PROVEN

PRagmatic Trial of Video Education in Nursing Homes

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2020 NIH Collaboratory Steering Committee Meeting
Novel Data Management and Integration Approaches
Novel Data Integration Approaches: An Exemplar for Pragmatic Trials

- Nursing Homes have Standard Functional Assessment Instrument; Computerized Minimum Data Set (MDS)
- MDS updated at least quarterly
- EMRs combine MDS with Billing & Clinical data
- NH EMRs can add supplemental records
- Using Medicare Beneficiary ID and other identifiers can match NH data with CMS data
- Virtual Research Data Center (VRDC) allows uploading MDS & EMR data for merging, matching & analysis
# PROVEN: Data Sources

<table>
<thead>
<tr>
<th>Data Element</th>
<th>Purpose</th>
<th>EMR</th>
<th>MDS</th>
<th>Medicare</th>
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Data Integration Plan

• MDS data AND new video exposure record obtained monthly from partners’ EMRs
• Integrated and updated with ID match
• Data uploaded to CMS Virtual Research Data Center (VRDC) for matching to Bene ID
• All Part A and B claims assembled for analyses

NIH Collaboratory Steering Committee Meeting
Top Barriers/Challenges and Recent Generalizable Lessons Learned
May 15, 2018
PROVEN: Data Flow

- MDS: hospitalization, Discharge Dead
- EMR
- Physician Orders; AD/DNR/DNH
- Video Status Report

Monthly Transmission

VRDC Project Data Base

2-3 Month Lag

CMS Data
Enrollment Record
Fee for Service Claims
Hospital, SNF, MD & Outpatient Visits
Accomplishments

• Last PROVEN patient’s 12 month follow-up:
• Last Data delivered from Partners
• Last upload of clinical data to VRDC
• Primary Outcome Analyses Completed

• May 31, 2019
• July 15, 2019
• September 30, 2019
• November 30, 2019
Advantages & Disadvantages

**Advantages**

- Claims very complete within 3 months; faster for inpatient claims;
- Claims Linkage quick
- Can track study subjects across settings;
- NO loss to follow-up; Vital Status updated every 2 weeks

**Disadvantages**

- VRDC Limited to one Analyst
- Output checked before released
- Only SAS & Stata
- Bayesian modeling very challenging
- Heavy CPU time means analyses very slow
- Data Sharing Prohibited
Summary

• Game Changer to use “real time” data
• Linking EMR and other data to VRDC permits many novel kinds of Cluster RCTs
• Disadvantages are largely technical;
• Increased Access possible if Privacy issues adequately addressed