



OHDSI Study pipeline and Research experience using Common Data Model

Seng Chan You



Odyssey (*noun*): \oh-d-si\

1. A long journal full of adventures





OHDSI (Observational Health Data Sciences and Informatics)

The odyssey to evidence generation





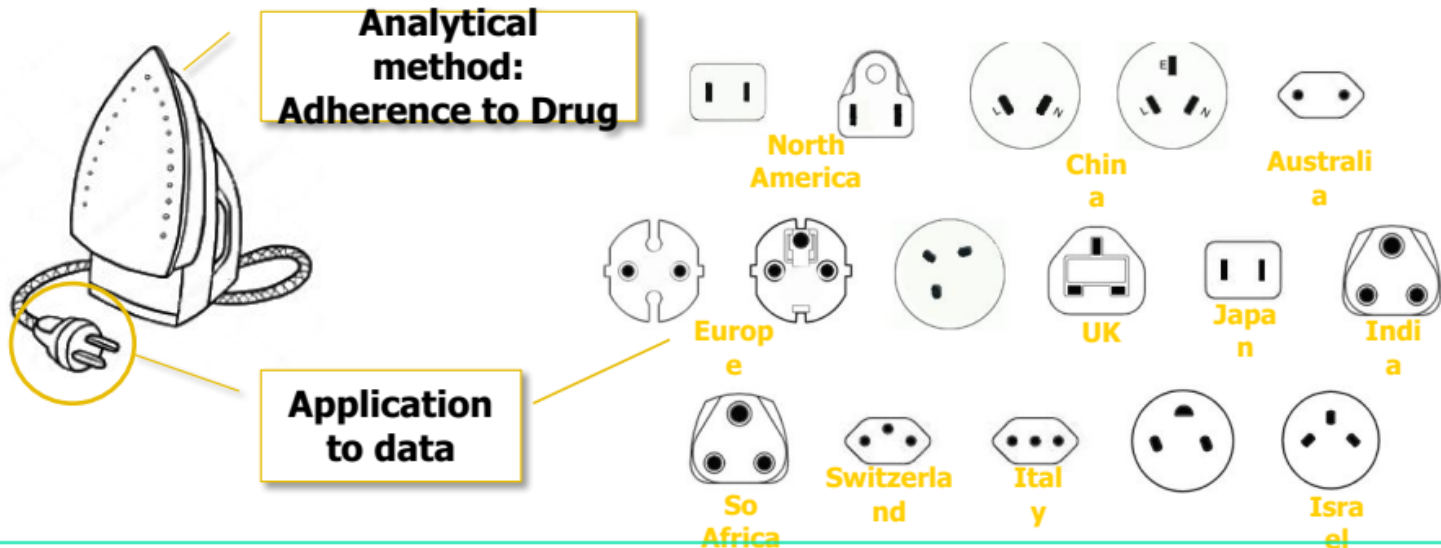
History of OHDSI

- **OMOP** (2008-2013) www.omop.org
 - OMOP = Observational Medical Outcomes Partnership
 - Research on methods for drug safety evaluation
 - Methods library developed; positive/negative drug outcome pairs
 - Common Data Model (then, was a byproduct)
 - Foundation for the NHI
 - Transition to Reagan Udall Foundation for the FDA
- **OHDSI** (after 2013) www.ohdsi.org
 - OHDSI = Observational Health Data Science and Informatics
 - Continues to use the name ‘OMOP CDM’
 - Community of researchers; public; non-pharma funded



New, script based input data mapping for every study

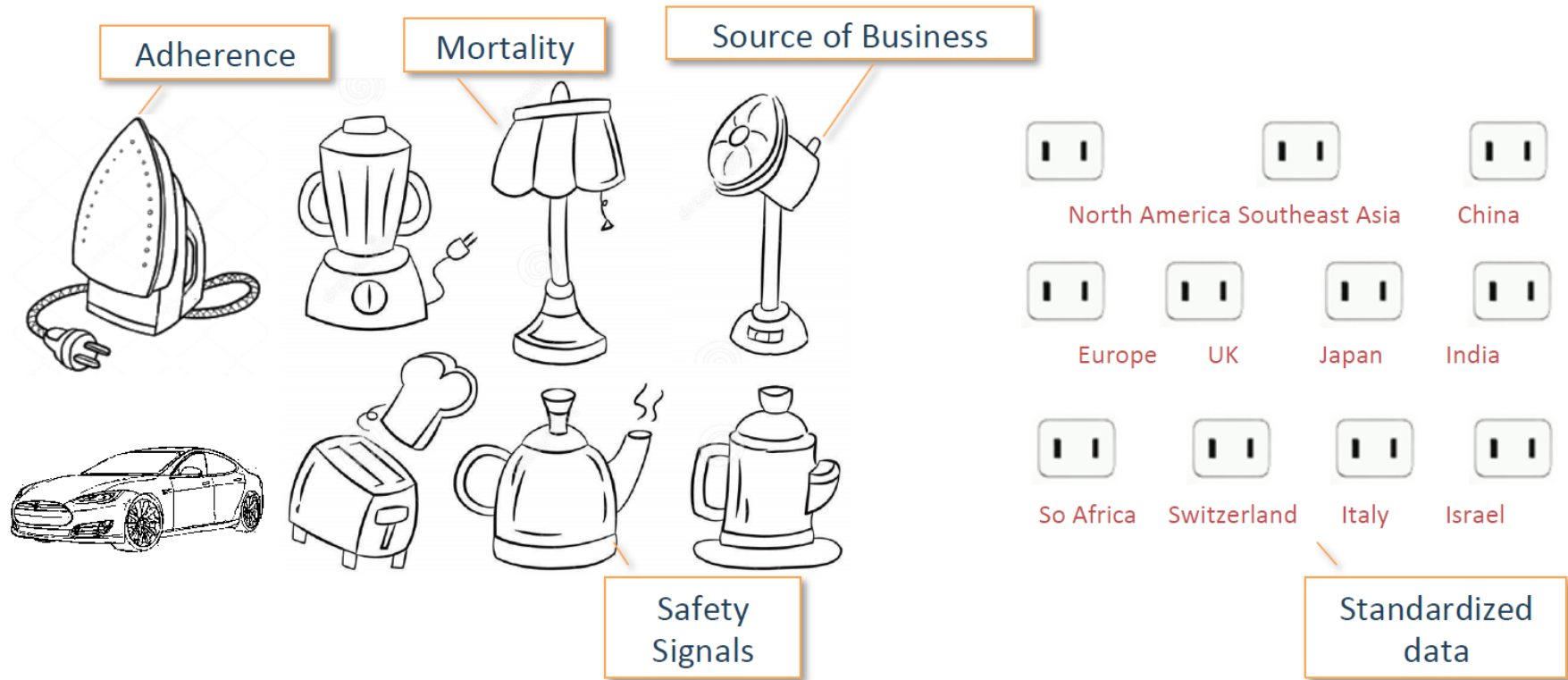
"What's the adherence to my drug in the data assets I can analyze?"



- Not scalable
- Expensive
- Slow
- Prohibitive to non-expert routine use



Data standardization enables systematic research: Scalability across the World



OHDSI Tools

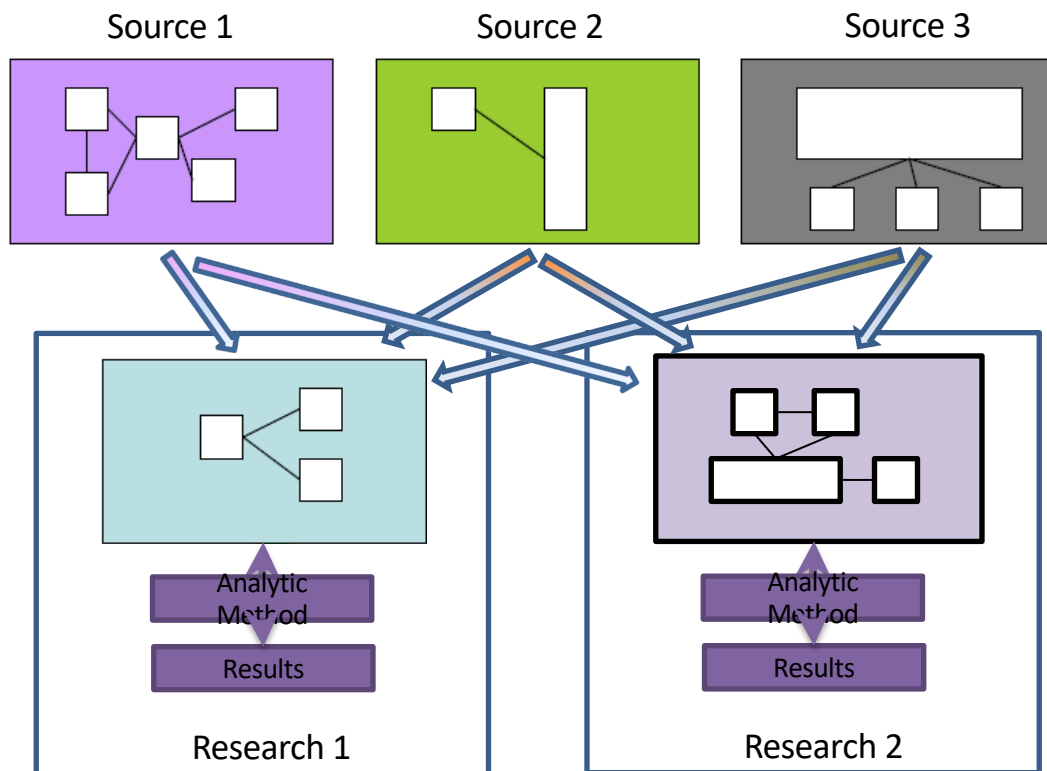
OMOP CDM



Why Common Data Model (CDM)?

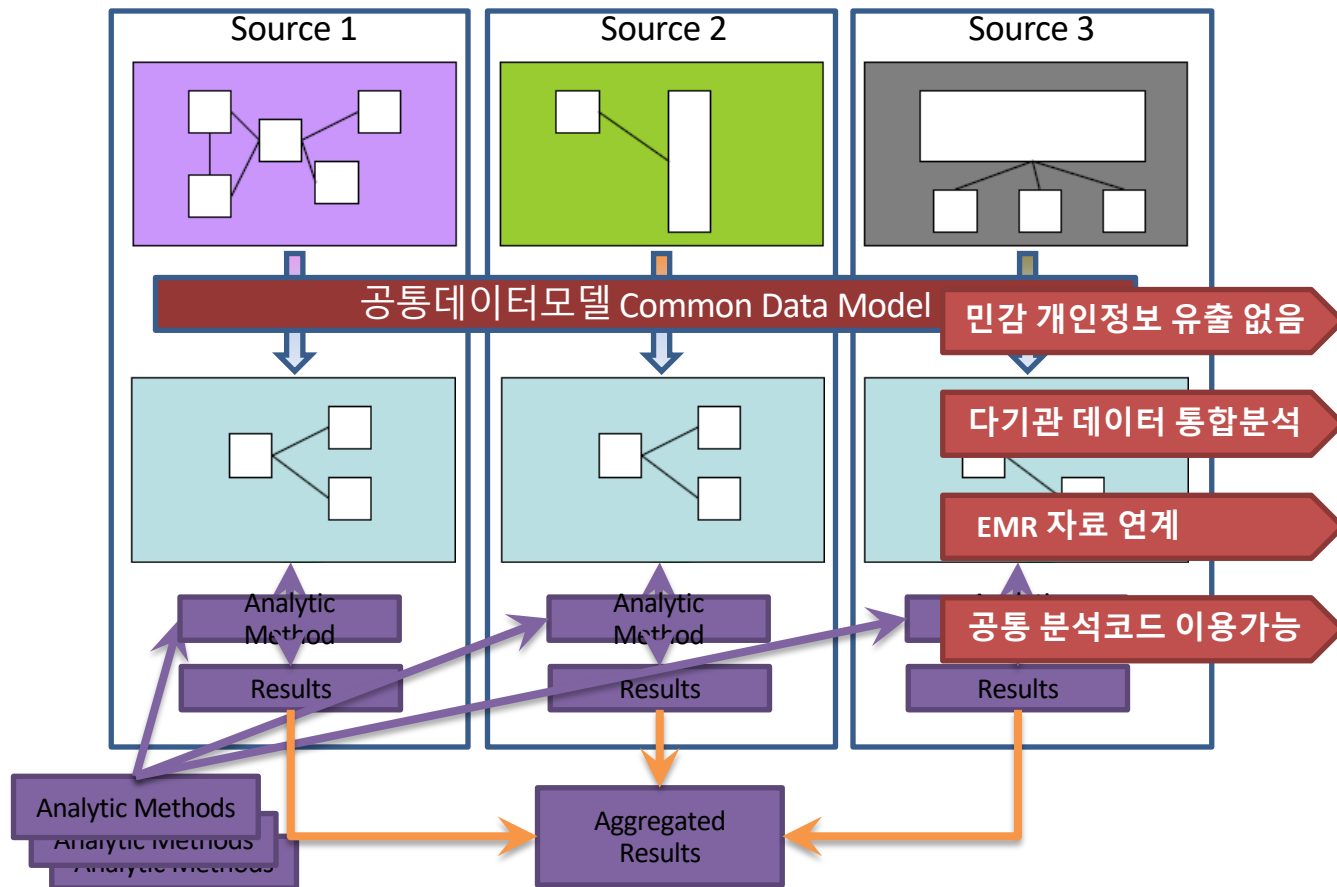
기존의 다기관 연구방법

연구 수행 때마다 데이터 모델을 맞추는 변환 작업을 수행해야 함



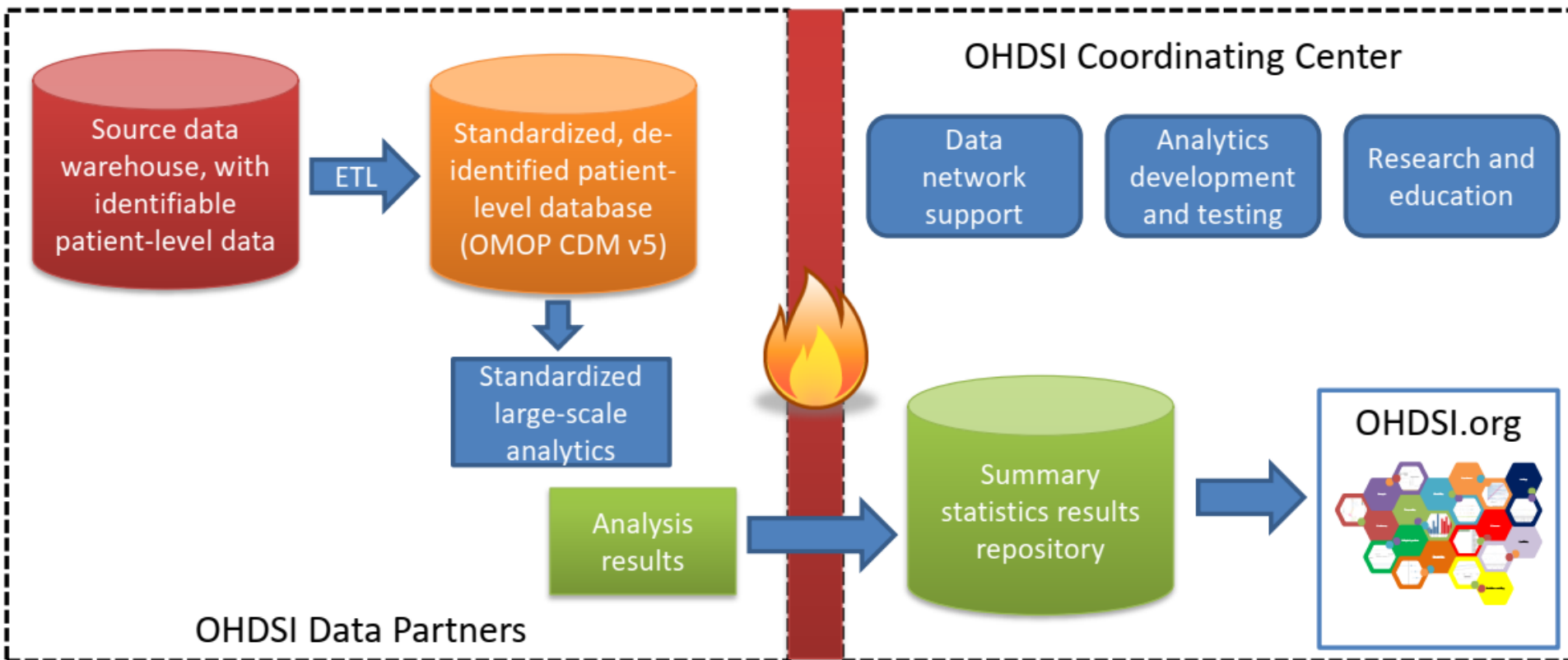


CDM in Distributed Research Network





How OHDSI works





OHDSI

- OHDSI projects was initiated to improve health, by **empowering a community to collaboratively generate the evidence** with adopting OMOP CDM to aggregate health data across world





Mission, Vision, and Values of OHDSI

- Our Mission

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

- Our Vision

A world in which observational research produces a comprehensive understanding of health and disease.



Objectives of OHDSI

- **Innovation 혁신성**: Observational research is a field which will benefit greatly from disruptive thinking. We actively seek and encourage fresh methodological approaches in our work.
- **Reproducibility 재현성**: Accurate, reproducible, and well-calibrated evidence is necessary for health improvement.
- **Openness 개방성**: We strive to make all our community's proceeds open and publicly accessible, including the methods, tools and the evidence that we generate.
- **Community 공동체 정신**: Everyone is welcome to actively participate in OHDSI, whether you are a patient, a health professional, a researcher, or someone who simply believes in our cause.
- **Collaboration 협력 정신**: We work collectively to prioritize and address the real world needs of our community's participants.
- **Beneficence 선행의 정신**: We seek to protect the rights of individuals and organizations within our community at all times.



Objectives of OHDSI

- Innovation 혁신성
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- Beneficence 선행의 정신

**➔ Collaborative International Community for
Open Science and federated Reproducible
Research**



What evidence does OHDSI seek to generate from observational data?

- **Clinical characterization**
 - **Natural history:** Who are the patients who have diabetes? Among those patients, who takes metformin?
 - **Quality improvement:** What proportion of patients with diabetes experience disease-related complications?
- **Population-level estimation**
 - **Safety surveillance:** Does metformin cause lactic acidosis?
 - **Comparative effectiveness:** Does metformin cause lactic acidosis more than glyburide?
- **Patient-level prediction**
 - **Precision medicine:** Given everything you know about me and my medical history, if I start taking metformin, what is the chance that I am going to have lactic acidosis in the next year?
 - **Disease interception:** Given everything you know about me, what is the chance I will develop diabetes?

OHDSI Methods Library for Medical researchers

Estimation methods



Cohort Method

New-user cohort studies using large-scale regression for propensity and outcome models



Self-Controlled Case Series

Self-Controlled Case Series analysis using few or many predictors, includes splines for age and seasonality.



Self-Controlled Cohort

A self-controlled cohort design, where time preceding exposure is used as control.



IC Temporal Pattern Disc.

A self-controlled design, but using temporal patterns around other exposures and outcomes to correct for time-varying confounding.



Case-control

Case-control studies, matching controls on age, gender, provider, and visit date. Allows nesting of the study in another cohort.



Case-crossover

Case-crossover design including the option to adjust for time-trends in exposures (so-called case-time-control).

Prediction methods



Patient Level Prediction

Build and evaluate predictive models for user-specified outcomes, using a wide array of machine learning algorithms.



Feature Extraction

Automatically extract large sets of features for user-specified cohorts using data in the CDM.

Method characterization



Empirical Calibration

Use negative control exposure-outcome pairs to profile and calibrate a particular analysis design.



Method Evaluation

Use real data and established reference sets as well as simulations injected in real data to evaluate the performance of methods. 

Supporting packages



Database Connector

Connect directly to a wide range of database platforms, including SQL Server, Oracle, and PostgreSQL.



Sql Render

Generate SQL on the fly for the various SQL dialects.



Cyclops

Highly efficient implementation of regularized logistic, Poisson and Cox regression.



Ohdsi R Tools

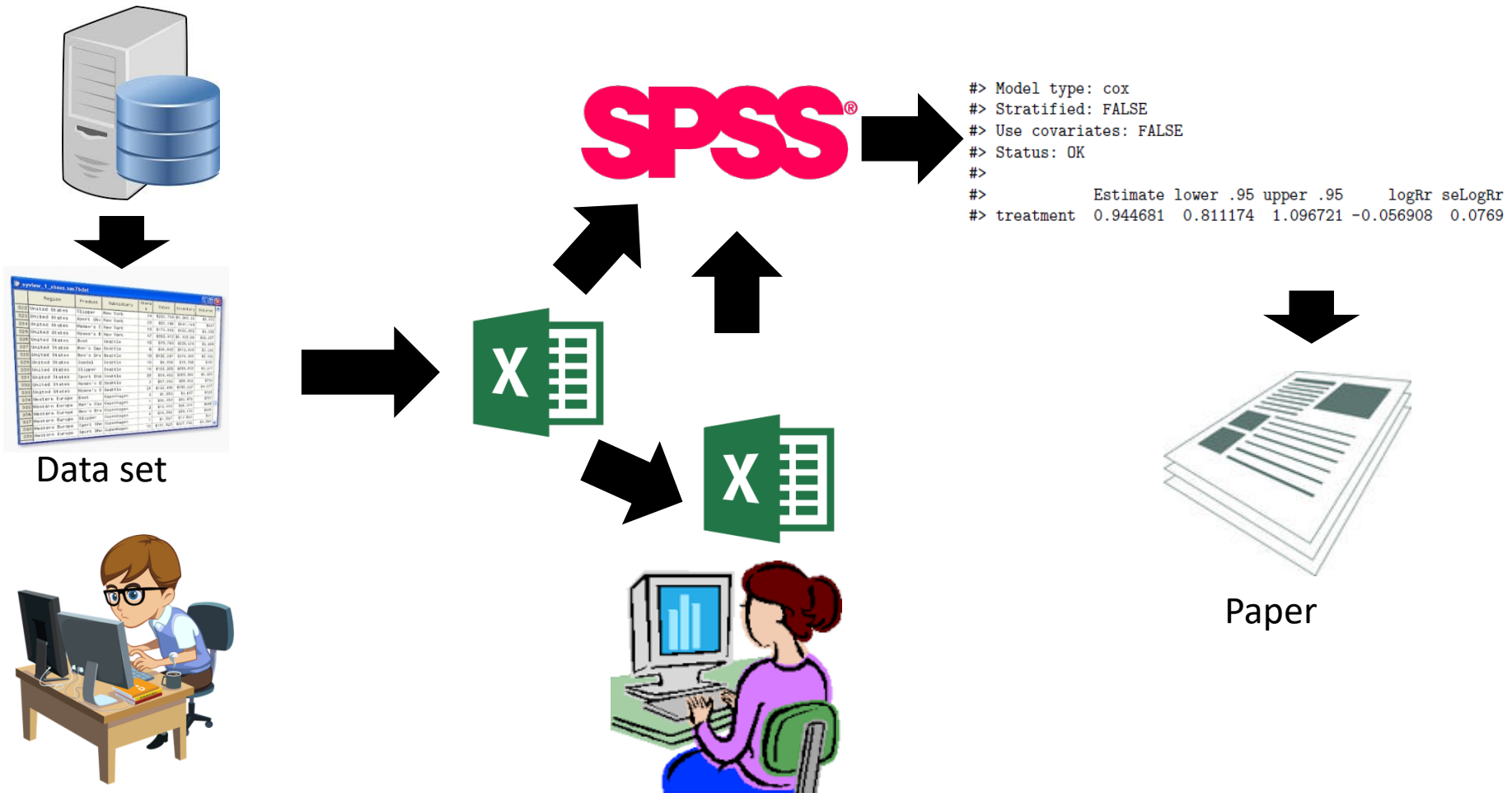
Support tools that didn't fit other categories, including tools for maintaining R libraries.



Under construction



What do epi studies currently look like?





A journey from data set to paper

START

FINISH

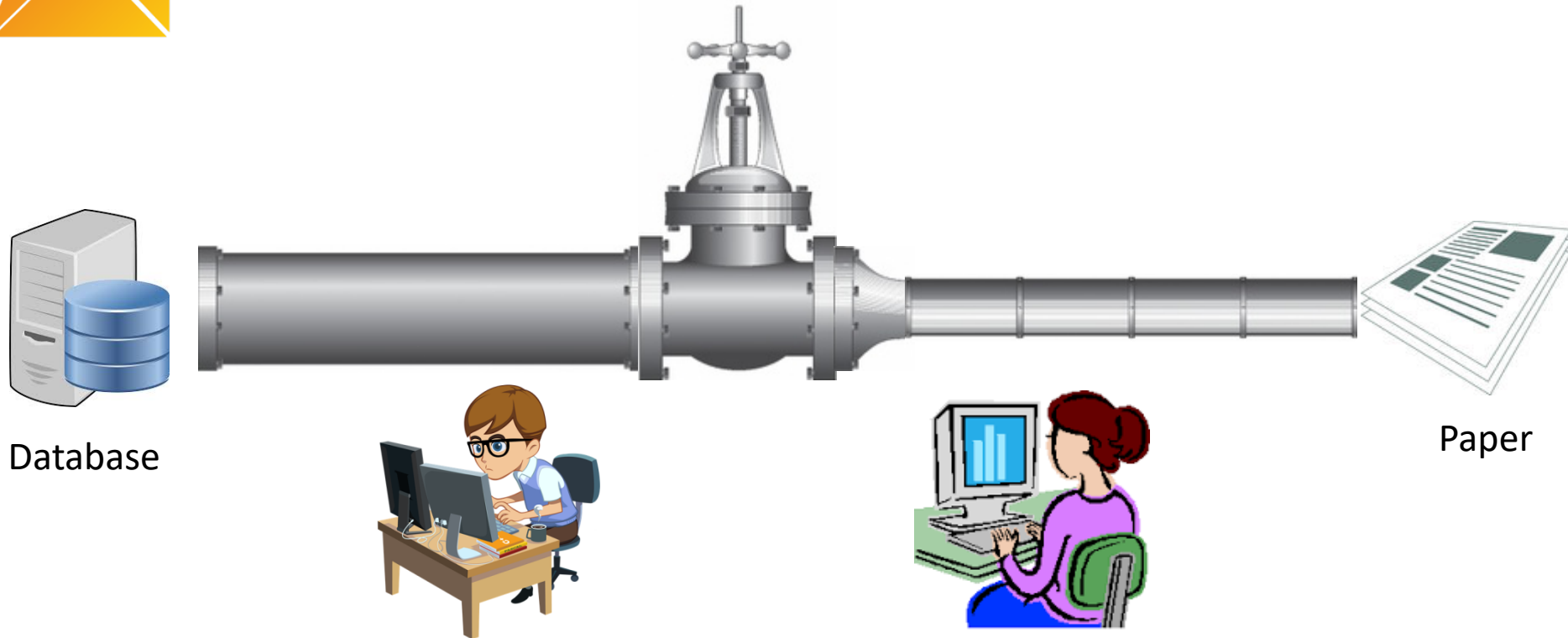


Most epidemiologists view a study as a journey from data set to paper.

- The protocol might be your map
- You will come across obstacles that you will have to overcome
- Several steps will require manual intervention
- In the end, it will be impossible to retrace your exact steps



What should OHDSI studies look like?



A study should be like a pipeline

- A fully automated process from database to paper
- 'Performing a study' = building the pipeline



OHDSI best practices



Logged in as: Martijn Schuemie (schuemie) [Update Profile](#) [Log Out](#)

 **Observational Health Data Sciences and Informatics**

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Documentation

Development

Research Studies

Projects & Workgroups

Other Resources

- Community Forums
- Data Network
- Funding Opportunities
- Call for Papers
- Conferences
- OHDSI Library
- Mailing Lists
- Realtime Chat (IRC)
- Community Publications

[+Add New Page](#)

OHDSI Development

Edit

Software

The OHDSI developer community is committed to the development of open-source, high-quality, and easy to use tools for making the most out of observational health data.

- [Developer Guidelines](#)
- [Architecture Overview](#)
- [Release Schedule](#)
- [GitHub Issue Tracker](#)
- [WebAPI services](#)

Edit

Methodology

OHDSI Methodology developers comprise experts in the fields of epidemiology, biostatistics, computer science, and clinical research who are committed to creating and validating high-quality methods for observational data research.

- [Best Practices for Estimating Population-Level Effects](#)

Edit

development:overview

Table of Contents

- OHDSI Development
 - Software
 - Methodology



development/overview.txt · Last modified: 2016/03/30 07:43 by schuemie

[\\$](#) [DONATE](#) [PHP](#) [POWERED](#) [W3C](#) [HTML5](#) [W3C](#) [CSS](#) [DOKUWIKI](#)



General principles

- **Prespecify** what you're going to estimate and how: this will avoid hidden multiple testing (publication bias, p-value hacking). Run your analysis only once.
- **Validation of your analysis**: you should have evidence that your analysis does what you say it does (showing that statistics that are produced have nominal operating characteristics (e.g. p-value calibration), showing that specific important assumptions are met (e.g. covariate balance), using unit tests to validate pieces of code, etc.)
- **Transparency**: others should be able to reproduce your study in every detail using the information you provide.

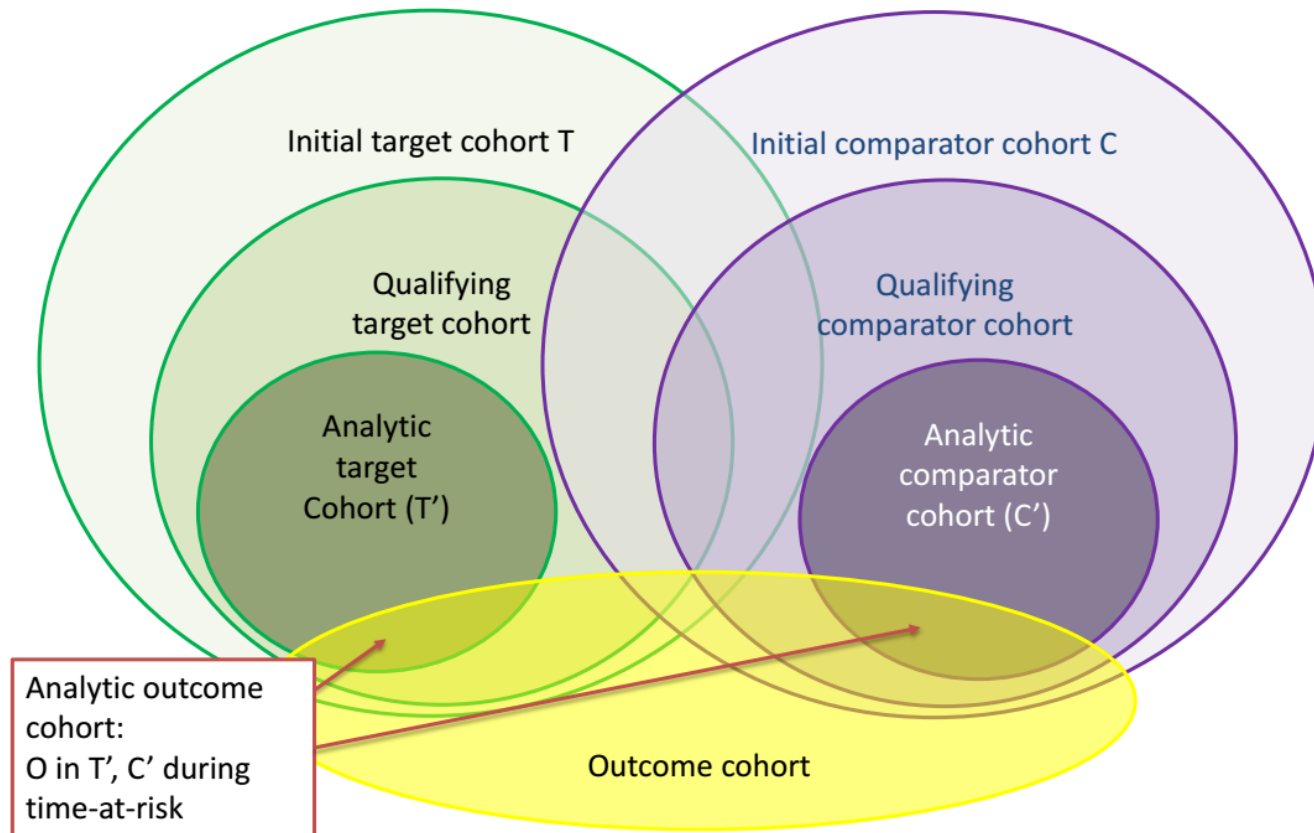


Best practices (generic)

- **Write a full protocol**, and make it public prior to running the study
 - Research question + hypotheses to be tested
 - Which method(s), data, cohort definitions. What is the primary analyses and what are sensitivity analyses?
 - Quality control
 - Amendments and Updates
- **Validate all code** used to produce estimates. The purpose of validation is to ensure the code is doing what we require it to do. Possible options are:
 - Unit testing
 - Simulation
 - Double coding
 - Code review
- Include **negative controls** (exposure-outcome pairs where we believe there is no effect)
- Produce **calibrated p-values**
- Make all analysis code available as **open source** so others can easily replicate your study



Study Pipeline 1. Define cohort: A database is full of cohorts, some of which may represent valid comparisons





Study Pipeline 1. Define cohort

- CIRCE [ATLAS]

ATLAS

Home

Data Sources

Vocabulary

Concept Sets

Cohorts

Incidence Rates

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Feedback

Cohort definition: A cohort is defined as the set of persons satisfying one or more inclusion criteria for a duration of time. One person may qualify for one cohort multiple times during non-overlapping time intervals. Cohorts are constructed in ATLAS by specifying cohort entry criteria and cohort exit criteria. Cohort entry criteria involve selecting one or more initial events, which determine the start date for cohort entry, and optionally specifying additional inclusion criteria which filter to the qualifying events. Cohort exit criteria are applied to each cohort entry record to determine the end date when the person's episode no longer qualifies for the cohort.

Patients who measures LDL level at 2009 and without prior statin for a year, previous IHD or stroke history.

All

Cohort Entry Criteria

Cohort Exit Criteria

Initial event cohort: Events are recorded time-stamped observations for the persons, such as drug exposures, conditions, procedures, measurements and visits. All events have a start date and end date, though some events may have a start date and end date with the same value (such as procedures or measurements). The event index date is set to be equal to the event start date.

People having any of the following:

Add Initial Event...

observation periods with the following criteria:

✗ observation period start is:

On or Before

2002-01-01

✗ observation period end is:

On or After

2008-12-31

✗ with age at period start

Greater Than

30

Add criteria attribute...

Delete Criteria

with continuous observation of at least

0

 days before and

0

 days after event index date

Limit initial events to:

all events

 per person.

Study Pipeline 1. Define cohort

- CIRCE [ATLAS]

ATLAS

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Initial event cohort: Events are recorded time-stamped observations for the persons, such as drug exposures, conditions, procedures, measurements and visits. All events have a start date and end date, though some events may have a start date and end date with the same value (such as procedures or measurements). The event index date is set to be equal to the event start date.

People having any of the following:

Add Initial Event...

observation periods with the following criteria:

Add criteria attribute...

Delete Criteria

✗ observation period start is: On or Before 2002-01-01

✗ observation period end is: On or After 2008-12-31

✗ with age at period start Greater Than 30

with continuous observation of at least 0 days before and 0 days after event index date

Limit initial events to: all events per person.

Add initial event inclusion criteria

Additional qualifying inclusion criteria: The qualifying cohort will be defined as all persons who have an initial event, satisfy the initial event inclusion criteria, and fulfill all additional qualifying inclusion criteria. Each qualifying inclusion criteria will be evaluated to determine the impact of the criteria on the attrition of persons from the initial cohort.

New qualifying inclusion criteria

1. No prior IHD

No prior ischemic heart disease

2. No prior stroke

No prior stroke

3. No prior brain imaging

No prior brain CT or MRI before

4. No prior CAG or coronary revascularization

No prior IHD

Copy

Delete

No prior ischemic heart disease

having all of the following criteria:

Add New Criteria...

with at most 0 using all occurrences of:

a condition occurrence of ischemic heart disease

Add

Add criteria attribute...

starting between All days Before and 0 days After event index date [and ending any time.](#)

Delete Criteria

24



Study Pipeline 2. Database connection / Cohort extraction

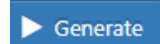
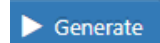
 Cohort

SCYou:HTN_combi_A_D180_per protocol(17.7.3)

SaveCloseCopyDelete

DefinitionConcept SetsGenerationReportingExploreExport

Available CDM Sources

	Source Name	Generation Status	Distinct People	Generated	Generation Duration
	Camel_DB	n/a	n/a	n/a	n/a
	NHID	COMPLETE	9942	5/10/2017 9:36:44 PM	37.812s

View Inclusion Report

Inclusion Report for NHID

		Match Rate	Matches	Total		
Summary Statistics:		32.99%	9,942	30,137	Attrition Visualization	
Inclusion Rule	N	% Remain	% Diff			
1. No RAS blocker during previous one year	20,932	69.46%	30.54%			
2. No diuretics during previous one year	19,745	65.52%	3.94%			
3. No beta-blocker during previous one year and within 180 days after index date	15,952	52.93%	12.59%			
4. No diuretics during previous one year and within 180 days after index date	13,767	45.68%	7.25%			
5. No previous or early death	13,767	45.68%	0.00%			
6. No previous IHD	11,226	37.25%	8.43%			
7. No previous HF	10,683	35.45%	1.80%			
8. No previous stroke	9,942	32.99%	2.46%			

Switch to intersect view



Study Pipeline 3. Define the statistical model and Compare

Specification

Utilities

Choose your target cohort:

SCYou:HTN_combi_AC180_wo_hx_per protocol

Choose your comparator cohort:

SCYou:HTN_combi_AD180_wo_hx_per protocol

Choose your outcome cohort:

SCYou:(outcome)any death

Specify the statistical model used to estimate the risk of outcome between target and comparator cohorts:

Cox proportional hazards

Define the time-at-risk window start, relative to target/comparator cohort entry:

0 days from cohort start date

Define the time-at-risk window end:

0 days from cohort start date

Minimum washout period applied to target and comparator cohorts:

0

Minimum required days at risk, applied to target and comparator cohorts:

0

Remove patients who enter both cohorts?

Yes

Remove patients who have observed the outcome prior to cohort entry?

Yes

Use propensity score adjustment as a confounding adjustment strategy for baseline covariates?

Yes



Study Pipeline 3. Define the statistical model and Compare

Specification

Utilities

Choose your target cohort:

SCYou:HTN_combi_AC180_wo_hx_per protocol

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0 ▼

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0 ▼

Remove patients who enter both cohorts?

Yes ▼

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Yes ▼

Use propensity score adjustment as a confounding adjustment strategy for baseline covariates?

Yes ▼



Study Pipeline 3. Define the statistical model and Compare

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Minimum washout period applied to target and comparator cohorts:

0 ▾

Minimum required days at risk, applied to target and comparator cohorts:

0 ▾

Remove patients who enter both cohorts?

Yes ▾

Remove patients who have observed the outcome prior to cohort entry?

Yes ▾

Use propensity score adjustment as a confounding adjustment strategy for baseline covariates?
Yes ▾



Study Pipeline 4. Recruiting data partners and Aggregating their results

- Recruiting data partners
 - Posting on Forum

Study on comparison of combination treatment in hypertension

■ Researchers



SCYou Seng Chan You

Sep '16

The new study below is planned to post to the OHDSI Research Network.

Comparison of combination treatment in hypertension

Objective: The objective of this study is to compare the effectiveness and adverse events between the combination treatments in hypertension

Rationale: The goal of antihypertensive therapy is to reduce cardiovascular end points including stroke, myocardial infarction, and heart failure by lowering blood pressure. Although it is evident that BP reduction per se is the primary determinant of CV risk reduction, the choice of initial drug therapy can exert some effect on long-term outcomes. Many large randomized trials have shown that two or more antihypertensive agents are required for reaching their treatment goals. Furthermore, recent data have suggested that the use of combination therapy in patients with hypertension may be beneficial for blood-pressure-lowering efficacy, obtaining blood pressure goals earlier, and reducing major adverse cardiovascular events. To date, However, the best combination treatment in hypertension have not been demonstrated. The evidence through OHDSI network can help clinicians to select the combination treatment for their patients.

Project Leads: Seng Chan You, Sungjae Jung, and Rae Woong Park from Ajou university

Please provide any comments or suggestions



4. Recruiting data partners and Aggregating their results

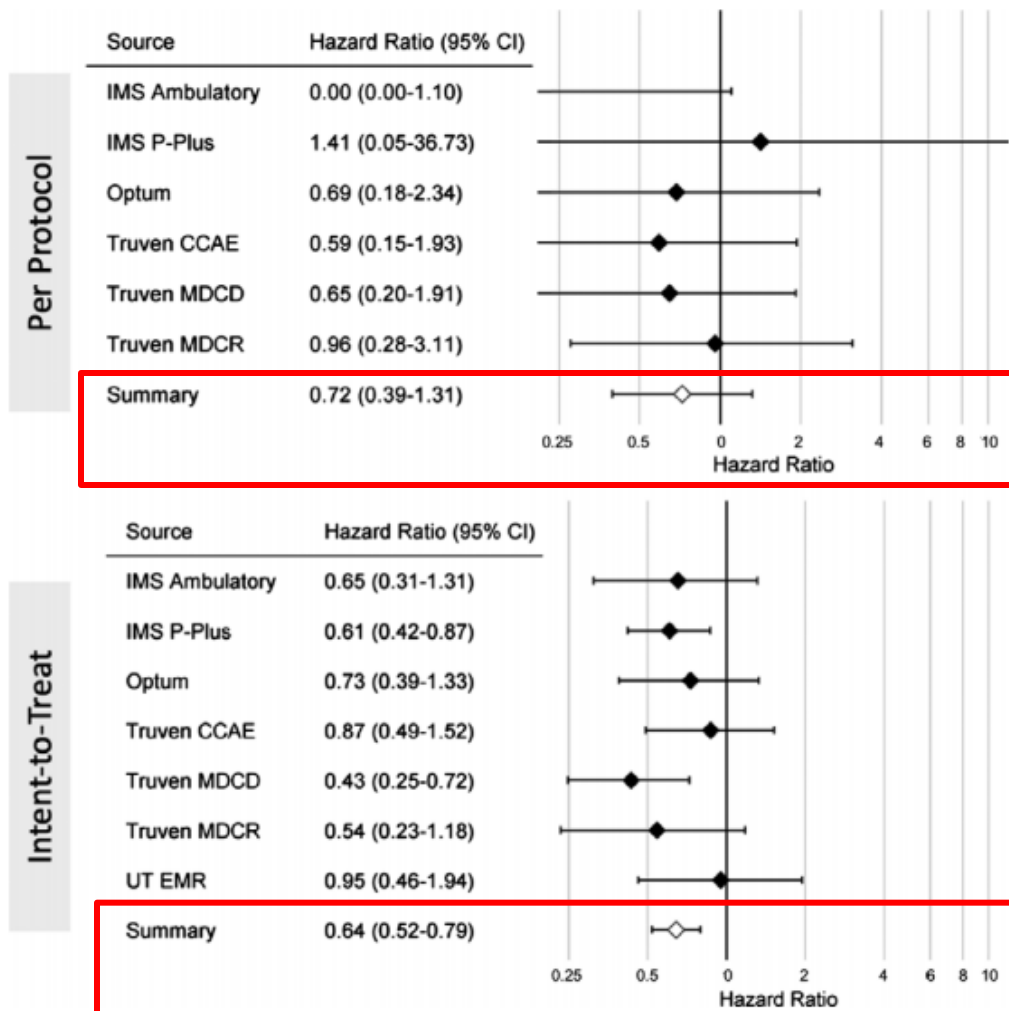


Figure 1.

Forest plots showing the HRs for angioedema with exposure to levetiracetam compared with phenytoin in patients with seizure disorder across multiple databases, as well as combined estimate, for the per-protocol and intent-to-treat analyses.

Epilepsia © ILAE



Our experience

- Head-to-head comparison of the mortality risk of **combination anti-hypertensive regimens** among patients without high risk for cardiovascular event
- AIM
 - To compare the **mortality risk** of combination regimens among patients initiating antihypertensive treatment
 - Analysis based on CDM for **reproducible research**



Method: Statistics

- Large scale propensity score matching
 - Caliper: 0.15
 - Max Ratio: 1:1
 - Univariate Cox regression with stratification

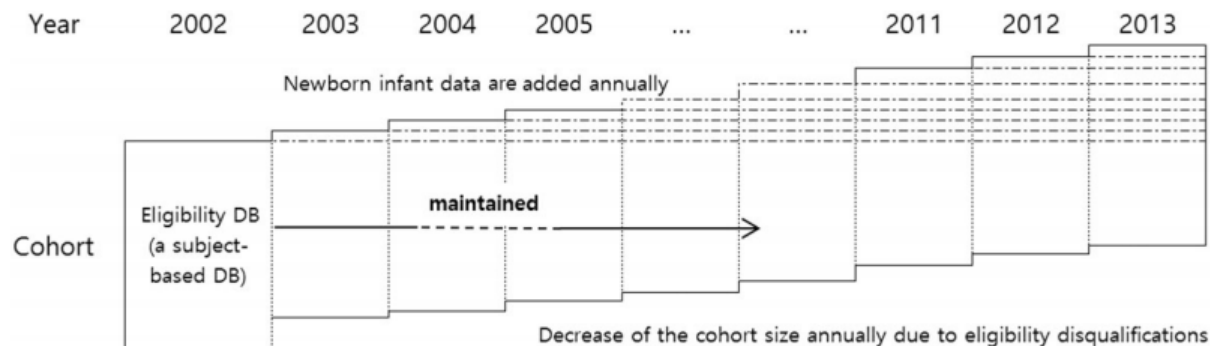
Martijn J. Schuemie, Marc A. Suchard and Patrick B. Ryan (2017). CohortMethod: New-user cohort method with large scale propensity and outcome models. R package version 2.4.3.

- Sensitivity analysis
 - Same analysis on patients **with various minimum periods (30, 365, 730 days)** of continuing the drug regimen
- Analytic R code is available for reproducible research:
<https://github.com/OHDSI/StudyProtocolSandbox/tree/master/HypertensionCombination>



Method: study population

- NHIS-national sample cohort (NHIS-NSC) DB
 - Consecutive observation for 1M patients who were randomly sampled from whole Korean population between 2002-2013
 - converted into OMOP Common Data Model version 5.0



Lee et al.,
Int J Epidemiol.
2016



Method: inclusion algorithm

- Inclusion criteria

- Adults (≥ 20 years) who used dual anti-hypertensive drugs within 30 days for treating hypertension
- **180 days** or more consecutive days of the two-drug prescription
- At least 365 days of pre-observation period before initiating the drugs. (preventing left-censoring)

- Exclusion criteria

- Prescription with anti-hypertensive medication during previous one year
- Any diagnosis for ischemic heart disease, heart failure, stroke, and death before drug initiation
- Use other anti-hypertensive drugs except the two before or within **180 days** after drug initiation



Method: outcomes

- Primary Outcome: All-cause mortality
- Secondary outcome:
 - Cardiovascular death
 - Newly developed myocardial infarction (MI)
 - Newly developed heart failure (HF)
 - Newly developed stroke
 - MACCE (MI+HF+Stroke+Any death)



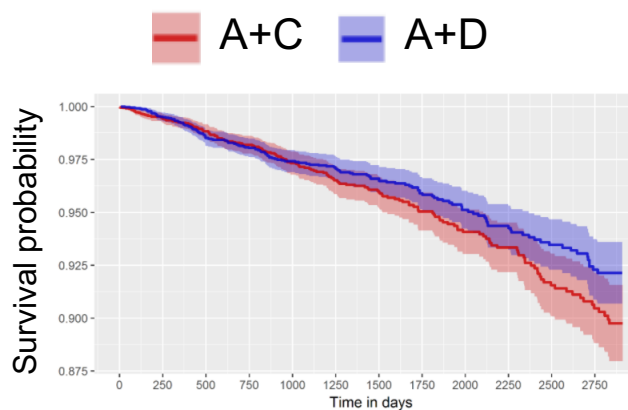
Result: baseline characteristics after matching

	A+C vs A+D			C+D vs A+C			C+D vs A+D		
	A+C (n=4751)	A+D (n=4751)	SD	C+D (n=1739)	A+C (n=1739)	SD	C+D (n=2382)	A+D (n=2382)	SD
Female, n (%)	2065 (43.5)	1932 (40.7)	0.06	859 (49.5)	882 (50.8)	-0.03	1340 (56.4)	1354 (57.0)	0.01
DM, n (%)	1593 (33.5)	1581 (33.3)	0.01	264 (15.2)	243 (14.0)	0.03	591 (24.9)	532 (22.4)	0.06
CKD, n (%)	111 (2.3)	79 (1.7)	0.05	30 (1.7)	21 (1.2)	0.04	33 (1.4)	20 (1.0)	0.05
Dyslipidemia, n (%)	2249 (47.3)	2252 (47.4)	0.00	577 (33.3)	510 (29.4)	0.08	706 (29.7)	655 (27.6)	0.05
CCI, mean	2.6	2.5	0.03	2.1	1.9	0.08	1.9	1.7	0.11

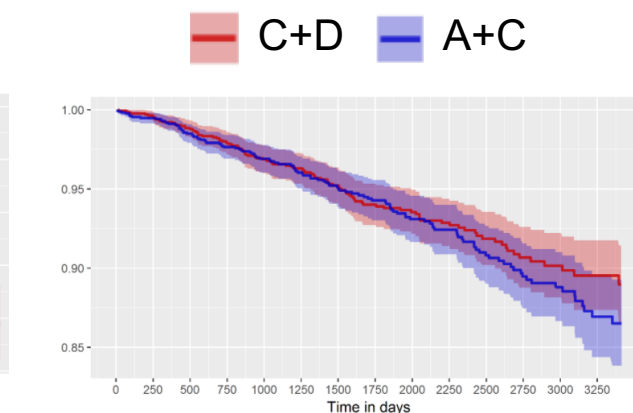
DM, diabetes mellitus; CKD, chronic kidney disease; AF, atrial fibrillation; CCI, Charlson comorbidity index



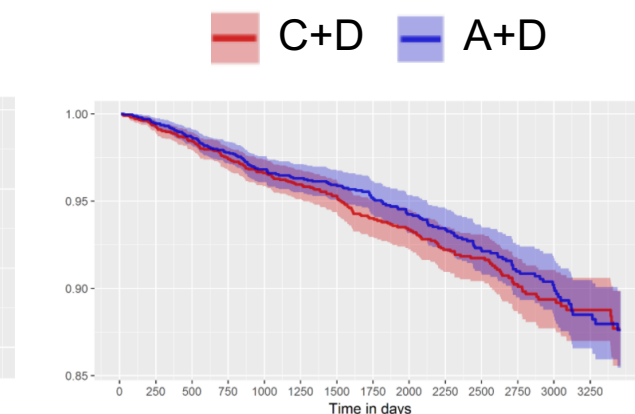
Result: Primary endpoint (All-cause mortality) in NHIS



$P = 0.465$



$P = 0.465$



$P = 0.478$



Result: Primary endpoint (All-cause mortality)

Result: All-cause mortality between dual combination treatment group after large scale propensity score matching (Minimum drug period : 180 days)

Active drug group	Comparator group	Number of active group after matching	Number of comparator group after matching	Hazard ratio	95% CI	P value
A+C	A+D	4751	4751	1.11	0.84-1.49	0.465
C+D	A+C	1739	1739	1.03	0.71-1.33	0.465
C+D	A+D	2382	2382	1.09	0.85-1.41	0.478

Abbreviations: CI, confidential interval; A, angiotensin-converting enzyme inhibitor/angiotensin receptor blocker; B, β -blocker; C, calcium channel blocker; D, thiazide-diuretics; CV, cardiovascular



There is **no difference in mortality between dual combination** of anti-hypertensive medication



OHDSI study: comparison of combination treatment in hypertension

Study on comparison of combination treatment in hypertension

■ Researchers



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jon_duke

9d

@SCYou We will try to run this on our Truven dataset here at GT.

Thanks!

Jon

1 Reply

♥ 🔗 🚩 📌 ↩ Reply



OHDSI study: comparison of combination treatment in hypertension

Study on comparison of combination treatment in hypertension

■ Researchers



SCYou Seng Chan You

Sep '16

The new study below is planned to post to the OHDSI Research Network.

Comparison of combination treatment in hypertension

Hi Chan:

You did a great job presenting at the OHDSI Symposium.

I just got internal J&J permission to participate in your study, so we are set to go. On Monday, I have my next team meeting, where executing your study will be a new project that will get assigned within the team. Martijn has already expressed interest in participating, and I suspect that at least one other in my team will want to join in as well. In terms of database contributions, I suspect we should have sufficient information in a few different US databases (Truven CCAE, Truven MDCR, Optum SES), in the IMS Germany and JMDC databases. We could consider applying for ISAC approval to use CPRD for UK EHR. It could be worth applying, but our experience is that can be quite time-consuming so we may not want to wait for the results before moving forward.

It was great seeing you and Rae at the Symposium. Thank you for all your valuable contributions to the community.

Cheers,

Patrick



OHDSI study: comparison of combination treatment in hypertension

Study on comparison of combination treatment in hypertension

■ Researchers



SCYou Seng Chan You

Sep '16

The new study below is planned to post to the OHDSI Research Network.

Comparison of combination treatment in hypertension

Hi Chen,

Greetings and congrats on your award. I'd like to join. I'm at the Univ of Colorado. We have not completed our medication mappings to OMOP- and obviously this will need to be done. Do you have an expected date that the data pull?

I'm also with the University of California Medical Centers, and I'll solicit their involvement too.

When I have chance, I'll review the protocol, etc

Lisa

Lisa Schilling, MD, MSPH
Professor of Medicine
Department of Medicine, Division of General Internal Medicine
University of Colorado, School of Medicine

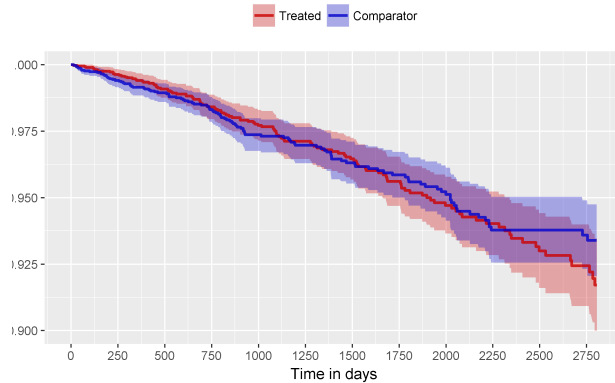


Result: Primary endpoint (All-cause mortality) in US (medicaid & medicare))

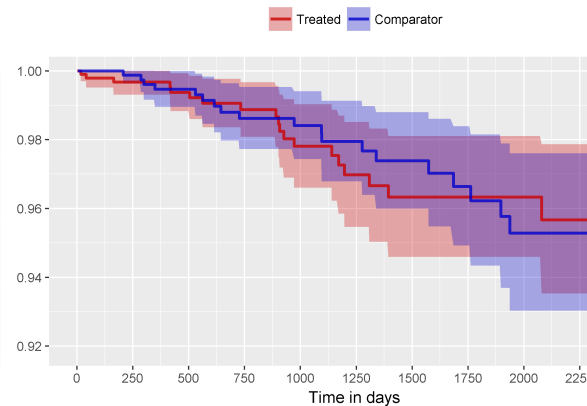
A+C A+D

C+D A+C

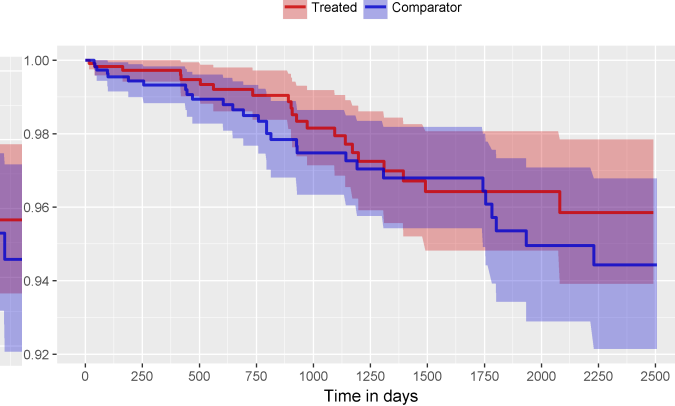
C+D A+D



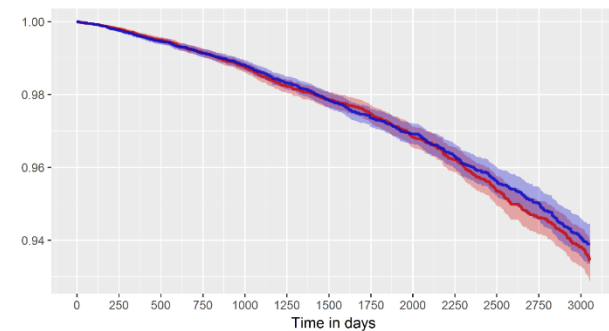
at risk	3,968	3,189	2,690	2,306	1,959	1,562	1,366	1,135	922	731	569	407
ated	3,958	3,169	2,705	2,329	1,985	1,580	1,370	1,148	935	775	625	465
rator												



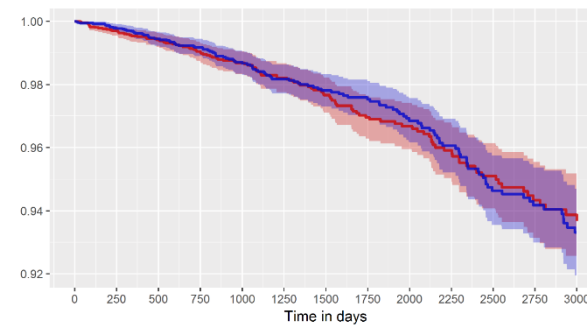
at risk	994	765	637	524	440	324	272	205	159	118
ated	995	770	633	548	468	358	297	238	184	145
rator										



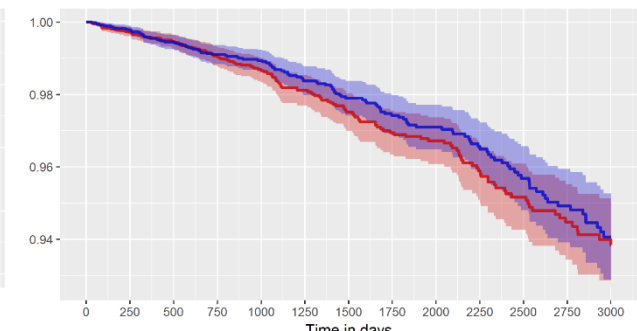
at risk	1,177	915	752	622	525	391	328	241	187	143	105
ated	1,178	897	737	620	528	407	339	271	217	175	134
rator											



at risk	33,519	28,532	23,990	20,364	16,884	13,720	11,341	9,537	8,027	6,690	5,600	4,648	3,694
ated	33,484	28,427	23,840	20,323	16,824	13,679	11,268	9,467	7,847	6,547	5,415	4,476	3,556
rator													

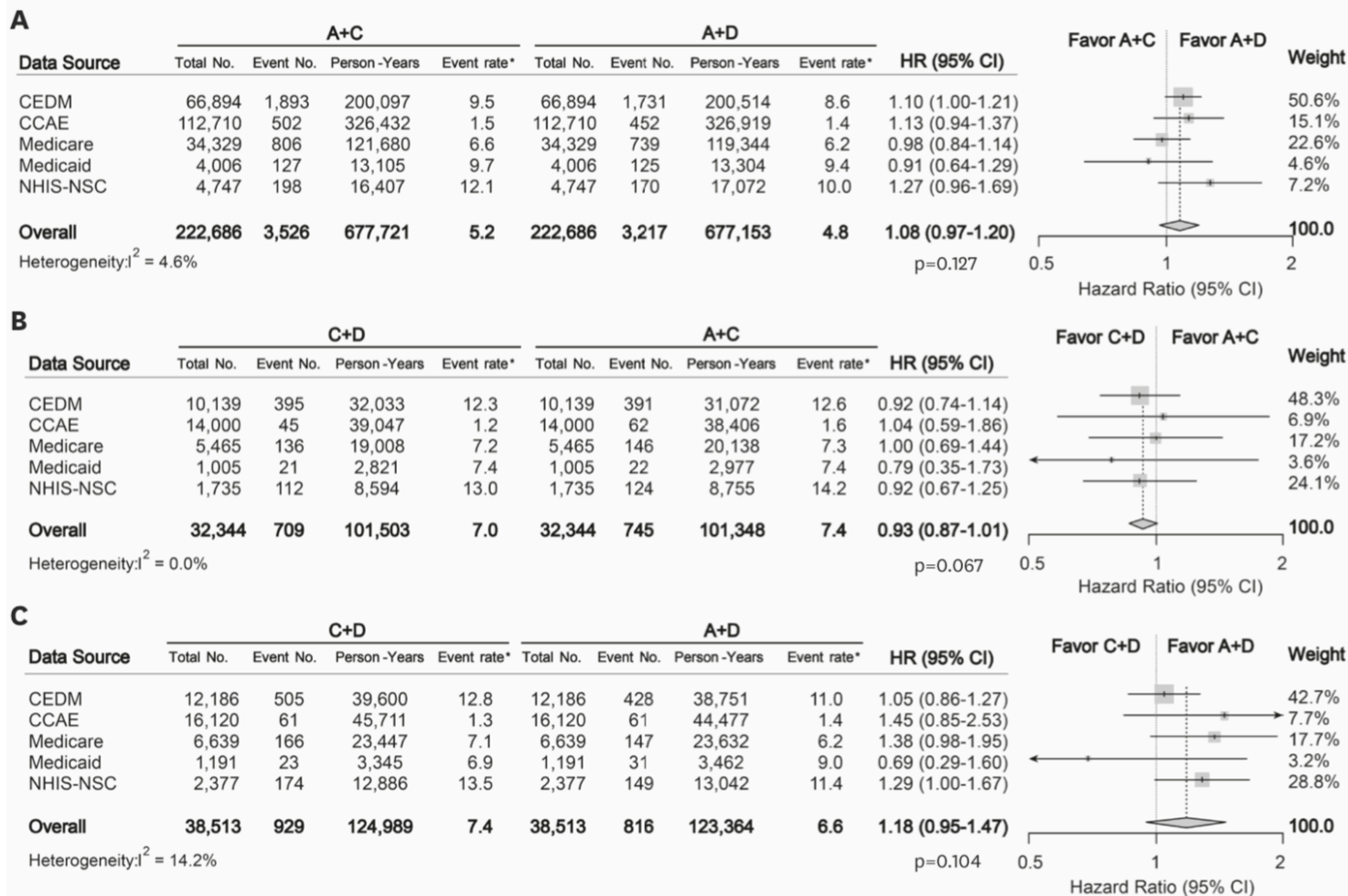


at risk	5,361	4,470	3,823	3,252	2,674	2,174	1,809	1,504	1,244	1,018	825	666	507
ated	5,358	4,603	3,915	3,365	2,847	2,346	1,943	1,602	1,333	1,103	914	774	603
rator													



at risk	6,510	5,442	4,652	3,980	3,288	2,691	2,245	1,867	1,563	1,282	1,047	853	657
ated	6,514	5,449	4,577	3,887	3,295	2,722	2,289	1,939	1,616	1,336	1,070	884	684
rator													

Result: Primary endpoint (All-cause mortality)



There is **no difference in mortality between dual combination** of anti-hypertensive medication



Large-Scale Evidence Generation and Evaluation in a Network of Databases (LEGEND)

Patrick Ryan, Martijn Schuemie, Marc Suchard
on behalf of the LEGEND team

OHDSI Symposium

12 October 2018



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

WRITING COMMITTEE MEMBERS

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Jeff D. Williamson, MD, PhD, FAHA##

56 pages
containing
106 recommendations

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Susan J. Pressler, PhD, RN, FAHA***; Barbara Riegel, PhD, RN, FAHA; Duminda N. Wijeyesundera, MD, PhD



8.1.6. *Choice of Initial Medication*

Recommendation for Choice of Initial Medication

References that support the recommendation are summarized in **Online Data Supplement 27** and **Systematic Review Report**.

COR	LOE	Recommendation
I	A ^{SR}	1. For initiation of antihypertensive drug therapy, first-line agents include thiazide diuretics, CCBs, and ACE inhibitors or ARBs. ^{S8.1.6-1,S8.1.6-2}

SR indicates systematic review.



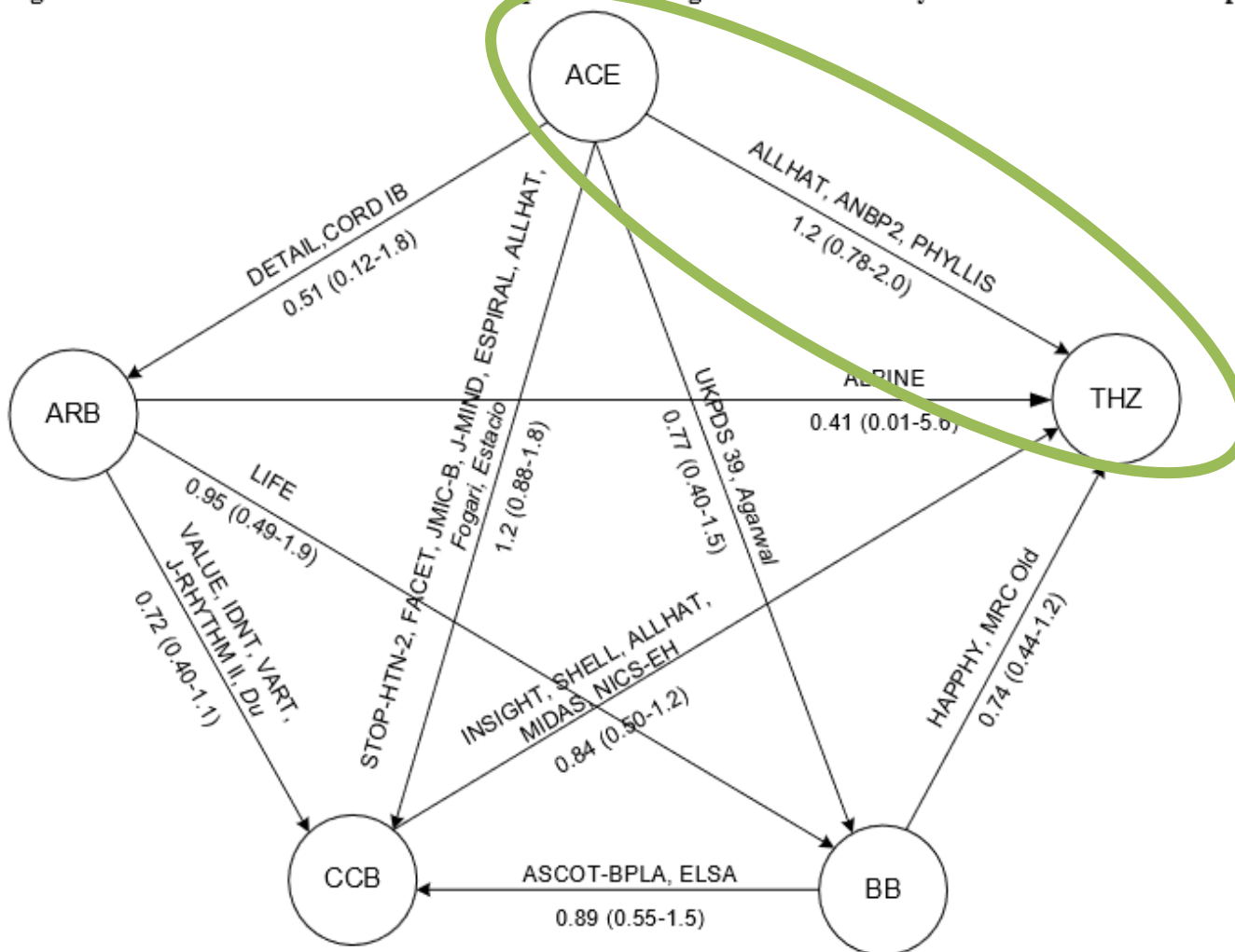
For initiation of antihypertensive drug therapy, how *SHOULD* patients be treated?

What evidence do we have about the comparative effects about alternative antihypertensive drugs?



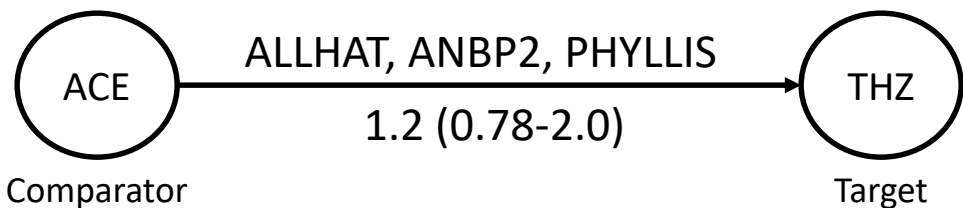
RCT evidence about comparative effectiveness for myocardial infarction

Figure 3.3 Network of clinical trials of antihypertensive drug classes in which myocardial infarction was reported (N=29). *





Dissecting the comparative evidence of ACE vs THZ on AMI

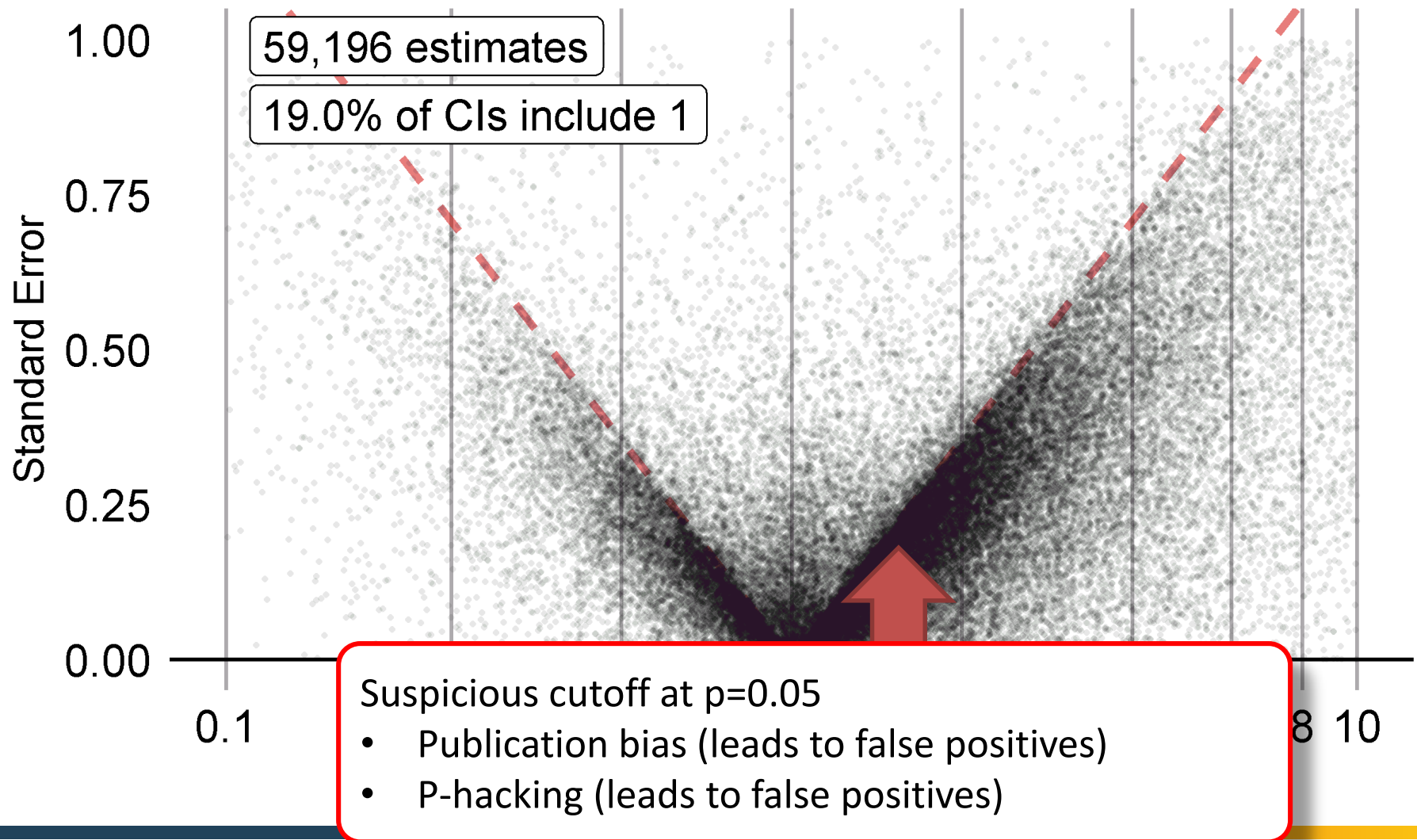


Study	Population	Target			Comparator		
		Drug	Exposed	Events	Drug	Exposed	Events
ALLHAT	Prior (treated) stage 1/2 hypertension with >=1 CVD risk factor	Chlorthalidone	15,255	1,362	Lisinopril	9,054	796
ANBP2	Australians aged 65-84 with SBP > 160mmHg (62% previously treated)	Hydrochlorothiazide	3,039	82	Enalapril	3,044	58
PHYLLIS	Italians age 45-70 with hypertension and hypercholesterolemia	Hydrochlorothiazide	127	3	Fosinopril	127	-

Effect estimate		
RR	LB95CI	UB95CI
1.01	0.93	1.10
1.47	1.02	2.13
not reported		



Published observational study results





LEGEND

LARGE-SCALE EVIDENCE GENERATION AND EVALUATION IN A NETWORK OF DATABASES



Building the process to generate the evidence





LEGEND Guiding Principles

1. Evidence will be generated at **large-scale**.
2. **Dissemination** of the evidence will not depend on the estimated effects.
3. Evidence will be generated by consistently applying a **systematic approach** across all research questions.
4. The evidence will be generated using a **pre-specified** analysis design.
5. The evidence will be generated using **open source** software that is freely available to all.
6. The evidence generation process will be **empirically evaluated** by including control research questions where the true effect size is known.
7. The evidence will be generated using **best-practices**.
8. LEGEND will **not** be used to **evaluate methods**.
9. The evidence will be **updated** on a regular basis.
10. **No patient-level data** will be shared between sites in the network, only aggregated data.



What would the 'target trial' look like to compare efficacy of two initial therapies?

Treatment strategies:

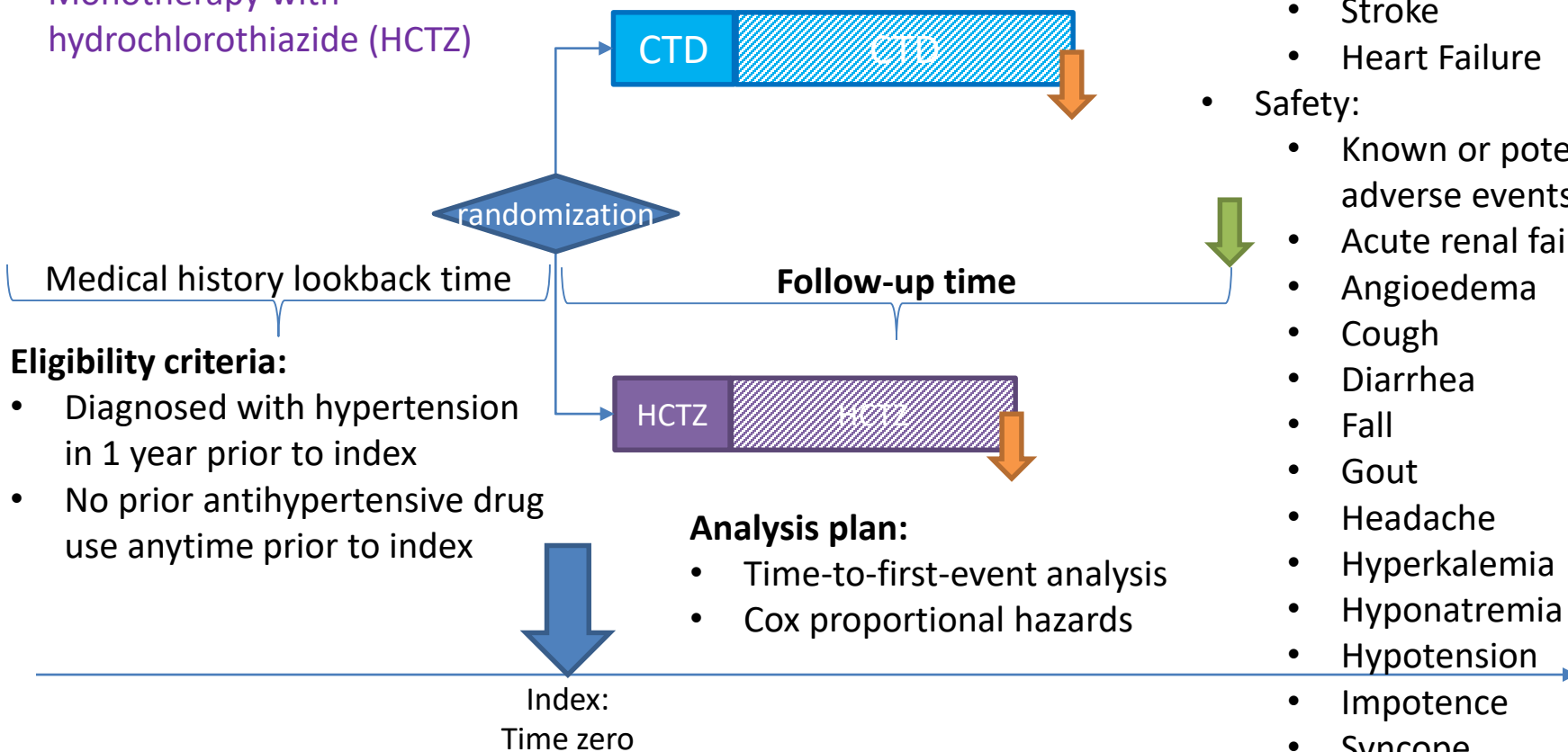
- Monotherapy with chlorthalidone (CTD)
- Monotherapy with hydrochlorothiazide (HCTZ)

Causal contrasts of interest:

- Intent-to-treat effect
- On-treatment effect

Outcomes:

- Efficacy:
 - Myocardial infarction
 - Stroke
 - Heart Failure
- Safety:
 - Known or potential adverse events, e.g.
 - Acute renal failure
 - Angioedema
 - Cough
 - Diarrhea
 - Fall
 - Gout
 - Headache
 - Hyperkalemia
 - Hyponatremia
 - Hypotension
 - Impotence
 - Syncope
 - Vertigo





Observational study to compare two initial therapies

Treatment strategies:

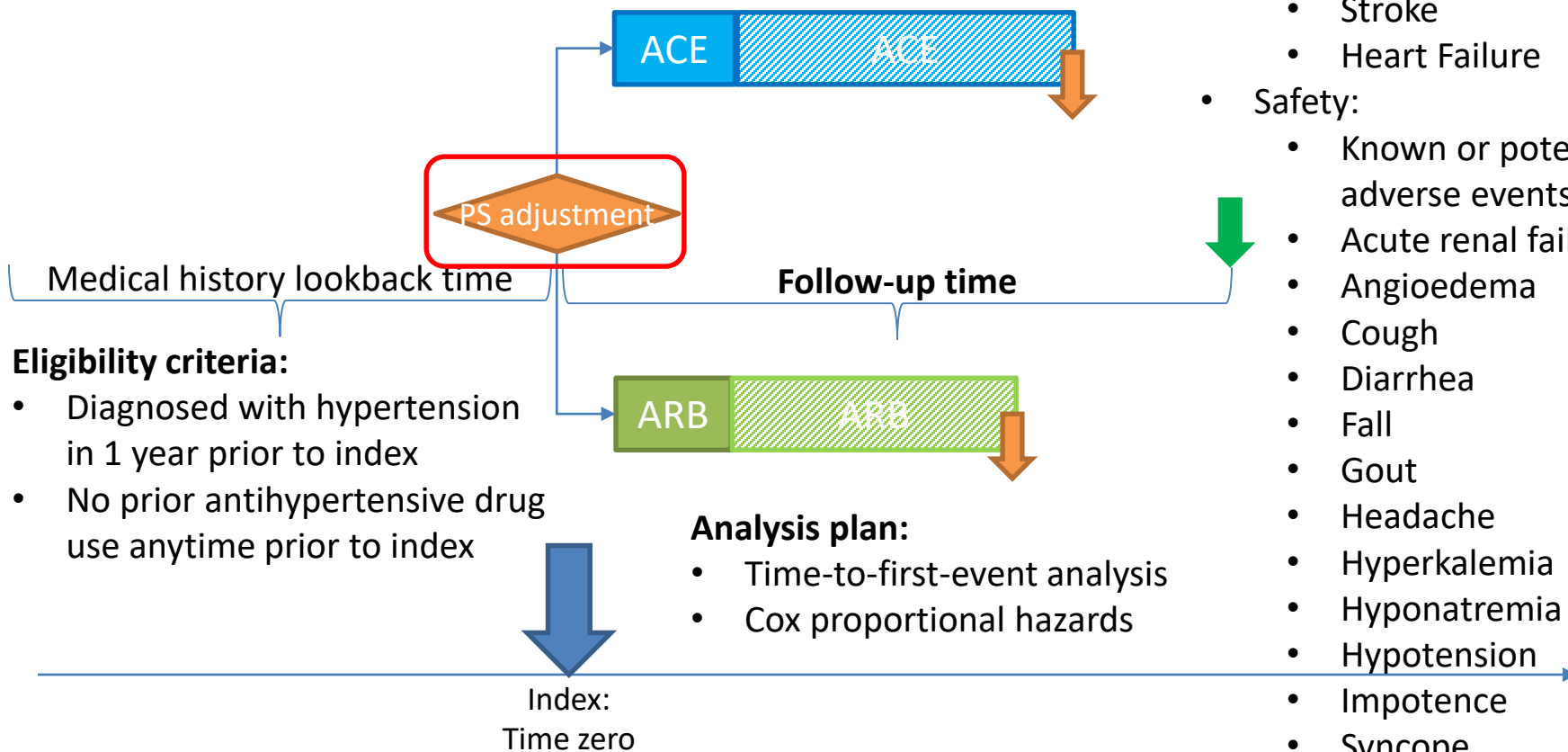
- Monotherapy with ACE
- Monotherapy with ARB

Causal contrasts of interest:

- Intent-to-treat effect
- On-treatment effect

Outcomes:

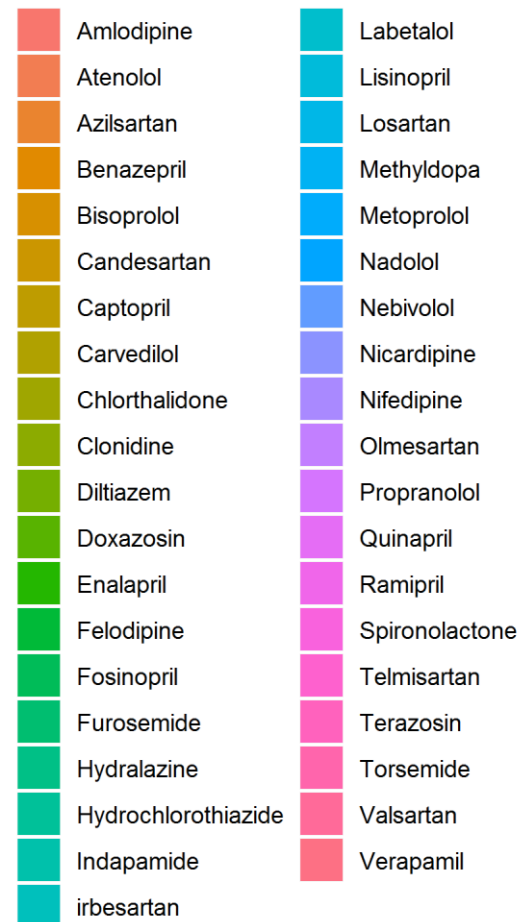
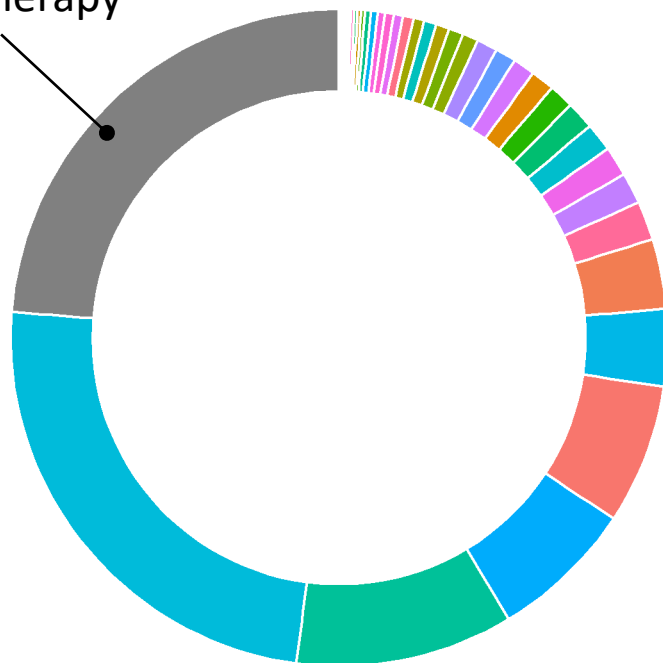
- Efficacy:
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 - Hypotension
 - Impotence
 - Syncope
 - Vertigo





Hypertension mono-therapy

Duo-therapy



Truven Health MarketScan CCAE. Therapies > 2 ingredients not shown



Comparisons of hypertension treatments

	Theoretical	Observed (n > 2,500)
Single ingredients	58	39
Single ingredient comparisons	$58 * 57 = 3,306$	1,296
Single drug classes	15	13
Single class comparisons	$15 * 14 = 210$	156



Comparisons of hypertension treatments

	Theoretical	Observed (n > 2,500)
Single ingredients	58	39
Single ingredient comparisons	$58 * 57 = 3,306$	1,296
Single drug classes	15	13
Single class comparisons	$15 * 14 = 210$	156
Dual ingredients	$58 * 57 / 2 = 1,653$	58
Single vs duo drug comparisons	$58 * 1,653 = 95,874$	3,810
Dual classes	$15 * 14 / 2 = 105$	32
Single vs duo class comparisons	$15 * 105 = 1,575$	832
Duo vs duo drug comparisons	$1,653 * 1,652 = 2,730,756$	2,784
Duo vs duo class comparisons	$105 * 104 = 10,920$	992
...	...	...
Total comparisons	2,843,250	10,278

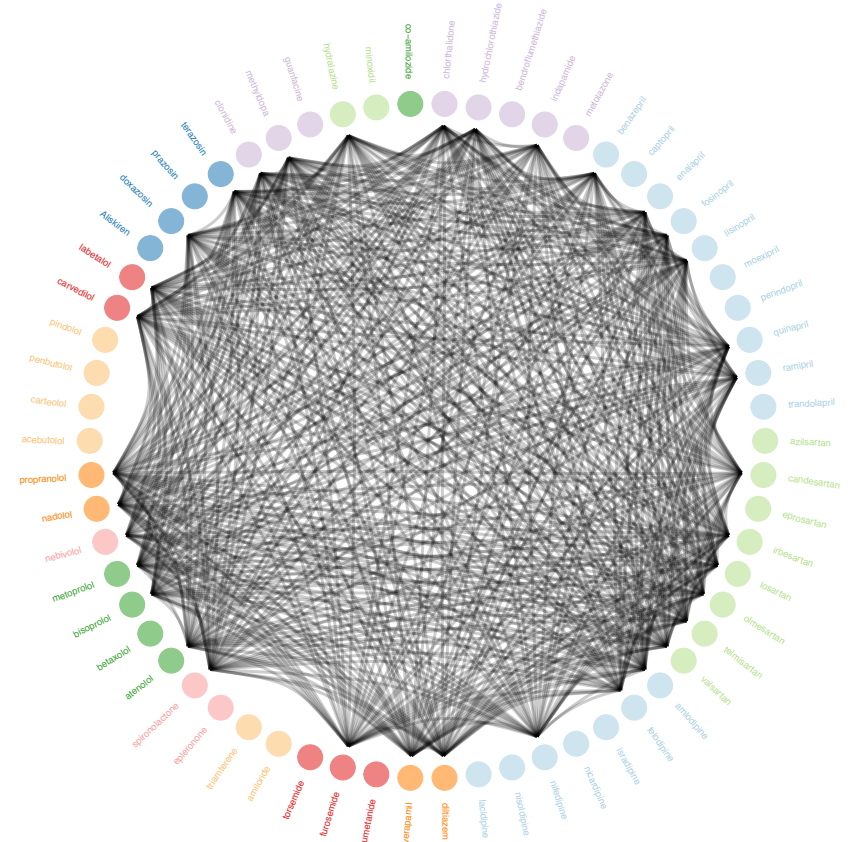


LEGEND knowledge base for hypertension

Head-to-head HTN drug comparisons



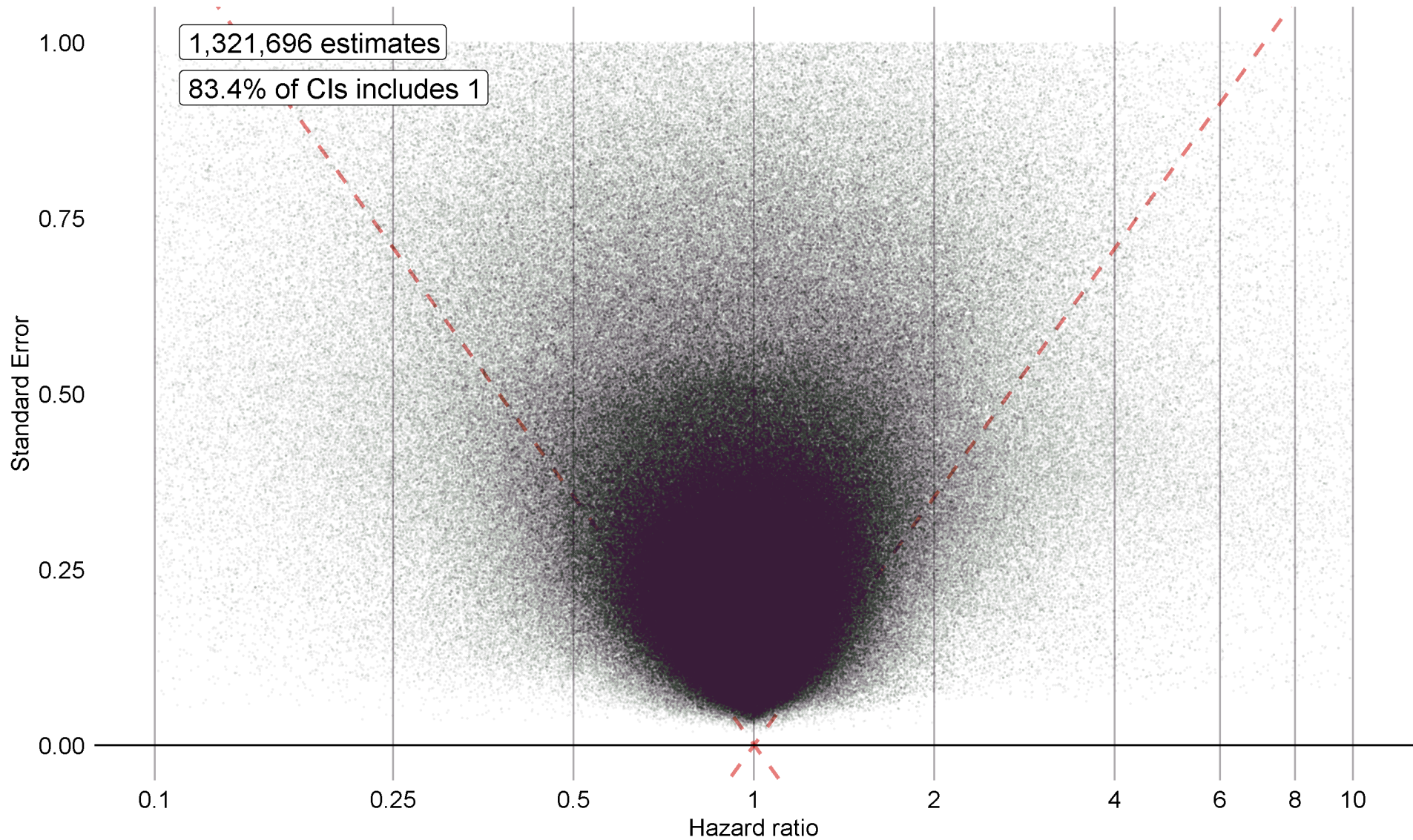
- Trials: 40
- $N = 102 - [1148] - 33K$



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



LEGEND results





Depression results publicly available

<http://data.ohdsi.org/SystematicEvidence/>

Supplementary data for 'Improving reproducibility using high-throughput observational studies with empirical calibration'

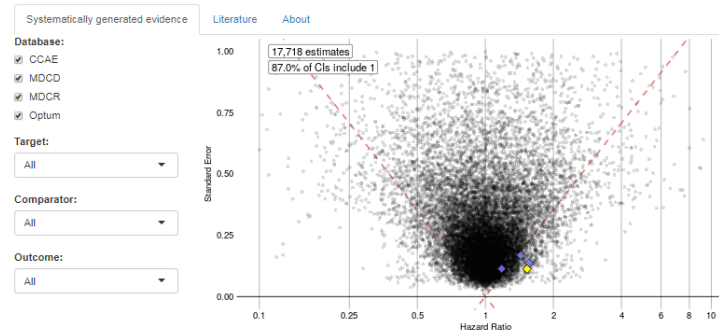


Figure S1. Systematically generated evidence from observational data. Each dot represents a calibrated hazard ratio and confidence interval for a comparison of two depression treatments with respect to an outcome of interest in one of the four databases. Use the controls on the left to filter the result set. After selecting an estimate, details will be shown below.

Details for Mirtazapine vs. duloxetine for Insomnia (MDCR)

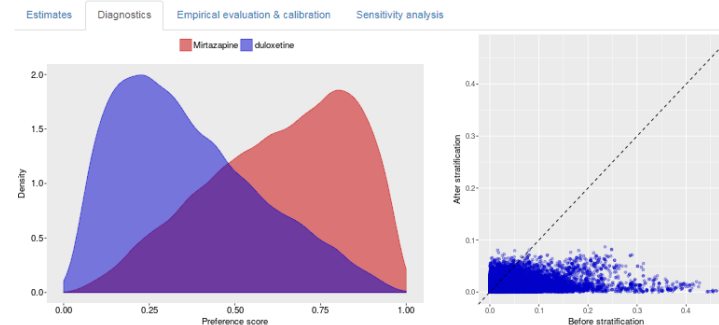


Figure S1.2. Preference score distribution. The preference score is a transformation of the propensity score that adjusts for differences in the sizes of the two treatment groups. A higher overlap indicates subjects in the two groups were more similar in terms of their predicted probability of receiving one treatment over the other.

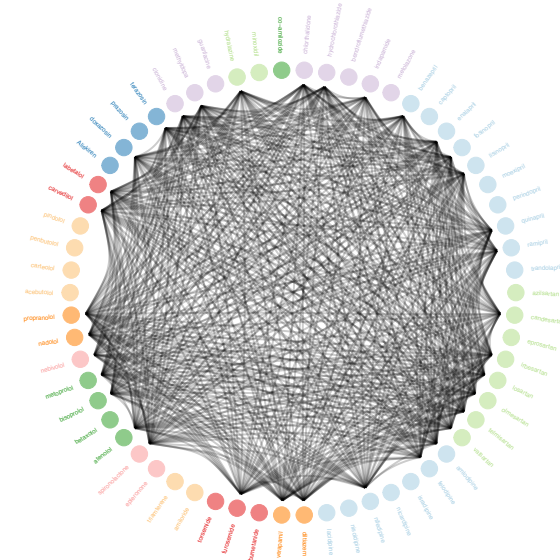
Figure S1.3. Covariate balance before and after stratification. Each dot represents the standardized difference in means for a single covariate before and after stratifying on the propensity score. Move the mouse arrow over a dot for more details.



Acknowledgments

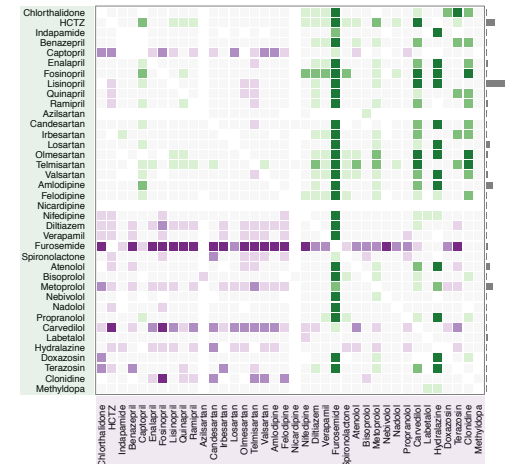
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- Seng Chan You
- Nicole Pratt
- David Madigan
- George Hripcsak
- Marc A. Suchard



Clinical Advisory Team:

- RuiJun Chen
- Jon Duke
- Rae Woong Park
- Christian Reich
- Peter R. Rijnbeek





Global collaborative research through OHDSI network:

Net Clinical Benefit of Ticagrelor compared to Clopidogrel in patients with Acute Coronary Syndrome following Percutaneous Coronary Intervention

Seng Chan You¹; Yeunsook Rho²; Jiwoo Kim²; Anastasios Siapos³; Ajit Londhe⁴; Jaehyeong Cho⁵; Jimyung Park⁵; Martijn Schuemie⁴; Marc A Suchard, MD, PhD^{6,7}; David Madigan PhD⁸; George Hripcsak MD⁹; Christian G. Reich³; Patrick B. Ryan⁴; Rae Woong Park, MD, PhD^{1,5}; Harlan M. Krumholz, MD¹⁰

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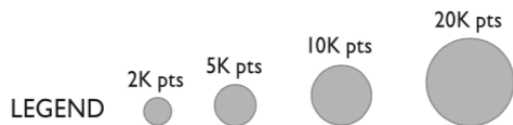
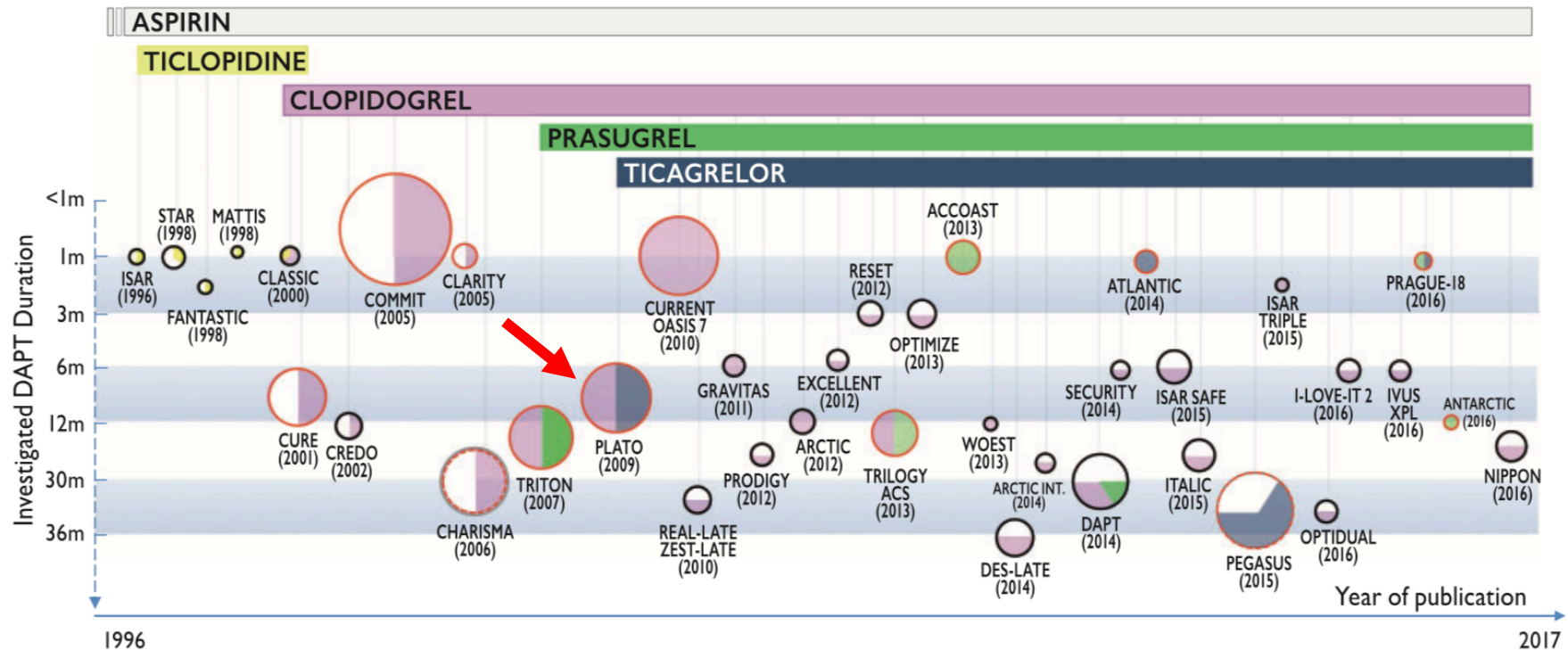


Disclosures

- Potential Conflict of interests
 - Dr. Ryan, Dr. Schuemie, and Ajit Londhe are employees of Janssen Research & Development, a subsidiary of Johnson & Johnson. Dr. Reich and Mr. Siapos are employees of IQVIA. Neither Janssen nor IQVIA had input in the design, execution, interpretation of results or decision to publish.
- Source of Funding
 - This work was supported by the Bio Industrial Strategic Technology Development Program (20001234) funded By the Ministry of Trade, Industry & Energy (MOTIE, Korea) and a grant from the Korea Health Technology R&D Project through the Korea Health Industry Development Institute (KHIDI), funded by the Ministry of Health & Welfare, Republic of Korea [grant number: HI16C0992]



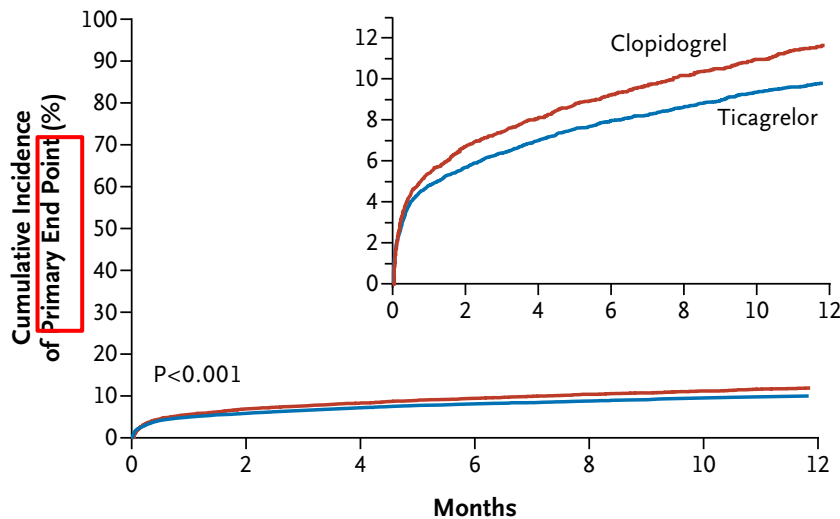
History of Dual AntiPlatelet Therapy (DAPT) in patients with coronary artery disease



- Mixed clinical presentation at the time of stent implantation
- Acute coronary syndrome at presentation
- DAPT initiated in patients with prior myocardial infarction
- DAPT for primary prevention



PLATelet inhibition and patient Outcomes (PLATO) Trial



No. at Risk

Ticagrelor	9333	8628	8460	8219	6743	5161	4147
Clopidogrel	9291	8521	8362	8124	6650	5096	4047

End Point	Ticagrelor Group	Clopidogrel Group	Hazard or Odds Ratio for Ticagrelor Group (95% CI) [†]	P Value
Primary safety end points — no./total no. (%)				
Major bleeding, study criteria	961/9235 (11.6)	929/9186 (11.2)	1.04 (0.95–1.13)	0.43
Major bleeding, TIMI criteria‡	657/9235 (7.9)	638/9186 (7.7)	1.03 (0.93–1.15)	0.57
Bleeding requiring red-cell transfusion	818/9235 (8.9)	809/9186 (8.9)	1.00 (0.91–1.11)	0.96
Life-threatening or fatal bleeding, study criteria	491/9235 (5.8)	480/9186 (5.8)	1.03 (0.90–1.16)	0.70
Fatal bleeding	20/9235 (0.3)	23/9186 (0.3)	0.87 (0.48–1.59)	0.66
Nonintracranial fatal bleeding	9/9235 (0.1)	21/9186 (0.3)		0.03
Intracranial bleeding	26/9235 (0.3)	14/9186 (0.2)	1.87 (0.98–3.58)	0.06
Fatal	11/9235 (0.1)	1/9186 (0.01)		0.02
Nonfatal	15/9235 (0.2)	13/9186 (0.2)		0.69
Secondary safety end points — no./total no. (%)				
Non-CABG-related major bleeding, study criteria	362/9235 (4.5)	306/9186 (3.8)	1.19 (1.02–1.38)	0.03
Non-CABG-related major bleeding, TIMI criteria	221/9235 (2.8)	177/9186 (2.2)	1.25 (1.03, 1.53)	0.03
CABG-related major bleeding, study criteria	619/9235 (7.4)	654/9186 (7.9)	0.95 (0.85–1.06)	0.32
CABG-related major bleeding, TIMI criteria	446/9235 (5.3)	476/9186 (5.8)	0.94 (0.82–1.07)	0.32
Major or minor bleeding, study criteria	1339/9235 (16.1)	1215/9186 (14.6)	1.11 (1.03–1.20)	0.008
Major or minor bleeding, TIMI criteria‡	946/9235 (11.4)	906/9186 (10.9)	1.05 (0.96–1.15)	0.33
Dyspnea — no./total no. (%)				
Any	1270/9235 (13.8)	721/9186 (7.8)	1.84 (1.68–2.02)	<0.001
Requiring discontinuation of study treatment	79/9235 (0.9)	13/9186 (0.1)	6.12 (3.41–11.01)	<0.001

Primary End Point: Vascular death, myocardial infarction and stroke

Wallentin et al., *NEJM*, 2009



Current clinical guideline for DAPT in ACS solely based on PLATO trial

Recommendations	Class ^a	Level ^b
In <u>patients with ACS, ticagrelor (180 mg loading dose, 90 mg twice daily)</u> on top of aspirin ^c is recommended, regardless of initial treatment strategy, including patients pre-treated with clopidogrel (which should be discontinued when ticagrelor is commenced) unless there are contraindications. ²⁰	I	B

2017 ESC/EACTS DAPT guideline

Recommendations for Specific P2Y₁₂ Inhibitors

COR	LOE	RECOMMENDATIONS
Ia	B-R	In <u>patients with ACS (NSTEMI-ACS or STEMI)</u> treated with DAPT after coronary stent implantation and in patients with NSTEMI-ACS treated with medical therapy alone (without revascularization), <u>it is reasonable to use ticagrelor in preference to clopidogrel for maintenance P2Y₁₂ inhibitor therapy (53,71,72).</u>

2016 ACC/AHA DAPT guideline



PLATO trial did not demonstrate superiority of Ticagrelor in North America and Asia

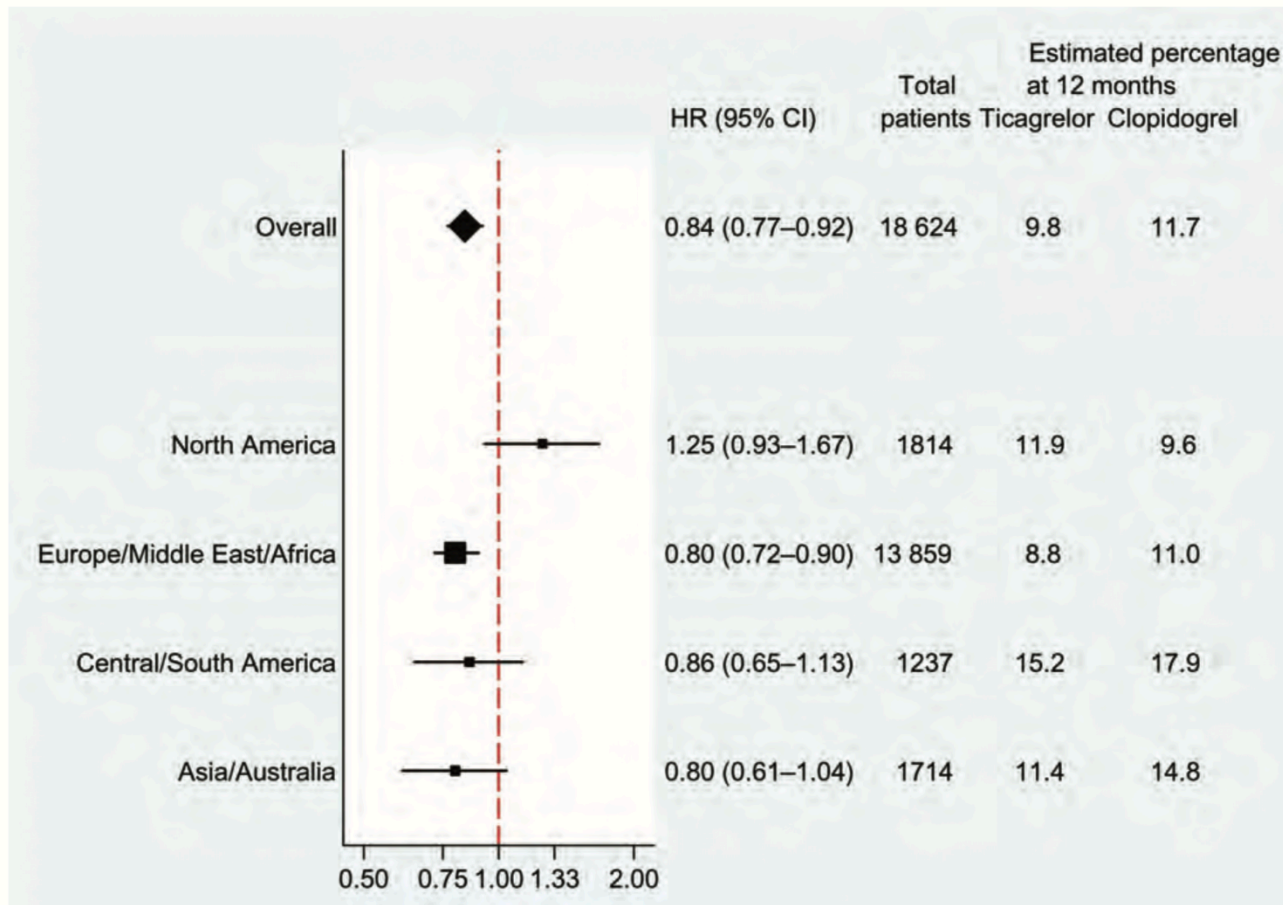


Figure 1 Estimated treatment effects by geographic region for the primary endpoint (CV death, MI, or stroke) of the PLATO trial (hazard ratios with 95% CIs, interaction *P*-value 0.05).



Objectives

- Compare risk of **net adverse clinical event (NACE)** between ticagrelor and clopidogrel in patients with Acute Coronary Syndrome (ACS) following percutaneous coronary intervention (PCI) through OHDSI network.



Method: Study Population

- Inclusion Criteria
 - Adults (≥ 20 yrs) who initiated ticagrelor or clopidogrel due to acute coronary syndrome (ACS) and undertook percutaneous coronary intervention (PCI)
- Exclusion Criteria
 - Prior history of stroke or gastrointestinal bleeding
 - Use of prasugrel or opposing drug within previous 30 days from index date



Method: Outcome

Primary endpoint: Net Adverse Clinical Event (NACE)

- Composite of recurrent myocardial infarction, any revascularization, ischemic stroke, intracranial hemorrhage, or gastrointestinal bleeding

Secondary endpoint

- Ischemic Event
 - Recurrent myocardial infarction
 - Any revascularization (PCI + CABG)
 - Ischemic stroke
- Hemorrhagic Event (major bleeding)
 - Intracranial hemorrhage
 - Gastrointestinal bleeding
- Overall death
- Dyspnea (Positive control)



Method: Statistical Analysis

- Primary analysis
 - Time windows: From 1 day to 365 days after the index date
 - Unconditioned Cox regression after 1-to-1 PS matching
- Sensitivity analyses
 - Time windows
 - On-treatment
 - 5-year
 - Statistical analysis
 - 1-to-1 PS matching with blanking period of outcome (28 days)
 - Variable-ratio PS matching
 - PS stratification
- Assessment of systemic errors
 - 96 Negative controls



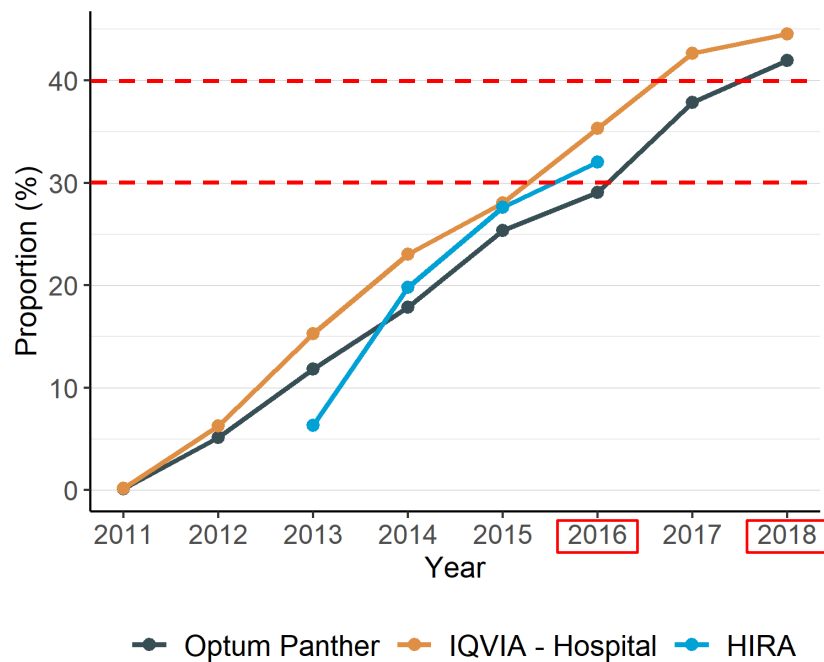
Method

- Data source
 - Optum Pan-Therapeutics (PanTher) : USA, EHR (86M)
 - IQVIA's Hospital data : USA, EHR (85M)
 - HIRA: South Korea, Nationwide Claim for patients undertaking PCI (0.4M)

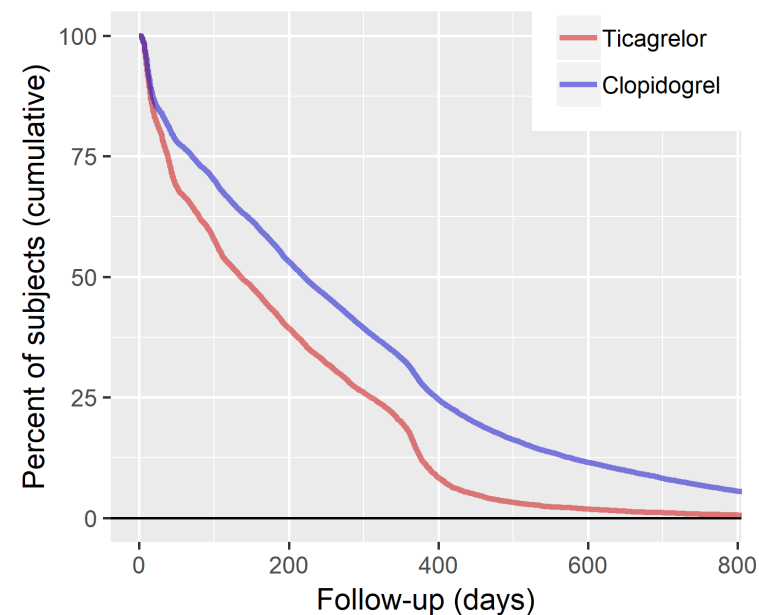


Proportion of ticagrelor across years and drug adherence in Korea

Proportion of Ticagrelor user among whole study population



Days of continuation of ticagrelor and clopidogrel



Days of Drug Continuation	1Q	Median	3Q
Ticagrelor	38	132	363
Clopidogrel	78	232	566

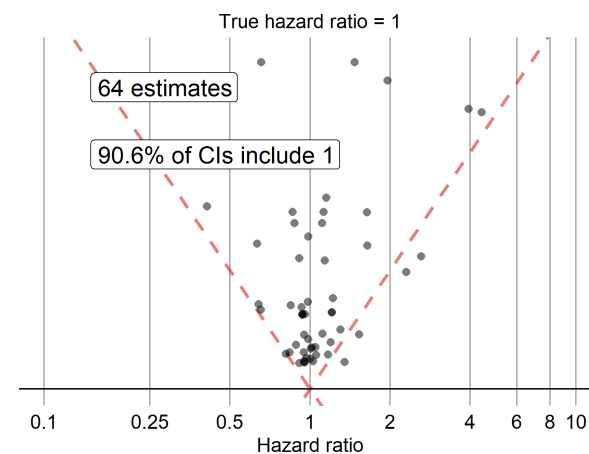
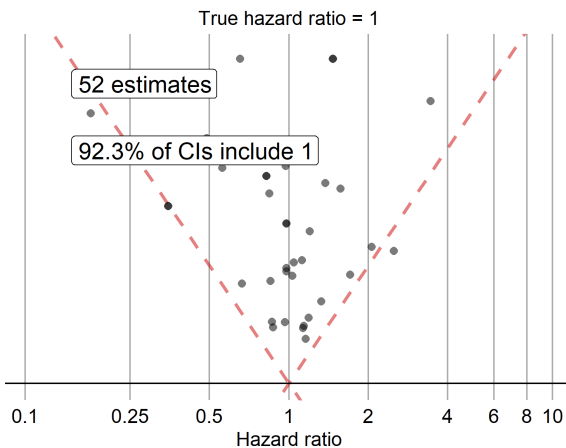
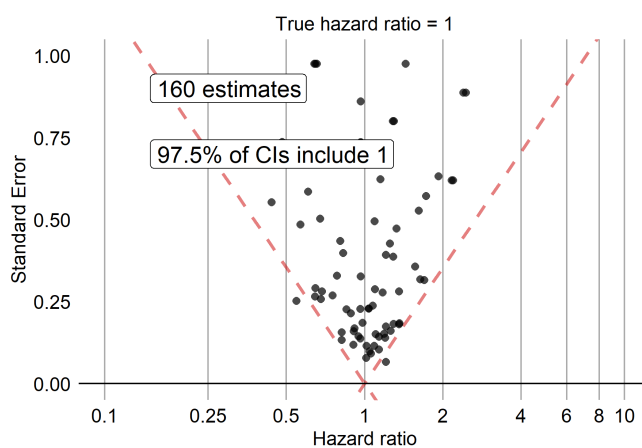
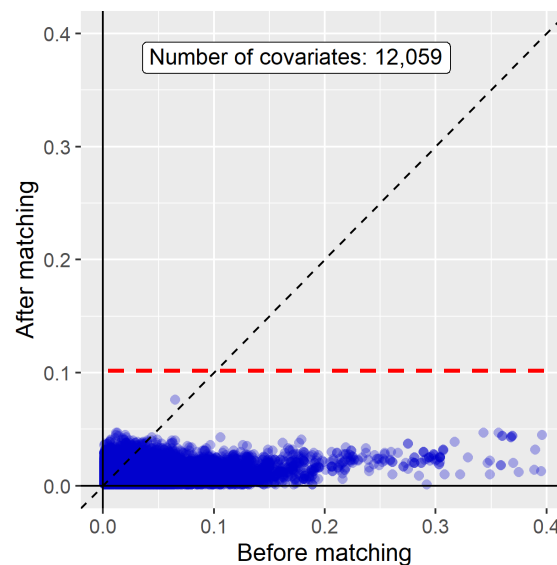
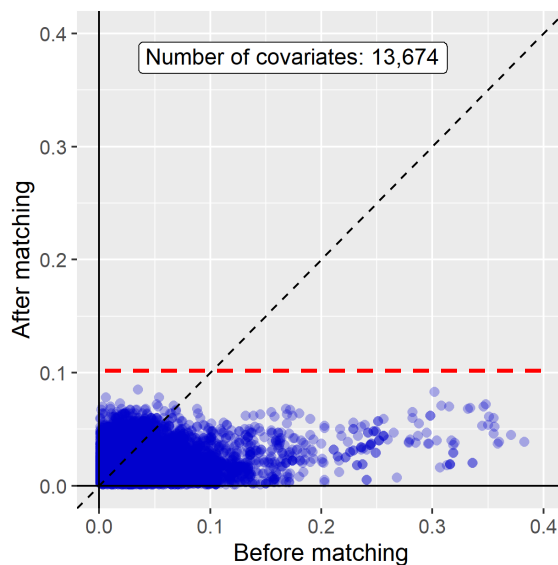
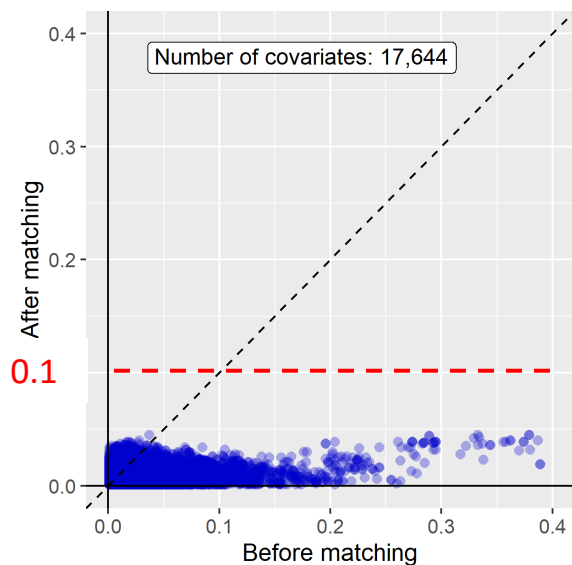


Balance before and after PS matching and Systematic error control

A. Optum PanTher

B. IQVIA-Hospital

C. HIRA

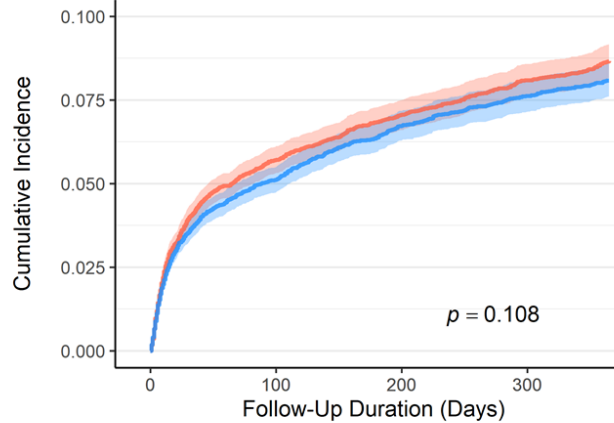


Uncalibrated



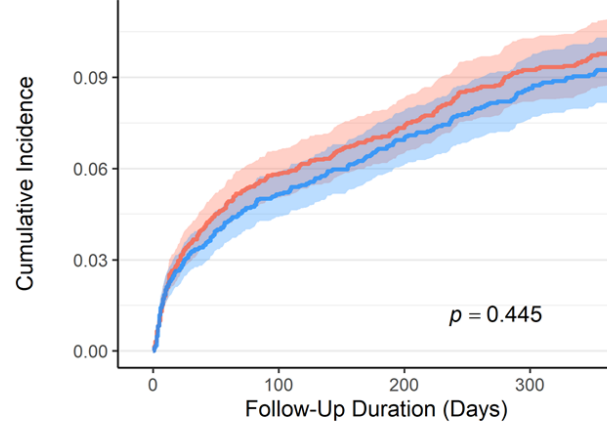
Primary endpoint: 1-year NACE

A. Optum PanTher



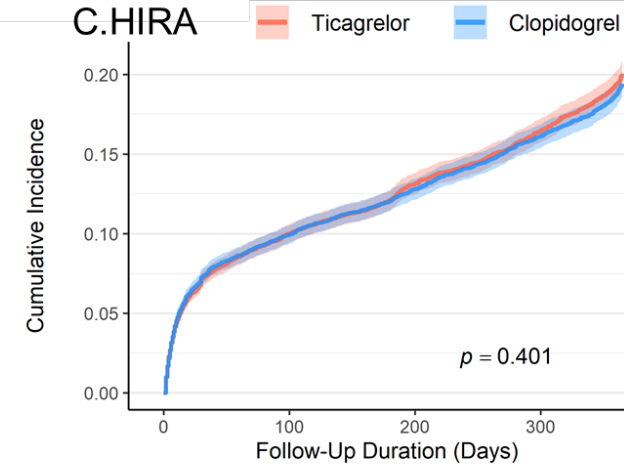
Number at risk				
Ticagrelor	13,569	11,149	9,873	8,860
Clopidogrel	13,569	10,883	9,553	8,429

B. IQVIA-Hospital



Number at risk				
Ticagrelor	4,002	2,769	2,263	1,941
Clopidogrel	4,002	2,734	2,242	1,887

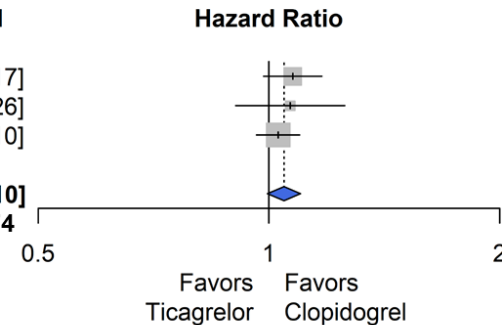
C. HIRA



Number at risk				
Ticagrelor	10,890	8,777	7,607	6,379
Clopidogrel	10,890	8,700	7,475	6,346

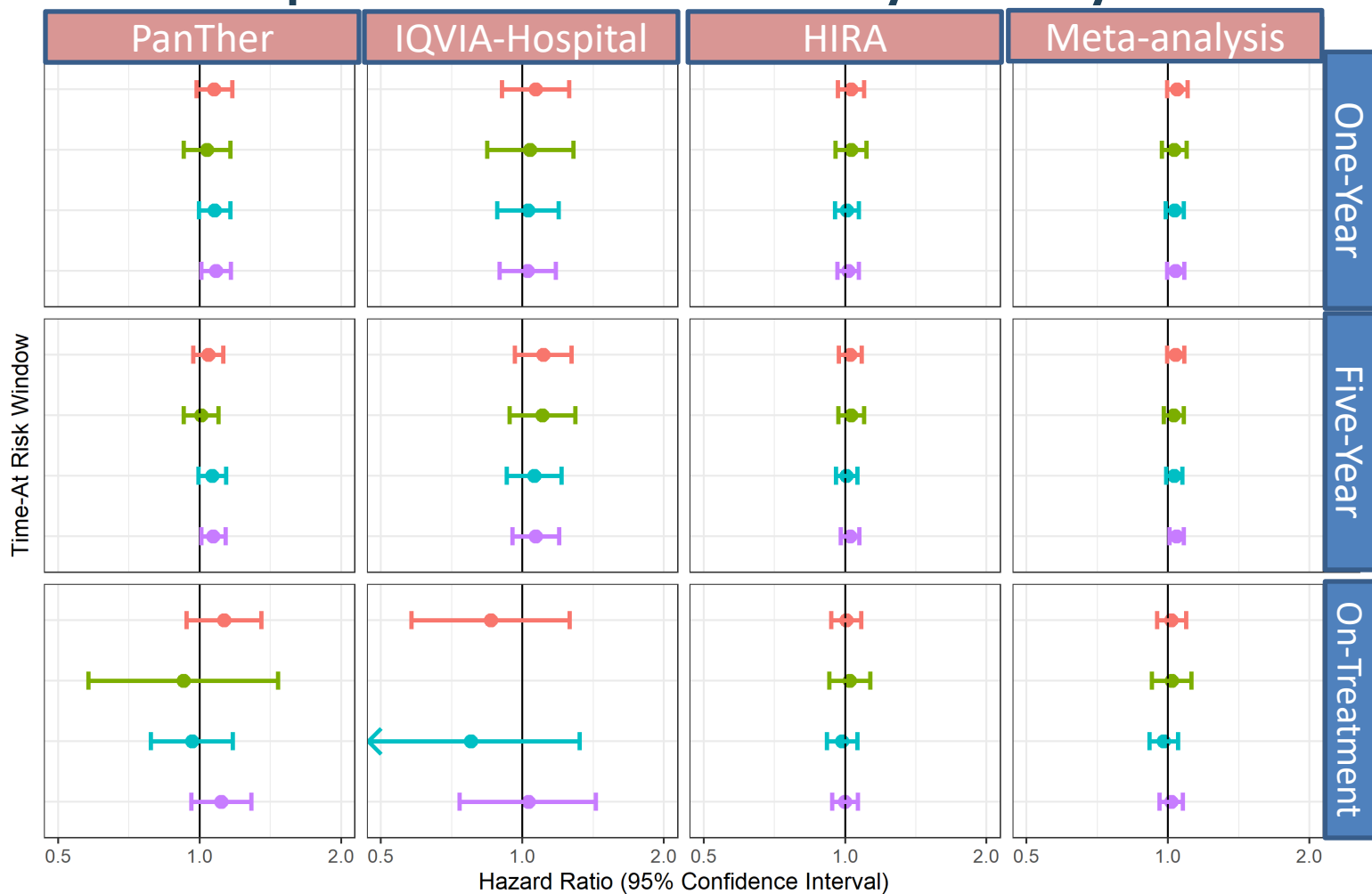
D. Meta-analysis

Source	Ticagrelor		Clopidogrel		HR	95% CI
	Total	Event	Total	Event		
Optum Panther	13,569	1,057	13,569	968	1.07	[0.98; 1.17]
IQVIA - Hospital	4,002	299	4,002	276	1.07	[0.90; 1.26]
HIRA	10,890	1,881	10,890	1,817	1.03	[0.96; 1.10]
Overall	28,461	3,237	28,461	3,061	1.05	[1.00; 1.10]
Heterogeneity: $I^2 = 0.0\%$						





Consistency in the results of the primary endpoint in sensitivity analyses



- 1-to-1 PS matching
- 1-to-1 PS matching with blanking period
- Variable-ratio PS matching
- PS stratification



Summary

- There appears to be **no significant difference** in **1-year NACE risk between ticagrelor and clopidogrel** users with ACS following PCI
- The findings for primary endpoint were consistent across sensitivity analyses
- **Ticagrelor** is associated with **higher risk of hemorrhagic events and dyspnea.**



Please, Join the Journey

- Main homepage
 - www.ohdsi.org
- 2019 OHDSI Symposium
 - Sep. 15-17th
 - Bethesda
- Github
 - <https://github.com/OHDSI>
- OHDSI Community meeting: 1AM (Korean time), Wed
 - http://www.ohdsi.org/web/wiki/doku.php?id=projects:ohdsi_community
- Workgroup meeting
 - Eastern hemisphere meeting: 4PM (Korean time), Wed,
 - Population-Level estimating workgroup:
<http://www.ohdsi.org/web/wiki/doku.php?id=projects:workgroups:est-methods>
 - Patient-Level prediction workgroup:
http://www.ohdsi.org/web/wiki/doku.php?id=projects:workgroups:patient-level_prediction



Please, Join the Journey

- Forum
 - <http://forums.ohdsi.org/>
- OHDSI in Korea Forum
 - <http://forums.ohdsi.org/c/For-collaborators-wishing-to-communicate-in-Korean>

📌 About the OHDSI in Korea category



제 3차 오딧세이 한국 데이터 네트워크 세미나 공지



건강보험공단 샘플 코호트의 OMOP-CDM ETL code 업로드



CDM 변환을 위한 실무자 정기 Teleconference(TC)



하드웨어 스펙



Levetiracetam and Angioedema network study가 출판되었습니다



Relationship 테이블의 ICD to SNOMED에서 다중매핑관련



OHDSI International Symposium 2017 in Korea 관련 자료 1



공통 데이터모델 (CDM) 기반 헬스케어 융합 빅데이터 생태계 구축

산업통상자원부 CDM 사업을 통한
FEEDER-NET 확장

CDM 활용 서비스



분산형 바이오헬스 통합 플랫폼

1 세 부



데이터 분석 도구

데이터 보안 지침 및 검증 기술

데이터 질 평가 지표 및 알고리즘

CDM 활용 수행 연구

플랫폼 고도화



기 FEEDER-NET 플랫폼

주관기관: 아주대, 책임자: 박래웅

총괄 협의체 운영/교육/홍보

협의체 운영

CDM 확산교육

CDM 세미나 활동

바이오헬스 데이터 망

2 세 부

FEEDER-NET 3차병원 중심 데이터망
(27개 병원, 54M 환자정보)



데이터망 확대

종합/전문 병원
종적 확대

최상위 3차 병원
횡적 확대

21개 병원, 42M 환자정보



IT전문업체

Cloud



On-premise





The Book of OHDSI

[https://ohdsi-korea.github.io/
TheBookOfOhdsiKorea](https://ohdsi-korea.github.io/TheBookOfOhdsiKorea)

The Book of OHDSI Korea

OHDSI-Korea

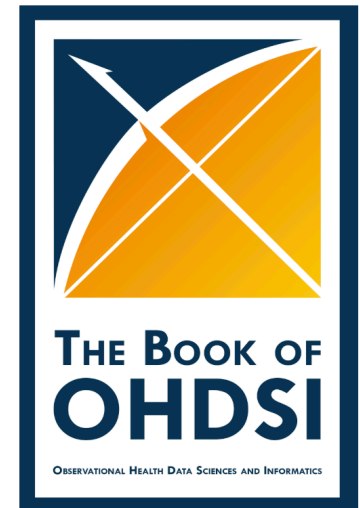
2019-10-18

서문

이 책은 관찰 보건 데이터 과학 및 정보학 (Observational Health Data Science and Informatics : OHDSI) 공동작업에 대한 내용을 담고있다. OHDSI 커뮤니티에 의해 작성된 이 책은 OHDSI 관련 모든 지식의 중앙저장소 역할을 담당하고자 쓰여졌으며 오픈소스 개발 도구들을 통해 커뮤니티에 의해 관리되는 생명력있는 문서로 계속 진화하고 있다. 또한 ohdsi-korea.github.io/TheBookOfOhdsiKorea/에서 온라인으로 항상 최신 버전의 책을 무료로 받아 볼 수 있으며 실물로 구입을 원할 경우 Amazon 등에서 구입이 가능하다.

이 책의 목표

이 책은 OHDSI 관련 모든 지식의 중앙저장소 역할을 담당하고자 쓰여졌으며 OHDSI 커뮤니티, OHDSI 데이터 기준과 OHDSI 도구들에 중점을 두었다. OHDSI의 초보자와 숙련자 모두를 위해 현실적으로 필요 이론과 사용방법에 대한 교육을 제공하는 실용적인 부분에 목표를 두고 있다. 이 책을 읽은 뒤 당신은 OHDSI란 무엇인가, 또한 그 여정에 어떻게 동참할 것인가에 관하여 이해하게 될 것이다. 또한 공통 데이터 모델(CDM)과 표준화된 용어들이 무엇인지, 이러한 것들이 관찰 보건 데이터베이스의 표준화에 어떻게 사용되는지 알게 될 것이다. 이 데이터에 대해 Clinical characterization, Population-level estimation,





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2019 OHDSI KOREA INTERNATIONAL SYMPOSIUM

December **12** (Thur) - **14** (Sat), 2019

Konjiam resort

● **Dec 12 (Thur)**

Basic Tutorial : CDM and Vocabulary / Phenotyping by ATLAS

● **Dec 13 (Fri)**

Opening ceremony (Long Min Baek)

Welcome to the Korean OHDSI journey (RaeWoong Park)

OHDSI Initiative (George Hripcsak)

EHDEN Project (Peter Rijnbeek)

OHDSI Network in Action

Parallel Session

National Perspectives on Bio-health IT in Korea

(Seongi Kim, Yunjeong Heo)

Adopting the OMOP CDM to Enable Standardized Analytics

(Christian Reich, Erica Voss, Mui van Zandt, Martijn Schuemie)

Sharing the International Experience from Asian-Pacific Region

(Nicole Pratt, Hua Xu, Mornin Feng, Akira Izumi, Mui van Zandt, Seng Chan You)

Closing Remarks

● **Dec 14(Sat)**

Advanced Tutorial : Population Level Estimation / Patient-Level Prediction

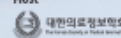
Registration



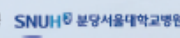
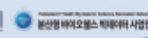
<http://www.ohdsikorea.org>



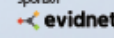
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*Thank
You*
for your time