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

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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

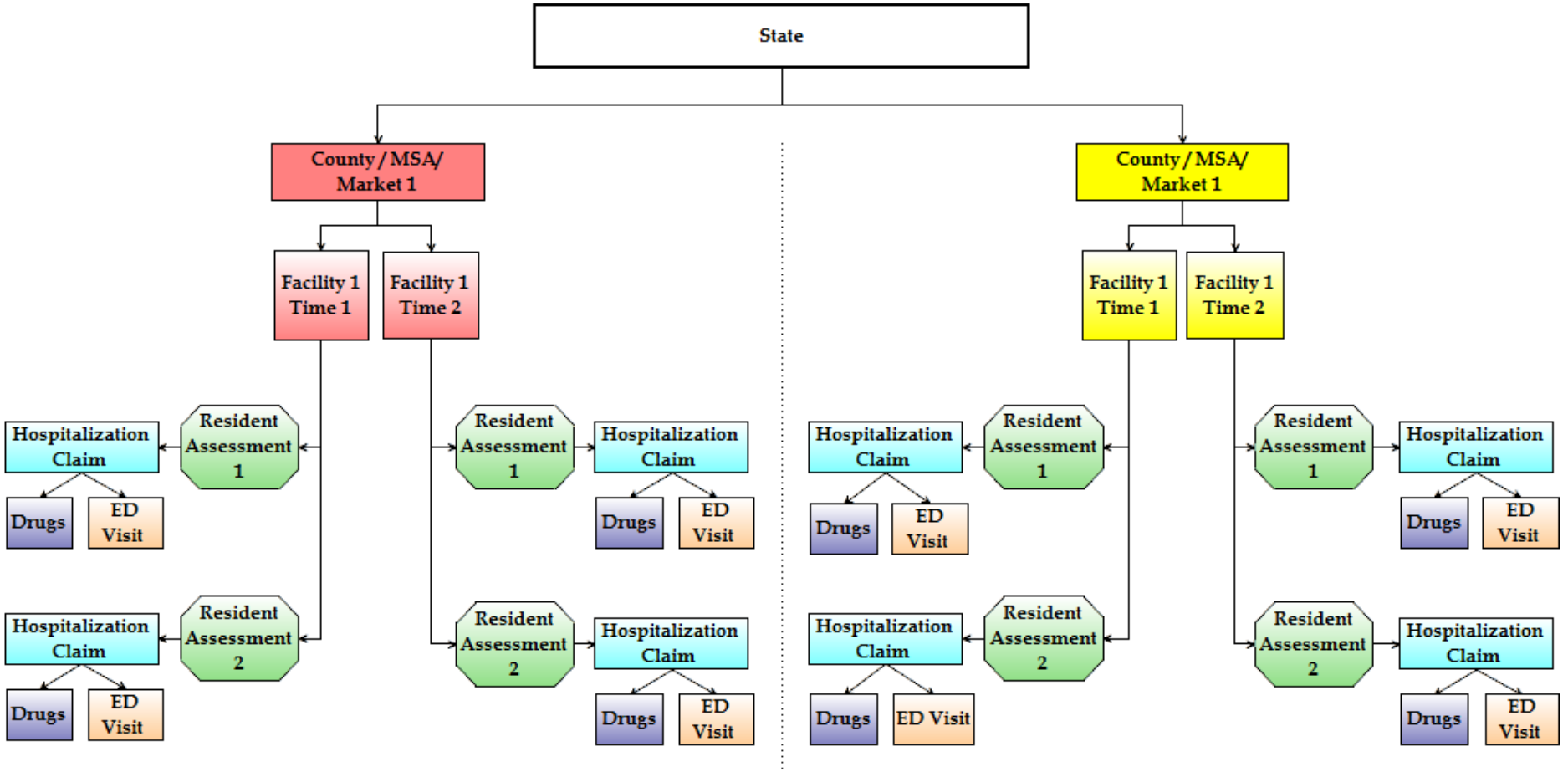
National Repository Volume Projections

- 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



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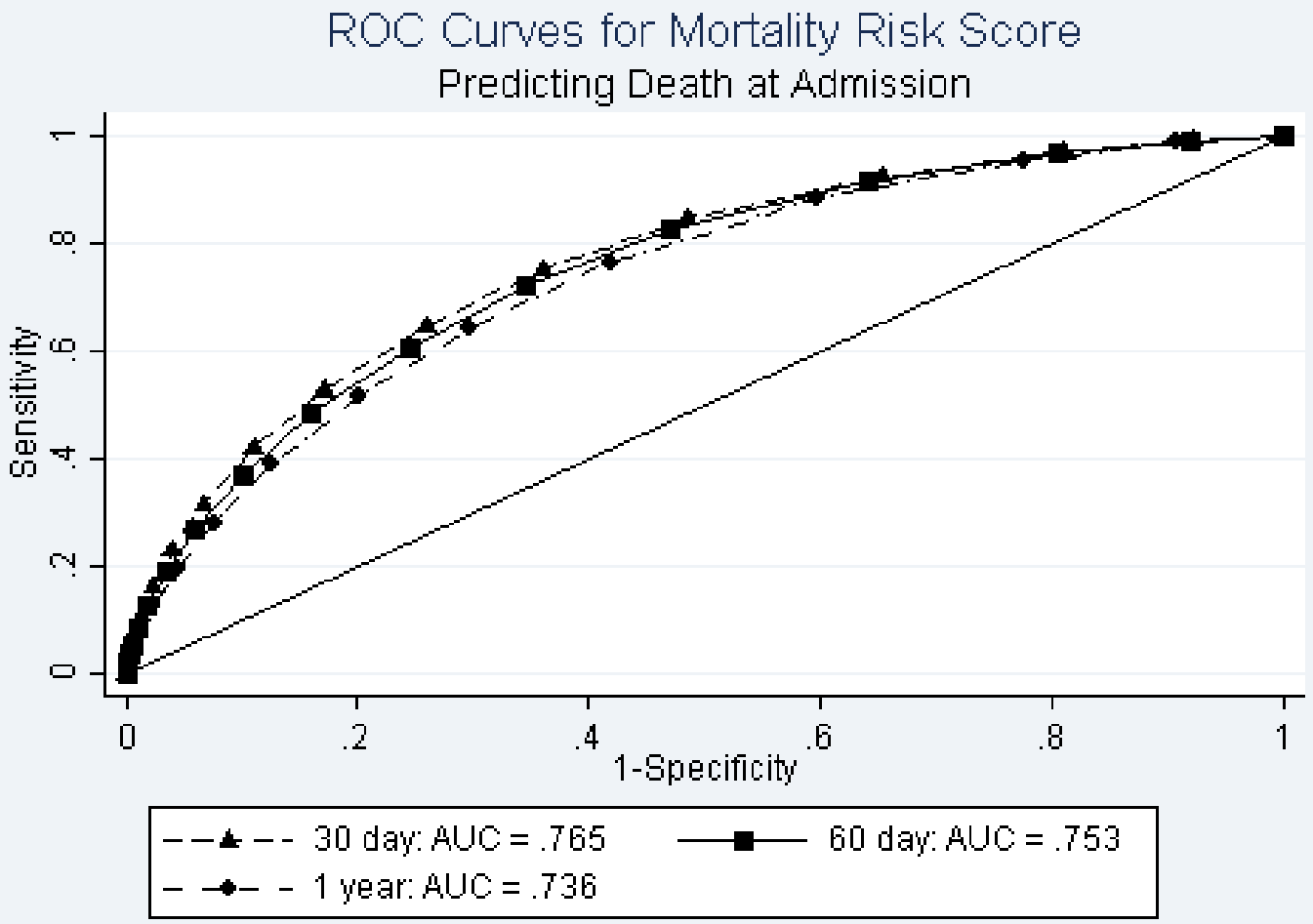
Reliability and Validity of the Data

- 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.

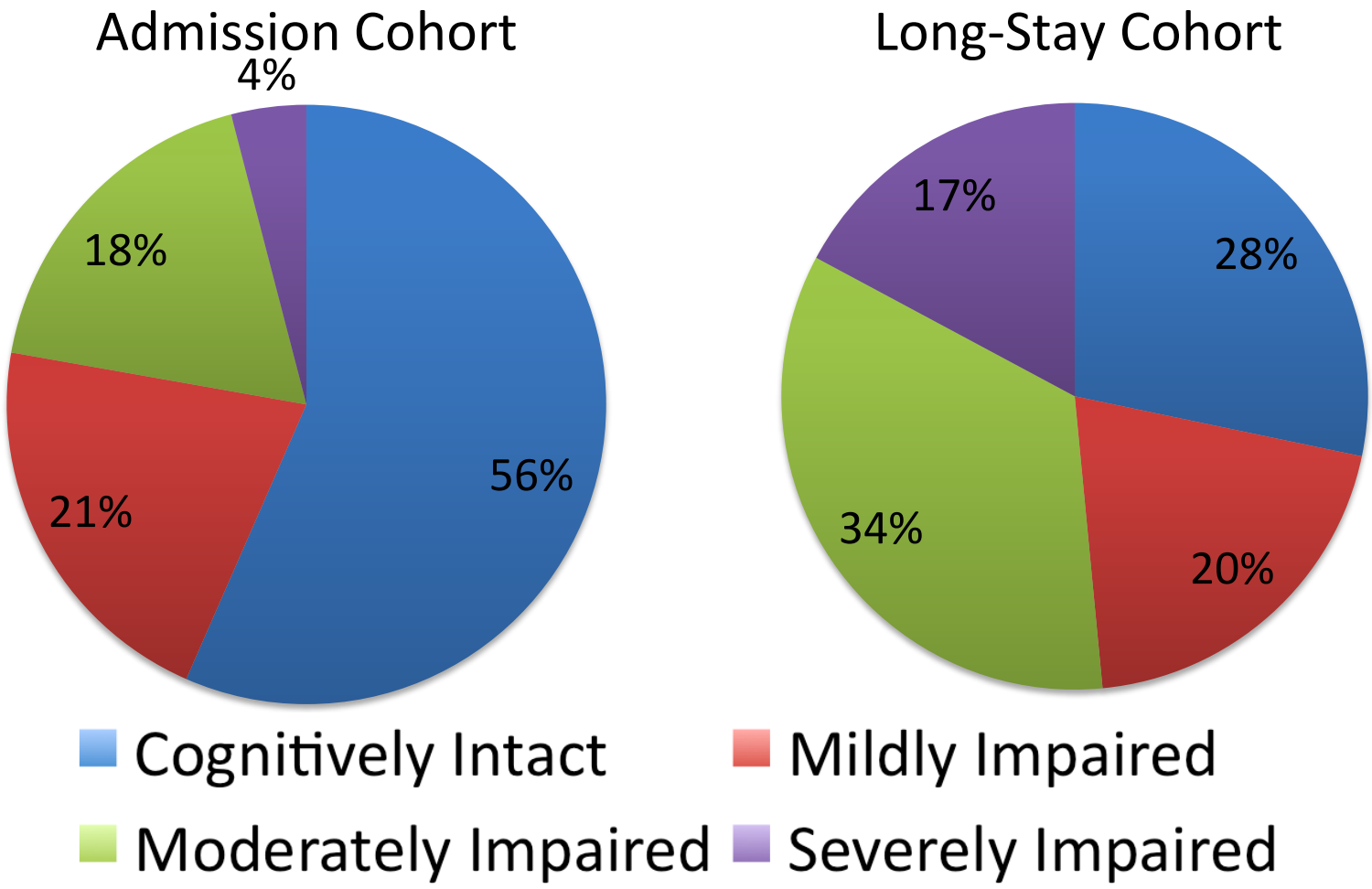
MDS 3.0 – Mortality Risk Score: Predicting Death at Admission



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



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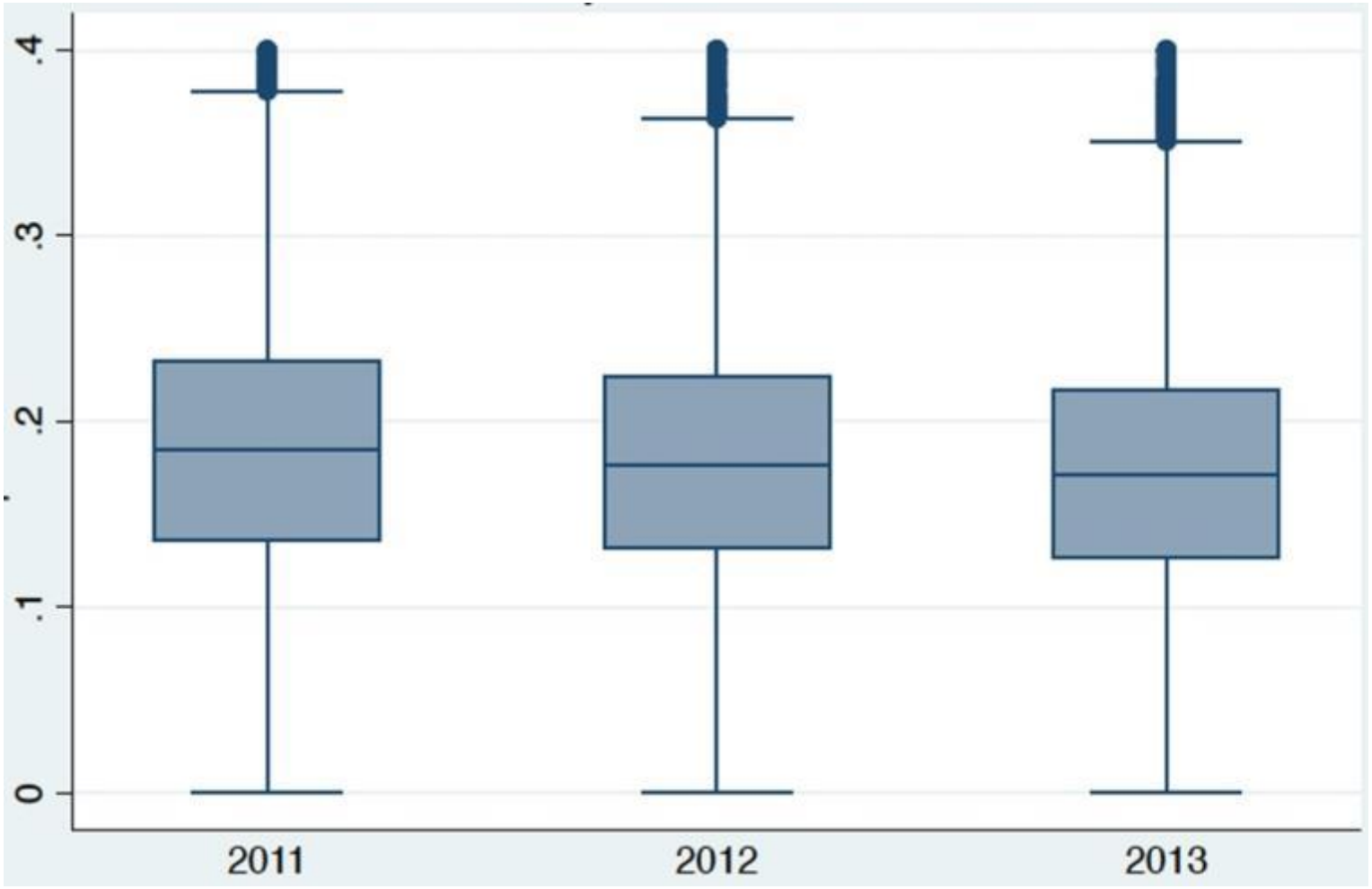
Distribution of Cognition-Related Clinical Items and Behaviors by CFS

	Admission Cohort					Long Stay Cohort				
	Intact	Mild Impairment	Moderate Impairment	Severe Impairment	Total	Intact	Mild Impairment	Moderate Impairment	Severe Impairment	Total
N	1,158,933	438,650	368,180	90,084	2,055,847	222,097	160,604	275,185	134,251	794,881
Communication Patterns										
Never Makes Self Understood	0	0.1	2.9	50.3	2.7	0	0.1	3.7	60	11.3
Never Able to Understand	0	0.1	1.8	40.3	2.1	0	0.1	2.3	49.9	9.1
Functional Impairments										
Totally Dependent in Dressing	3.2	6.2	13.3	47.8	7.7	8.1	10.5	18.6	58.7	20.8
Totally Dependent in Eating	1.7	3.4	9	44.9	5.3	2.7	3.5	9.1	50	13.1
Average ADL Score (28 Point Scale)	16.4	17.6	19.3	23.6	17.5	15.9	17	19	24.2	18.9
Wandering Behaviors										
Wandering	0.1	0.5	3.2	4.2	0.9	0.2	0.7	4.2	5.4	2.6

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



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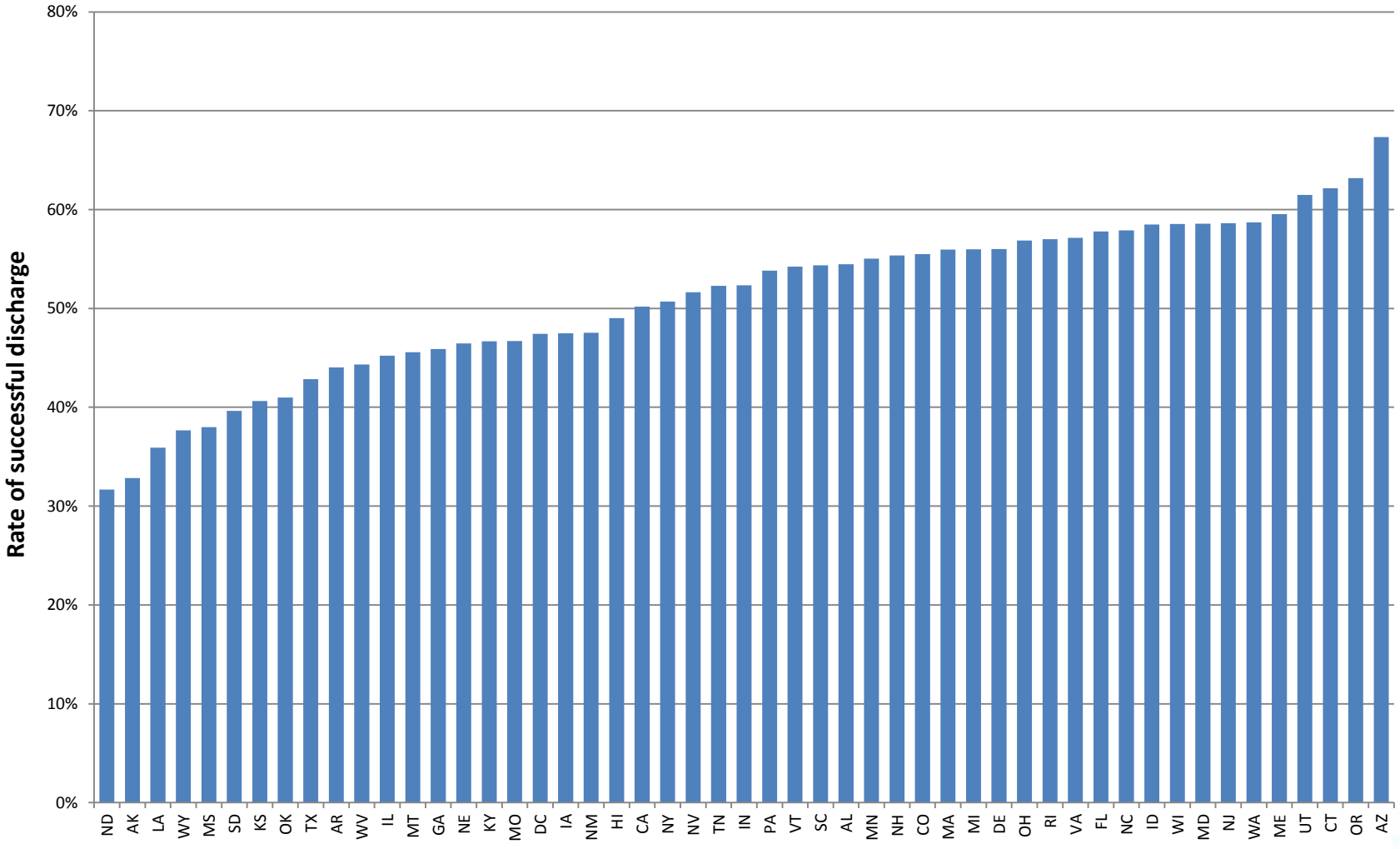
Creating Outcome Measures

- 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



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Change in ADL Self-Performance Scores between Admission and Discharge

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

Wysocki A, Thomas KS, Mor V. Functional improvement among short-stay nursing home residents in the MDS 3.0. J Am Med Dir Assoc. 2015 Jun 1; 16 (6) : 470-4.

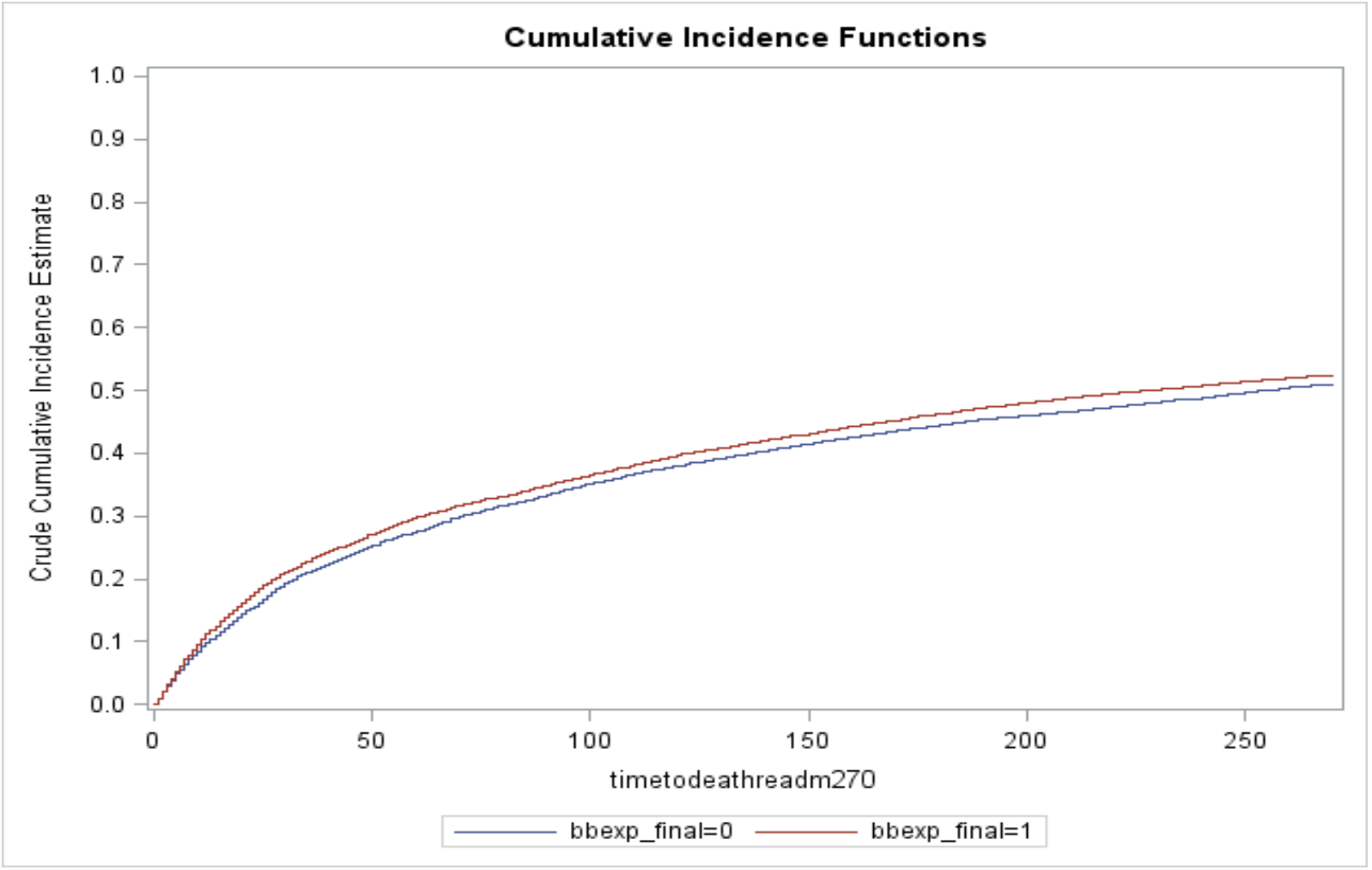
Geriatric Pharmaco-Epidemiology: Enhanced with Clinical Data

- 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



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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

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LTC focus

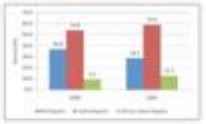
Long-term Care: Facts on Care in the US

Create a Map | Research Findings

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

Creating a Platform for Phase V Cluster RCTs

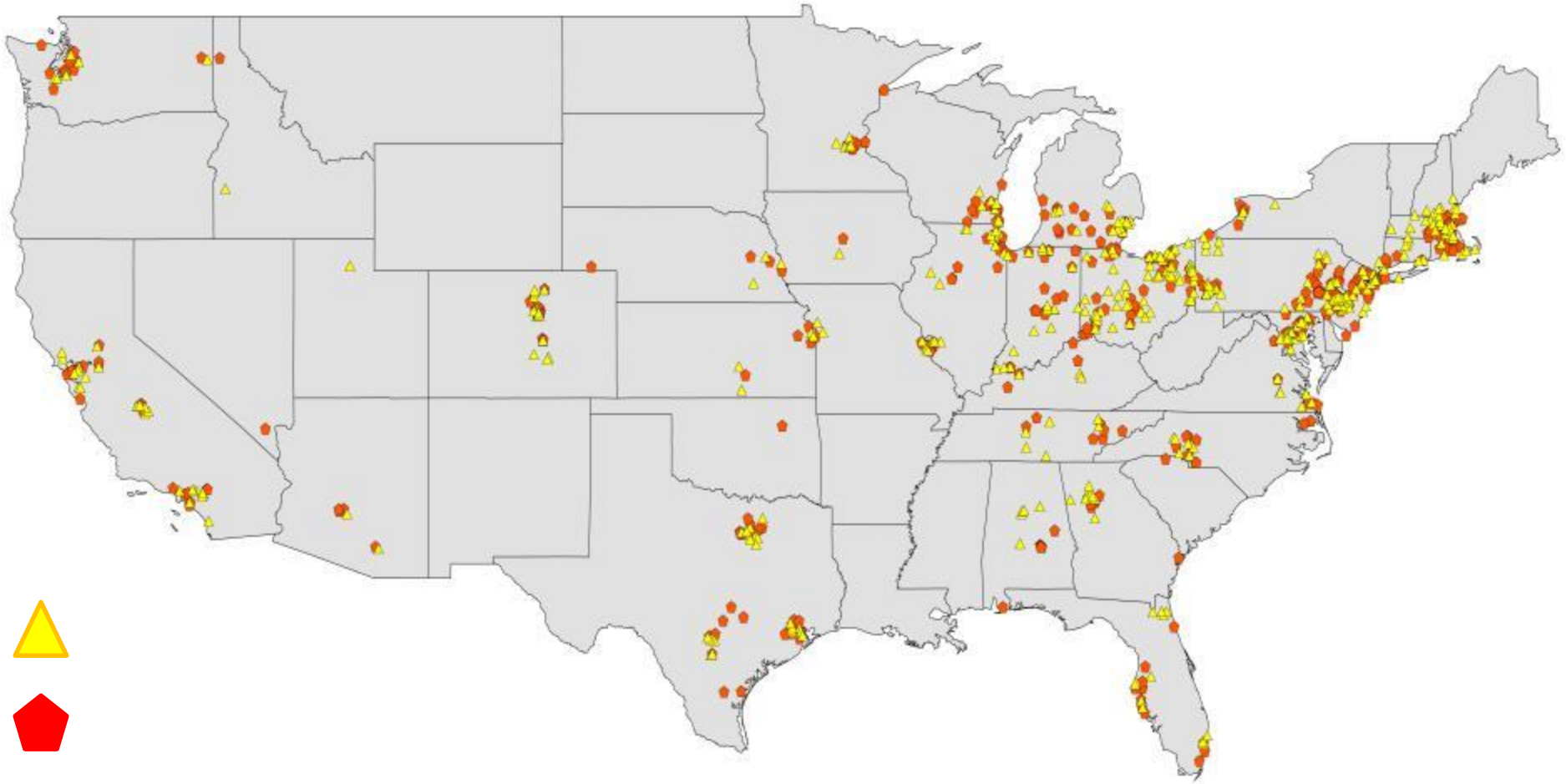
- Uniform, consistent data flow on nearly 4 million unique patients annually
- Linkage to Medicare means complete ascertainment and no loss to follow-up
- Existing data allow precise facility selection
- Repeated assessments facilitate precise selection of prevalent and incident patients
- Outcome monitoring: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

Pragmatic Cluster RCT of High-Dose Influenza Vaccine in Nursing Homes

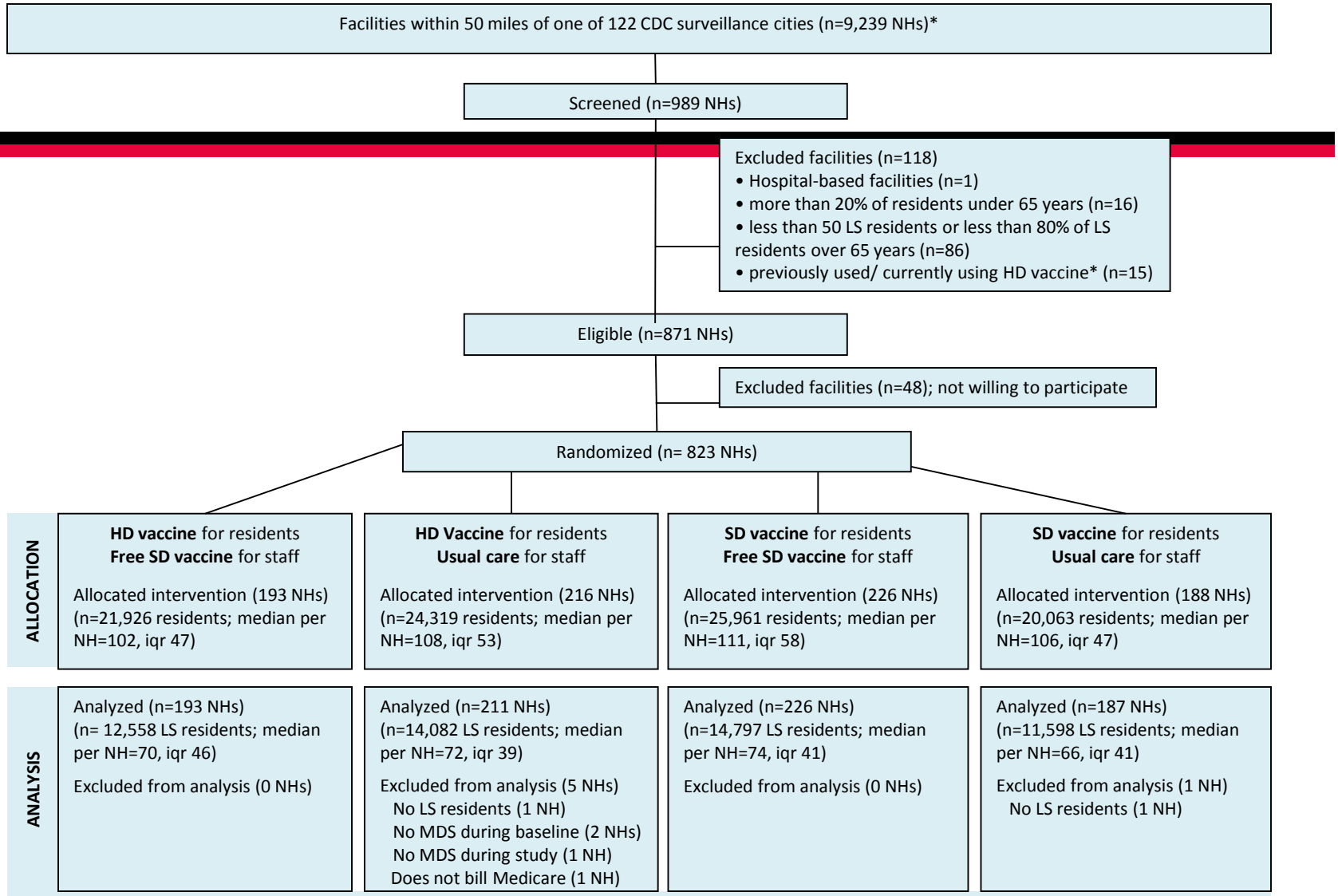
- Recruited nursing homes in or within 50 miles of the 122 cities in the CDC Influenza Surveillance System
- Minimum Data Set (MDS)
  - Identified long-stay NH residents with selected demographic and functional characteristics
  - Identified hospital admissions from participating NHs
- Use Medicare vital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

Gravenstein, et al. *Clinical Trials.* 2016

Participating NHs by State (n=823)



Nursing Home Facilities Selection and Randomization

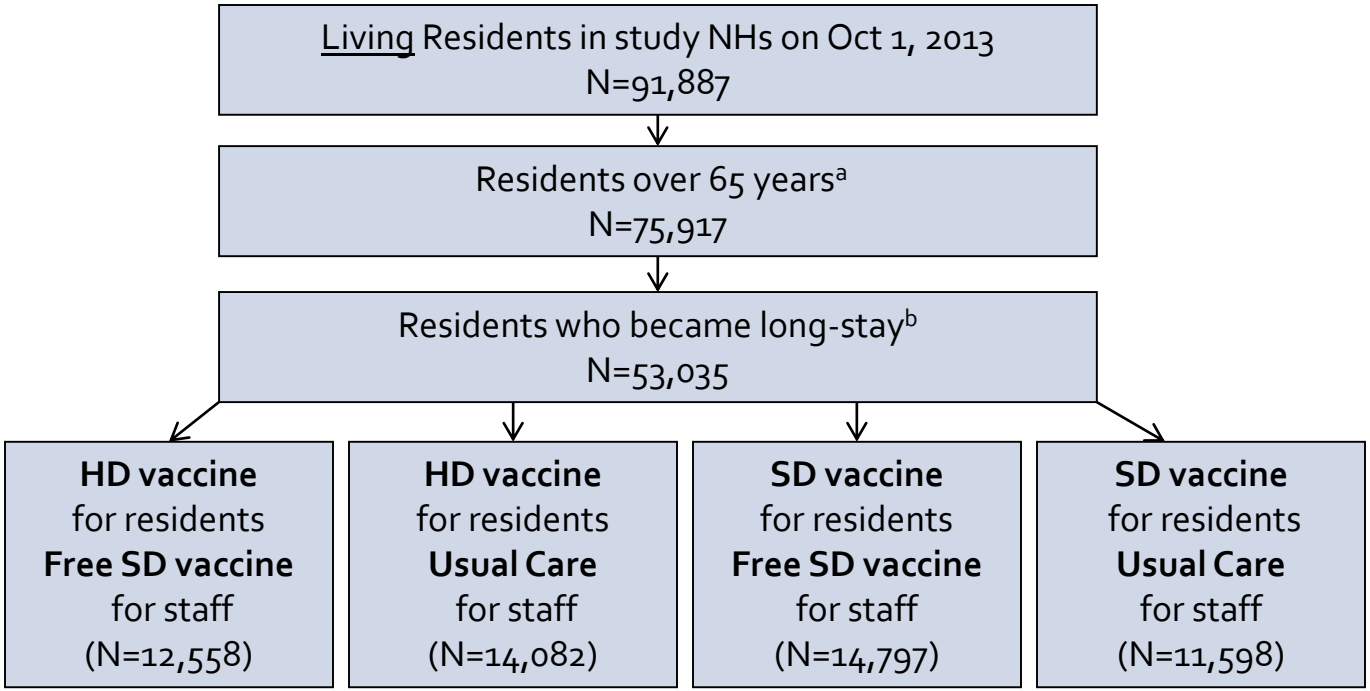


* Matched with Medicare metadata and geocodes. Exception was state of New Jersey of which all facilities were eligible.
The trials follows an intent-to-treat analysis at random assignment, therefore there is no loss to follow -up.
HD, high-dose; IQR, interquartile range (p75-p50); LS, long-stay; MDS,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

NH Groups Are Similar (N=823 NHs)

	HD Vaccine for Residents		SD Vaccine for Residents	
Characteristics	Staff Free (mean, SD)	Staff Usual Care (mean, SD)	Staff Free (mean, SD)	Staff Usual Care (mean, SD)
Nursing homes randomized (N)	193	216	226	188
NH-Reported Data				
Residents per home (N)	118.0 (52.3)	118.7 (52.1)	118.3 (50.0)	112.2 (53.2)
% residents vaccinated	81.7 (14.4)	79.9 (16.6)	81.5 (16.3)	81.6 (15.4)
% LTC residents	77.4 (15.9)	78.2 (14.8)	78.2 (13.6)	79.8 (13.6)
% LTC residents vaccinated	86.0 (14.8)	86.5 (31.8)	84.4 (17.4)	85.2 (16.4)
% staff vaccinated	53.5 (26.2)	56.3 (26.9)	55.6 (26.6)	55.0 (26.4)
Medicare Claims/NH Data				
% Medicaid	59.9 (18.1)	64.2 (16.1)	63.3 (15.7)	61.7 (18.5)
Ratio of RN/RN+LPN	0.361 (0.15)	0.355 (0.16)	0.363 (0.15)	0.357 (0.15)
Average ADL score (0-28)	17.0 (1.77)	16.9 (2.10)	16.9 (2.13)	16.8 (2.24)

Cohort Selection, 2013-14
(ALL Long-stay NH Residents over 65 Years)



[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)]

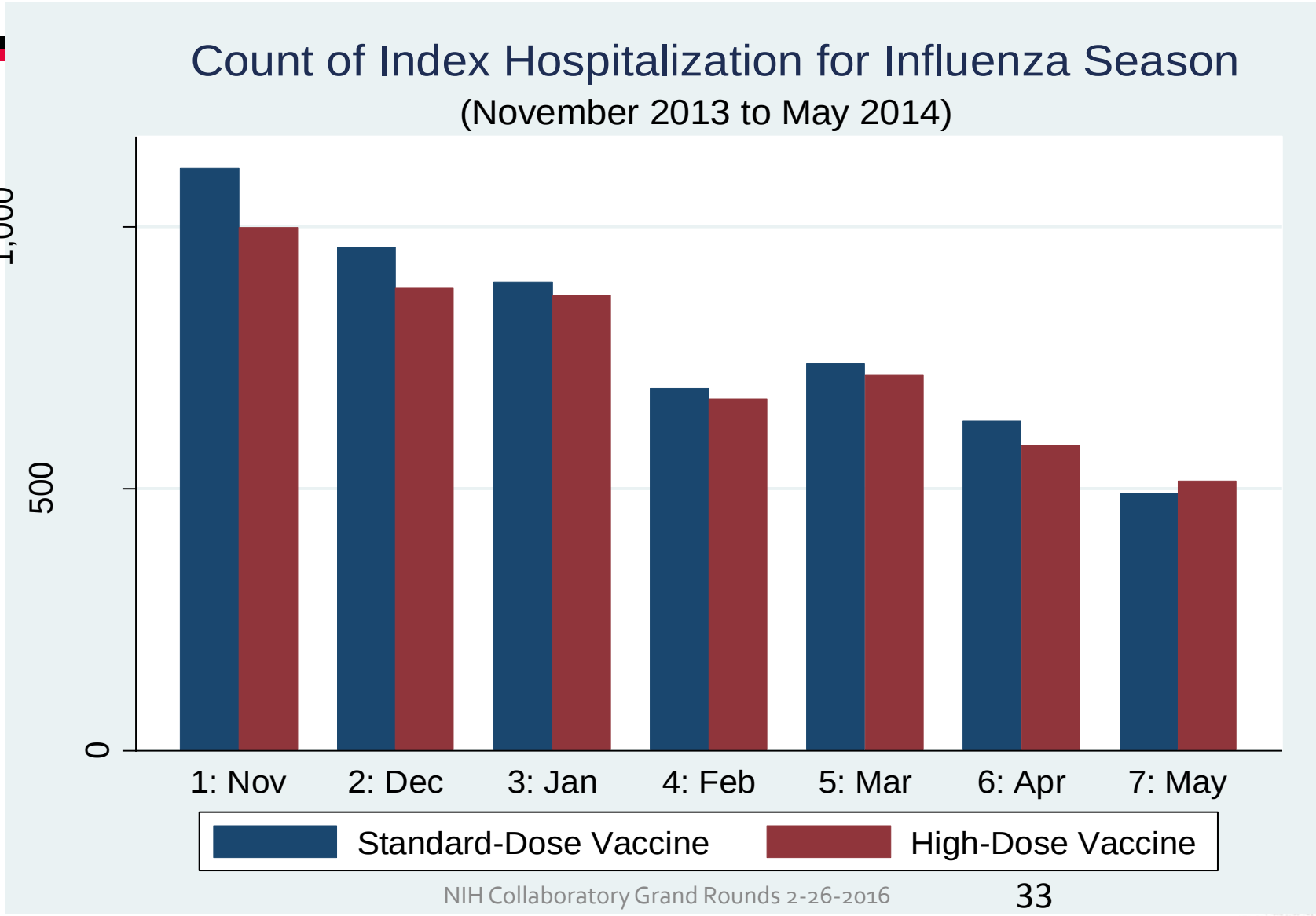
NH Resident Groups Are Similar (N=53,035)

	HD Vaccine for Residents		SD Vaccine for Residents	
Characteristics	Free Vaccine for Staff (N, %)	Usual Care for Staff (N, %)	Free Vaccine for Staff (N, %)	Usual Care for Staff (N, %)
LS residents over 65 years	12,558	14,082	14,797	11,598
Age (mean, sd)	83.3 (8.7)	83.1 (8.8)	83.1 (8.8)	83.1 (8.9)
Female	9,020 (71.8)	10,234 (72.7)	10,689 (72.2)	8,351 (72.0)
African American	1,803 (14.4)	2,083 (14.8)	2,195 (14.8)	1,782 (15.4)
White	9,481 (75.5)	10,679 (75.8)	11,156 (75.4)	8,706 (75.1)
Hispanic	713 (5.7)	683 (4.9)	782 (5.3)	509 (4.4)
Married	2,332 (18.7)	2,693 (19.5)	2,777 (19.0)	2,240 (19.6)
Heart Failure	2,551 (20.3)	2,864 (20.3)	3,126 (21.1)	2,341 (20.2)
Stroke/ CVA/ TIA	2,454 (19.5)	2,802 (19.9)	3,094 (20.9)	2,312 (19.9)
Hypertension	9,969 (79.4)	11,142 (79.1)	11,713 (79.2)	9,151 (78.9)
Diabetes Mellitus	4,235 (33.7)	4,816 (34.2)	5,163 (34.9)	4,039 (34.8)
Asthma/COPD/CLD	2,406 (19.2)	2,859 (20.3)	3,097 (20.9)	2,337 (20.2)

Results: Censoring Is Balanced

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

Seasonal Index Hospitalizations by Month



Ever Hospitalized

Multivariable logistic regression	Odds Ratio*	LCL	UCL	p-value
Treatments				
High dose vs. standard dose vaccine	0.930	0.875	0.988	0.0195
Free staff vaccine vs. usual staff care	1.018	0.958	1.081	0.572

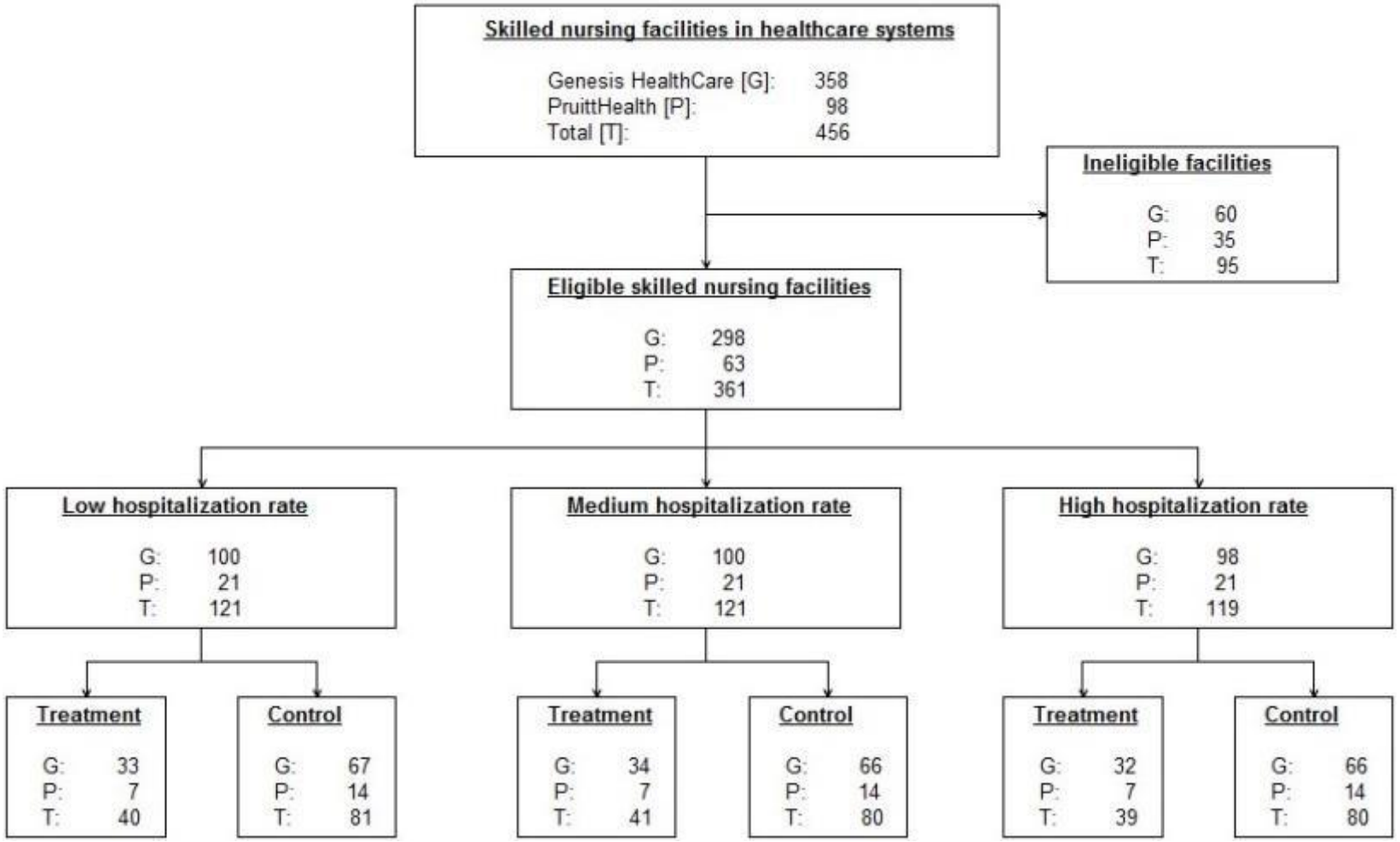
* Adjusted for prior year hospitalization rate, age of resident, mean age of residents in home, individual ADL score, mean ADL score in home, Cognitive Function Score (CFS), mean CFS in home, history of CHF risk-group, prevalence of CHF risk-group in home

- Statistically significant effect of high dose vaccine for NH residents
- No evidence of effect for providing free vaccine to NH staff

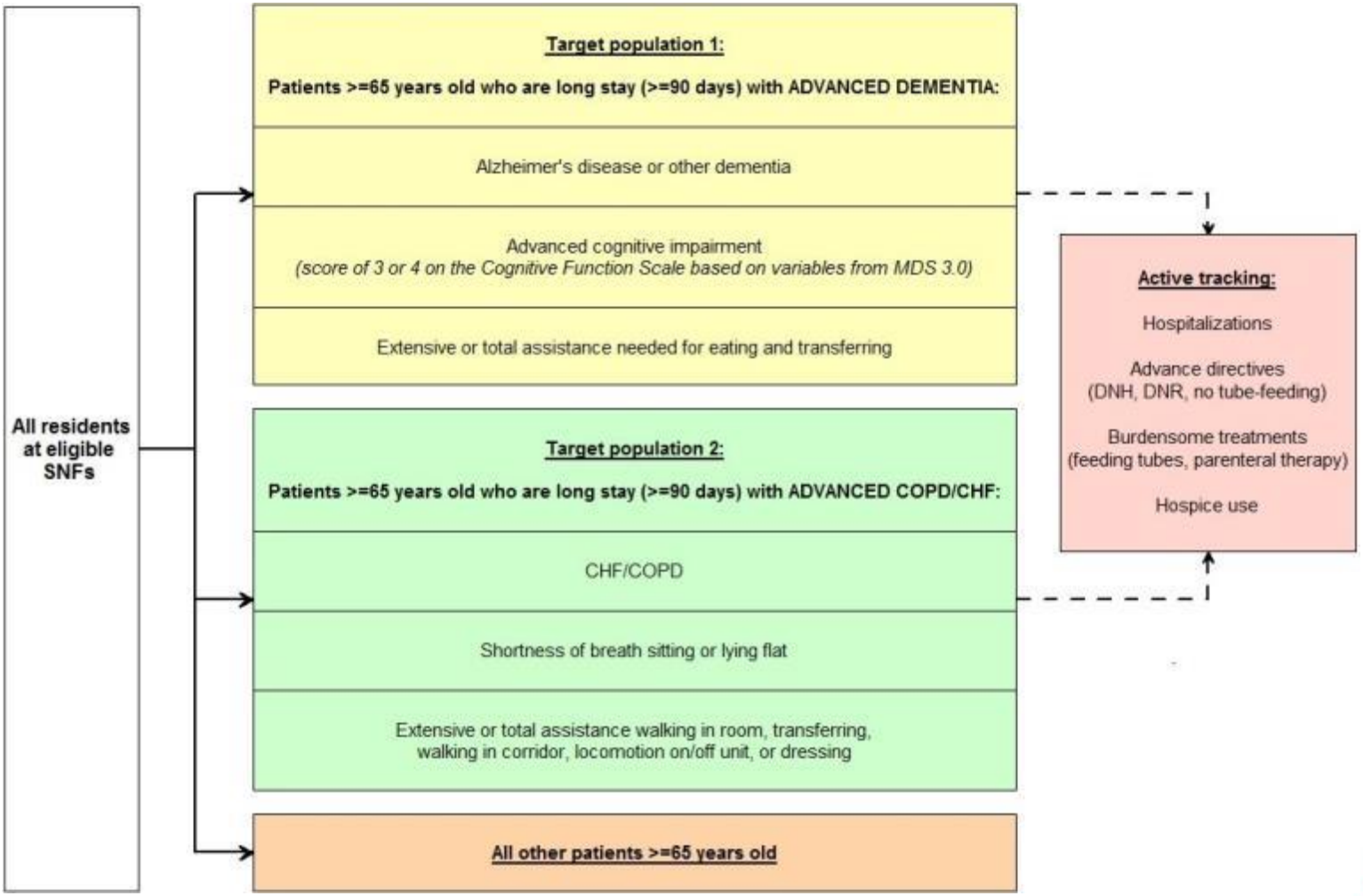
PROVEN

PRagmatic Trial of Video Education in Nursing Homes

Facility Eligibility, Stratification, and Randomization



Target Patient Sub-groups



Preliminary Data for Target NH Patients with Advanced Disease, 7/1/2013 – 12/31/2014

Resident Characteristics	Long-Stay			Not Long-Stay		
	Total	Genesis Health Care	Pruitt Health	Total	Genesis Health Care	Pruitt Health
Total Residents	32701	26616	6085	135566	118322	17244
Advanced Dementia	10488 32.1%	8343 31.3%	2145 35.3%	7700 5.7%	6202 5.2%	1498 8.7%
Advanced COPD/CHF	5689 17.4%	3851 14.5%	1838 30.2%	11199 8.3%	9195 7.8%	2004 11.6%
Advanced Dementia or Advanced COPD/CHF	14345 43.9%	11382 42.8%	2963 48.7%	18041 13.3%	14781 12.5%	3260 18.9%

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