Pragmatic Trials in Nursing Homes: Benefits of a Uniform Minimal Clinical Data Set Linked to Medicare Data

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  - Angelo Volandes, MD
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- Database development collaborators:
  - Joan Teno, MD, MS
  - Pedro Gozalo, Ph.D.
  - Jeffrey Hiris, MA
  - Julie Lima, Ph.D.

- NIA Program Project: P01AG027296
Explosion of Research on Long Term Care Made Possible by Data

- Before 1999, very limited data available
  - First National Nursing Home Survey in 1963
  - National Long Term Care Survey linked to Medicaid and Medicare, but limited in scope
  - Medicare/Medicaid Provider of Service file

- With advent of national MDS, patient admission and prevalent population could be differentiated at state, county and provider level
NH RAI MDS Background

- Mandated in OBRA ‘87; in effect 1991
- MDS Version 2.0 introduced in 1996
- Admission, Annual, Quarterly & Discharge assessments done on all residents
- Since 1998, all MDS records are computerized and submitted to CMS
- MDS 3.0 including a patient interview: 2011
Minimum Data Set Content

- Demographics (link to Medicare enrollment files)
- Physical and Cognitive Functioning
- Diagnoses and Medical Conditions/Symptoms
- Mood, Behavioral Disturbances and QoL
- Pressure Ulcers, Pain, Continence
- Treatments
- Therapy and Drugs
- Professional Care
Implications of a National MDS Data Base

- Common language for clinical care
- Common definitions for epidemiological and health services research
- Creation of case-mix reimbursement classification
- Creation of quality “performance measures” for regulators, consumers, purchasers and providers
- Monitor changing composition of users
National Repository Volume Projections

- Over 20 million MDS records are filed per year into the National Repository
- Most patients on any day are long-stay residents, but most admissions are Medicare (private insurance)-covered short-stay residents
- Longitudinal per-person files created with linkage of HIC#, Beneficiary ID, etc.
- Match to Medicare hospital & SNF claims
- Match to states’ Medicaid data and to federal consolidation of it [MAX]
Further Data Linkages

- Matched to Medicare Enrollment
  - Demographics, MA status, Dual Eligibility, residence zip code
- Linked to SNF Provider files
  - Ownership, location, staffing, inspection results, geo-code and distance
- Linked to County Area Resource File
- Linked to State Medicaid Policy information
Hierarchical and Longitudinal Data Relationships
Reliability and Validity of the Data

- Numerous inter-rater reliability studies
  - Generally very good comparison to research RNs
  - BUT, inter-facility variation in reliability, sensitivity and specificity*
- Cross-walk with research instruments mixed
  - ADL, cognition, hospital-related dx are “good/excellent”
  - Mood, behavior, pain under-reported
- MDS data predict hospitalization, death and successful discharge
- MDS discharge record corresponds well to Medicare claims

*Mor, et al. Temporal and Geographic Variation in the validity of the Nursing Home Resident Assessment Minimum Data Set. BMC Health Serv Res. 11:78; 2011.
MDS 3.0 – Mortality Risk Score: Predicting Death at Admission

ROC Curves for Mortality Risk Score
Predicting Death at Admission

- 30 day: AUC = .765
- 60 day: AUC = .753
- 1 year: AUC = .736
Distribution of Cognitive Status among Admissions & Residents

- MDS includes measures of cognitive functioning based on standardized tests
- Patients unable to respond to test are rated by staff
- Combining these into a Cognitive Function Score clearly shows how different those admitted to and living in SNFs are
- Construct validity of the CFS good
Distribution of CFS Scores

**Admission Cohort**
- Cognitively Intact: 56%
- Mildly Impaired: 18%
- Moderately Impaired: 21%
- Severely Impaired: 4%

**Long-Stay Cohort**
- Cognitively Intact: 28%
- Mildly Impaired: 34%
- Moderately Impaired: 20%
- Severely Impaired: 17%
Distribution of Cognition-Related Clinical Items and Behaviors by CFS

<table>
<thead>
<tr>
<th></th>
<th>Admission Cohort</th>
<th>Long Stay Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intact</td>
<td>Mild Impairment</td>
</tr>
<tr>
<td>N</td>
<td>1,158,933</td>
<td>438,650</td>
</tr>
<tr>
<td>Communication Patterns</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never Makes Self Understood</td>
<td>0</td>
<td>0.1</td>
</tr>
<tr>
<td>Never Able to Understand</td>
<td>0</td>
<td>0.1</td>
</tr>
<tr>
<td>Functional Impairments</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Totally Dependent in Dressing</td>
<td>3.2</td>
<td>6.2</td>
</tr>
<tr>
<td>Totally Dependent in Eating</td>
<td>1.7</td>
<td>3.4</td>
</tr>
<tr>
<td>Average ADL Score (28 Point Scale)</td>
<td>16.4</td>
<td>17.6</td>
</tr>
<tr>
<td>Wandering Behaviors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wandering</td>
<td>0.1</td>
<td>0.5</td>
</tr>
</tbody>
</table>

NIH Collaboratory Grand Rounds 2-26-2016 14
Measuring Discharges

- MDS 3.0 Discharge to Hospital cross-walks well with Medicare Hospital Claim
  - Advantage: Includes MA patients
  - Advantage: Includes most observation stays
  - Disadvantage: Overstates events; ED visits?
  - Disadvantage: Conditional on length of stay
  - Disadvantage: No diagnosis

- MDS 3.0 Discharge Due to Death cross-walks with Medicare Date of Death (~100%)
30 Day Re-hospitalization Rate Directly from SNF by Year: MDS 3.0
Creating Outcome Measures

- Combine discharge record with re-admission monitoring to create “Successful Discharge”

- Combine admission and discharge ADL data to document “improvement” or decline

- Changes in behavior, mood and treatments; e.g. anti-psychotic use
Average Unweighted Successful Discharge Rates by State, 2013

Rate of successful discharge

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Change in ADL Self-Performance Scores between Admission and Discharge

<table>
<thead>
<tr>
<th></th>
<th>Mean Change (SD)</th>
<th>% No Change, Stable</th>
<th>% Improved</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Long-form ADL Scale 0–28</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full sample</td>
<td>3.35 (4.43)</td>
<td>26.1</td>
<td>64.9</td>
</tr>
<tr>
<td>Discharged home</td>
<td>3.86 (4.48)</td>
<td>22.8</td>
<td>70.4</td>
</tr>
<tr>
<td>Hip fracture</td>
<td>3.80 (4.52)</td>
<td>23.3</td>
<td>69.6</td>
</tr>
<tr>
<td><strong>Early loss (dressing and personal hygiene) 0–8</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full sample</td>
<td>0.96 (1.53)</td>
<td>48.9</td>
<td>45.9</td>
</tr>
<tr>
<td>Discharged home</td>
<td>1.11 (1.56)</td>
<td>44.5</td>
<td>51.2</td>
</tr>
<tr>
<td>Hip fracture</td>
<td>1.08 (1.54)</td>
<td>46.9</td>
<td>49.4</td>
</tr>
<tr>
<td><strong>Mid/late loss (bed mobility, transfer, eating, toilet use) 0–16</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Full sample</td>
<td>1.78 (2.56)</td>
<td>35.9</td>
<td>56.1</td>
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<tr>
<td>Discharged home</td>
<td>2.05 (2.59)</td>
<td>32.6</td>
<td>61.2</td>
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<tr>
<td>Hip fracture</td>
<td>1.98 (2.58)</td>
<td>33.3</td>
<td>60.0</td>
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<tr>
<td><strong>Walking (in room and corridor) 0–8</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full sample</td>
<td>1.32 (1.98)</td>
<td>45.6</td>
<td>49.2</td>
</tr>
<tr>
<td>Discharged home</td>
<td>1.52 (2.02)</td>
<td>41.1</td>
<td>54.5</td>
</tr>
<tr>
<td>Hip fracture</td>
<td>1.74 (2.13)</td>
<td>39.5</td>
<td>57.1</td>
</tr>
<tr>
<td><strong>Locomotion (on and off unit) 0–8</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full sample</td>
<td>1.20 (1.93)</td>
<td>47.4</td>
<td>46.8</td>
</tr>
<tr>
<td>Discharged home</td>
<td>1.37 (1.97)</td>
<td>43.5</td>
<td>51.5</td>
</tr>
<tr>
<td>Hip fracture</td>
<td>1.42 (1.99)</td>
<td>43.9</td>
<td>51.6</td>
</tr>
</tbody>
</table>

Geriatric Pharmaco-Epidemiology: Enhanced with Clinical Data

- Link Medicare Part D claims with Medicare Part A, carrier files and MDS
- Drug “exposures” (presence, quantity & frequency) are observed by day
- Consistently prescribed drugs very likely taken by residents
- Also useful for studies of general Medicare population because enhances available covariates for any “ever” SNF users
Testing the Effect of Beta Blocker Use in “Unstudied” Populations

- Guidelines suggest beta blockers post MI; BUT:
- Very old, long-term care patients not studied
- Identified 17,836 long stay NH residents without beta blockers hospitalized for MI 2007-2010, and tracked Part A and Part D
- Created propensity-matched cohorts and compared 60% with BB to those without on mortality, hospitalization and functioning
- 14% died, 34% re-hospitalized; 11% of survivors declined functionally
Impact of Beta-Blocker Use on Mortality Post-MI among Long Stay NH Residents
Creating a Public Resource: LTCFocus.org

- LTCFocus.org – Nursing home, county and state level data; creates maps and allows for data downloads
- Over 30,000 visits by 20,000 unique users since November 2009
- About 1,500 downloads of the data
- 1,080 users on the mailing list
- Updated through 2014
Create Custom Reports on Long-Term Care

LTCfocus.org provides data on nursing home care in the US. Our goal is to allow researchers to trace relationships between state policies, local market forces and the quality of long-term care and enable policymakers to craft state and local guidelines that promote high-quality, cost-effective, equitable care for older Americans. - Learn More

Data Spotlight

- Documenting Increased Nursing Home Use Among Hispanics

News and Updates

- Meals on Wheels Reduces NH Use
- Newspaper Portrayal of NHs
- NH Medical Staff Organization & Processes of Care

Download Our Data

Download our entire data set, broken out by year. All you need is a verified email address! - Learn More

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Creating a Platform for Phase V Cluster RCTs

- Uniform, consistent data flow on nearly 4 million unique patients annually
- Linkage to Medicare means complete ascertainment and no loss to follow-up
- Existing data allow precise facility selection
- Repeated assessments facilitate precise selection of prevalent and incident patients
- Outcome monitoring: mortality, morbidity, functioning and QoL
Pragmatic Cluster RCT of High-Dose Influenza Vaccine in Nursing Homes

- Recruited nursing homes in or within 50 miles of the 122 cities in the CDC Influenza Surveillance System
- Minimum Data Set (MDS)
  - Identified long-stay NH residents with selected demographic and functional characteristics
  - Identified hospital admissions from participating NHs
- Use Medicare vital status records to identify deaths
- Medicare hospital claims data: hospitalization for influenza (P&I) and cardiovascular exacerbations of influenza

Participating NHs by State (n=823)
Nursing Home Facilities Selection and Randomization

Facilities within 50 miles of one of 122 CDC surveillance cities (n=9,239 NHs)*

Screened (n=989 NHs)

- Excluded facilities (n=118)
  - Hospital-based facilities (n=1)
  - more than 20% of residents under 65 years (n=16)
  - less than 50 LS residents or less than 80% of LS residents over 65 years (n=86)
  - previously used/ currently using HD vaccine* (n=15)

Eligible (n=871 NHs)

- Excluded facilities (n=48); not willing to participate

Randomized (n= 823 NHs)

- HD vaccine for residents
  - Free SD vaccine for staff
  - Allocated intervention (193 NHs)
    - (n=21,926 residents; median per NH=102, iqr 47)

- HD Vaccine for residents
  - Usual care for staff
  - Allocated intervention (216 NHs)
    - (n=24,319 residents; median per NH=108, iqr 53)

- SD vaccine for residents
  - Free SD vaccine for staff
  - Allocated intervention (226 NHs)
    - (n=25,961 residents; median per NH=111, iqr 58)

- SD vaccine for residents
  - Usual care for staff
  - Allocated intervention (188 NHs)
    - (n=20,063 residents; median per NH=106, iqr 47)

Analyzed (n=193 NHs)
(n= 12,558 LS residents; median per NH=70, iqr 46)
Excluded from analysis (0 NHs)

Analyzed (n=211 NHs)
(n=14,082 LS residents; median per NH=72, iqr 39)
Excluded from analysis (5 NHs)
No LS residents (1 NH)
No MDS during baseline (2 NHs)
No MDS during study (1 NH)
Does not bill Medicare (1 NH)

Analyzed (n=226 NHs)
(n=14,797 LS residents; median per NH=74, iqr 41)
Excluded from analysis (0 NHs)

Analyzed (n=187 NHs)
(n=11,598 LS residents; median per NH=66, iqr 41)
Excluded from analysis (1 NH)
No LS residents (1 NH)

* Matched with Medicare metadata and geocodes. Exception was state of New Jersey of which all facilities were eligible.
The trials follows an intent-to-treat analysis at random assignment, therefore there is no loss to follow up.
HD, high-dose; IQR, interquartile range (p75-p50); LS, long-stay; MDS, minimum data set assessment; NHs, nursing homes; SD, standard dose
### NH Groups Are Similar (N=823 NHs)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>HD Vaccine for Residents</th>
<th>SD Vaccine for Residents</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Staff Free (mean, SD)</td>
<td>Staff Usual Care (mean, SD)</td>
</tr>
<tr>
<td>Nursing homes randomized (N)</td>
<td>193</td>
<td>216</td>
</tr>
<tr>
<td>NH-Reported Data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Residents per home (N)</td>
<td>118.0 (52.3)</td>
<td>118.7 (52.1)</td>
</tr>
<tr>
<td>% residents vaccinated</td>
<td>81.7 (14.4)</td>
<td>79.9 (16.6)</td>
</tr>
<tr>
<td>% LTC residents</td>
<td>77.4 (15.9)</td>
<td>78.2 (14.8)</td>
</tr>
<tr>
<td>% LTC residents vaccinated</td>
<td>86.0 (14.8)</td>
<td>86.5 (31.8)</td>
</tr>
<tr>
<td>% staff vaccinated</td>
<td>53.5 (26.2)</td>
<td>56.3 (26.9)</td>
</tr>
<tr>
<td>Medicare Claims/NH Data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Medicaid</td>
<td>59.9 (18.1)</td>
<td>64.2 (16.1)</td>
</tr>
<tr>
<td>Ratio of RN/RN+LPN</td>
<td>0.361 (0.15)</td>
<td>0.355 (0.16)</td>
</tr>
<tr>
<td>Average ADL score (0-28)</td>
<td>17.0 (1.77)</td>
<td>16.9 (2.10)</td>
</tr>
</tbody>
</table>
Cohort Selection, 2013-14
(ALL Long-stay NH Residents over 65 Years)

- Residents who were 65 years old on October 1, 2013.
  - N=75,917

- Residents who became long-stay
  - N=53,035

- HD vaccine for residents
  - Free SD vaccine for staff
    - (N=12,558)

- HD vaccine for residents
  - Usual Care for staff
    - (N=14,082)

- SD vaccine for residents
  - Free SD vaccine for staff
    - (N=14,797)

- SD vaccine for residents
  - Usual Care for staff
    - (N=11,598)

- a Residents who were 65 years old on October 1, 2013.
- b Long-stay residents are NH residents with quarterly and annual MDS assessments. Residents who were discharged from the nursing home to: 1) the community, 2) inpatient rehabilitation facility, 3) hospice, 4) other location, or 5) as dead in the baseline period are excluded from the analytical sample. Residents are included if they were discharged to another nursing home, acute hospital, psychiatric hospital, or MR/DD facility.

[Note: We could not obtain MDS records for 6 NH facilities (i.e., 1 veteran’s home; 2 rehabilitation facilities that were randomized prior to their withdrawal; 1 facility stopped operation in Nov/Dec 2013)]
NH Resident Groups Are Similar (N=53,035)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>HD Vaccine for Residents</th>
<th>SD Vaccine for Residents</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Free Vaccine for Staff</td>
<td>Usual Care for Staff</td>
</tr>
<tr>
<td></td>
<td>(N, %)</td>
<td>(N, %)</td>
</tr>
<tr>
<td>LS residents over 65 years</td>
<td>12,558</td>
<td>14,082</td>
</tr>
<tr>
<td>Age (mean, sd)</td>
<td>83.3 (8.7)</td>
<td>83.1 (8.8)</td>
</tr>
<tr>
<td>Female</td>
<td>9,020 (71.8)</td>
<td>10,234 (72.7)</td>
</tr>
<tr>
<td>African American</td>
<td>1,803 (14.4)</td>
<td>2,083 (14.8)</td>
</tr>
<tr>
<td>White</td>
<td>9,481 (75.5)</td>
<td>10,679 (75.8)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>713 (5.7)</td>
<td>683 (4.9)</td>
</tr>
<tr>
<td>Married</td>
<td>2,332 (18.7)</td>
<td>2,693 (19.5)</td>
</tr>
<tr>
<td>Heart Failure</td>
<td>2,551 (20.3)</td>
<td>2,864 (20.3)</td>
</tr>
<tr>
<td>Stroke/ CVA/ TIA</td>
<td>2,454 (19.5)</td>
<td>2,802 (19.9)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>9,969 (79.4)</td>
<td>11,142 (79.1)</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>4,235 (33.7)</td>
<td>4,816 (34.2)</td>
</tr>
<tr>
<td>Asthma/COPD/CLD</td>
<td>2,406 (19.2)</td>
<td>2,859 (20.3)</td>
</tr>
</tbody>
</table>
# Results: Censoring Is Balanced

<table>
<thead>
<tr>
<th>Outcome</th>
<th>HD vaccine (N, %)</th>
<th>SD vaccine (N, %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete Follow-up</td>
<td>21,469 (80.6)</td>
<td>21,195 (80.3)</td>
</tr>
<tr>
<td>Death</td>
<td>4,677 (17.6)</td>
<td>4,653 (17.6)</td>
</tr>
<tr>
<td>Lost: Discharged to acute inpatient, no return</td>
<td>77 (0.3)</td>
<td>78 (0.3)</td>
</tr>
<tr>
<td>Lost: Discharged to another institution, no return</td>
<td>40 (0.15)</td>
<td>55 (0.21)</td>
</tr>
<tr>
<td>Lost: Discharge to community or hospice</td>
<td>261 (0.98)</td>
<td>293 (1.1)</td>
</tr>
<tr>
<td>Lost: No discharge record</td>
<td>116 (0.44)</td>
<td>121 (0.46)</td>
</tr>
<tr>
<td>Total</td>
<td>26,640</td>
<td>26,395</td>
</tr>
</tbody>
</table>
Seasonal Index Hospitalizations by Month

Count of Index Hospitalization for Influenza Season
(November 2013 to May 2014)

<table>
<thead>
<tr>
<th>Month</th>
<th>Standard-Dose Vaccine</th>
<th>High-Dose Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov</td>
<td>1,000</td>
<td>1,000</td>
</tr>
<tr>
<td>Dec</td>
<td>500</td>
<td>500</td>
</tr>
<tr>
<td>Jan</td>
<td>1,000</td>
<td>1,000</td>
</tr>
<tr>
<td>Feb</td>
<td>500</td>
<td>500</td>
</tr>
<tr>
<td>Mar</td>
<td>800</td>
<td>800</td>
</tr>
<tr>
<td>Apr</td>
<td>600</td>
<td>600</td>
</tr>
<tr>
<td>May</td>
<td>300</td>
<td>300</td>
</tr>
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</table>
## Ever Hospitalized

<table>
<thead>
<tr>
<th>Multivariable logistic regression</th>
<th>Odds Ratio*</th>
<th>LCL</th>
<th>UCL</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatments</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High dose vs. standard dose vaccine</td>
<td>0.930</td>
<td>0.875</td>
<td>0.988</td>
<td>0.0195</td>
</tr>
<tr>
<td>Free staff vaccine vs. usual staff care</td>
<td>1.018</td>
<td>0.958</td>
<td>1.081</td>
<td>0.572</td>
</tr>
</tbody>
</table>

* Adjusted for prior year hospitalization rate, age of resident, mean age of residents in home, individual ADL score, mean ADL score in home, Cognitive Function Score (CFS), mean CFS in home, history of CHF risk-group, prevalence of CHF risk-group in home

- Statistically significant effect of high dose vaccine for NH residents
- No evidence of effect for providing free vaccine to NH staff
PROVEN
PRagmatic Trial of Video Education in Nursing Homes
Facility Eligibility, Stratification, and Randomization

Skilled nursing facilities in healthcare systems
- Genesis HealthCare [G]: 358
- PruittHealth [P]: 98
- Total [T]: 456

Ineligible facilities
- G: 60
- P: 35
- T: 95

Eligible skilled nursing facilities
- G: 298
- P: 63
- T: 361

Low hospitalization rate
- G: 100
- P: 21
- T: 121

Medium hospitalization rate
- G: 100
- P: 21
- T: 121

High hospitalization rate
- G: 98
- P: 21
- T: 119

Treatment
- G: 33
- P: 7
- T: 40

Control
- G: 67
- P: 14
- T: 81

Treatment
- G: 34
- P: 7
- T: 41

Control
- G: 66
- P: 14
- T: 80

Treatment
- G: 32
- P: 7
- T: 39

Control
- G: 66
- P: 14
- T: 80
Target Patient Sub-groups

**Target population 1:**
Patients $\geq 65$ years old who are long stay ($\geq 90$ days) with ADVANCED DEMENTIA:

- Alzheimer’s disease or other dementia
- Advanced cognitive impairment (score of 3 or 4 on the Cognitive Function Scale based on variables from MDS 3.0)
- Extensive or total assistance needed for eating and transferring

**Target population 2:**
Patients $\geq 65$ years old who are long stay ($\geq 90$ days) with ADVANCED COPD/CHF:

- CHF/COPD
- Shortness of breath sitting or lying flat
- Extensive or total assistance walking in room, transferring, walking in corridor, locomotion on/off unit, or dressing

**Active tracking:**
- Hospitalizations
- Advance directives (DNH, DNR, no tube-feeding)
- Burdensome treatments (feeding tubes, parenteral therapy)
- Hospice use

**All other patients $\geq 65$ years old**
Preliminary Data for Target NH Patients with Advanced Disease, 7/1/2013 – 12/31/2014

<table>
<thead>
<tr>
<th>Resident Characteristics</th>
<th>Long-Stay</th>
<th></th>
<th>Not Long-Stay</th>
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NIH Collaboratory Grand Rounds 2-26-2016
Data Integration Plan

- Bi-weekly MDS data AND video exposure record obtained from partner EMRs
- New data integrated with already sent data with ID match
- Intervention Adherence Reports sent to experimental providers by patient type
- Data uploaded to CMS Virtual Research Data Center for matching to claims
- Interim analyses for DSMB
Summary

- Availability of detailed, uniform, longitudinal person-level clinical and functional data opens the way to many investigations otherwise not possible
- Observational data analyses are much more powerful, BUT:
- Real-time data tracking under cluster RCTs is truly revolutionary