Real World Data Use in Embedded Pragmatic Clinical Trials

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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

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

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.

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www.ctti-clinicaltrials.org