OHDSI 2022 Tutorial:
An introductory journey from data to evidence
Welcome!
We thank the FDA for their generous support of the 2022 OHDSI symposium through the FDA SCIENTIFIC CONFERENCE GRANT PROGRAM (R13FD006972)
OHDSI’s mission

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

Where The OHDSI Community Has Been And Where We Are Going

2022 edition
The journey to real-world evidence

Patient-level data in source system/schema

Reliable evidence
The journey to real-world evidence

**Different types of observational data:**

- **Populations**
  - Pediatric vs. elderly
  - Socioeconomic disparities
- **Care setting**
  - Inpatient vs. outpatient
  - Primary vs. secondary care
- **Data capture process**
  - Administrative claims
  - Electronic health records
  - Clinical registries
- **Health system**
  - Insured vs. uninsured
  - Country policies

Patient-level data in source system/schema
The journey to real-world evidence

Types of evidence desired:

- Clinical characterization
  - Clinical trial feasibility
  - Treatment utilization
  - Disease natural history
  - Quality improvement

- Population-level effect estimation
  - Safety surveillance
  - Comparative effectiveness

- Patient-level prediction
  - Precision medicine
  - Disease interception

Patient-level data in source system/schema

Reliable evidence
### Full-day Tutorial – October 15
#### An Introductory Journey From Data To Evidence

<table>
<thead>
<tr>
<th>Time</th>
<th>Title</th>
<th>Faculty</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:30 am - 8:30 am</td>
<td>Registration/Lite Breakfast (White Oak Foyer)</td>
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<tr>
<td>8:30 am - 9:00 am</td>
<td>Overview of the OHDSI Journey: where are we going?</td>
<td>Patrick Ryan</td>
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<tr>
<td>9:00 am - 9:50 am</td>
<td>OMOP Common Data Model and vocabulary</td>
<td>Clair Blacketer</td>
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<tr>
<td>9:50 am - 10:00 am</td>
<td>Energy Break</td>
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<tr>
<td>10:00 am - 10:50 am</td>
<td>ETL a source database into OMOP CDM</td>
<td>Melanie Philofsky</td>
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<tr>
<td>10:50 am - 11:00 am</td>
<td>Energy Break</td>
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<tr>
<td>11:00 am - 11:50 am</td>
<td>Creating Cohort Definitions</td>
<td>Asieh Golzar</td>
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<tr>
<td>11:50 am - 12:30 pm</td>
<td>Buffet Lunch</td>
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<tr>
<td>12:30 pm - 1:20 pm</td>
<td>Phenotype Evaluation</td>
<td>Gowtham Rao</td>
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<tr>
<td>1:20 pm - 1:30 pm</td>
<td>Energy Break</td>
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<tr>
<td>1:30 pm - 2:20 pm</td>
<td>Characterization</td>
<td>Kristin Kostka</td>
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<td>2:20 pm - 2:30 pm</td>
<td>Energy Break</td>
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<tr>
<td>2:30 pm - 3:20 pm</td>
<td>Estimation</td>
<td>Martijn Schuemie</td>
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<td>3:20 pm - 3:30 pm</td>
<td>Energy Break</td>
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<tr>
<td>3:30 pm - 4:20 pm</td>
<td>Prediction</td>
<td>Jenna Reps</td>
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<tr>
<td>4:20 pm - 5:00 pm</td>
<td>Recap of the OHDSI Journey: Where do we go from here?</td>
<td>George Hripcsak</td>
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</tbody>
</table>
To improve health by empowering a community to collaboratively generate the evidence that promotes better health decisions and better care.
HADES (formerly known as the OHDSI Methods Library) is a set of open source R packages for large scale analytics, including population characterization, population-level causal effect estimation, and patient-level prediction.

The packages offer R functions that together can be used to perform an observation study from data to estimates and supporting statistics, figures, and tables. The packages interact directly with observational data in the Common Data Model (CDM), and are designed to support both large datasets and large numbers of analyses (e.g. for testing many hypotheses including control hypotheses, and testing many analyses design variations). For this purpose, each Method package includes functions for specifying and subsequently executing multiple analyses efficiently. HADES supports best practices for use of observational data as learned from previous and ongoing research, such as transparency, reproducibility, as well as measuring of the operating characteristics of methods in a particular context and subsequent empirical calibration of estimates produced by the methods.

HADES has already been used in many published clinical and methodological studies, as can be seen in the Publications section.

Installation

See the Support section for instructions on setting up the R environment for HADES, including Java and RTools. Each package in HADES can be installed independently, but it is also possible to install all HADES packages at once, as described here. You can learn how connect to your database using HADES here.

Learn How to Use HADES
ZESTRIL - lisinopril tablet
Almatica Pharma LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ZESTRIL safely and effectively. See full prescribing information for ZESTRIL
ZESTRIL® (lisinopril) tablets, for oral use
Initial U.S. Approval: 1988

WARNING: FETAL TOXICITY
See full prescribing information for complete boxed warning.
- When pregnancy is detected, discontinue Zestril as soon as possible. (5.1)
- Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus. (5.1)

INDICATIONS AND USAGE
Zestril is an angiotensin converting enzyme (ACE) inhibitor indicated for:
- Treatment of hypertension in adults and pediatric patients 6 years of age and older (1.1)
- Adjunct therapy for heart failure (1.2)
- Treatment of Acute Myocardial Infarction (1.3)
Angioedema

Head and Neck Angioedema

Angioedema of the face, extremities, lips, tongue, glottis and/or larynx, including some fatal reactions, have occurred in patients treated with angiotensin converting enzyme inhibitors, including Zestril, at any time during treatment. Patients with involvement of the tongue, glottis or larynx are likely to experience airway obstruction, especially those with a history of airway surgery. Zestril should be promptly discontinued and appropriate therapy and monitoring should be provided until complete and sustained resolution of signs and symptoms of angioedema has occurred.

Patients with a history of angioedema unrelated to ACE inhibitor therapy may be at increased risk of angioedema while receiving an ACE inhibitor [see Contraindications (4)]. ACE inhibitors have been associated with a higher rate of angioedema in black than in non-black patients.

Intestinal Angioedema

Intestinal angioedema has occurred in patients treated with ACE inhibitors. These patients presented with abdominal pain (with or without nausea or vomiting); in some cases there was no prior history of facial angioedema and C-1 esterase levels were normal. In some cases, the angioedema was diagnosed by procedures including abdominal CT scan or ultrasound, or at surgery, and symptoms resolved after stopping the ACE inhibitor.
Comprehensive comparative effectiveness and safety of first-line antihypertensive drug classes: a systematic, multinational, large-scale analysis

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

Summary

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

Method We developed a comprehensive, systematic, multinational, large-scale analysis of published comparative effectiveness...
Tutorial infrastructure

- Atlas  http://tutorial5.us-east-1.elasticbeanstalk.com
- Jupyter  http://jupyter.tutorial5.us-east-1.elasticbeanstalk.com
- RStudio  http://rstudio.tutorial5.us-east-1.elasticbeanstalk.com

There are 170 RStudio user accounts: 'user1' - 'user170'. The password is 'Password1'