

# Tackling Nursing Home Quality

### Big Data as a Catalyst for Policy Research, Pharmaco-Epidemiology and Cluster Randomized Clinical Trials

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### Conflict of Interest Disclosures

- Chair, Scientific Advisory Committee, naviHealth, a post-acute care convener serving MA plans and Hospital Systems
- Former Chair, Independent Committee on Quality, HCR-ManorCare, long term care company
- Founder of PointRight, an information services company for long term care; no further interest

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   Exemplary Nodes of Care for Outcomes and Reduced Expenditures (ENCORE) for High Needs Patients Study"
- Unrestricted Grant from Sanofi to test High Dose vaccine in NH setting

### Purpose

- Promote a "vision" of the potential for universally available clinical assessment data to transform research on care quality
- Relate a story of assembling "Big Data"
- Offer examples of Research Applications
- Data as the "key" to creating a learning health care system
- The next "frontier" Pragmatic Cluster RCTs

## Mandatory, Standardized Geriatric Assessment

- 1991 the Nursing Home Resident Assessment was mandated in 16K+ NHs
- 1995 FIM (IRF-PAI) mandated in Chronic & Rehab
- 1998 a home care version (OASIS) mandated for outcome monitoring & payment
- 2014 IMPACT Act Mandate for common elements across care settings

SECTION G. PHYSICAL FUNCTIONING AND STRUCTURAL PROBLEMS								
1.	(A)	(A) AOL SELF-PERFORMANCE—(Code for resident's PERFORMANCE OVER ALL SHIFTS during last 7 days—Not indusing setup)						
	0.	$INDEPENDENT\_No help or oversight\_OR\_Help/oversight provided only 1 or 2 times during last 7 days.$						
	1.	SUPERVISION—Oversight, encouragement or quaing provided 3 or more times during test? days — OR — Supervision (3 or more times) plus physical assistance provided only 1 or 2 times during last? 7 days						
	2	MTED ASSISTANCE—Resident highly involved in activity, received physical help in ided maneuvering of limbs or other norwell of bearing assistance 3 or more times — R—More help provided only 1 or 2 times during least 7 days.						
	3.	EXTENSIVE ASSISTANCE—While resident performed part of activity over last 7-day period, help of following type(s) provided 3 or more times:  —Weight-bearing support  —Full staff performence during part (but not all) of last 7 days						
	4.	TOTAL DEPENDENCE—Full staff performance of activity during entire 7 days						
	П.	ACTIVITY DID NOT OCCLIR during entire 7 days						
	(B)	ADL SUPPORT PROVIDED—(Code for MOST SUPPORT PROVIDED ONER ALL SHIFTS during last 7 days; code regardless of resident's set.  (A) (B)						

#### **NEURO/EMOTIONAL/BEHAVIORAL STATUS**

		<ul> <li>Functioning: Patient's current (day of assessment) le ension, concentration, and immediate memory for simple</li> </ul>	Somatic/Anxiety Factor Language Factor Agitated Behavior Scale (ABS)				
Enter Code	0	Alert/oriented, able to focus and shift attention, compre independently.	Disinhibition Aggression Lability				
	1	Requires prompting (cuing, repetition, reminders) only conditions.	Days of Posttraumatic Amnesia (PTA) Disability/Standardized Instruments				
	2	Requires assistance and some direction in specific situ involving shifting of attention) or consistently requires I distractibility.	Functional Independence Measure (FIM) FIM Motor FIM Cognitive Sickness Impact Profile (SIP)				
	3	Requires considerable assistance in routine situations to shift attention and recall directions more than half the	Physical subscale Psychosocial subscale SF-36 Health Functioning				
	4	Totally dependent due to disturbances such as consta vegetative state, or delirium.	Physical Component Summary Mental Component Summary Disability/Assistance Required				
(M1710) When Confused (Reported or Observed Within the Last 14 Da  Minutes of Assistance (average daily) from the Help at Home Diary							
	0	Never	Supervision Questionnaire for Caregivers				
Enter Code	1	In new or complex situations only					
	2	On awakening or at night only					
	3	During the day and evening, but not constantly					
	4	Constantly					
	NA	Patient nonresponsive					
(M1720) When Anxious (Reported or Observed Within the Last 14 Days):							
	0	None of the time					

Table 1: Summary of Instruments and Abbreviations

Neurobehavioral Cognitive Status Exam (NbCSE)

Neurobehavioral Rating Scale (NbRS)

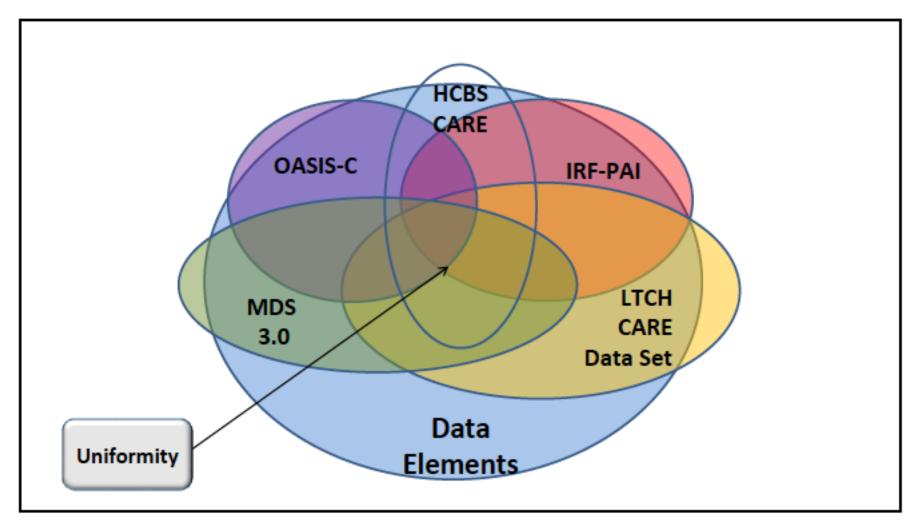
Cognition/Energy Factor

Metacognition Factor

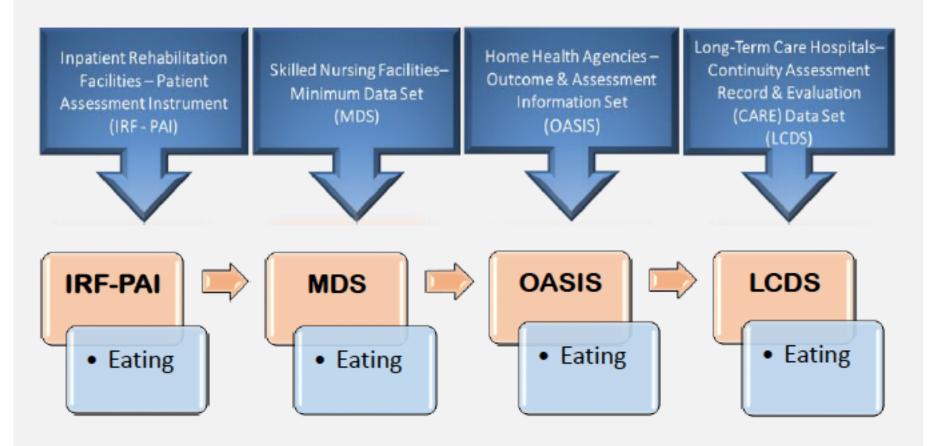
Neurobehavioral Impairments

Orientation
Attention
Comprehension
Repetition
Naming
Construction
Memory
Calculation
Similarities
Judgment

#### Data Elements: Standardization

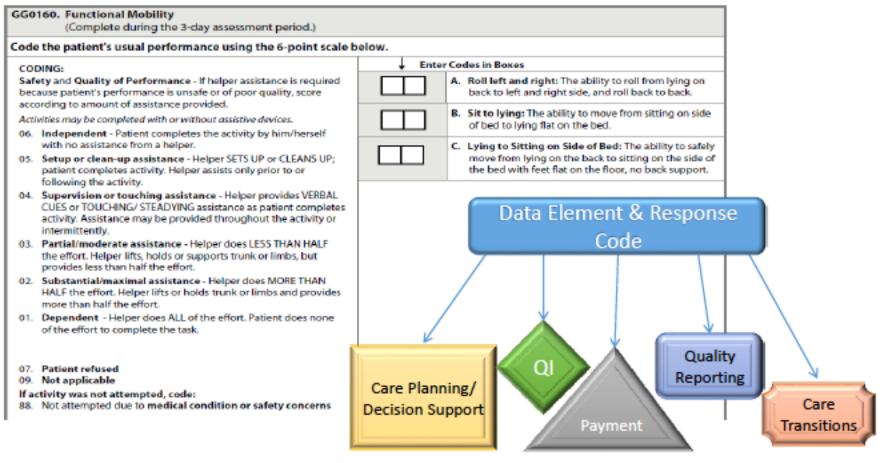


## What is Standardization? Standardizing Function at the Item Level



#### Standardized Assessment Data Elements

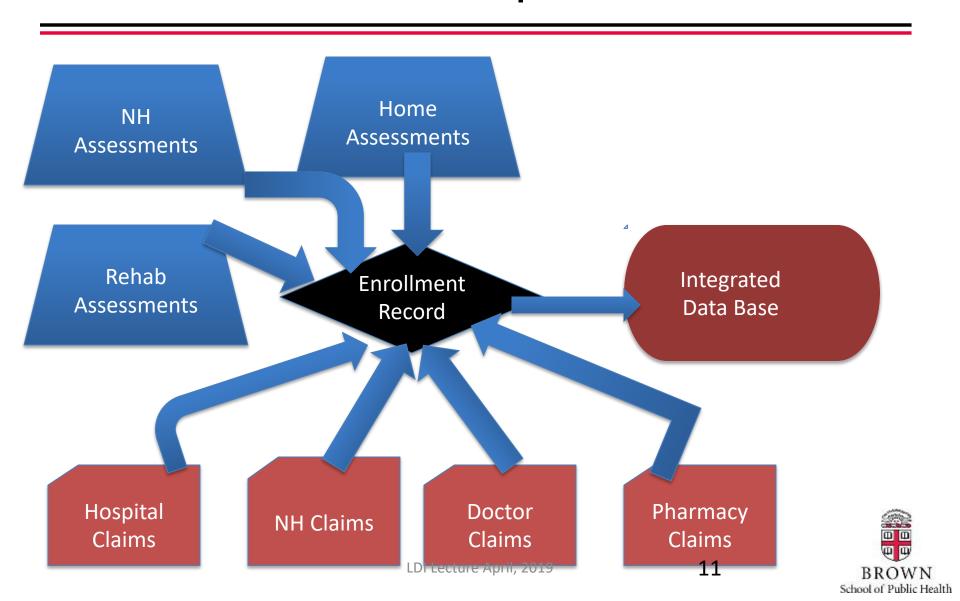
#### One Question: Much to Say → One Response: Many Uses



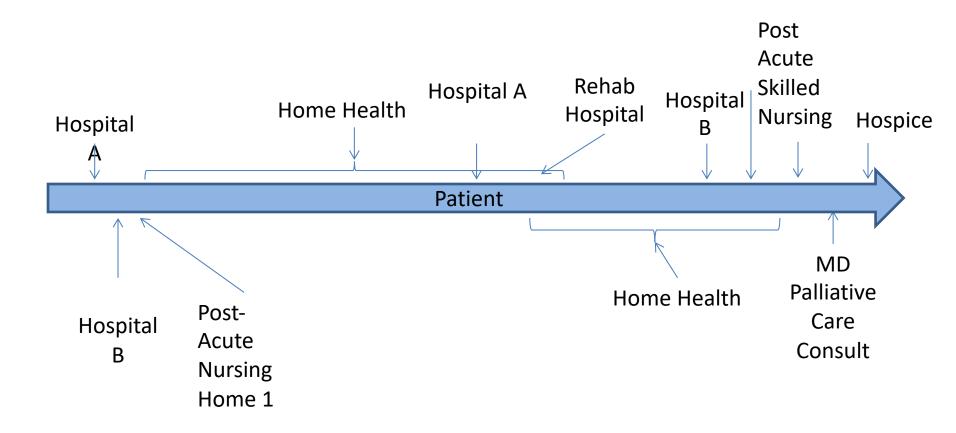
# Building Research Infrastructure: Adding Knowledge, Measuring Quality & Testing Treatments

- Linking Mandated Assesments: Common ID
- Linking Assessments to Medicare Claims
- Concatenating Records as Patient Histories
- Linking Provider Characteristics to Patients
- Aggregating Patients to Describe Providers
- Creating Population Numerators in relation to Geography based Denominators

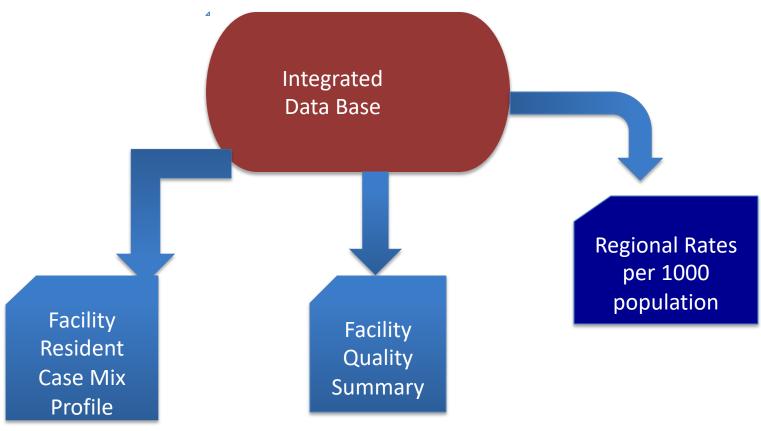
### Data Inputs



# Residential History File: A Daily History



### Aggregating Data: Creating Provider and Regional Profiles



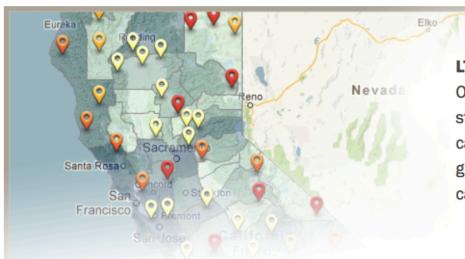






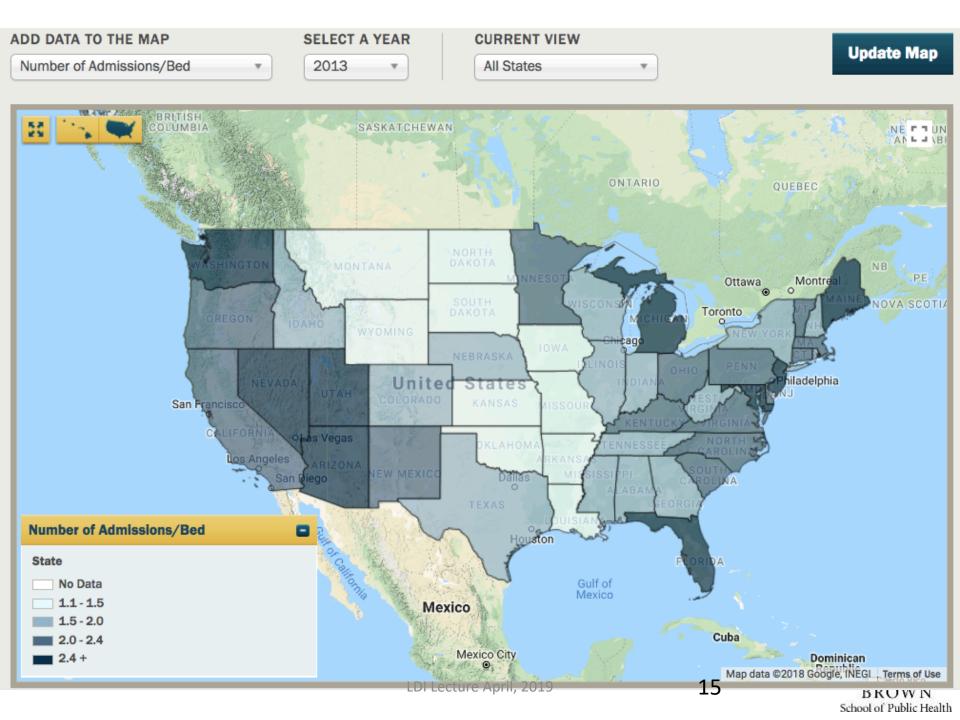


#### **Create Custom Reports on Long-Term Care**



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



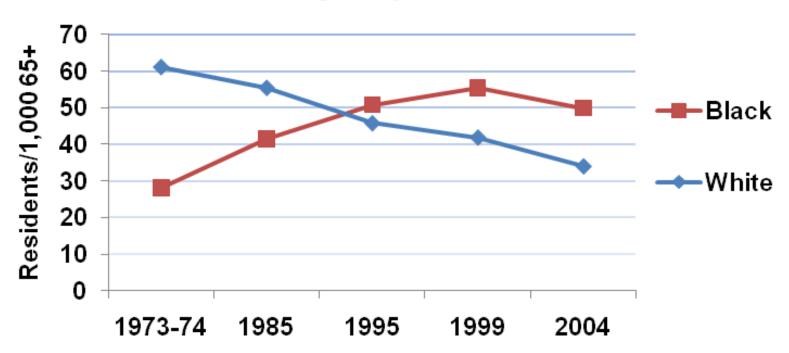
## Applications: From Policy Analysis to Cluster Randomized Clinical Trials

- Variation and Changes in the NH population
- Evaluating Medicaid & Medicare Policy Changes
- Examining Post-Acute care in the "data free" zone of Medicare Advantage
- Estimating Drugs' Adverse Effects
- Source of Outcome Data for Cluster Randomized Clinical Trials



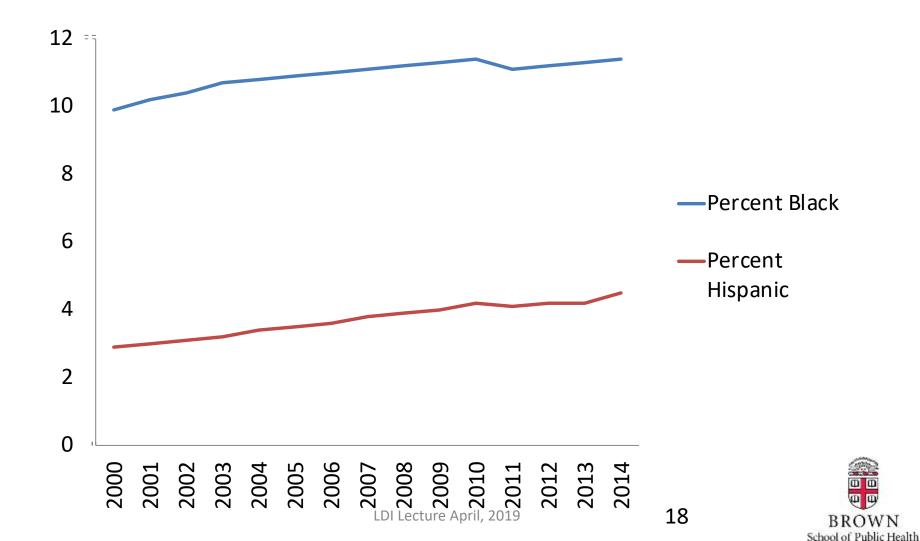
# Changing Demographics of Nursing Home Use

## Trends in White and Black Nursing Home Use Rates, Age-adjusted, 1973-2004



Source: NCHS, Health, United States, 2007: Table 104.

## Proportion of Black & Hispanics among US Nursing Home Residents



## Geographic Concentration and Correlates of Nursing Home Closures: 1999-2008

Zhanlian Feng, PhD; Michael Lepore, PhD; Melissa A. Clark, PhD; Denise Tyler, PhD; David B. Smith, PhD; Vincent Mor, PhD; Mary L. Fennell, PhD

**Background:** While demographic shifts project an increased need for long-term care for an aging population, hundreds of nursing homes close each year. We examine whether nursing home closures are geographically concentrated and related to local community characteristics such as the racial and ethnic population mix and poverty.

**Methods:** National Online Survey Certification and Reporting data were used to document cumulative nursing facility closures over a decade, 1999 through 2008. Census 2000 zip code level demographics and poverty rates were matched to study facilities. The weighted Gini coefficient was used to measure geographic concentration of closures, and geographic information system maps to illustrate spatial clustering patterns of closures. Changes in bed supply due to closures were examined at various geographic levels.

**Results:** Between 1999 and 2008, a national total of 1776 freestanding nursing homes closed (11%), compared with

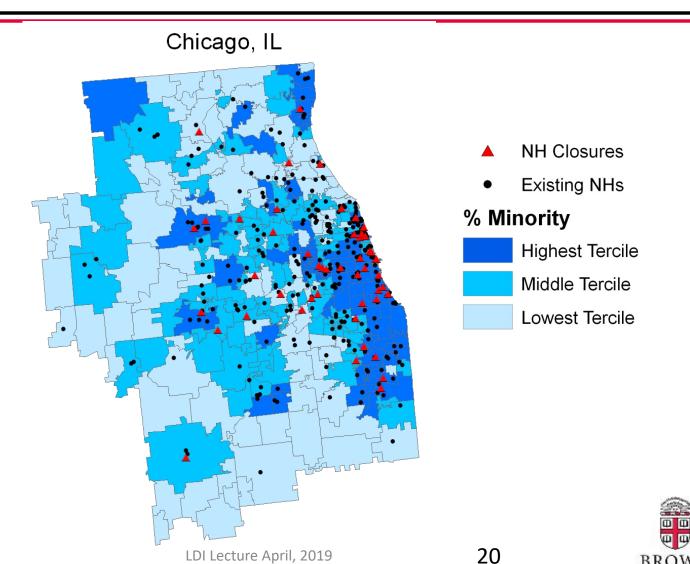
1126 closures of hospital-based facilities (nearly 50%). Combined, there was a net loss of over 5% of beds. The relative risk of closure was significantly higher in zip code areas with a higher proportion of blacks or Hispanics or a higher poverty rate. The weighted Gini coefficient for closures was 0.55 across all metropolitan statistical areas and 0.71 across zip codes. Closures tended to be spatially clustered in minority-concentrated zip codes around the urban core, often in pockets of concentrated poverty.

**Conclusions:** Nursing home closures are geographically concentrated in minority and poor communities. Since nursing home use among the minority elderly population is growing while it is declining among whites, these findings suggest that disparities in access will increase.

Arch Intern Med. Published online January 10, 2011. April, 2019.1001/archinternmed **3**010.492



### Spatial Clustering of Closures (1999-2008) Across Zip Codes in Selected MSAs (cont.)



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# Impact of Increasing Medicaid Payment Rate on NH Quality\*

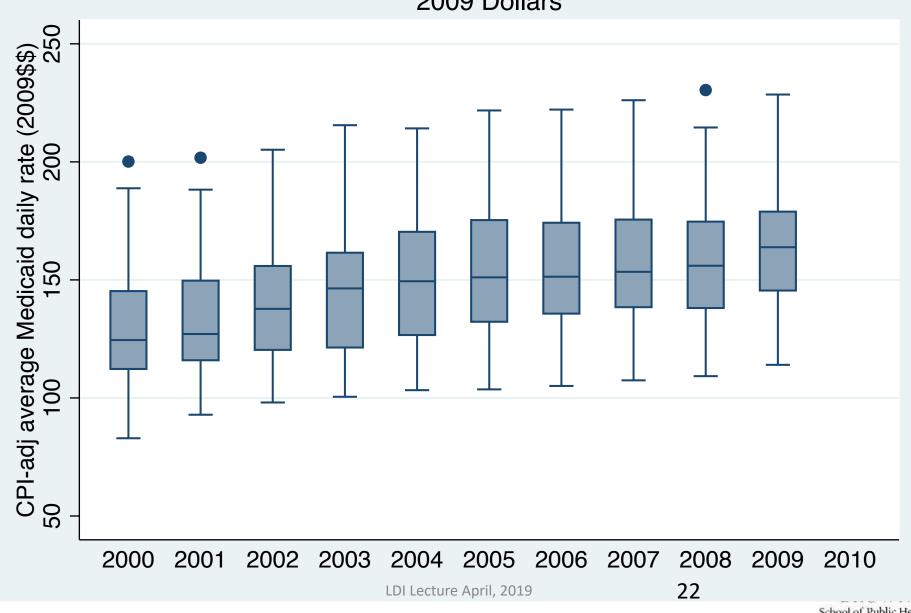
 Long history of quality problems in US nursing homes

 Medicaid NH payment rates vary by state and over time; lower than Medicare

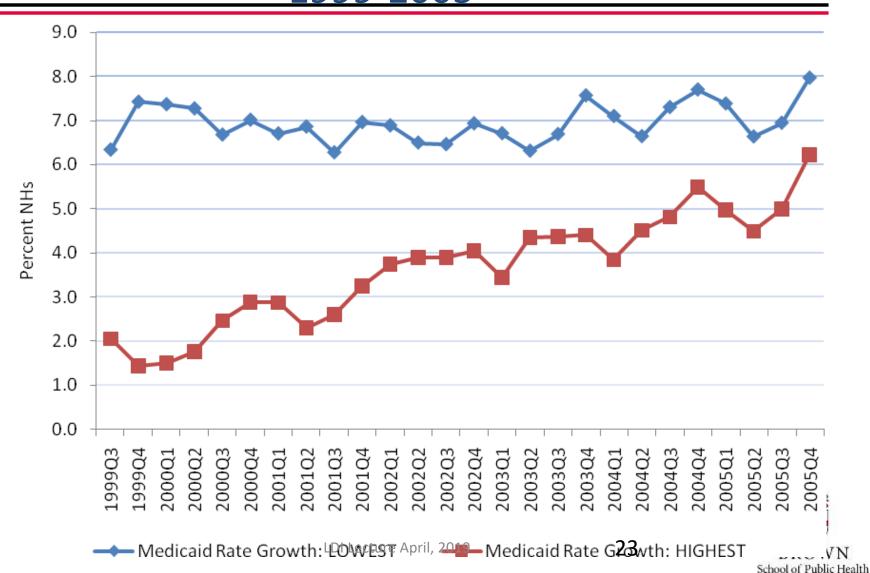
 Past research finds higher pay associated with better quality; cross-sectional



## Inter-State Variation in Medicaid Payment Rates 2009 Dollars



# Percent of Nursing Homes Reaching Quality Threshold on ADL Decline for long stay residents: 1999-2005



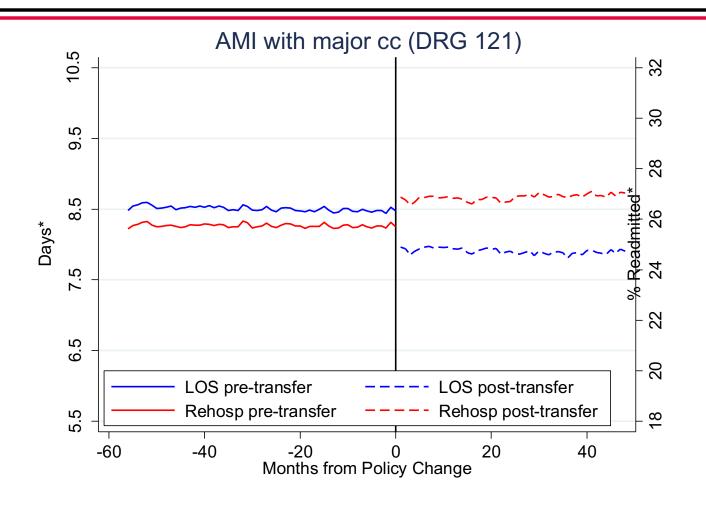
## Medicare Policy Change: Setting Minimum LoS for PAC Transfers

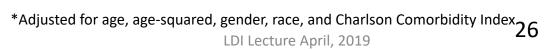
- Since 1983 when DRGs introduced hospital LoS dropped by 100%; paid by stay, not day or costs;
- Discharges to post-acute care i.e. NH increased dramatically
- In 2002 Medicare set a floor on LoS for selected DRGs transferred to post-acute care

## Testing Unintended Consequences: Medicare hospital "claw back" policy

- Identified AMI patient admissions
- Merged Hospital and SNF claims
- Tracked re-hospitalization within 30 days of hospital discharge to SNF
- Since policy changed Oct 1, 2002, examined changes around the discontinuity in policy

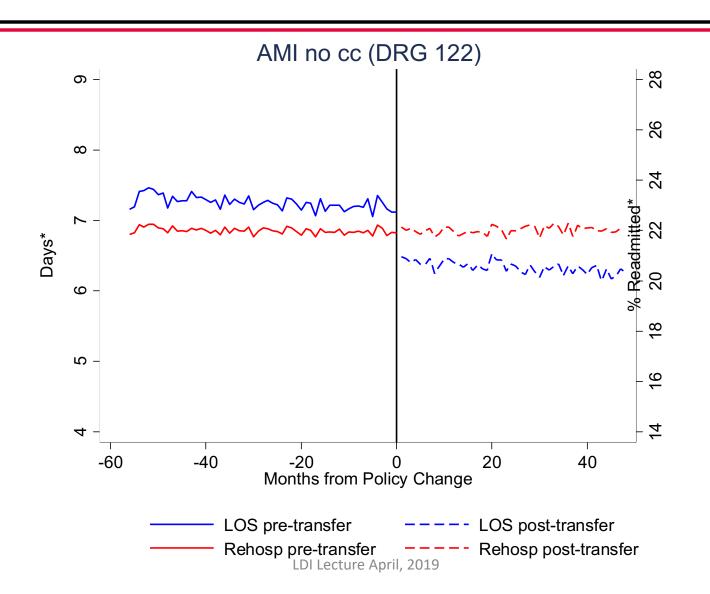
### RESULTS: Risk adjusted means





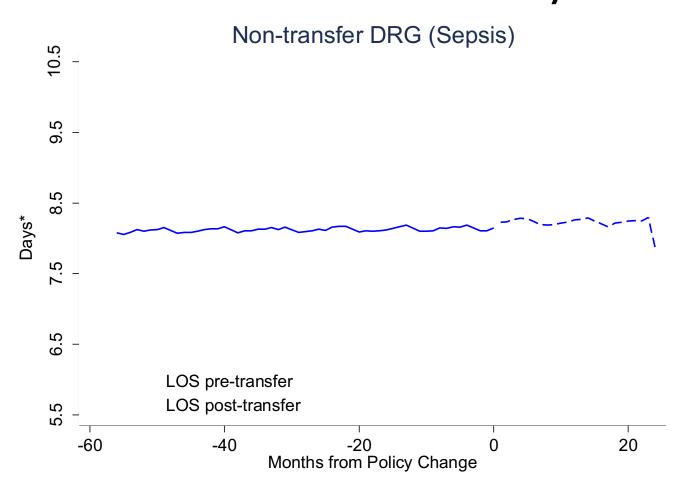


### RESULTS: Risk adjusted means





### LOS for Sepsis NOT Affected by Transfer DRG Policy





### **Implications**

- Results demonstrate the influence of LOS on readmissions, particularly for more complex cases
- Results illuminate the difficulty policy makers encounter in avoiding unintended consequences when designing policies aimed at controlling costs
- Policy extracted "excess" hospital days BUT, hospitals kept the \$\$ not Medicare

## Providers' Response to Hospitals' Changing Accountability for Re-hospitalizations

- CMS penalties for re-hospitalizations lead to hospitals demanding change from post-acute care (PAC) providers (varies by market)
- PAC networks formed
- Hospitals demand performance metrics
- SNFs respond by hiring NPs, changing transition practices



### Hospital – SNF Partnerships

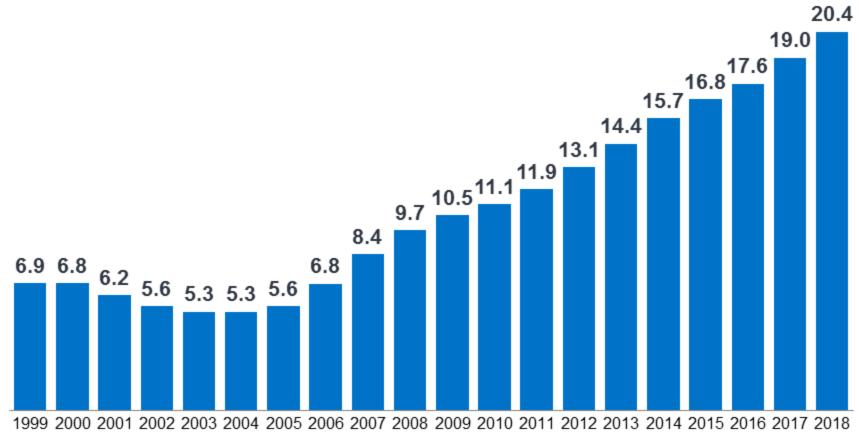
- Hospitals refer >50% of SNF discharges to their hospital based facility which have lower risk adjusted re-hospitalizations
- Hospitals that concentrate SNF discharges to fewer SNFs have lower re-hospitalizations
- How common is this practice and are hospitals in ACOs referring to networks?

## Change in hospital's rehospitalization rates between 2009-10 and 2011 regressed on change in share of hospital's discharges to SNFs with different Adjusted Rehospitalization Rates (ARR)

VARIABLES	(1) Change in hospital's adjusted rehospitalization rate between 2009-10 and 2011	
Change in hospital's share of discharges to SNFs in ARR quartile 1 between 2009-10 and 2011	-0.0983*** [-6.092]	Hospitals that
Change in hospital's share of discharges to SNFs in ARR quartile 2 between 2009-10 and 2011	-0.0334** [-2.131]	Redirect discharges To SNFs reduce Re-hospitalizations
Change in hospital's share of discharges to SNFs in ARR quartile 3 between 2009-10 and 2011	-0.0317** [-2.048]	
Change in hospital's number of discharges to SNF between 2009-10 and 2011	1.83E-05 [0.107]	
Constant	-0.0129 [-0.126]	
Observations	3,194	•
R-squared	0.012	

Figure 1

### Total Medicare Advantage Enrollment, 1999-2018 (in millions)

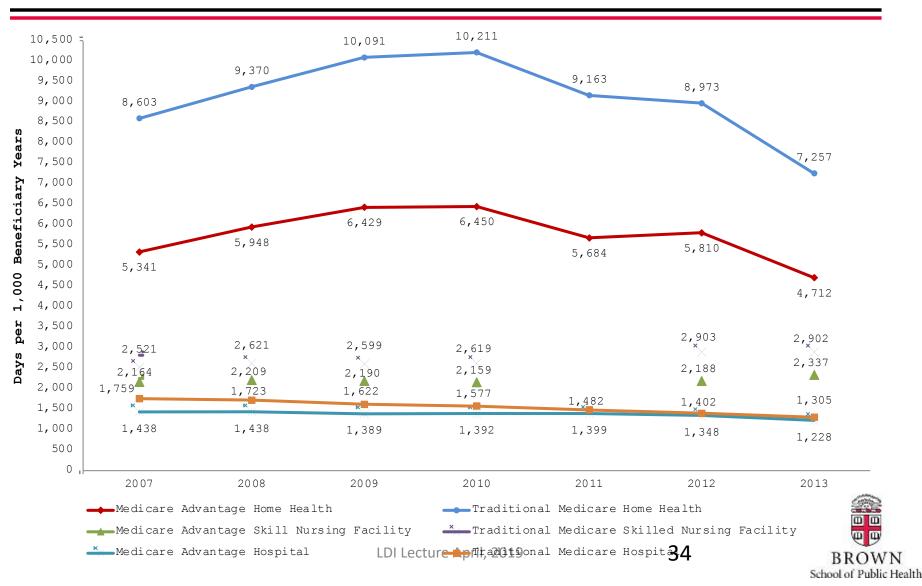


% of Medicare 18% 17% 15% 14% 13% 13% 16% 19% 22% 23% 24% 25% 27% 28% 30% 31% 31% 33% 34% Beneficiaries

NOTE: Includes cost plans as well as Medicare Advantage plans. About 61 million people are enrolled in Medicare in 2018. SOURCE: Kaiser Family Foundation analysis of CMS Medicare Advantage enrollment files, 2008-2018, and MPR, 1999-2007; enrollment numbers from March of the respective year, with the exception of 2006, which is from April.



## Trends in the Use of Home Health Care, Skilled Nursing Facility, and Hospital Care for Medicare Advantage and Traditional Medicare Enrollees





#### RESEARCH ARTICLE

Comparing post-acute rehabilitation use, length of stay, and outcomes experienced by Medicare fee-for-service and Medicare Advantage beneficiaries with hip fracture in the United States: A secondary analysis of administrative data

Amit Kumar<sup>1</sup>, Momotazur Rahman<sup>1</sup>, Amal N. Trivedi<sup>1,2</sup>, Linda Resnik<sup>1,2</sup>, Pedro Gozalo<sup>1,2</sup>, Vincent Mor<sup>1,2</sup>\*

1 Center for Gerontology and Health Care Research, Department of Health Services, Policy, and Practice, School of Public Health, Brown University, Providence, Rhode Island, United States of America,

2 Providence Veterans Affairs Medical Center, Providence, Rhode Island, United States of America



### **Background**

- Following implementation of Medicare prospective payment systems, there was an increase in the quantity of therapy for FFS patients which is not explained by changes in case mix (i.e., patient severity)
- Office of Inspector General Report: Inappropriate payments to SNFs cost Medicare more than a billion dollars in 2009
- Payments to SNFs for ultra high therapy (high payment RUG) increased from \$5.7 billion in 2006 to \$10.7 billion in 2008, without change in resident characteristics

•Does More Therapy in Skilled Nursing Facilities Lead to Better Outcomes in Patients With Hip Fracture? Hye-Young Jung, Amal N. Trivedi, David C. Grabowski, Vincent Mor Phys Ther. 2016 Jan; 96(1): 81–89.





### Research Aim

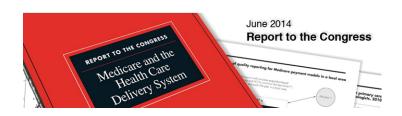
 Examine differences in health services utilization and associated patient outcomes between traditional Medicare Fee-for-service (FFS) and Medicare Advantage (MA) enrollees discharged from hospitals to skilled nursing facilities (SNFs) following hip fracture

#### **Process of Care/Utilization**

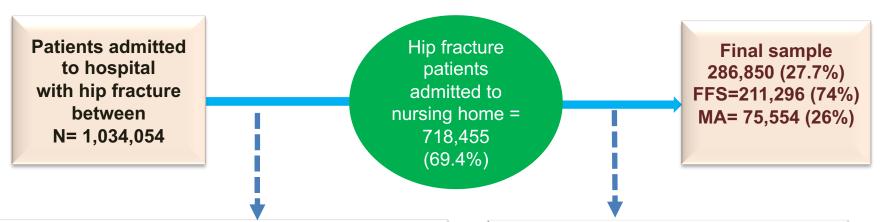
- Length of stay in the SNF
- 2. Amount of rehabilitation care (minutes)

#### **Health Outcomes**

- 1. 30-Day Hospital Readmission
- 2. Successful Discharge to the Community
- 3. Change in Functional Status (ADL)
- 4. Becoming a long-term resident



## **Study Cohort**



#### **Excluded at Hospital Level**

Patients from hospital with no information on disproportionate share = 103,399

Length of Stay > 15 = 14,544

Missing information on median household income and education = 16.551

Discharged to other post-acute settings (inpatient rehabilitation facilities/home health) =181,105

Previous nursing home stay in past twelve months = 213,873

Previous hospitalization in past twelve months = 54,785

Not admitted to SNF within 3 days of discharge

from hospital= 109,949

#### **Excluded at SNF Level**

Previous nursing home stay in past twelve months = 213,873

Previous hospitalization in past twelve months = 54,785

Not admitted to SNF within 3 days of discharge from hospital= 109,949

Patients in coma = 283

First MDS assessment after 10 days of admission = 12.612

Missing BMI, Cognition, Marital, Dual, and outliers = 23,033

Missing information or extreme therapy minutes = 15,703 Hawaii, Virgin Island, Puerto Rico = 1,367

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### **Algorithm to Capture MA Claims**

#### **Hospital Cost Report**

Safety Net Hospital
Disproportionate Share Hospital
(DSH%)
Medical Education Payments

Healthcare Effectiveness Data and Information Set (HEDIS)

Collects detailed information on health services utilization in the different MA health plans

Hospitals that received disproportionate-share or medical education payments from Medicare are required to submit claims for Medicare Advantage enrollees starting in 2008. Hospitals that did were larger and more likely to be teaching centers, and accounted for 90% of Medicare discharges in the period 2011–15.

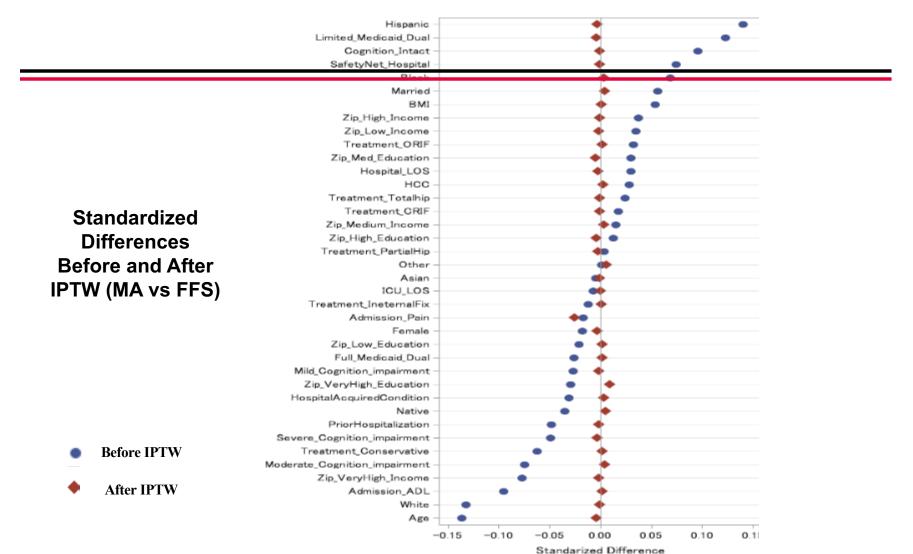
### **Analysis**

Stage 1: Generated a Propensity Score that reflected the probability of individuals to be in a MA versus FFS program using observable baseline characteristics: Propensity Score Model included: Age, Sex, Race, Marital status, Dual Status, Hospital-Safety-net Status, State, Residential Zip code's Median Household Income and Household Education, HCC Score, Number of Prior Hospitalization, ICU days, Hospital LOS, Fracture Management, BMI

Stage 2: Inverse Probability of Treatment Weighting (IPTW): generated from the propensity scores. Weights in the analysis → balanced the samples (MA & FFS) on baseline characteristics

**For patient's outcomes**, unweighted and weighted summary statistics with standard differences were computed after applying IPTW and accounted for patient characteristics and **SNF fixed effect** 

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## **Demographics**

Variables	Before IPTW		After IPTW	
	FFS	MA	FFS	MA
	211,296	75,554		
<b>A a a</b>	(73.6%)	(26.3%)	02 0 (0 0)	92 0 (14 5)
Age Female	84.2 (7.5) 77.4	83.2 (7.5) 76.5*	83.9 (8.8) 77.2	83.9 (14.5) 77.3
Married	33.3	76.3 36.3*	34.1	34.5
Race	33.3	30.3	O <del>4</del> .1	0 <del>1</del> .0
White	91.8	88.2 *	90.9	90.9
Black	3.0	4.2 *	3.3	3.4
Hispanic	3.2	6.0*	3.8	3.7
Asian	1.5	1.3	1.4	1.4
Native Americans	0.3	0.1	0.3	0.3
Others	0.03	0.04	0.03	0.04
Dual	14.8	16.7*	15.5	15.5
Safety-net Hospitals	22.3	25.5**	23.1	23.1
%				

<sup>\*\*</sup>p<0.01, \*p<0.05,

### **Clinical Characteristics**

Variables	Before IPTW		After IPTW	
	FFS	MA	FFS	MA
Hospital Length of Stay	4.9 (2.1)	5.0 (2.2)	5.0 (2.5)	4.9 (4.4)
ICU Length of Stay	0.4 (1.5)	0.4 (1.5)	0.4 (1.7)	0.4 (2.9)
HCC Score Comorbidity Index	1.4 (0.5)	1.4 (0.5)	1.4 (0.6)	1.4 (1.1)
Hospital Acquired Condition%	18.6	17.3*	18.2	18.5
Body Mass Index	24.5 (5.0)	24.8 (5.1) *	25.5 (5.9)	24.5 (9.8)
Admission ADL, mean (SD)	18.5 (3.2)	18.2 (3.2) *	18.4 (3.8)	18.4 (6.1)
Admission Pain Status%	45.6	44.9*	45.7	44.6**
Cognition%				
Intact	54.8	59.7*	56.1	55.9
Mild Impairment	21.8	20.8*	21.5	21.5
Moderate Impairment	19.8	16.7*	18.9	19.1
Severe Impairment	3.5	2.6*	3.3	3.3

<sup>\*\*</sup>p<0.01, \*p<0.05,

# Differences in mortality rates between FFS and MA patients

	Before IPTW			IPTW-Adjusted		
	FFS %	MA %	Differences based on linear probability model (95% CI) [p-value]	Odds Ratio based on logit model (95% CI) [p-value]	Differences after IPTW- Adjusted based on linear probability model (95% CI) [p-value]	Odds Ratio based on logit model (95% CI) [p-value]
Six- Month Mortality	8.9	7.9	-1.1 (-1.4 to -0.9) [<.0001]	0.88 (0.85 to 0.91) [<.0001]	-0.1 (-0.3 to 0.3) [0.502]	1.01 (0.97 to 1.04) [0.501]
One- Year Mortality	9.8	8.9	-1.1 (-1.0 to -0.9) [<.0001]	0.89 (0.86 to 0.92) [<.0001]	-0.2 (-0.3 to 0.5) [0.287]	1.01 (0.98 to 1.05) [0.285]

#### **Process of Care MA versus FFS**

		Unadju	ısted	Ad	Adjusted		
	FFS	MA	Differences	Differences after IPTW-Adjusted	Differences after IPTW- Adjusted SNF Fixed Effect		
SNF Length of Stay	44.7	36.9	-7.8	-5.7	-5.1		
Mean (SD)	(41.7)	(37.9)	(-8.1 to -7.5)**	(-6.0 to -5.4)**	(-5.4 to -4.8)**		
Rehabilitation Therapy (M	linutes) Mear	n (SD)					
Total Physical Therapy	1307.3	1003.9	-303.3	-279.2	-241.9		
	(614.1)	(595.0)	(-316.3 to -290.4)**	(-283.8 to -274.7)**	(-252.7 to -231.1)**		
Total Occupational Therapy	1159.3	898.4	-260.9	-242.3	-220.9		
	(567.6)	(553.7)	(-272.9 to -248.9)**	(-246.5 to -238.1)**	(-230.8 to -210.9)**		
Total Rehabilitation Therapy	2466.7	1902.3	-564.3	-521.5	<b>-462.8**</b>		
	(1133.9)	(1106.8)	(-588.4 to -540.2)**	(-530.0 to -513.2)**	(-483.2 to -442.4)		
Rehabilitation	85.1	71.3	-13.8	-13.7	-12.1		
Therapy/Day	(22.9)	(29.9)	(-14.5 to -13.0)**	(-13.9 to -13.5)**	(-12.7 to -11.4)**		

<sup>\*\*</sup> p<0.01, \* p<0.1

#### Patient-Centered Outcomes FFS Versus MA

<u>-</u>			Unadjusted			Adjusted	
	FFS	MA	Differences based on linear probability model (95% CI)	Odds Ratio based on logit model (95% CI)	Differences after IPTW Adjusted based on linear probability model (95% CI)	Odds Ratio based on logit model (95% CI)	Differences after IPTW- Adjusted SNF Fixed Effect
Change in ADL	3.7	3.2	-0.6* (- 0.7 to -0.6)		-0.7* (-0.8 to -0.6)		-0.4* (- 0.5 to -0.3)
30-Day Hospital Readmission %	10.3	8.3	-1.9** (-2.1 to -1.6)	0.81** (0.78 to 0.83)	-1.3** (-1.0 to -1.5)	0.84** (0.81 to 0.87)	-1.2** (-1.5 to -1.1)
Became Long- Stay Resident %	6.8	5.3	-1.5** (-1.7 to -1.3)	0.76** (0.73 to 0.79)	-0.7** (-0.9 to -0.4)	0.88** (0.84 to 0.92)	-0.6** (-0.8 to -0.3)
Successful Discharge to Community %	71.7	77.3	5.6** (5.2 to 6.0)	1.32** (1.29 to 1.35)	3.0** (2.6 to 3.4)	1.18 ** (1.15 to 1.20)	3.2** (2.7 to 3.7)

Change in ADL: (Discharge ADL - Admission ADL) and the score was reversed in positive for better understanding. Higher score in ADL change indicates greater improvement in functional status.

Long Stay Resident: Stayed more than 100 days.

Successful Discharge to the Community: Discharge to community within 100 days in SNF followed by uninterrupted 30 days stay in Community/home/home health. \*\*p<0.01, \*p<0.05



## Summary

- Despite less rehabilitation and shorter lengths of stay, MA patients' experience outcomes that are at least as good, if not better than FFS patients treated in the same SNF
- Functional Status: There was a small but statistically significantly lower rate of ADL improvement BUT had fewer days to demonstrate improved ADL before being discharged
- Similar patients treated in the SAME SNFs received slightly less therapy per day and fewer days and there were no adverse effects on outcome
- Additional days in the SNF may not translate into superior outcomes in the case of hip fracture patients in skilled nursing home care
- Would these findings extend to other non-oprthopedic conditions?

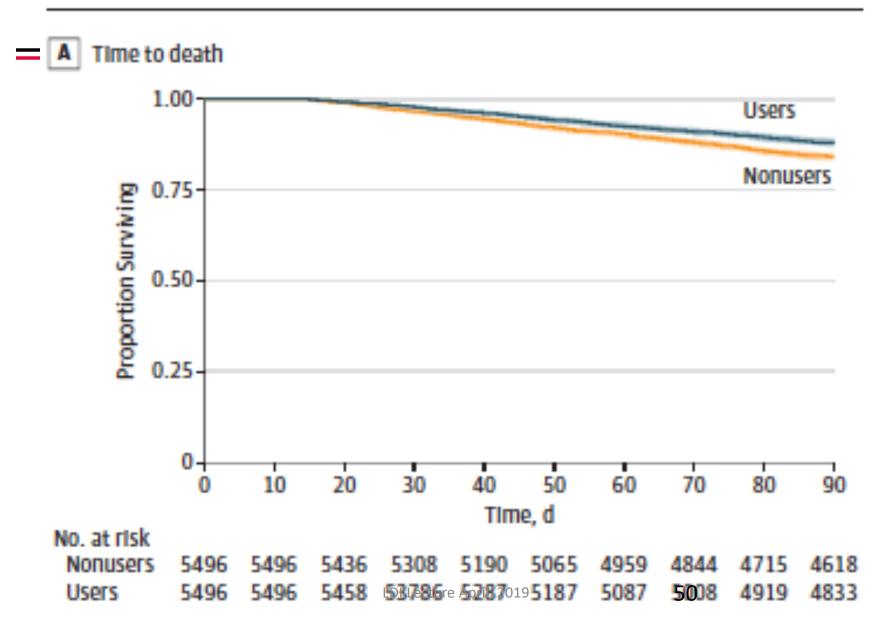
# Geriatric Pharmaco-Epidemiology: Enhanced with Clinical Data

- 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

# Testing the Effect of Beta Blocker Use in "Unstudied" populations

- Guidelines suggest Beta Blockers post MI; BUT,
- Very old, long term care patients never 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

Figure 1. Association Between β-Blocker Use and Death or Rehospitalization



NN

## Results: Relative Effect of Beta Blockers

At 3 months after NH admission:

Outcome	Measure	Estimate	95% Confidence Limits
Functional Decline	Relative Risk	1.17	1.03, 1.33
Rehospitalization	Hazard Ratio	1.04	0.98, 1.10
Mortality	Hazard Ratio	0.73	0.66, 0.80

## Implications for Clinical Practice

- Beta Blockers post-MI appropriate for even very impaired
- Only cognitively impaired patients lose physical function with Beta Blocker use
- None of these insights possible without standardized clinical assessment data

# Creating a Platform for Phase V Cluster RCTs

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

# Comparative effectiveness of high-dose versus standard-dose influenza vaccination on numbers of US nursing home residents admitted to hospital: a cluster-randomised trial

Stefan Gravenstein, H Edward Davidson, Monica Taljaard, Jessica Ogarek, Pedro Gozalo, Lisa Han, Vincent Mor

#### Summary

Background Immune responses to influenza vaccines decline with age, reducing clinical effectiveness. We compared the effect of the more immunogenic high-dose trivalent influenza vaccine with a standard-dose vaccine to identify the effect on reducing hospital admissions of nursing home residents in the USA.

Methods We did a single-blind, pragmatic, comparative effectiveness, cluster-randomised trial with a 2×2 factorial design. Medicare-certified nursing homes in the USA located within 50 miles of a Centers for Disease Control influenza reporting city were recruited, so long as the facilities were not located in a hospital, had more than 50 longstay residents, had less than 20% of the population aged under 65 years, and were not already planning to administer the high-dose influenza vaccine to residents. Enrolled nursing homes were randomised to a facility-wide standard of care for the residents of either high dose or standard dose as the vaccine for the 2013-14 influenza season and half of each group were randomly allocated to free vaccines for staff. Individual residents were included in the analysis group if they were aged 65 years or older and were long-stay residents (ie, had been in the facility 90 days or more before commencing the influenza vaccination programme). The analysts and investigators with access to the raw data were masked to study group by coding the groups until after the analyses were complete. The primary outcome was hospital admissions related to pulmonary and influenza-like illness between Nov 1, 2013, and May 31, 2014, identified from Medicare hospital claims available for residents who were without private health insurance (is, those who were considered Medicare fee-for-service). We obtained data from the Centers for Medicare & Medicaid (CMS) and enrolled facilities. The analyses used marginal Poisson and Cox proportional hazards regression, accounting for clustering of residents within homes, on an intention-to-treat basis, adjusting for facility clustering and pre-specified covariates. Safety data were voluntarily reported according to the standard of care. This trial is registered with ClinicalTrials.gov, number NCT01815268.

Findings 823 facilities were recruited to the study between March and August, 2013 to participate in the trial, of which 409 facilities were randomised for residents to receive high-dose vaccine, and 414 facilities for residents to receive standard-dose vaccine. The facilities housed 92269, of whom 75917 were aged 65 years or older and 53008 were also long-stay residents, and 38256 were matched to Medicare hospital claims as of Nov 1, 2013. Staff vaccination rates did not differ between groups, so analyses focused on the high-dose versus standard-dose vaccine comparison. On the basis of Medicare fee-for-service claims, the incidence of respiratory-related hospital admissions was significantly lower in facilities where residents received high-dose influenza vaccines than in those that received standard-dose influenza vaccines (0.185 per 1000 resident-days or 3.4% over 6 months; 0.211 per 1000 resident-days or 3.9% over 6 months; adjusted relative risk 0.873, 95% CI 0.776-0.982, p=0.023).

Interpretation When compared with standard-dose vaccine, high-dose influenza vaccine can reduce risk of respiratory-related hospital admissions from nursing home residents aged 65 years and older.

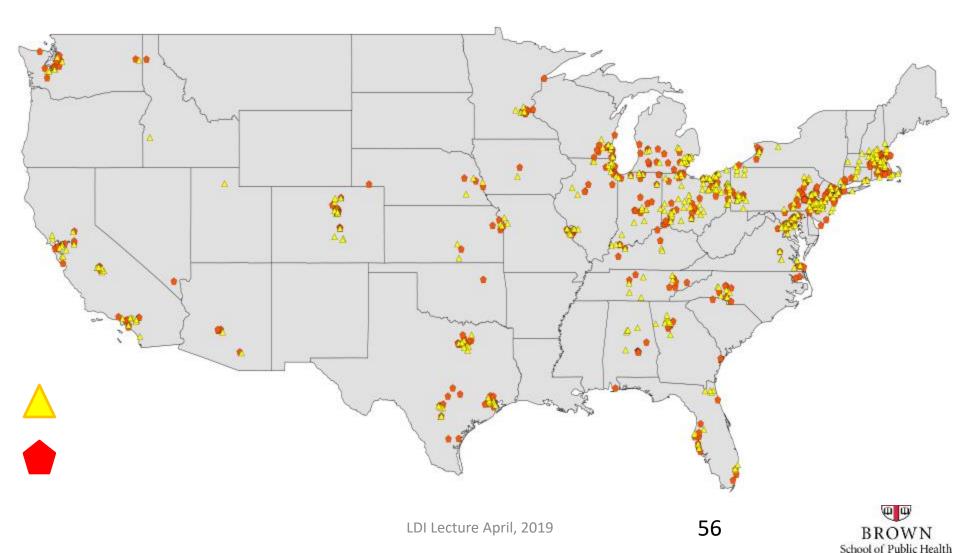
LDI Lecture April, 2019



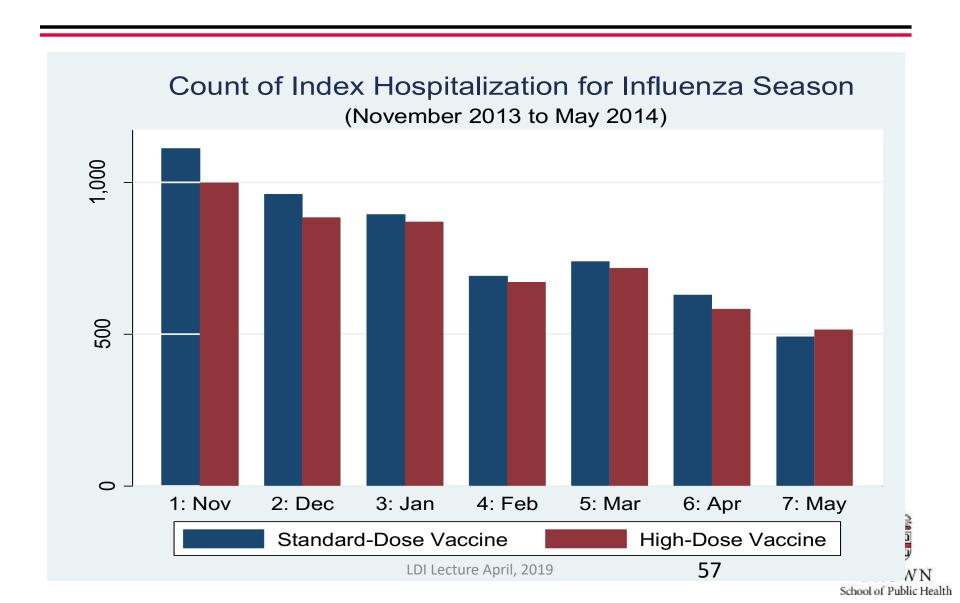
# Pragmatic Cluster RCT of High Dose Influenza Vaccine in Nursing Homes

- Recruited nursing homes (NHs) in or within 50 miles of the 122 cities in the CDC Influenza Surveillance System
- Use MDS
  - To identify long-stay NH residents with selected demographic and functional characteristics
  - To identify hospital admissions coming from participating NHs
- Use Medicare vital status records to identify deaths
- Medicare hospital claims to evaluate relative outcomes of hospitalization for Influenza (P&I)

# Participating NHs by State (n=823)



### Seasonal Index Hospitalizations by Month



	Number of residents	Adjusted relative risk (95% CI)	p value
FFS group analysis			
Hospital admissions for respiratory illness	38225	0.873 (0.776-0.982)	0-023
Hospital admissions for pneumonia	38225	0.791 (0.267-0.953)	0.013
All-cause hospital admissions	38225	0.915 (0.863-0.970)	0-0028
MDS group analysis			
All-cause hospital admission	52968	0.933 (0.884-0.985)	0.012
Functional decline (change in ADL score of at least four points)	48 429	0.996 (0.956–1.038)	0-86
All-cause mortality	52 968	0.985 (0.931-1.038)	0.57

Analysis was adjusted for age and average age of facility residents, ADL scale and average ADL of facility residents, cognitive function, facility hospital admissions in the previous year, and patient chronic heart failure as reported in the MDS. One facility had missing facility covariates and was excluded from all adjusted analyses. Relative risk was calculated between facilities providing high-dose and standard-dose vaccine groups. Refer to table 2 for relative distribution between groups. ADL=activities of daily living. FFS=fee-for-service. MDS=minimum data set.

Table 3: Adjusted regression analysis results of primary and secondary outcomes accounting for clustering by 817 nursing homes

#### CLINICAL TRIALS

(S)SAGE

PRagmatic trial Of Video Education in Nursing homes: The design and rationale for a pragmatic cluster randomized trial in the nursing home setting

Vincent Mor<sup>1,2</sup>, Angelo E Volandes<sup>3,4</sup>, Roee Gutman<sup>5</sup>, Constantine Gatsonis<sup>5,6</sup> and Susan L Mitchell<sup>4,7,8</sup>

Clinical Trials

I-II

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## PROVEN: Design

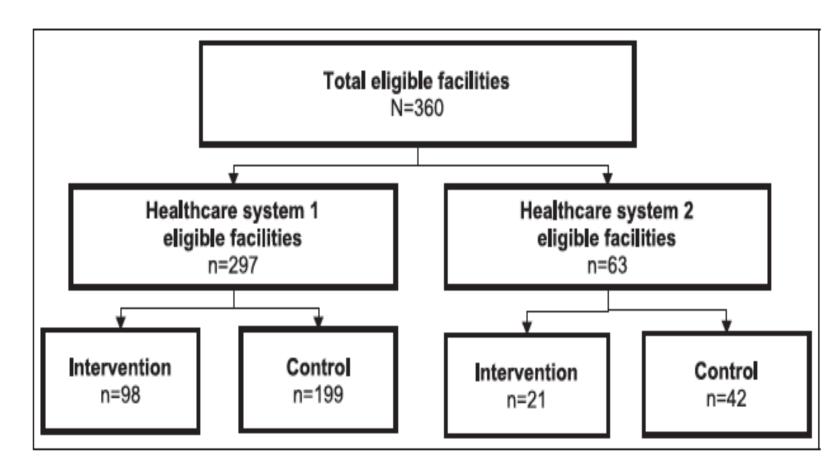


Figure 1. Stratification and randomization of nursing home facilities.

#### Music & Memory

- Personalized Music for persons with advanced dementia seems to reduce behavioral disorders
- Analysis of assessment data comparing ADRD patients in facilities with and without M&M reveals better reduction in behavioral problems and anti-psychotic use

#### Individualized Music Program is Associated with Improved Outcomes for U.S. Nursing Home Residents with Dementia

Kali S. Thomas, Ph.D., M.A., Rosa Baier, M.P.H., Cyrus Kosar, M.A., Jessica Ogarek, M.S., Alissa Trepman, M.A., M.P.H., Vincent Mor, Ph.D.

Objectives: The objective of this study was to compare resident outcomes before and after implementation of an individualized music program, MUSIC & MEMORY (M&M), designed to address the behavioral and psychological symptoms associated with dementia (BPSD). Setting: 98 nursing bomes trained in the M&M program during 2013 and 98 matched-pair comparisons. Participants: Long-stay residents with Alzbeimer's disease and related dementias (ADRD) residing in M&M participating facilities (N = 12,905) and comparison facilities (N = 12,811) during 2012-2013. Intervention: M&M is a facility-level quality improvement program that provides residents with music specific to their personal bistories and preferences. Measurements: Discontinuation of anxiolytic and antipsychotic medications, and reductions in behavioral problems and depressed mood in 2012 (pre-intervention) and 2013 (intervention), calculated using Minimum Data Set (MDS) assessments. Results: The proportion of residents who discontinued antipsychotic medication use over a 6-month period increased from 17.6% to 20.1% among M&M facilities, while remaining stable among comparison facilities (15.9% to 15.2%). The same trend was observed for anxiolytic medications: Discontinuation of anxiolytics increased in M&M facilities (23.5% to 24.4%), while decreasing among comparison facilities (24.8% to 20.0%). M&M facilities also demonstrated increased rates of reduction in bebavioral problems (50.9% to 56.5%) versus comparison facilities (55.8% to 55.9%). No differences were observed for depressed mood. Conclusions: These results offer the first evidence that the M&M individualized music program is associated with reductions in antipsychotic medication use, anxiolytic medication use, and BPSD symptoms among long-stay nursing bome residents with ADRD. (Am J Geriatr Psychiatry 2017; ■■:■■-■■)

Key Words: Music therapy, hursing liones, Alzhelmer's disease, nonpharma 22 gical intervention



# METRIcAL - Music & MEmory: a Pragmatic TRIal for Nursing Home Residents with ALzheimer's Disease

- NIA funded pragmatic cluster randomized trial of M&M effects on ADRD NH patients
- Hybrid Standard Experiment vs. Control & 3 wave Step-Wedge design
- Outcomes from Assessments AND interviews of aides and research staff observation
- Documenting how long music heard per study subject



## Summary

- Availability of detailed, uniform, longitudinal person level, clinical and functional data led to an explosion of knowledge about long term care
- While actionable payment & Quality Reporting policies may lead to code creep like DRGs
- Observational data for Policy Evaluations and Pharmaco-epi are much more powerful, BUT
- Real time data tracking in cluster RCTs is truly revolutionary!