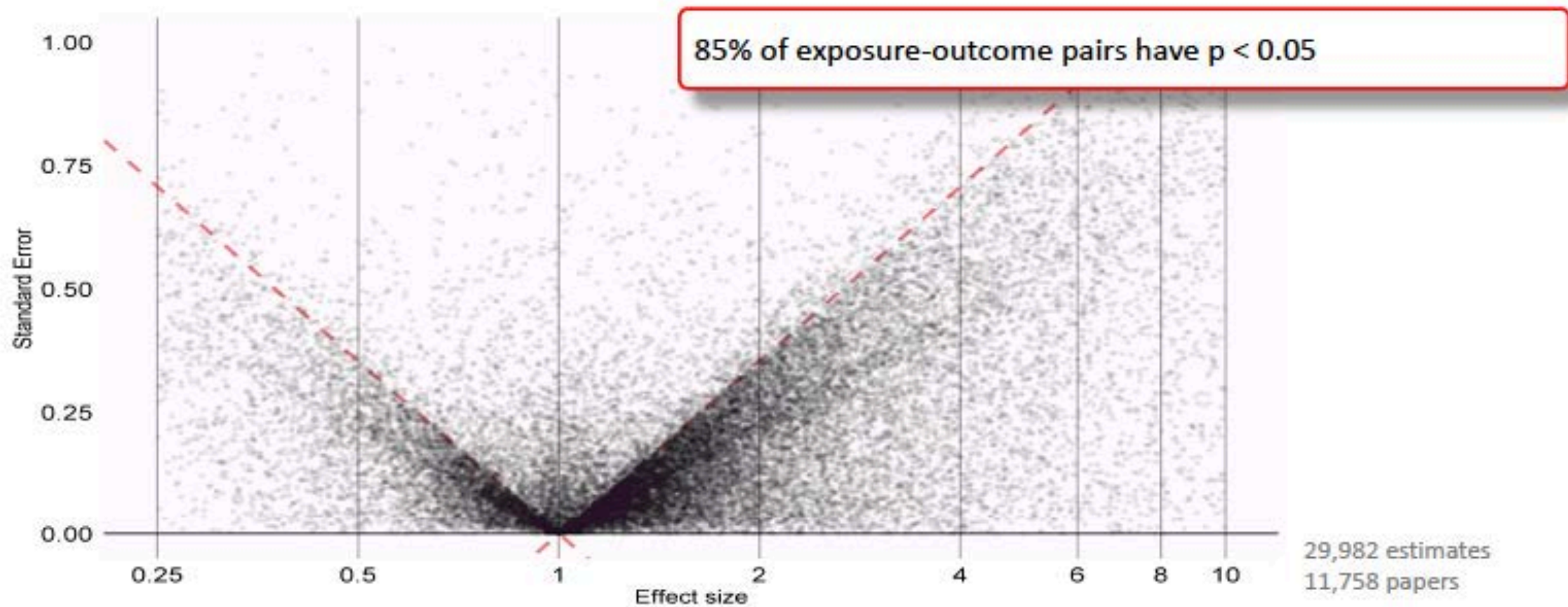
Email Address *

Three unlikely collaborators are at the heart of the fast-moving COVID-19 research scandal, which led to [retractions last week by The Lancet and The New England Journal of Medicine \(NEJM\)](#), and the withdrawal of an online preprint, after the trove of patient data they all relied on

Not open science -> p-Hacking



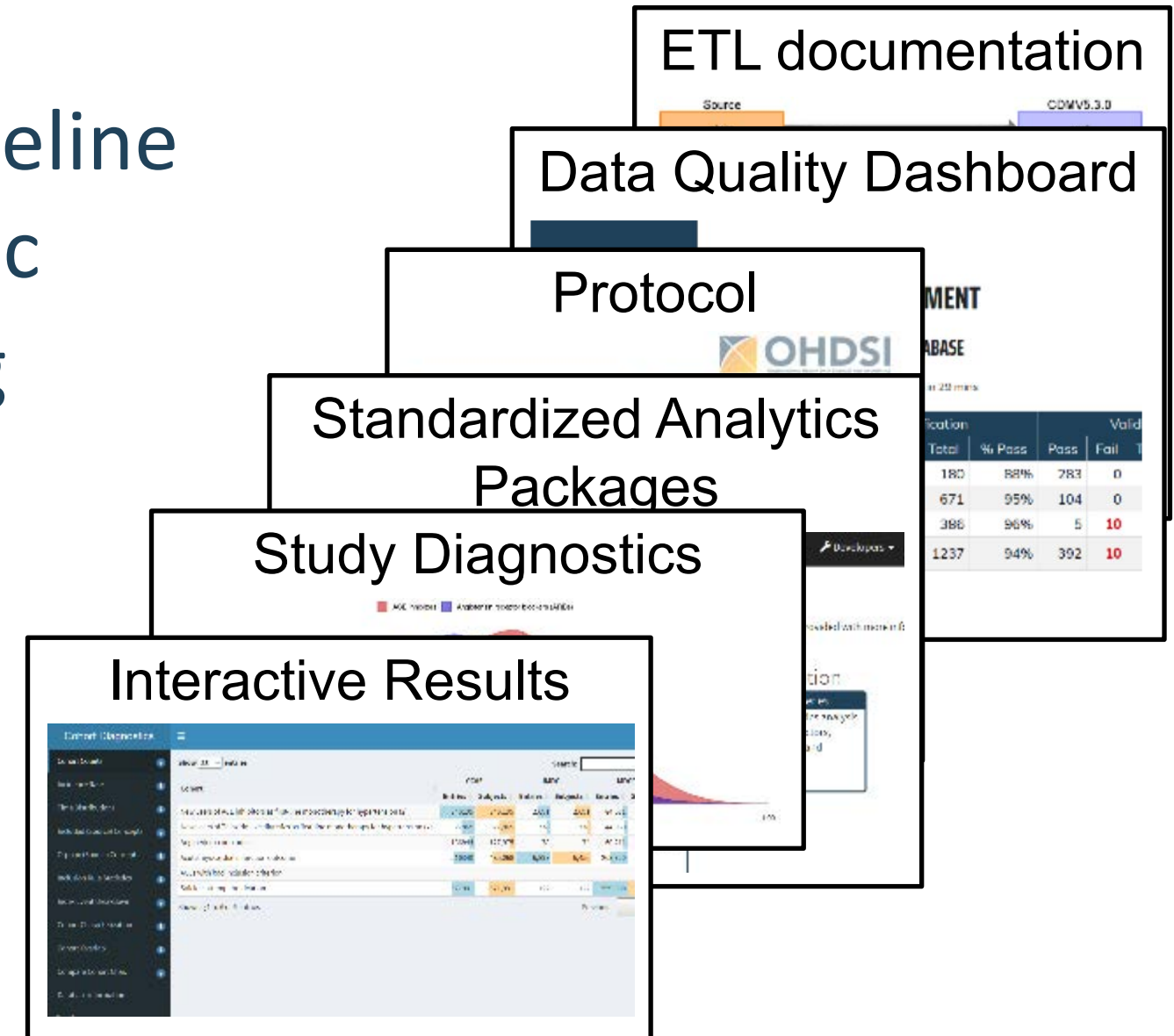
Observational research results in literature





How can 'Open Science' help?

- All artifacts of our analytics pipeline are made available to the public
- In doing so, we are encouraging others to do the same
- **Transparency** is key to
 - **Reproducibility**
 - **Interpretability**
 - **Trustworthiness**





The FULL transparency agenda

- 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>



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OHDSI
OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

#OHDSICOVID19

OHDSI COVID-19 International Study-A-Thon

Follow our
COVID19 Updates

[www.ohdsi.org/
covid-19-updates](http://www.ohdsi.org/covid-19-updates)

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#JoinTheJourney

**Collaborating to design and execute observational research and
generate real-world evidence to inform the global pandemic**

March 26-29, 2020



The original plan ...

OHDSI Europe 2020

- 300 to 350 people
- In Oxford
- Talking science
- Learning





The original plan ...

OHDSI Europe 2020

- 300 to 350 people
- In Oxford
- Talking science
- Learning
- ... and **having fun!**





Instead ... #flattenthecurve

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EHDSI

OHDSI
OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

We regret to inform you that the 2020 European Symposium "From data to impact: the journey towards improving clinical practice" is cancelled due to the COVID-19 outbreak

[More Info](#)



OHDSI

OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

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The Journey Newsletter ▾ Past Events Upcoming Events

[Home](#) > [COVID-19 Updates Page](#)

COVID-19 Updates Page

The Observational Health Data Sciences and Informatics (OHDSI) international community will host a COVID-19 virtual study-a-thon this week (March 26-29) to inform healthcare decision-making in response to the current global pandemic.

Day 4

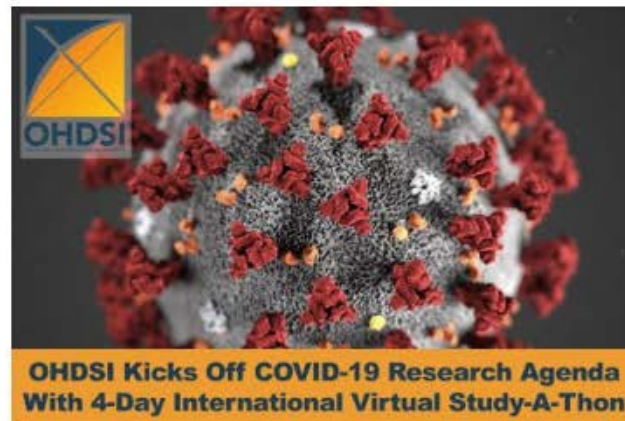
Early Call: [Video](#)

Global Call: [Video](#)

FINAL CALL: [Use This Link To Watch Live](#) (regardless of whether you registered)

Please take a look at the early calls, but we're going to save the exciting study-a-thon updates for our final call tonight! [This link will work for anybody](#), regardless of whether you registered for the study-a-thon. We are so excited to share our studies and early results with the world. Please share this link with people in your networks, so they can see the power of global collaboration in the OHDSI community.

Day 3 Updates



What did we achieve?

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

- Convene **351** participants from **30** countries
- Hold **12** Global Huddles, **>100** collaborator calls, **>13,000** chat messages
- Engage **15** concurrent channels
- Review **>10,000** publications
- Draft **9** study protocols
- Release **13** study packages
- Design **355** cohort definitions
- Assemble a distributed data network with **37** partners signed on to execute studies

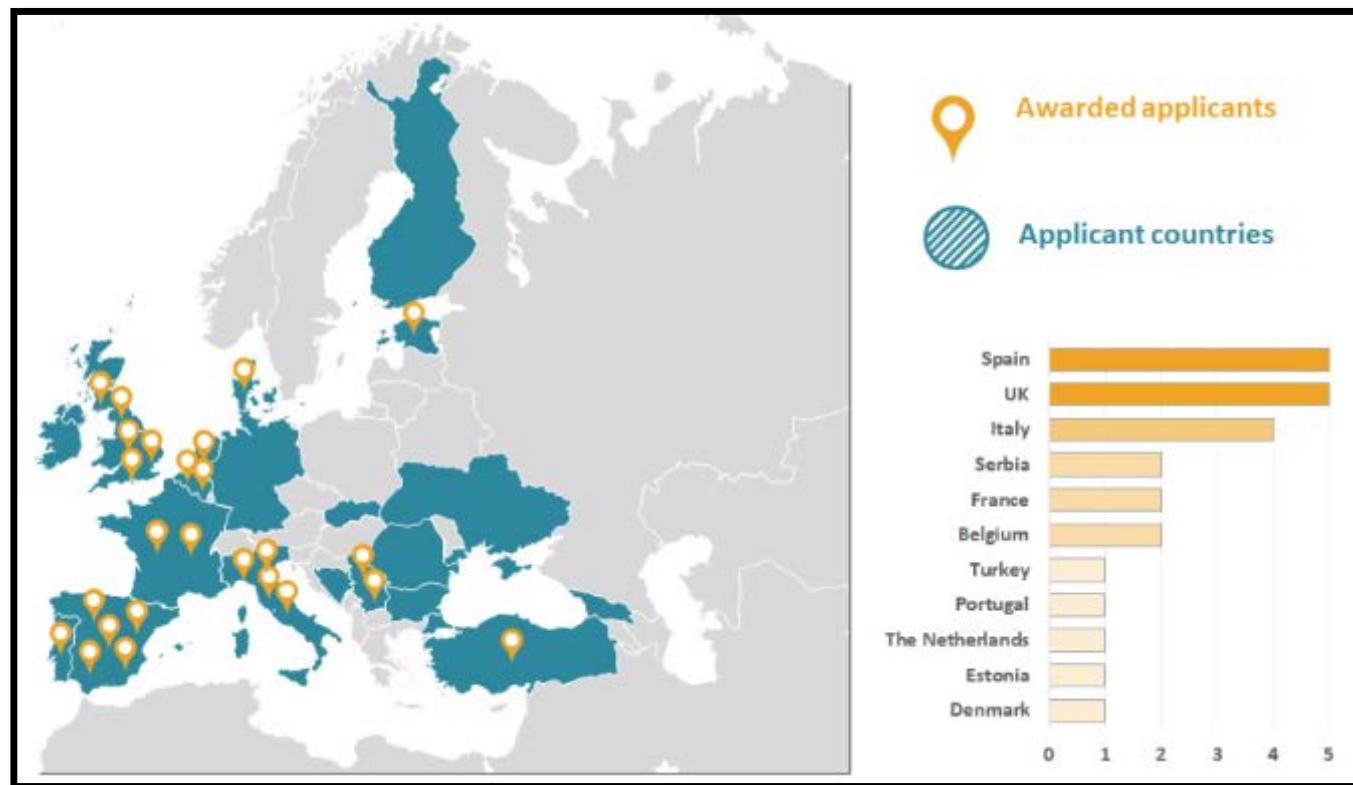
<https://www.ohdsi.org/covid-19-updates/>



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

- First large-scale characterization of COVID patients in Europe, US and Asia
- First prediction model externally validated on COVID patients to inform shielding strategies
- Largest study ever conducted on the safety of hydroxychloroquine

- 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*



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What is COVID-19? Ideal definition

- Clinically relevant
- Actionable/interoperable for different types of data
- Transportable (across a network of international db)
- Sensitive
- ... and specific
- POSSIBLE?!





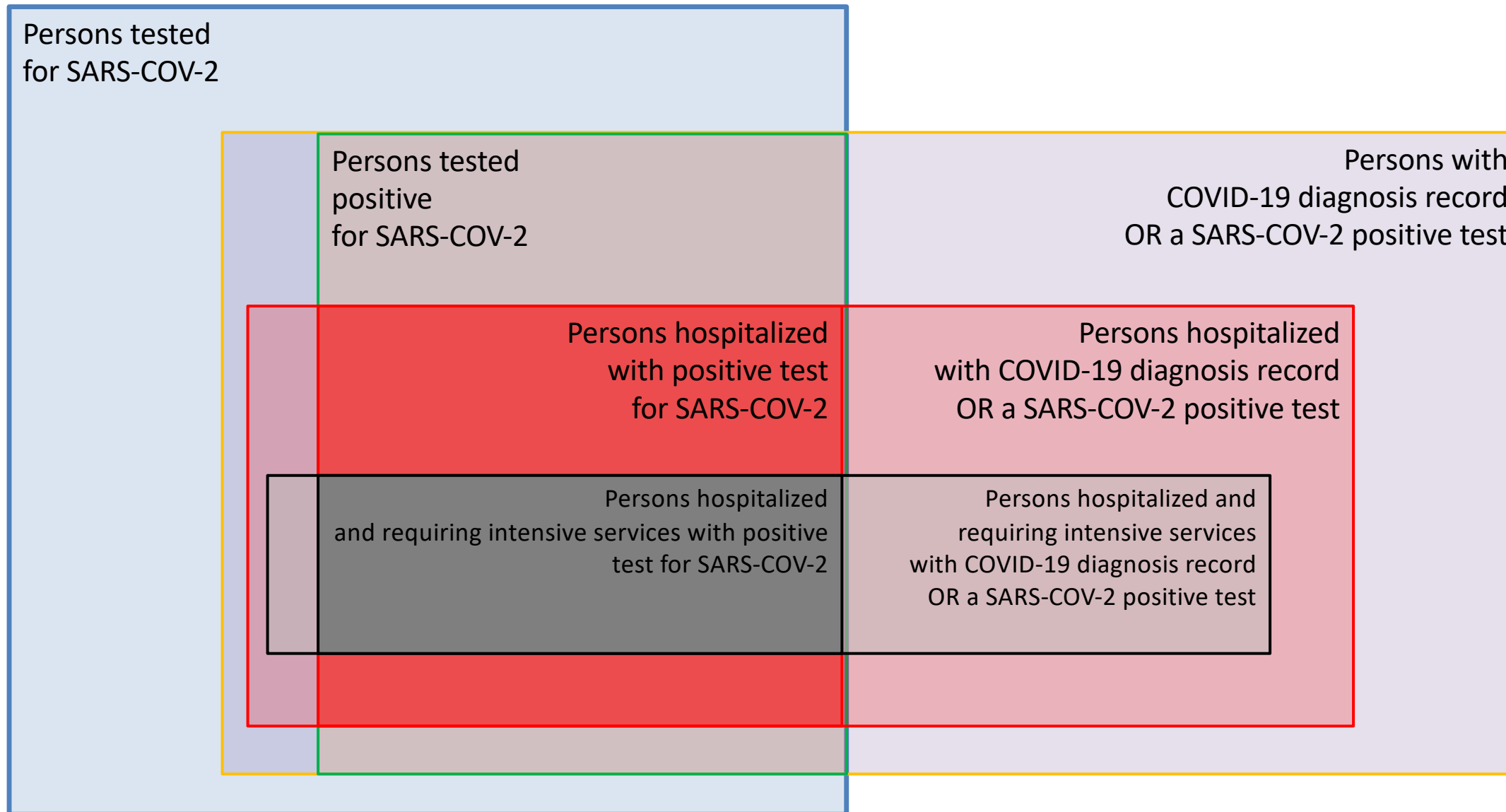
What is COVID-19? Operational definitions

- Tested positive in RT-PCR for SARS-CoV-2
- Clinically diagnosed with COVID-19
- Hospitalized with a recorded diagnosis of COVID-19
- Admitted in ICU with a diagnosis of COVID-19
- Death with COVID-19
- ... [add here]



Characterization

CHARYBDIS target cohorts

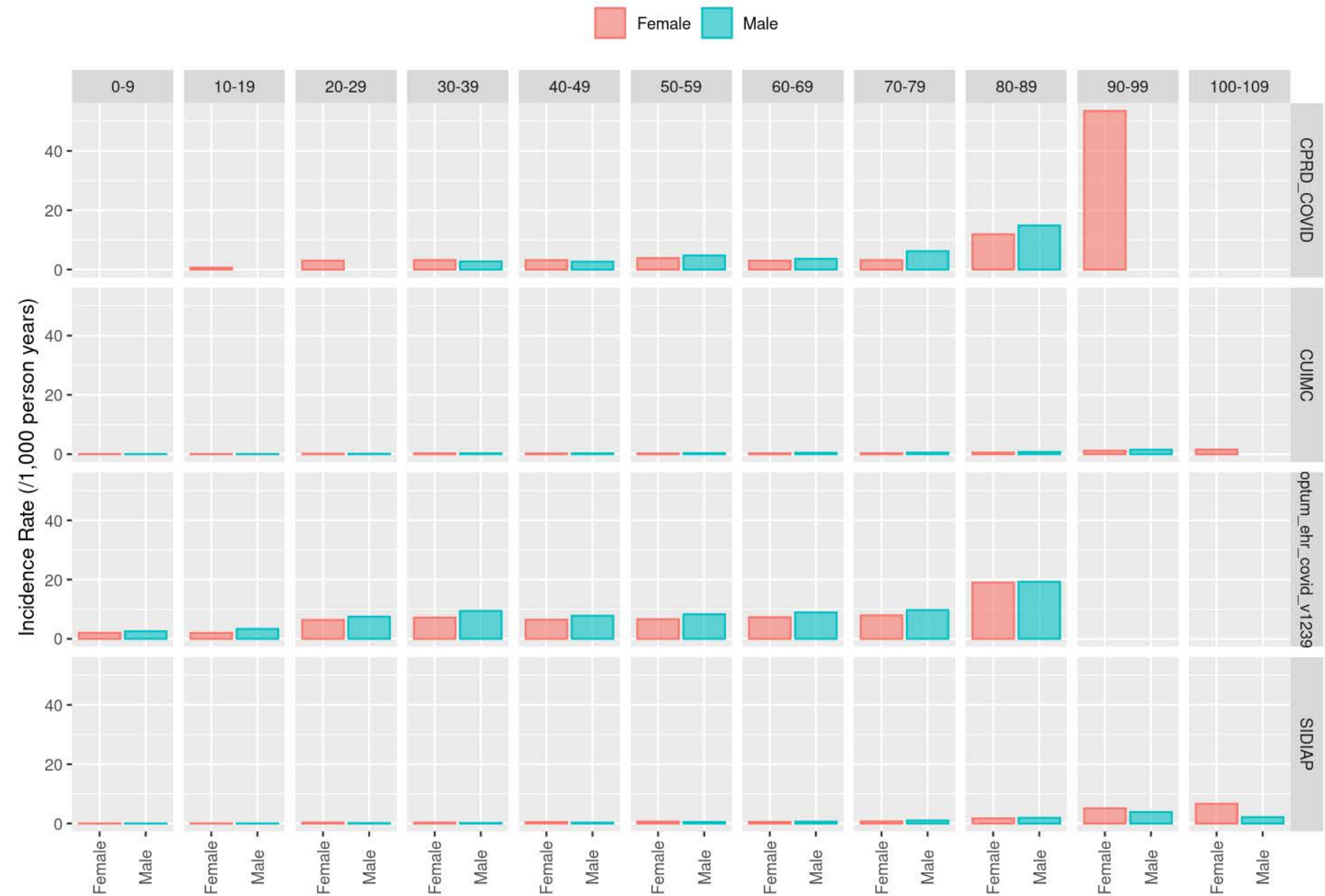




<https://data.ohdsi.org/Covid19CharacterizationCharybdisDiagCovid/>

Tested +

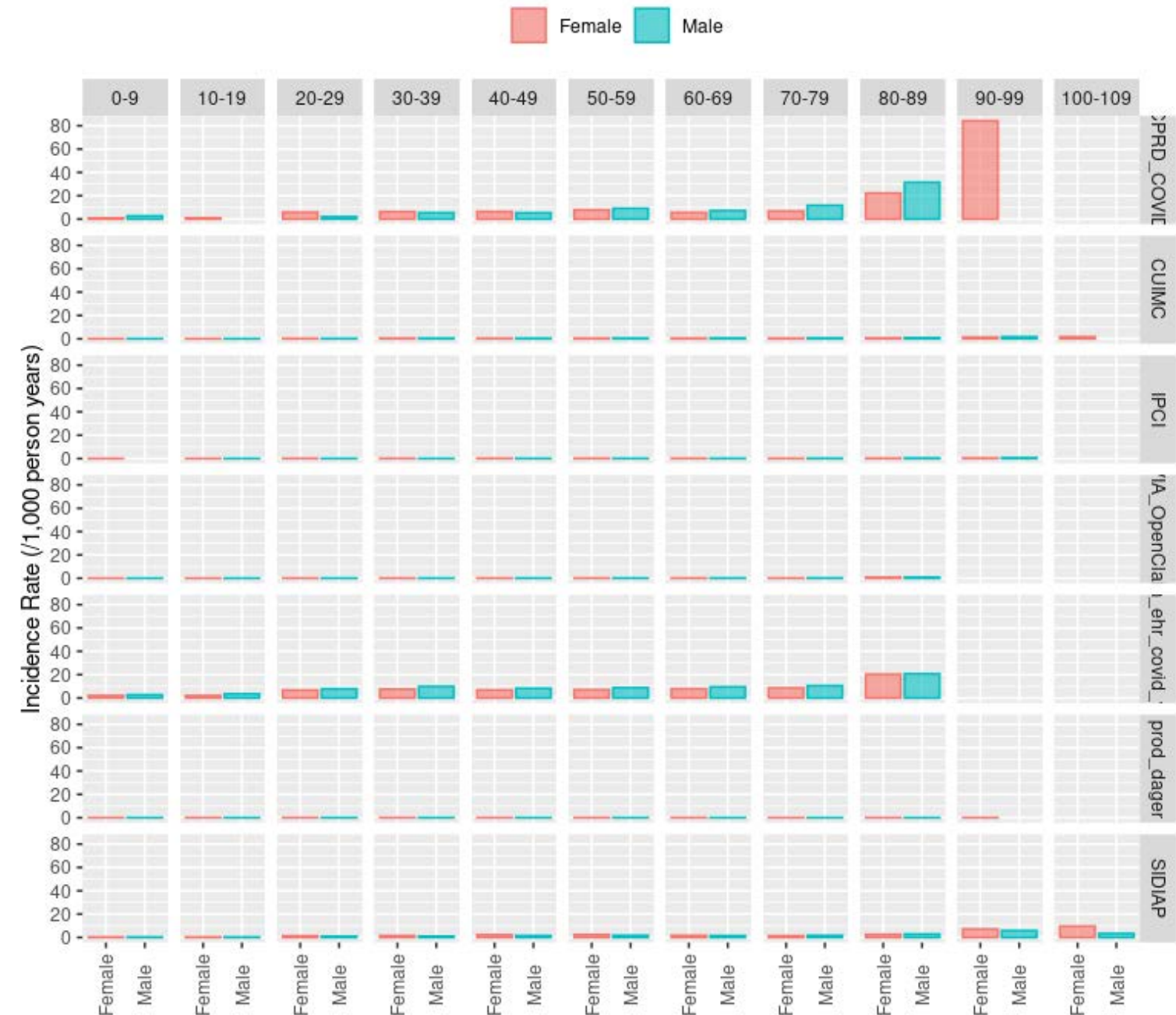
- TARGET DBs
 - Hospital EMRs: **CUIMC**, **Optum EHR**, HM-ES
 - Claims: IQVIA Open Claims
 - GP databases: IPCI-NL, **SIDIAP-ES**, **CPRD-UK**
 - Ambulatory: IQVIA LPD-FR, IQVIA DA-Germany





Diagnosed OR Tested +

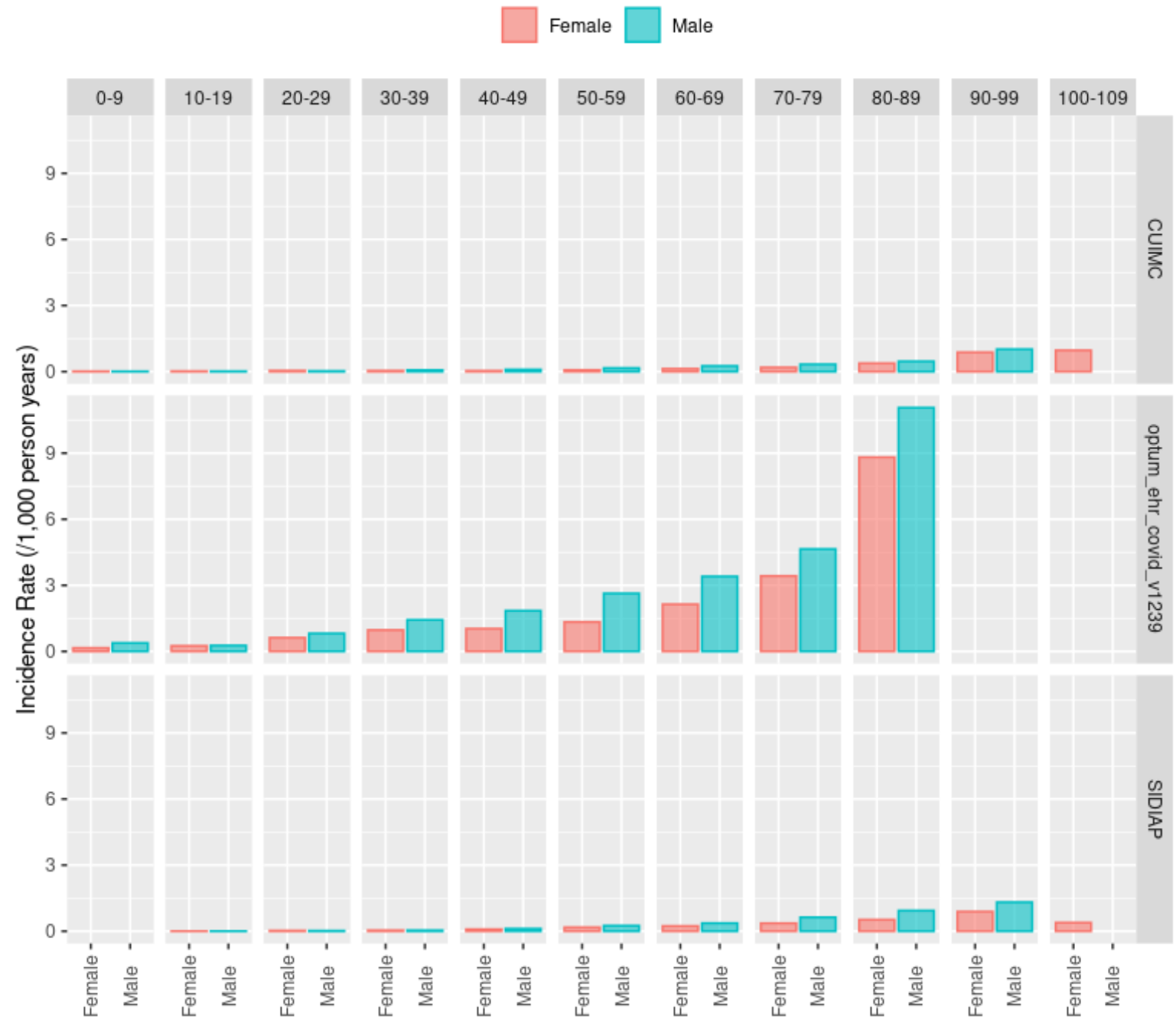
- TARGET DBs
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Hospitalized with a Test +

- TARGET DBs
 - Hospital EMRs: **CUIMC**, **Optum EHR**, HM-ES
 - Claims: IQVIA Open Claims
 - GP databases: IPCI-NL, **SIDIAP-ES**, CPRD-UK
 - Ambulatory: IQVIA LPD-FR, IQVIA DA-Germany

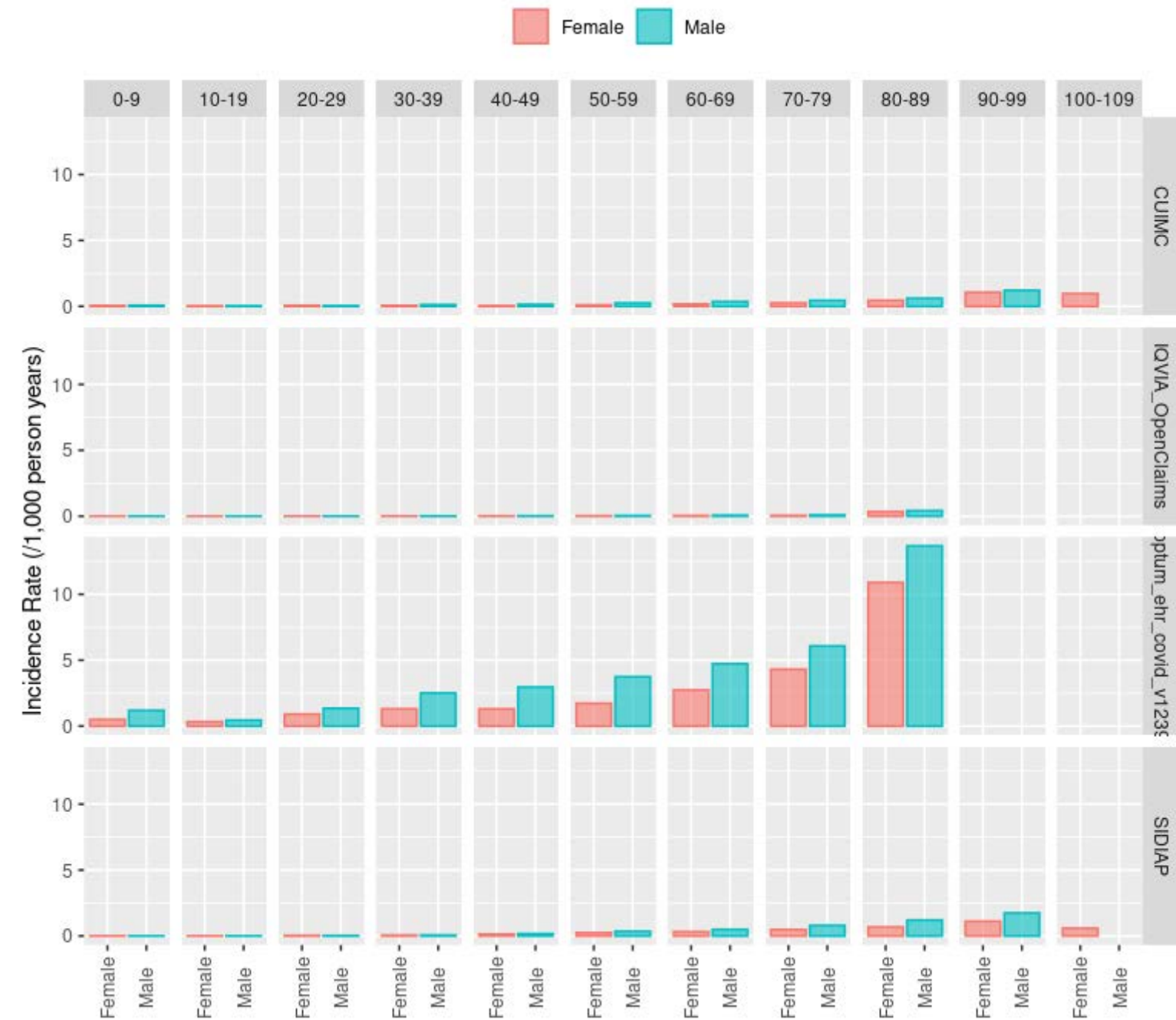




<https://data.ohdsi.org/Covid19CharacterizationCharybdisDiagCovid/>

Hospitalized with a
COVID diagnosis OR Test +

- TARGET DBs
 - Hospital EMRs **CUIMC**, **Optum EHR**, HM-ES
 - Claims: **IQVIA Open Claims**
 - GP databases: IPCI-NL, **SIDIAP-ES**, CPRD-UK
 - Ambulatory: IQVIA LPD-FR, IQVIA DA-Germany





Admitted to ICU with COVID diagnosis OR Test +

- TARGET DBs
 - Hospital EMRs **CUIMC**, **Optum EHR**, HM-ES
 - Claims: **IQVIA Open Claims**
 - GP databases: IPCI-NL, SIDIAP-ES, CPRD-UK
 - Ambulatory: IQVIA LPD-FR, IQVIA DA-Germany

<https://data.ohdsi.org/Covid19CharacterizationCharybdisDiagCovid/>





APPLIED ACROSS THE OHDSI NETWORK ...

COHORT	HEALTH VERITY	PREMIER	HIRA SK	OPTUM EHR	STARR OMOP	TUFTS TRDW	VA- OMOP	IQVIA OPENCLAI MS	COLUMBI A CUIMC	DAIJO U SK	NANF ANG CHINA	SIDIAP-ES	IPCI- NL	HM- ES	CPRD -UK	IQVIA LPD-FR	IQVIA DA- GERM ANY
Tested	2424240	219230	230268	411580	56881	6950	193001	783214	22094	N/A	397	150187	N/A	N/A	1873	N/A	N/A
Tested +	274271	N/A	N/A	42909	1880	1035	N/A	N/A	6959	N/A	392	37975	N/A	N/A	1376	N/A	N/A
Tested AND (Diagnosed OR Test+)	363043	21503	6013	43386	4095	1097	12859	74793	7998	N/A	393	42325	N/A	N/A	1390	N/A	N/A
Diagnosed OR Test+	371153	66132	7603	45508	4788	1250	25538	493949	10437	559	403	124221	1417	2089	2679	23592	2440
Hospitalized AND (Diagnosis OR Test+)	14205	36019	7599	13283	744	326	5843	139971	3439	46	304	18364	7	2089	N/A	N/A	N/A
Hospitalized AND (Diagnosis OR Test+) AND 1+y lookback	3613	132	7599	10534	615	186	5510	133091	2600	30	24	18197	7	N/A	N/A	N/A	N/A
Hospitalized AND Test+ AND 1+y lookback	2364	N/A	N/A	9841	86	140	N/A	N/A	2344	N/A	16	13520	N/A	N/A	N/A	N/A	N/A
Hospitalized AND ICU AND (Diagnosis OR Test+) AND 1+y lookback	237	28	130	1345	46	40	1013	14633	56	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A



APPLIED TO THE OHDSI NETWORK ...

Requiring Test data

Tested

N = 4,499,915

Tested+

N = 366,797 (8.15%)

Hospitalized with a Test+

N = 28,311

7.72% of Tested+

0.6% of Tested



APPLIED TO THE OHDSI NETWORK ...

Happy with clinical diagnosis

Clinical diagnosis or Test+

N = 1,183,758

Hospitalized and diagnosed or Test+

N = 242,239 (20.5%)

Hospitalized AND +1y lookback

N = 182,138 (75.2% of above)

Above AND ICU

N = 17,528 (9.6% of above)



Summary – COVID19 definitions/phenotypes

- Different phenotypes will provide different levels of confidence (eg test+ AND vs test+ OR clinical diagnosis)
- ... and reflect different disease severity (eg diagnosed vs hospitalized vs ICU admitted)
- They will accommodate different types of data and different geographical areas
- NOTE: Things might change over time, with increasing test capacity and different patterns of community transmission



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Primum non nocere (First, do no harm)

Hydroxychloroquine ...

- Cheap, generic drug
- Indicated for RA, SLE and malaria prophylaxis for >40y!
- Relatively safe, but:
 - Retinal toxicity
 - QT lengthening
- “In vitro” activity vs SARSCov2
- Great publicity ...

Coronavirus: Trump says he is taking unproven drug hydroxychloroquine

🕒 19 May 2020

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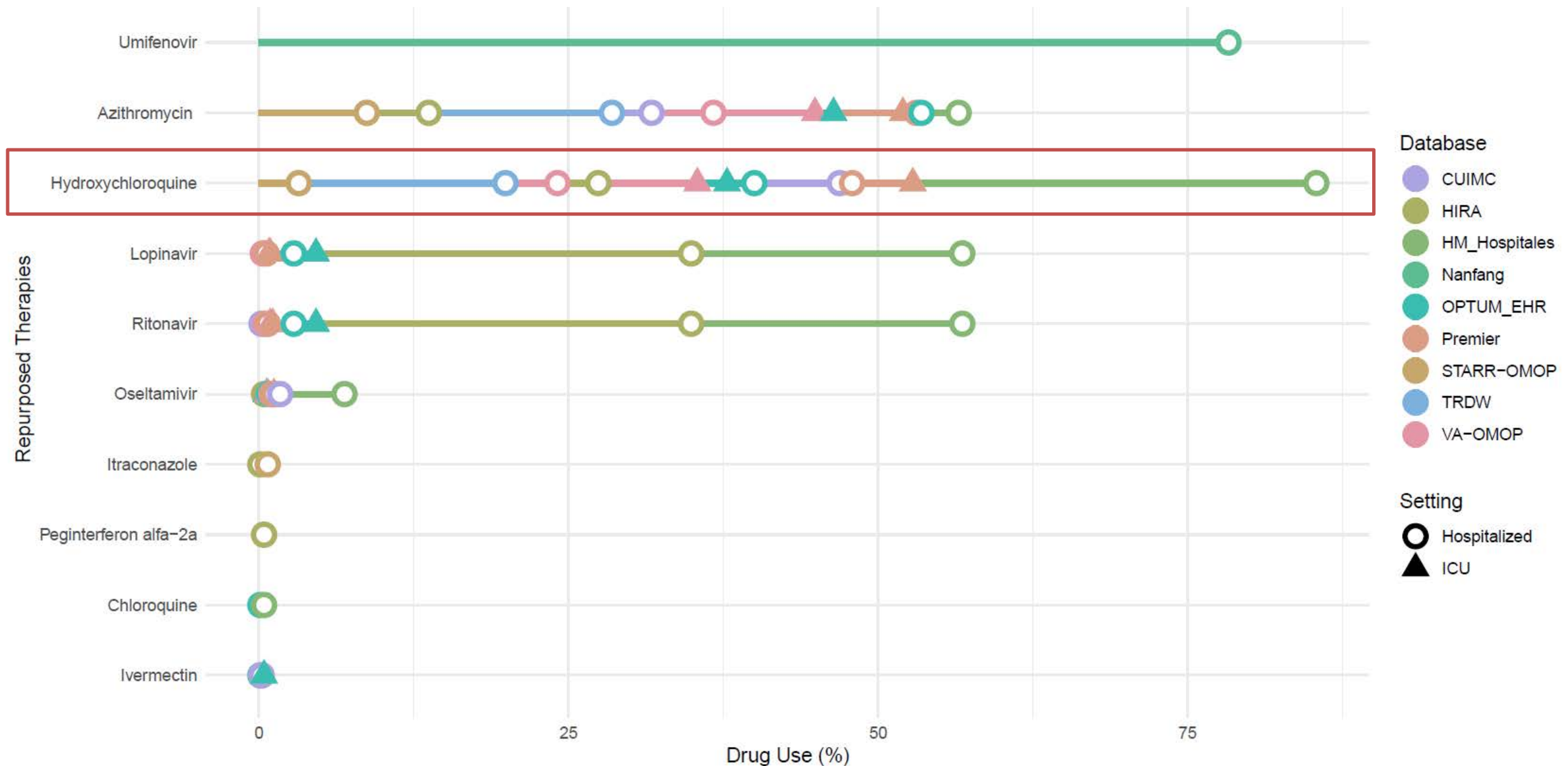
Coronavirus pandemic



Trump: "If it's not good, I'll tell you right, I'm not going to get hurt by it"



Potential public health impact: CHARYBDIS DUS results





Aim/s

We used historical data from >900,000 previous users of HCQ for other indications (RA) to learn:

- What is the risk of serious adverse events (leading to hospital admission) associated with HCQ (vs SSZ as active comparator)?
- What is the risk of serious adverse events associated with the addition of AZM (vs AMX as active comparator) amongst users of HCQ?



Methods

Data source/s: Routine data (electronic medical records and claims) from Germany, Japan, Spain, S Korea, US, and the UK

Design: Comparative cohort analysis (+ SCCS, not covered today)

Participants:

- Age 18+ , 1+ years of data 'visibility'
- Diagnosis of Rheumatoid Arthritis + use of one of the study drugs/ combinations



Methods (2)

Follow-up:

- 30-day (from initiation of study drug/combination)
- On treatment (for as long as treatment is continued)

Analyses:

1. Federated analytics -> db-specific findings -> meta-analysis
2. Building large-scale propensity scores
3. Diagnostics (imbalances observed confounders + negative control outcomes for unobserved confounders) -> analyses only conducted if OK
4. Propensity score stratification + NCO calibration



RESULTS

<http://evidence.ohdsi.org/Covid19EstimationHydroxychloroquine>

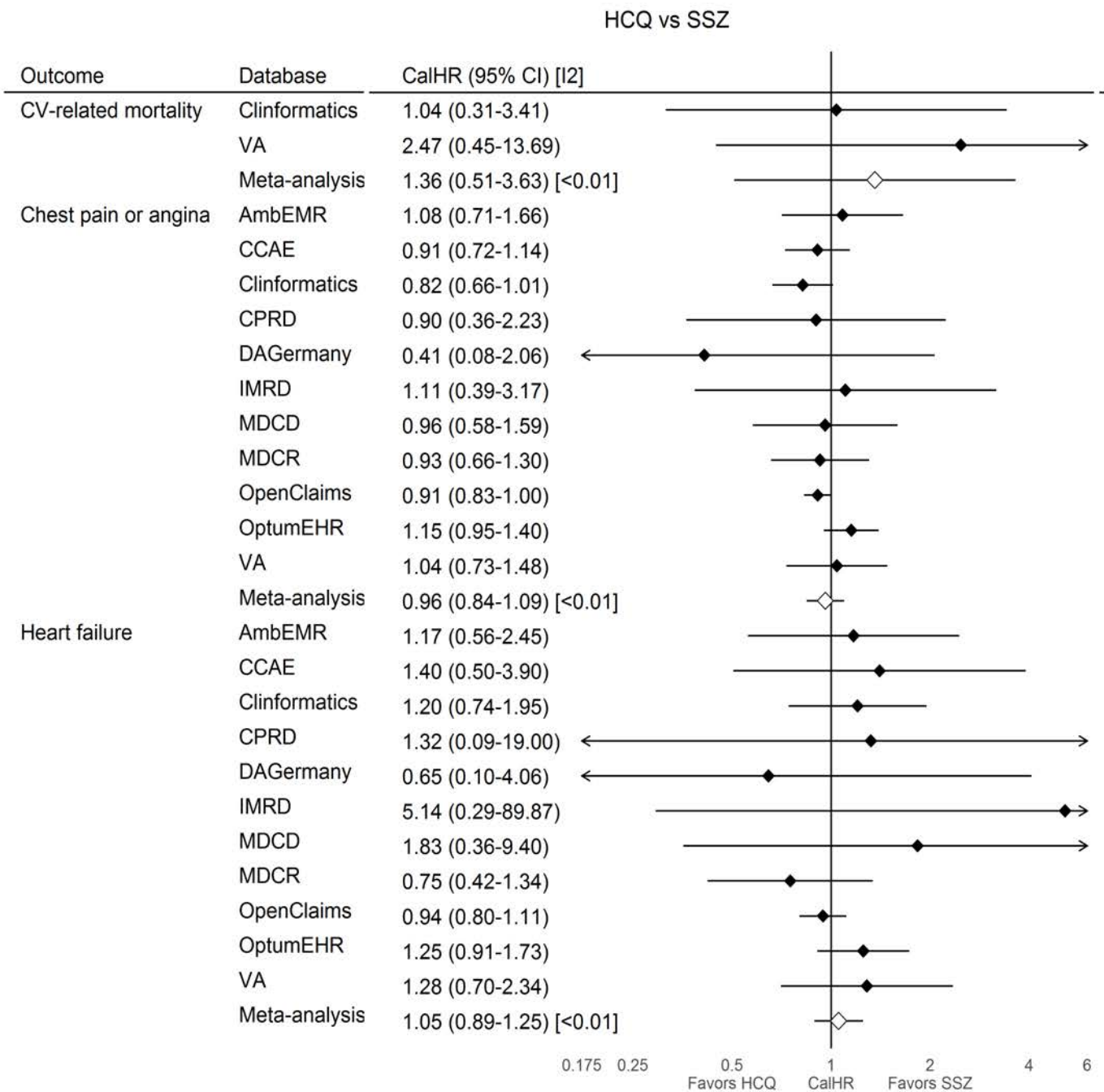


Patient counts

Data source	Hcq	SSZ
AmbEMR	57,140	15,268
CCAe	65,935	22,173
Clinformatics	50,698	17,221
CPRD	9,114	11,388
DAGermany	3,884	5,045
IMRD	8,843	8,452
MDCD	7,982	2,177
MDCR	15,690	5,150
OpenClaims	617,628	182,776
OptumEHR	76,844	21,549
VA	31,824	14,276
<i>Meta-analysis</i>	<i>945,582</i>	<i>305,475</i>

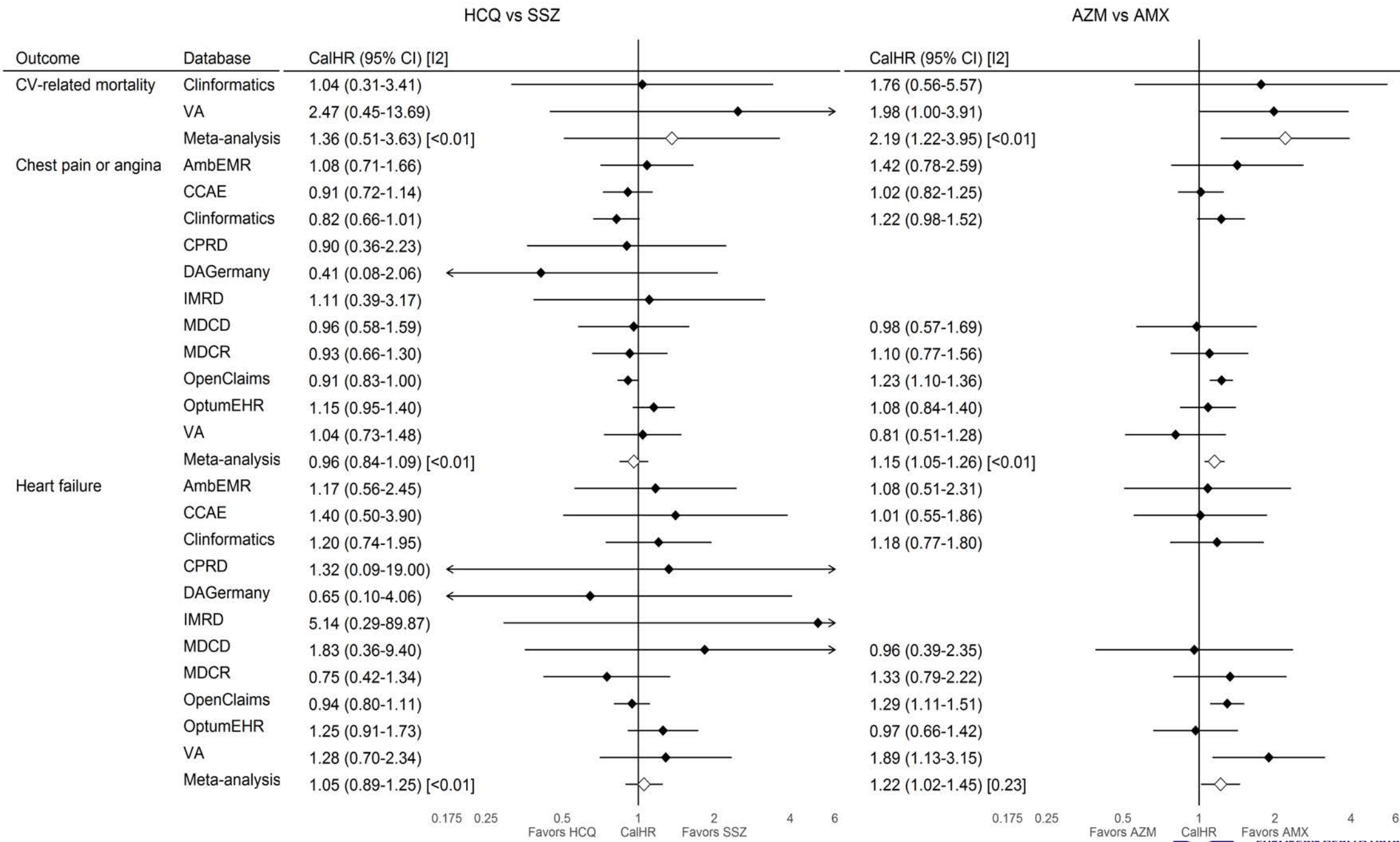


Short-term (30-day) main event/s safety



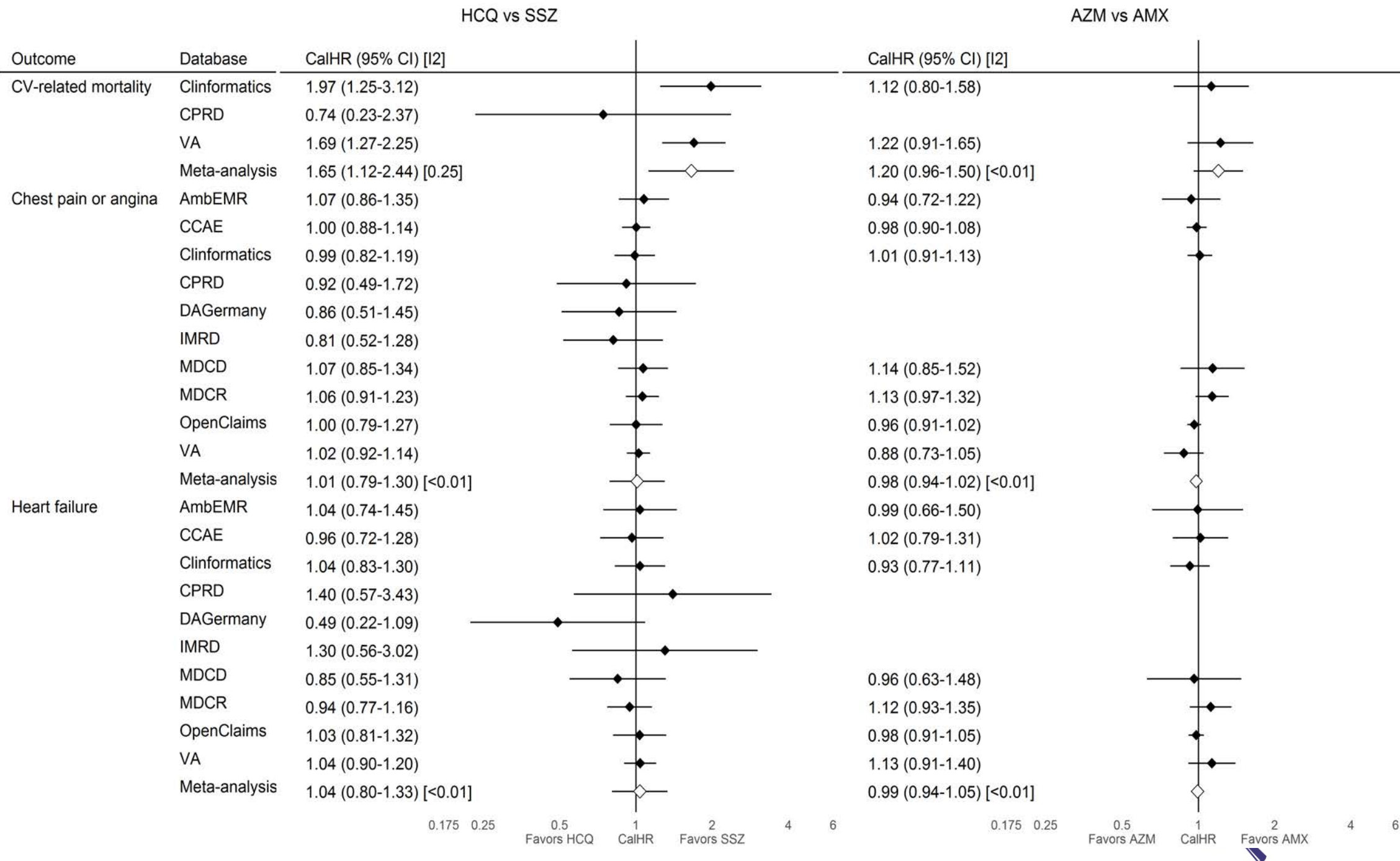


Short-term (30-day) main event/s



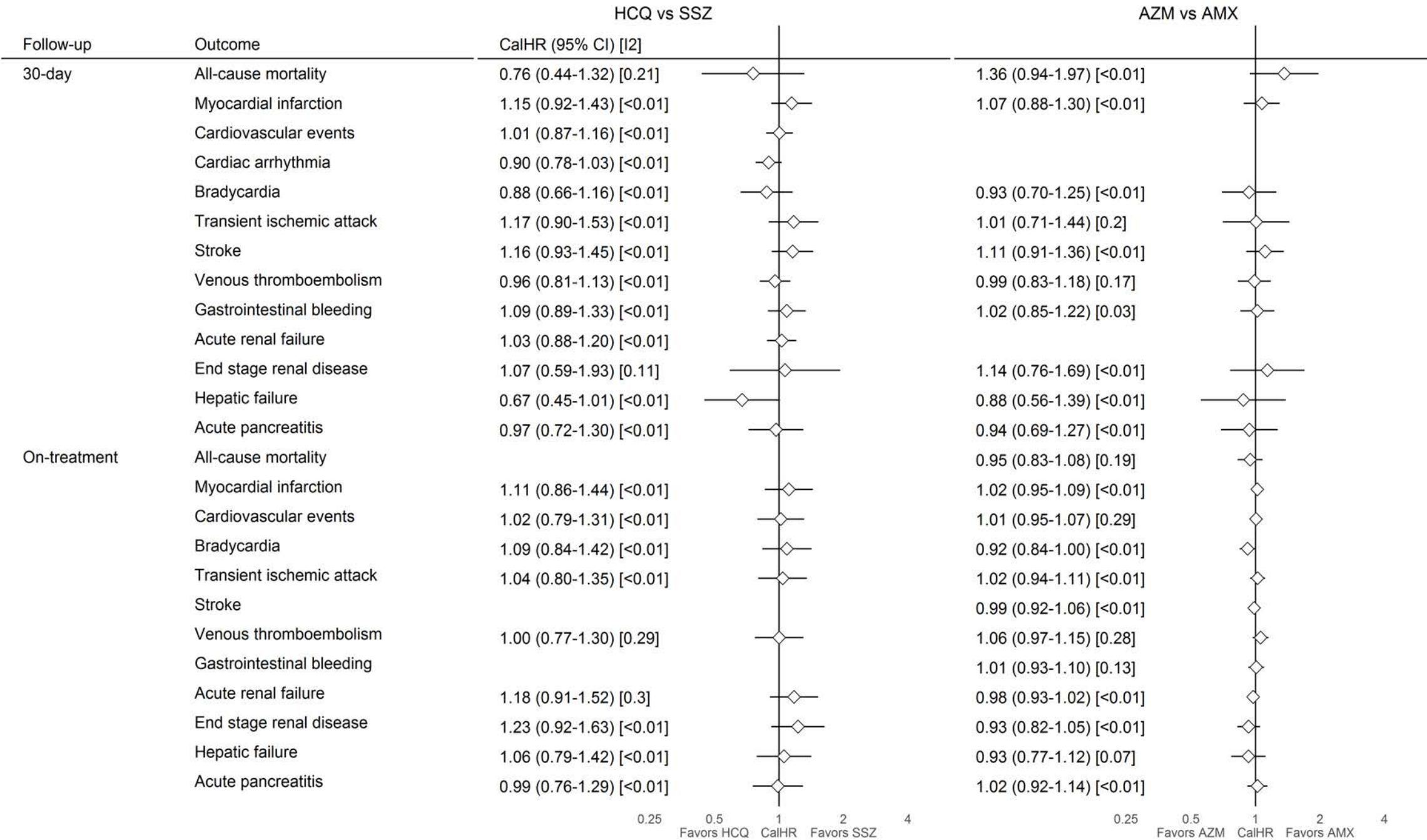


Long-term (on treatment) main event/s





SAE (others)





IMPACT (1)

Safety of hydroxychloroquine

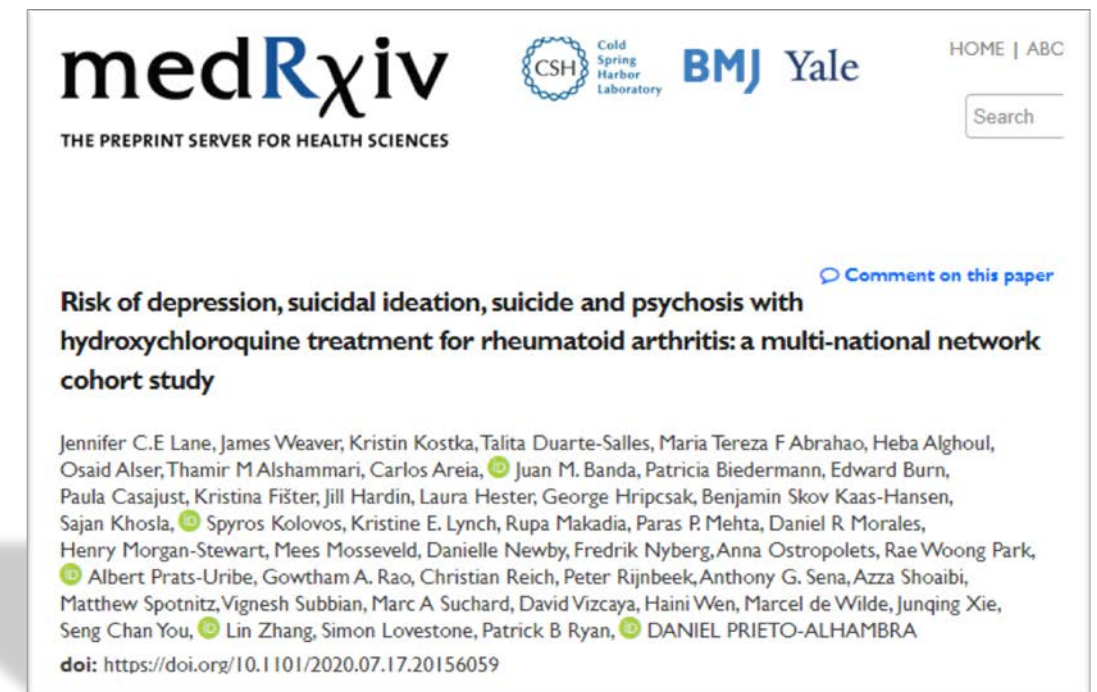
- Findings:
 - In history use in RA population, HCQ alone is generally safe but in combination with AZ it shows a doubling of risk of 30-day cardiovascular mortality.



- Psychiatric safety of hydroxychloroquine: EMA was concerned about risk of neuropsychiatric events associated with HCQ based on spontaneous reports.

Findings:

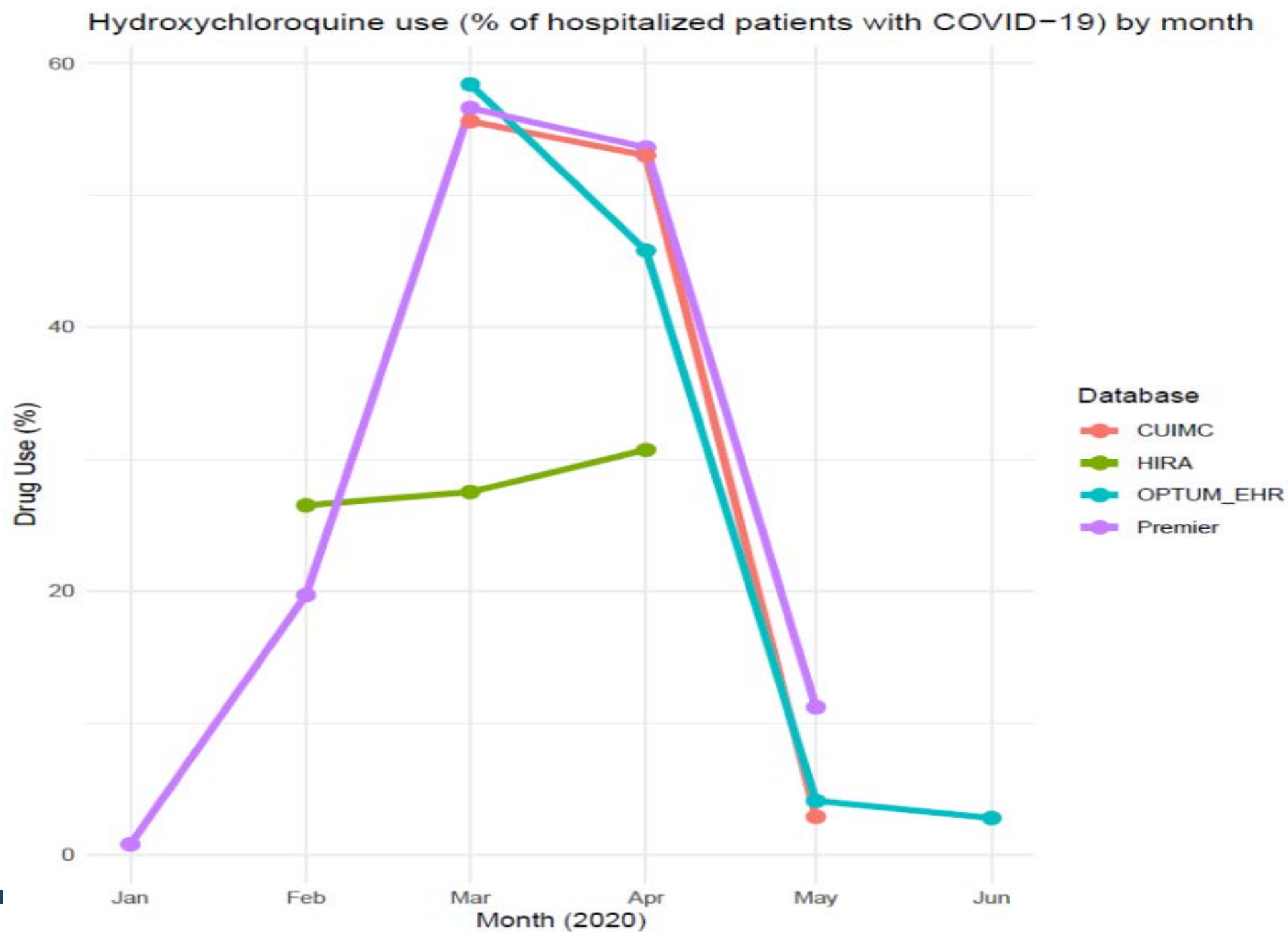
- No increased risk of depression, suicidal ideation or psychosis for new users of HCQ with RA.
- Utilized claims and electronic medical records from 10 databases across 3 different countries

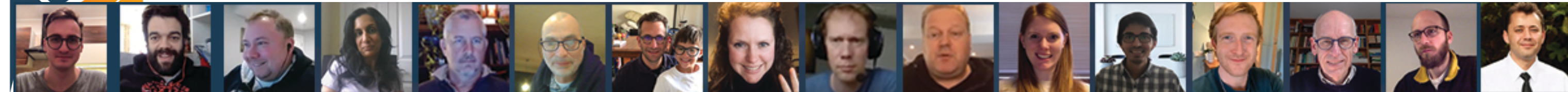


Under review at *Rheumatology*

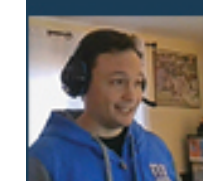
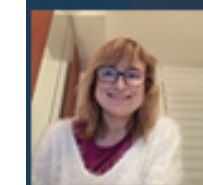
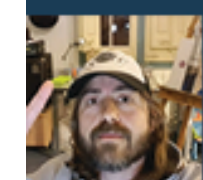
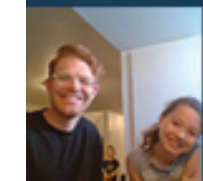
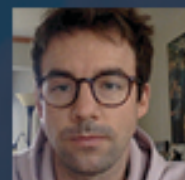


IMPACT (3) - The rise and fall of hydroxychloroquine





Shabbir Syed Abdul
Aaron Abend
Tereza Abrahao
Amanda Alberga
Heba Alghoul
Muath Alser
Osaid Alser
Thamir Alshammari
Min Ho An
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Jill Hardin
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Oscar Hayes
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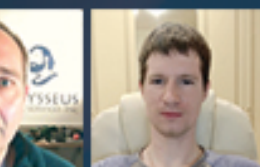
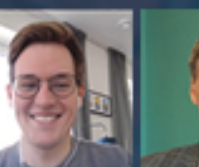
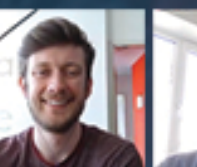
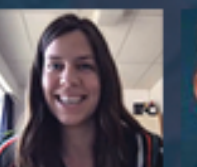
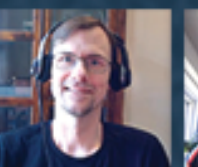
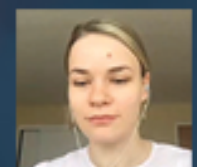
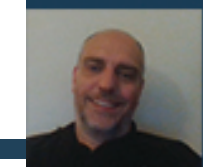
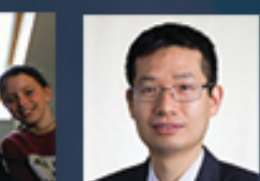
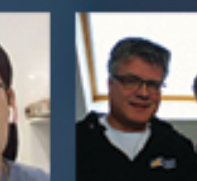
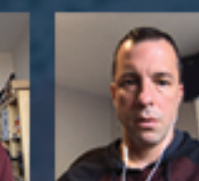
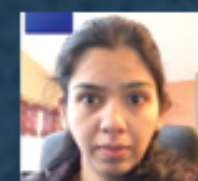
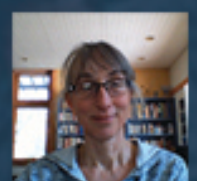
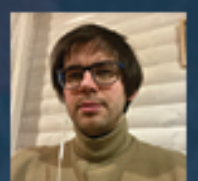
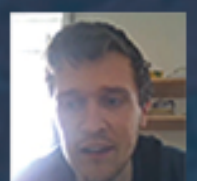
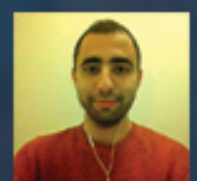
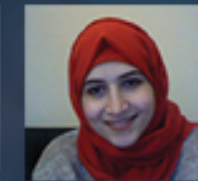
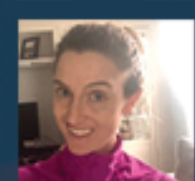
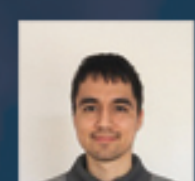
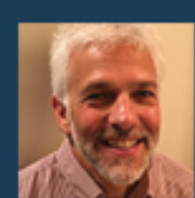
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Siva Thotapalli
Yahui Tian
Annalisa Trama

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Kees von Bochove
Emma Vos
Bridget Wang
Siting Wang
Yiting Wang
Zhixiao Wang
Jamie Weaver
Wu Wei
Rachel Weinstein
Haini Wen
Chunhua Weng
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