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Real World Data Use in Embedded Pragmatic Clinical Trials

Sarah Leatherman, PhD

Associate Center Director – Point of Care Program

VA Cooperative Studies Program, Boston, MA

Disclaimer

- ▶ The views and opinions expressed in this presentation are those of the individual presenter and do not necessarily reflect the views of the Clinical Trials Transformation Initiative or the Veterans Health Administration.

VA Point-of-Care Research

- ▶ Trials embed research into clinical care
- ▶ Minimal disruption to clinical workflow
- ▶ Minimal burden for patients
- ▶ Reduce research infrastructure and costs
- ▶ Use of RWD for all study processes
 - Medication tracking/compliance
 - Outcomes and safety events

Case Study

- The Diuretic Comparison Project (DCP) is designed to compare hydrochlorothiazide and chlorthalidone on MACE outcomes.
- After randomization, PCPs provide usual care to patients without follow-up study visits, labs, phone calls, etc.
- Currently enrolling at 13 sites with ~30 more in start-up.

Medication Adherence

Data Sources

- ▶ VA Pharmacy Records
 - Corporate Data Warehouse
 - MCA National Data Extracts
 - Pharmacy Benefits Management
- ▶ Medicare

Example from DCP

Variable	Meaning	Example Data
LocalDurgNameWithDose	VA Product	HYDROCHLOROTHIAZIDE 25MG TAB
NationalFormularyName	Generic name	HYDROCHLOROTHIAZIDE TAB
DaysSupply	Days of supply	90
Qty	Total quantity	90
Sig	Patient instructions	TAKE ONE TABLET BY MOUTH EVERY DAY FOR BLOOD PRESSURE
DispenseUnits	Units to take each time	1
DoseOrdered	Dosage amount	25
Unit	Dosage units	MG
MedRoute	Medication route	ORAL

Algorithm Development

Define medication of interest

- Name
- Dose
- Administration method

Define “on therapy”

- Fill and dispense dates
- Combination drugs

Deployment

- ▶ Manual adjudication if needed
- ▶ Regular review of database entries

Outcome Phenotyping

Data Sources

- ▶ VA Corporate Data Warehouse
- ▶ VA EHR (front end)
- ▶ Medicare
 - 18 month delay

Algorithm Development

- ICD 9/10 adjudication through chart review
- Identification of relevant structured data
- Development of tools to process unstructured data

Algorithm Use

- Accept there will be error!
- May differ across data sources
- Validation
- Reusable!

THANK YOU.



Sarah Leatherman

Sarah.Leaherman@va.gov



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