Linking Inpatient Registries with Part D Data to Assess Post-Discharge Adherence

Lesley H. Curtis, Ph.D.

(ARS Response Card: Channel 41)

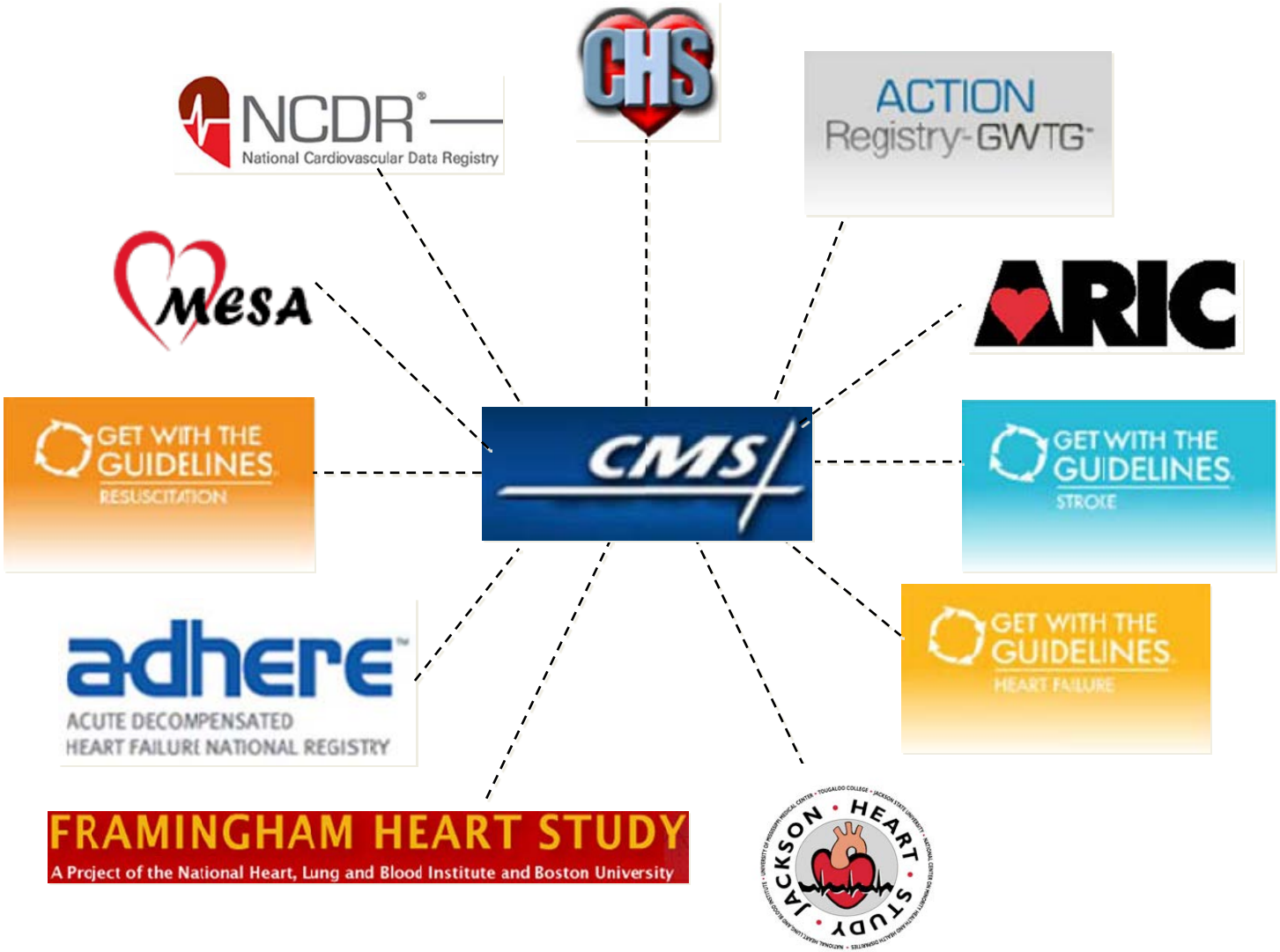
Disclosures

"I, Lesley Curtis, declare no conflicts of interest or financial interests in any product or service mentioned in this presentation, including grants, employment, gifts, stock holdings, or honoraria."

Learning objectives

- To demonstrate how inpatient clinical registries can be linked with Medicare Part D prescription drug event data

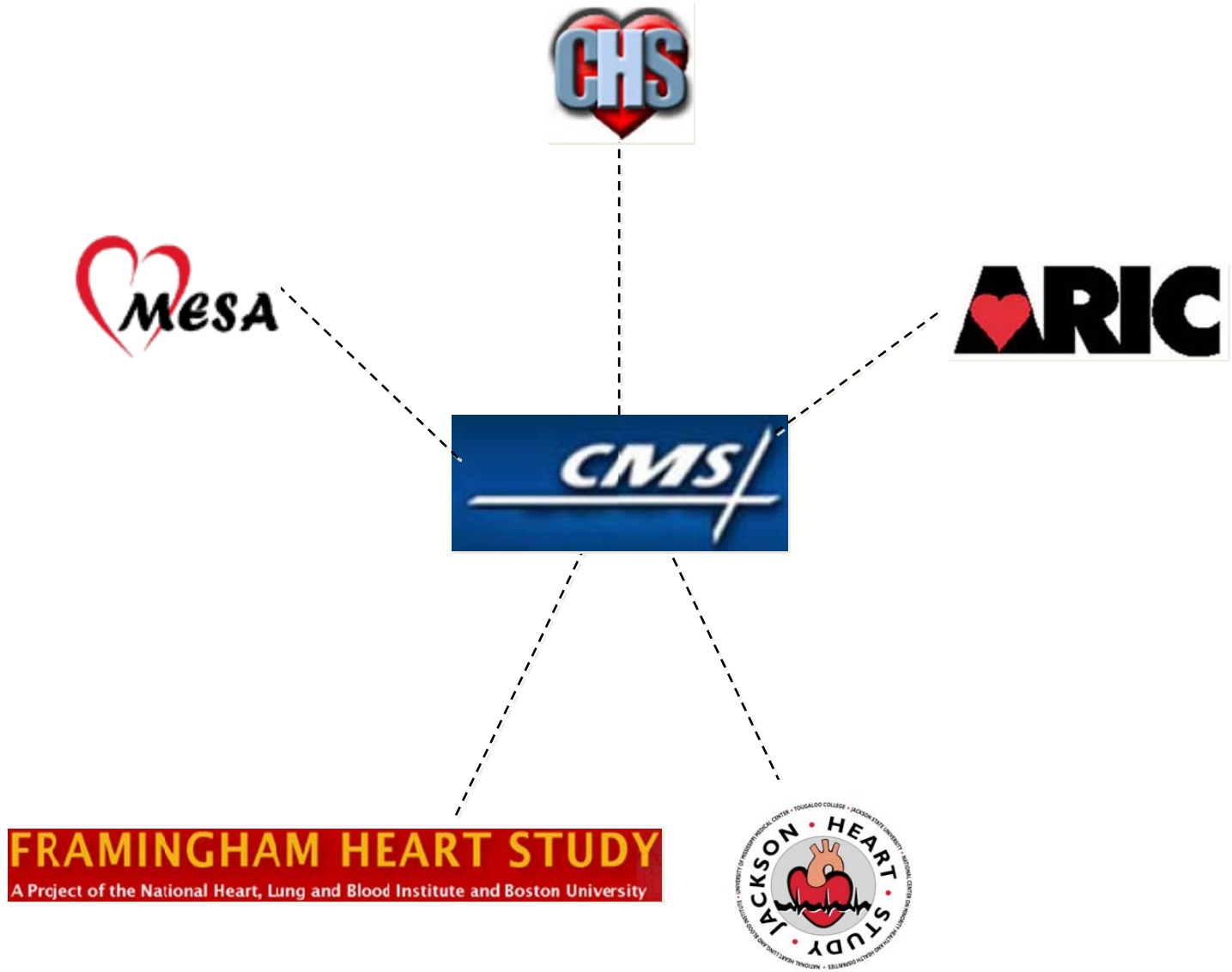
- To illustrate how Part D data linked with national registries can be used to assess post-discharge medication adherence



Linking to Medicare Data via Direct Identifiers

- **Direct identifiers**
  - Name, address, SSN, date of birth, etc.
  - Goal: Identify each patient in the Medicare data

- **Examples**
  - NHLBI cohort studies and Medicare claims
  - SEER-Medicare
  - Health plan data and National Death Index



Linking with Medicare Data via Indirect Identifiers

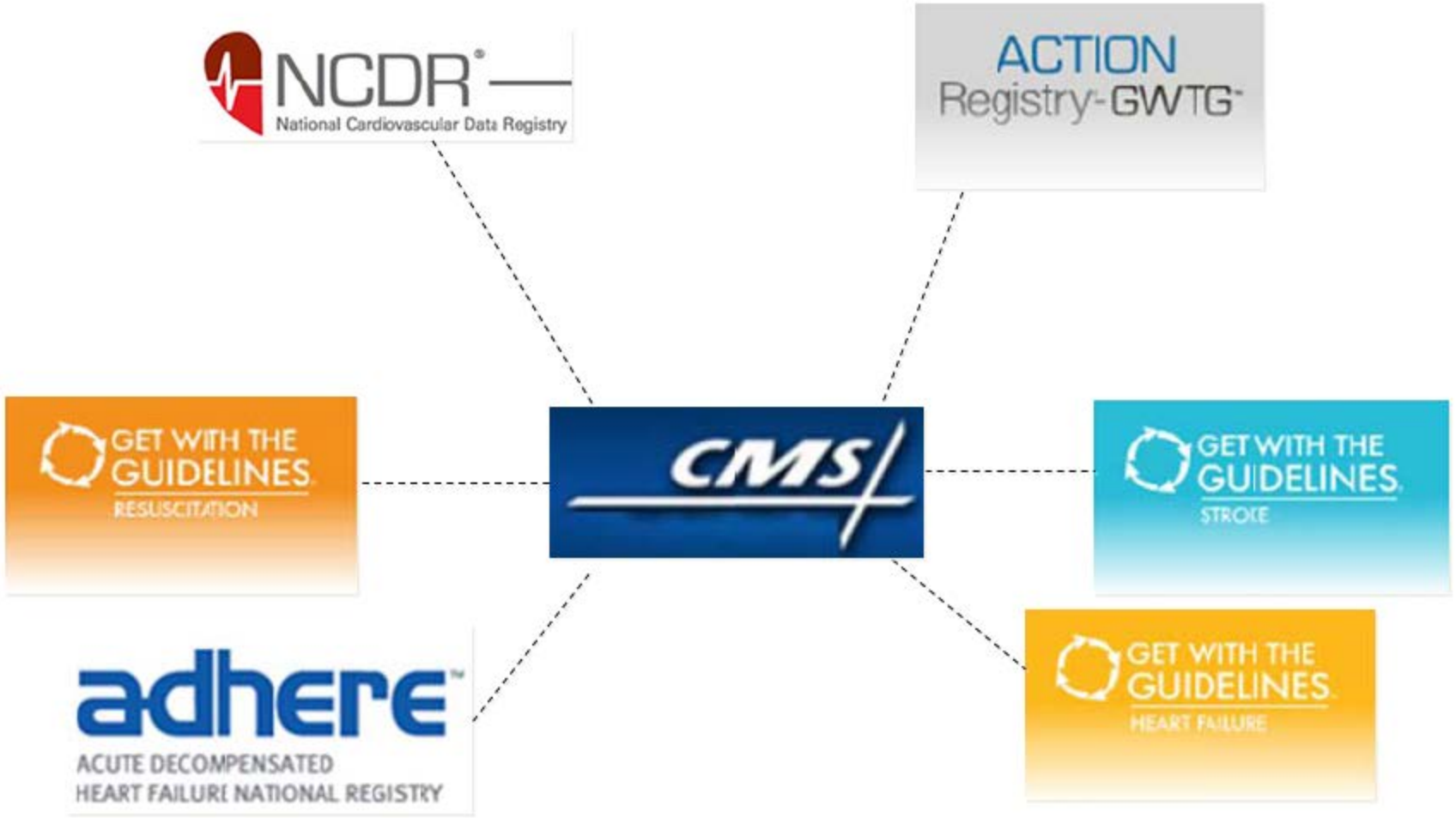
Indirect identifiers

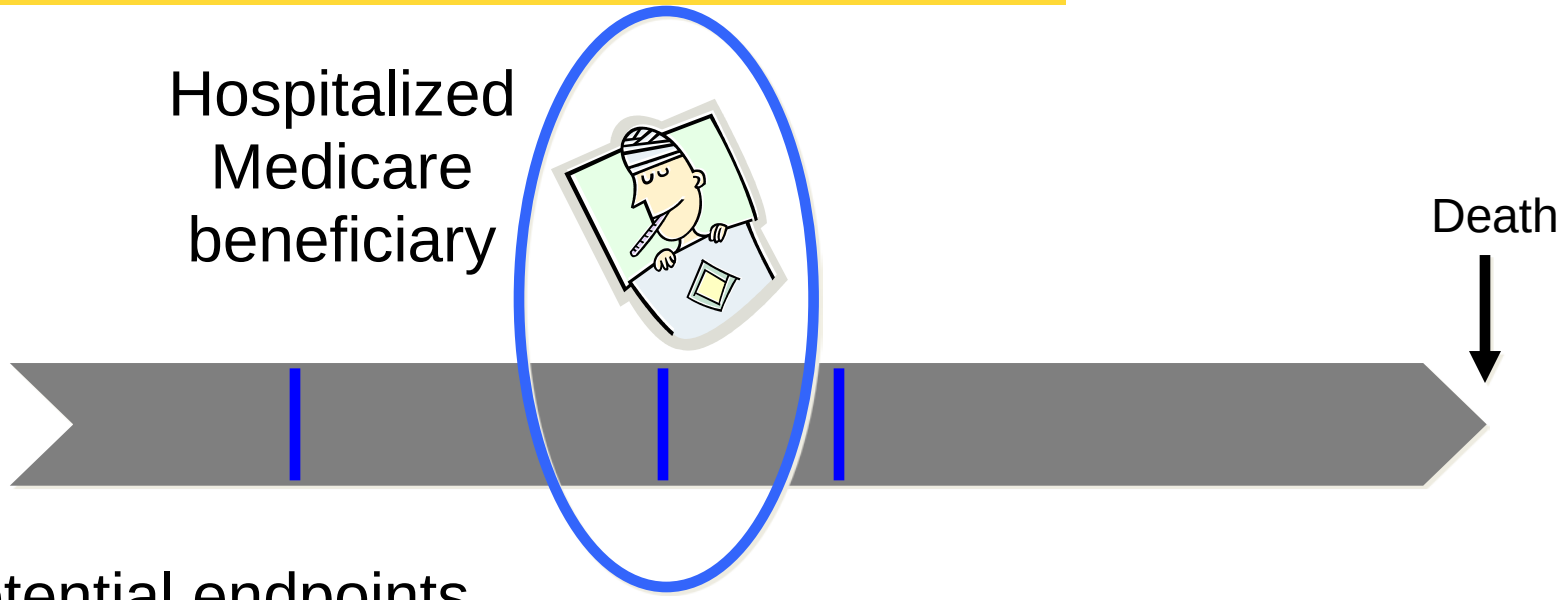
- Service dates, date of birth (or age), sex

Goal: Identify each *registry hospitalization* in the Medicare data

Examples

- Numerous inpatient registries and Medicare claims





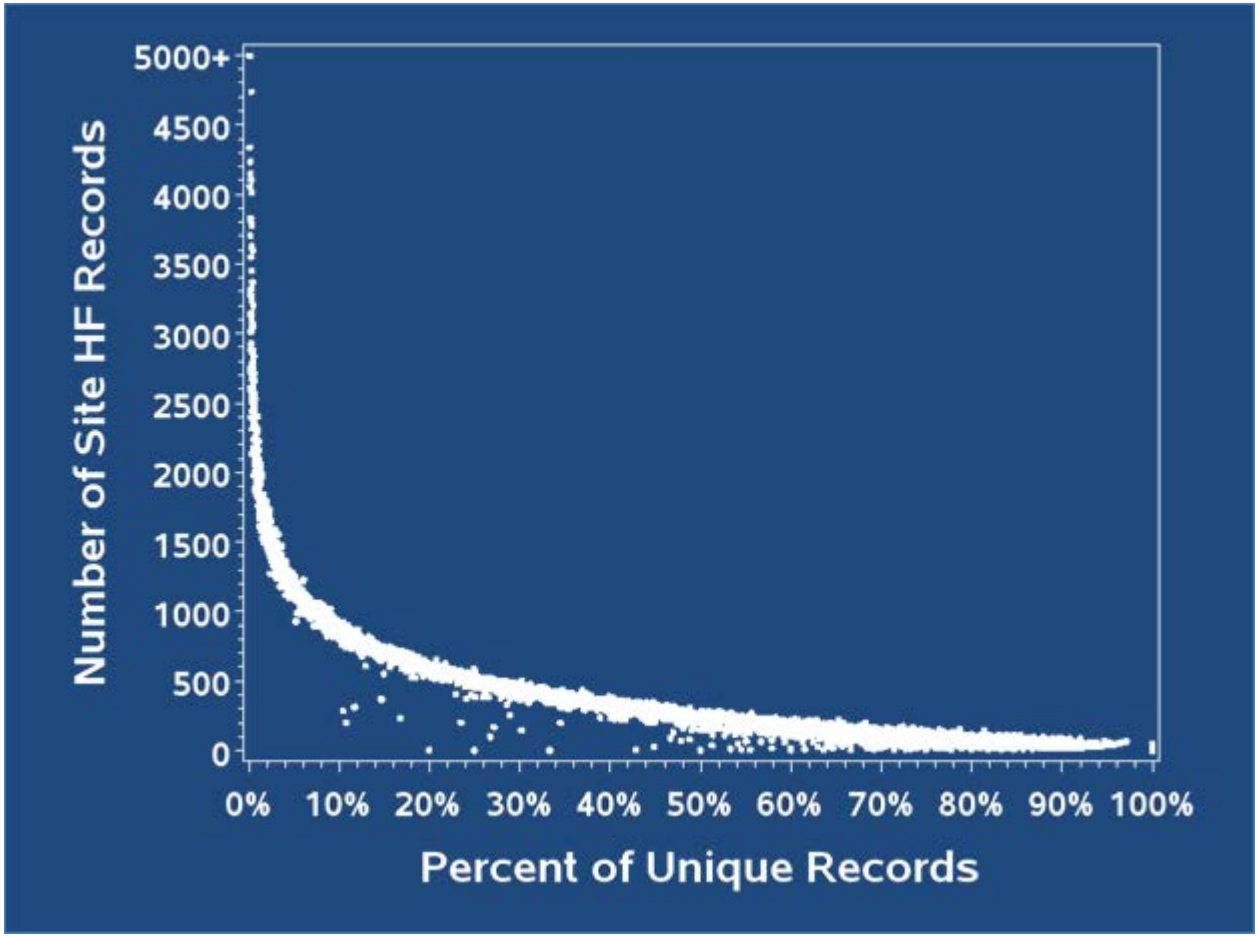
Potential endpoints

- Mortality
- Readmission
- Procedure
- Adverse events (based on coded diagnoses and procedures)

Percent of Unique Records within Sites

2007 Medicare HF Records (Heart failure diagnosis in any claim position)

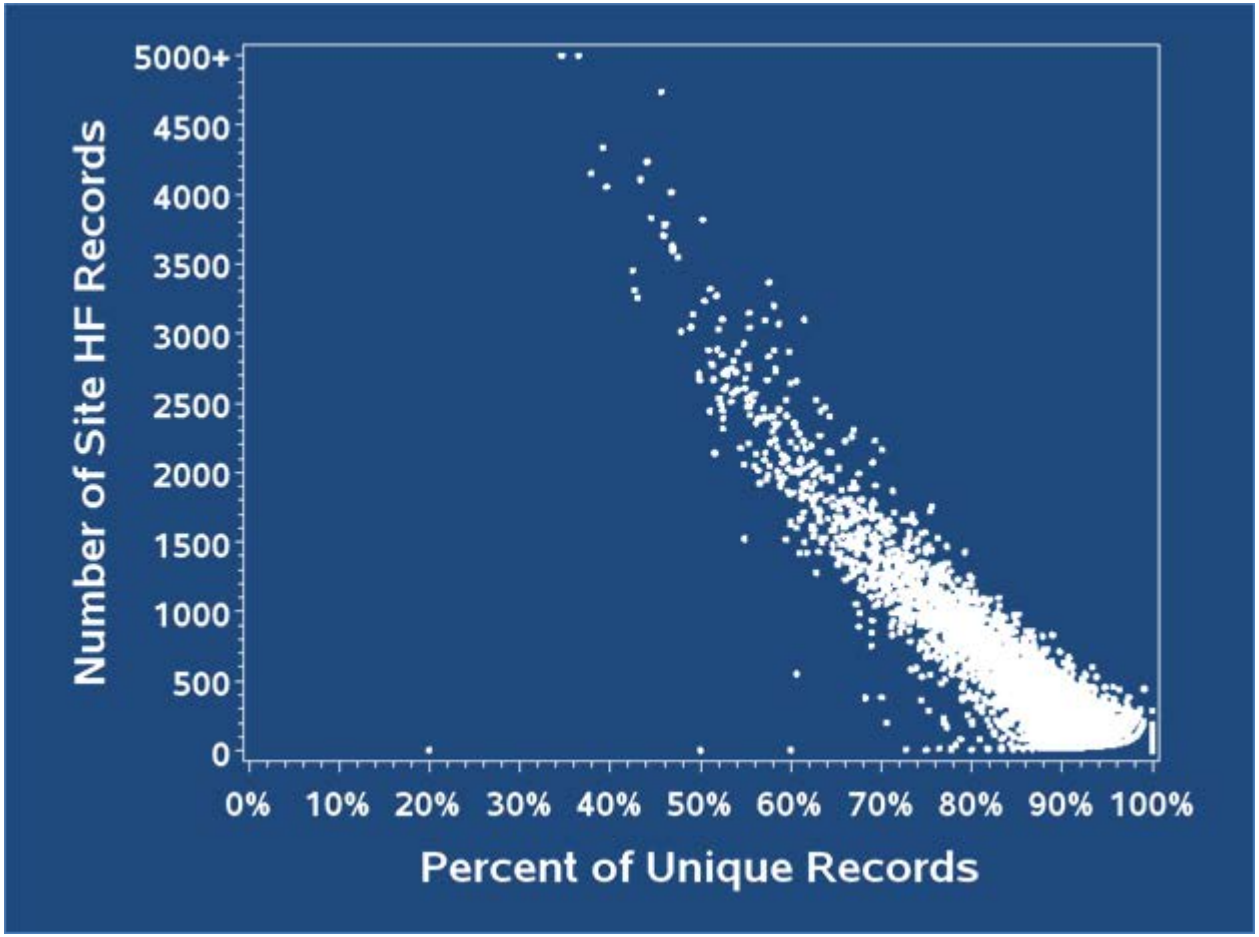
Admit



Percent of unique records within Sites

2007 Medicare HF Records

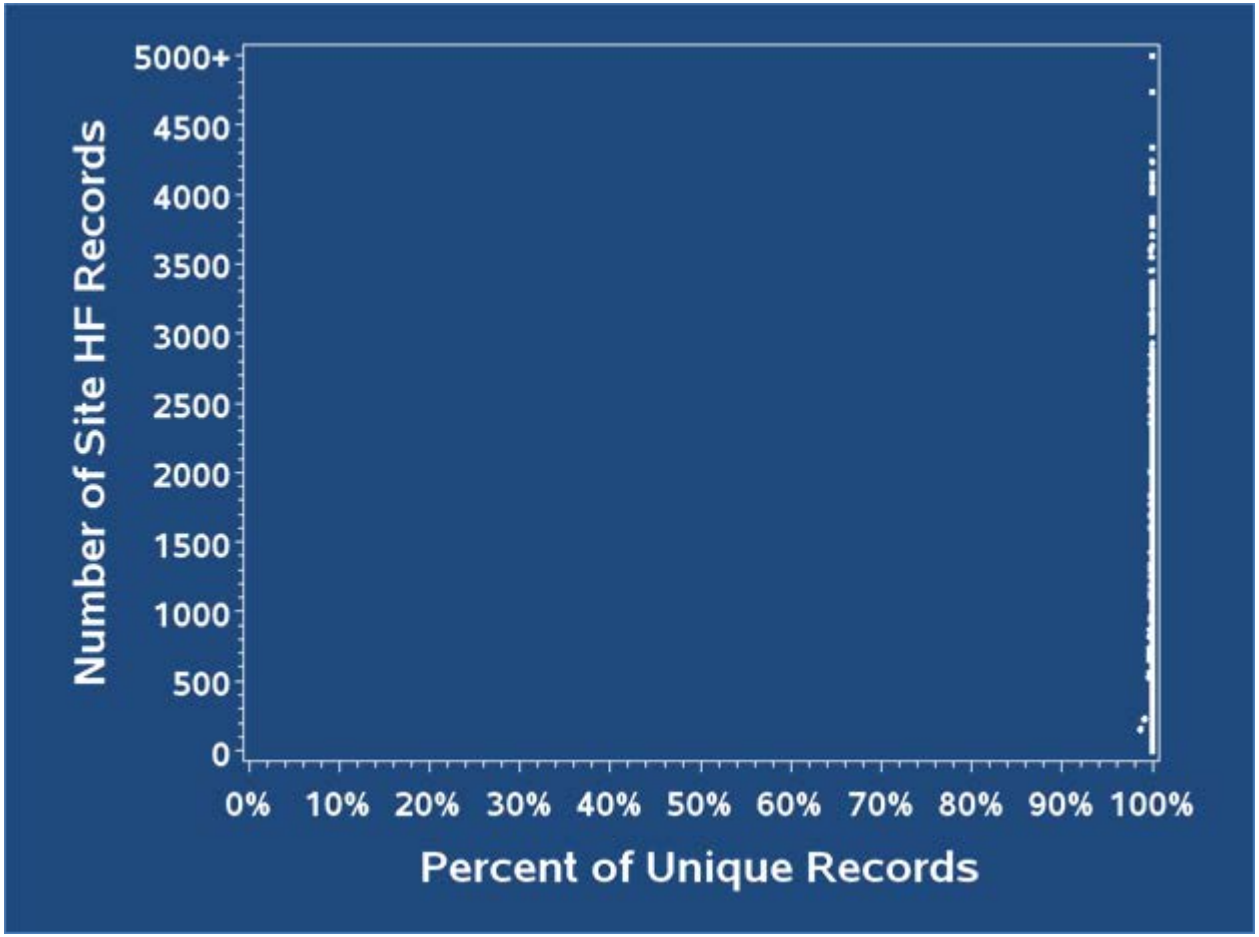
Admit Discharge



Percent of Unique Records within Sites

2007 Medicare HF Records

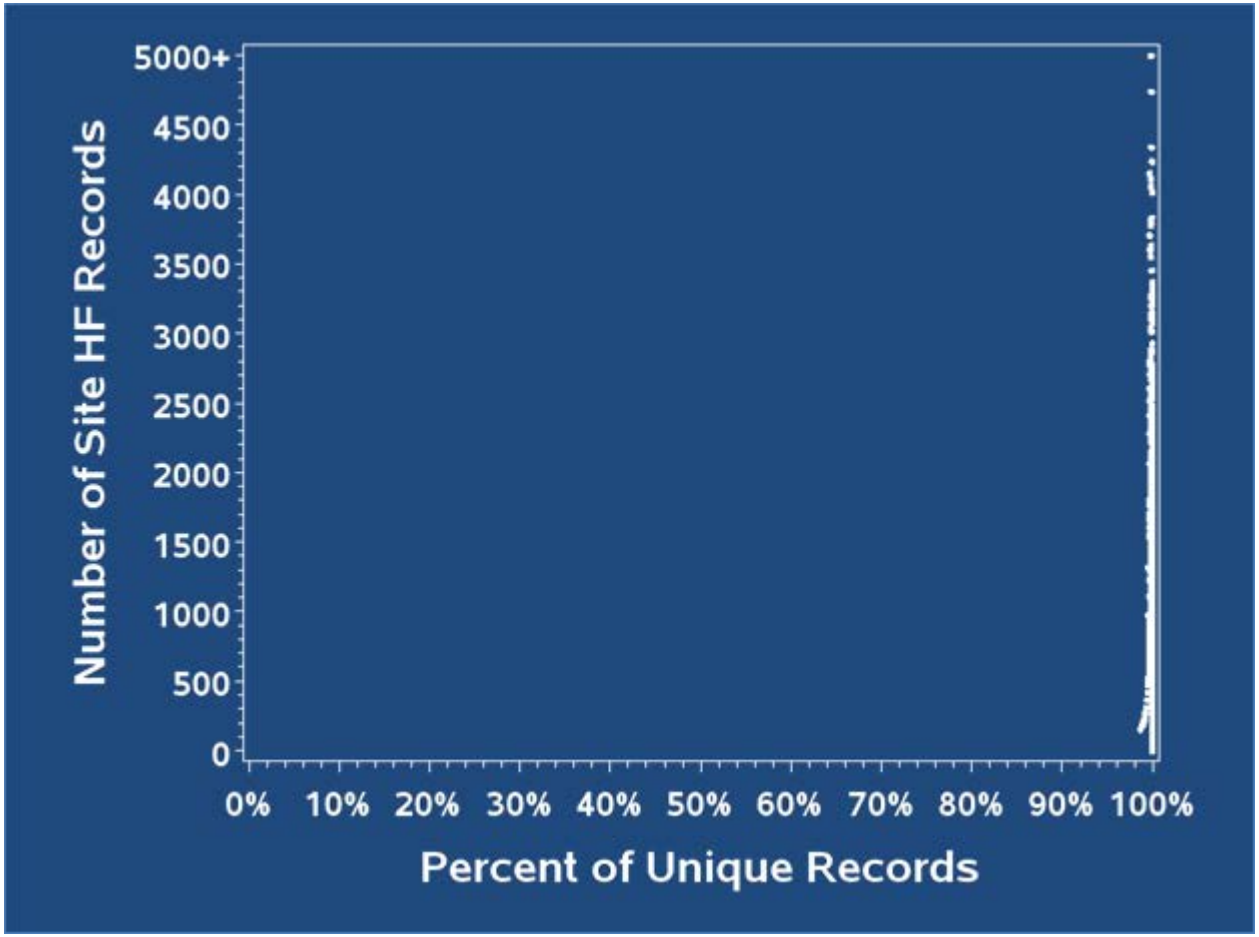
Admit Discharge DOB



Percent of Unique Records within Sites

2007 Medicare HF Records

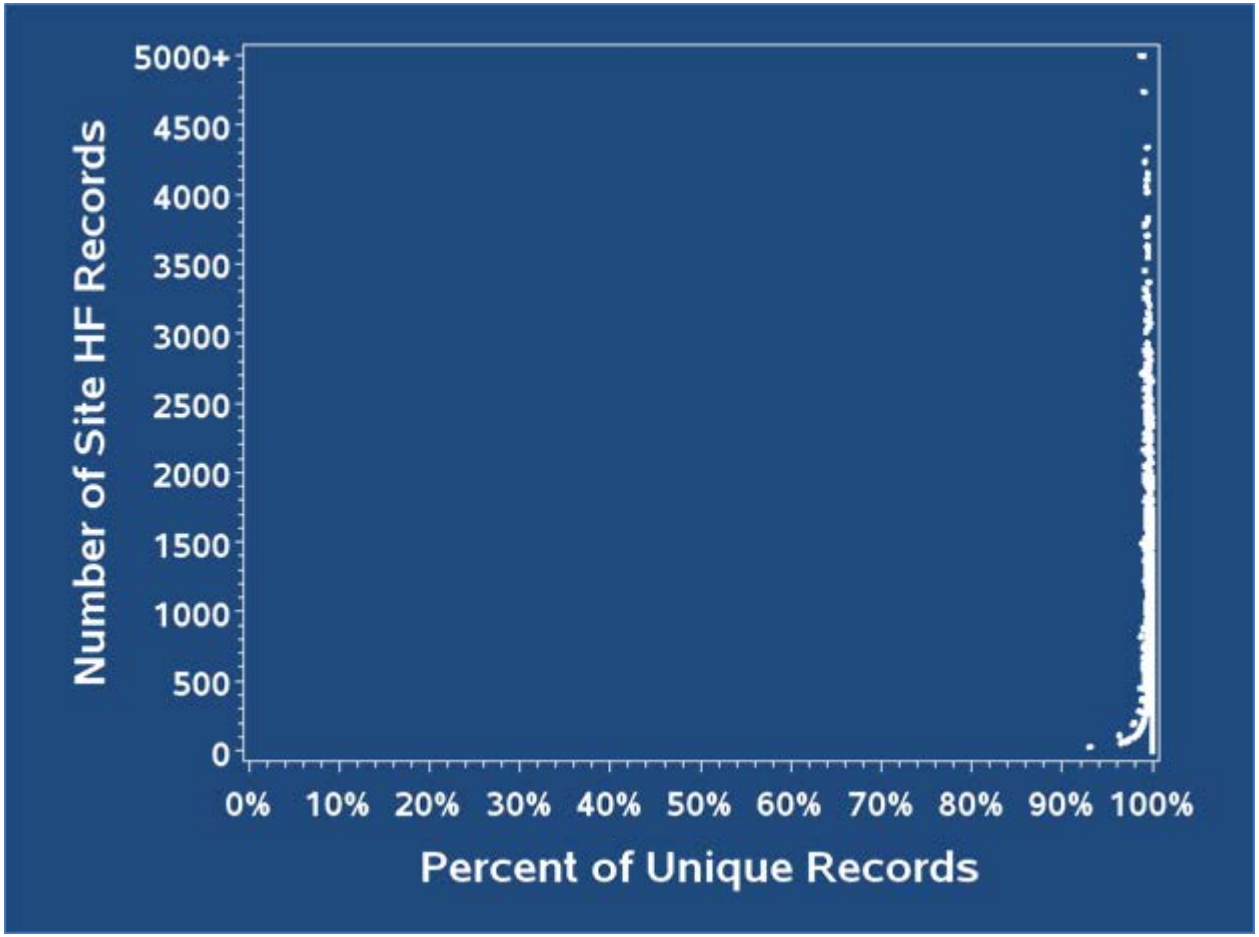
Admit DOB



Percent of Unique Records within Sites

2007 Medicare HF Records

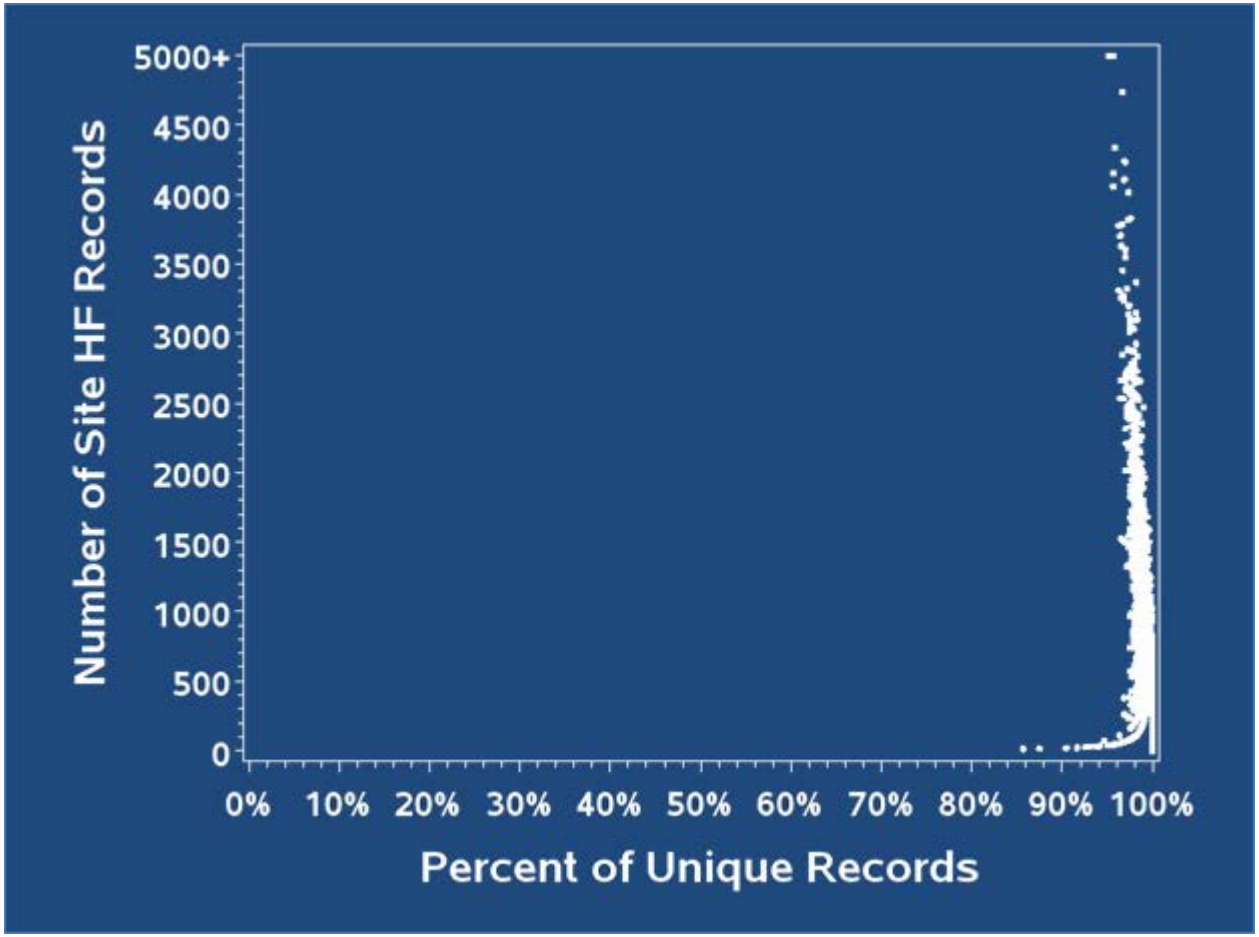
Admit Discharge 2/3 DOB



Percent of Unique Records within Sites

2007 Medicare HF Records

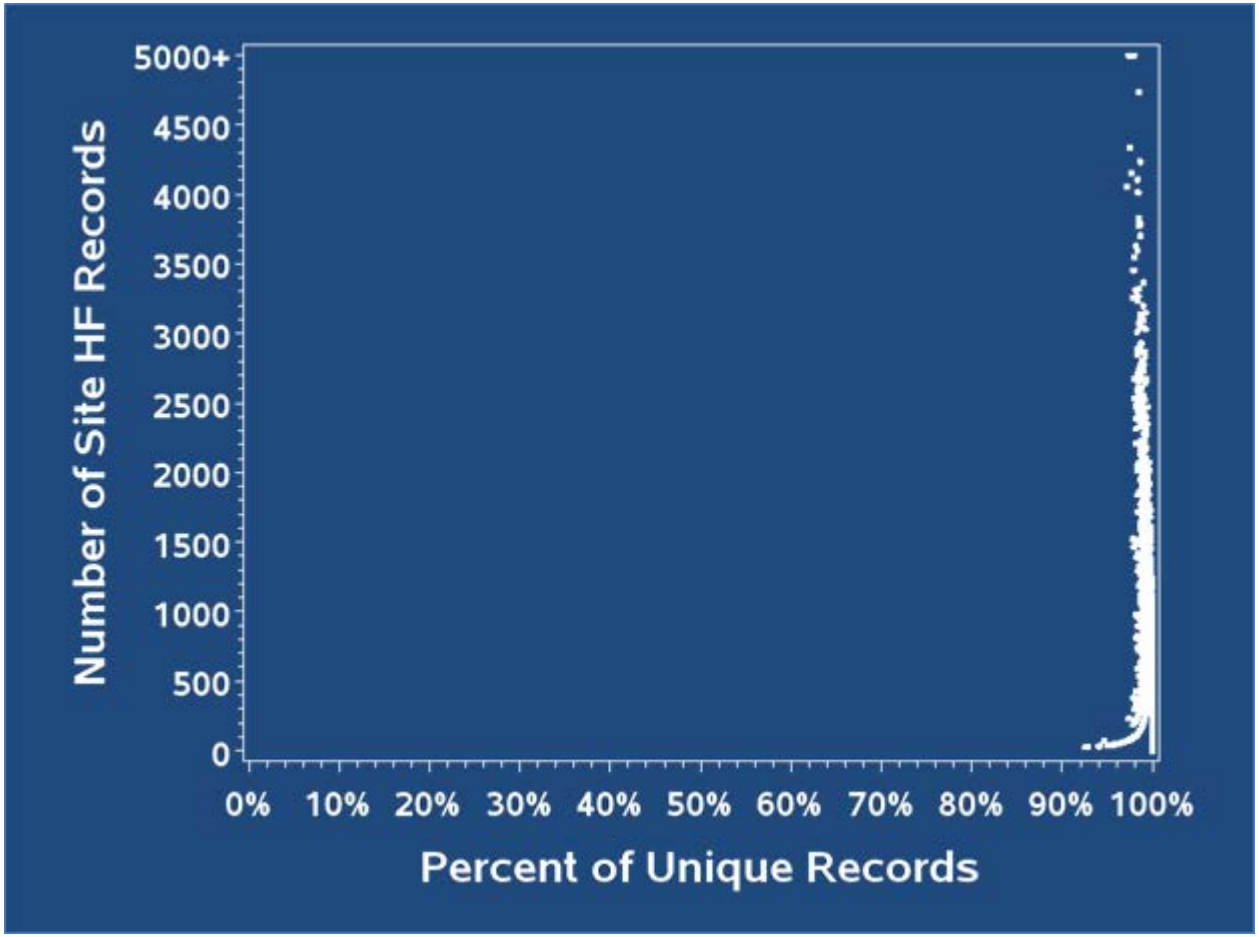
Admit Discharge Age



Percent of Unique Records within Sites

2007 Medicare HF Records

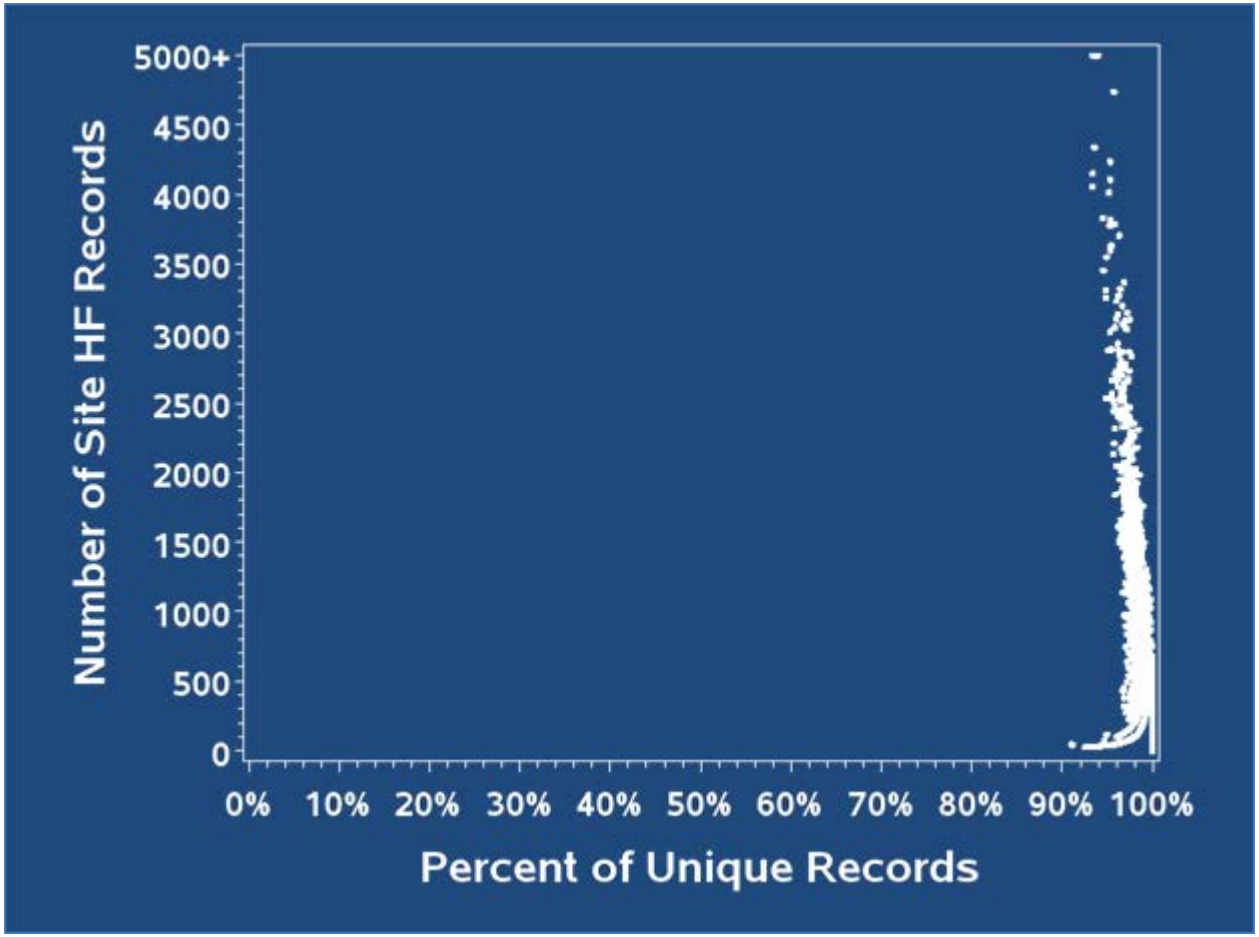
Admit Discharge Age Sex



Percent of Unique Records within Sites

2007 Medicare HF Records

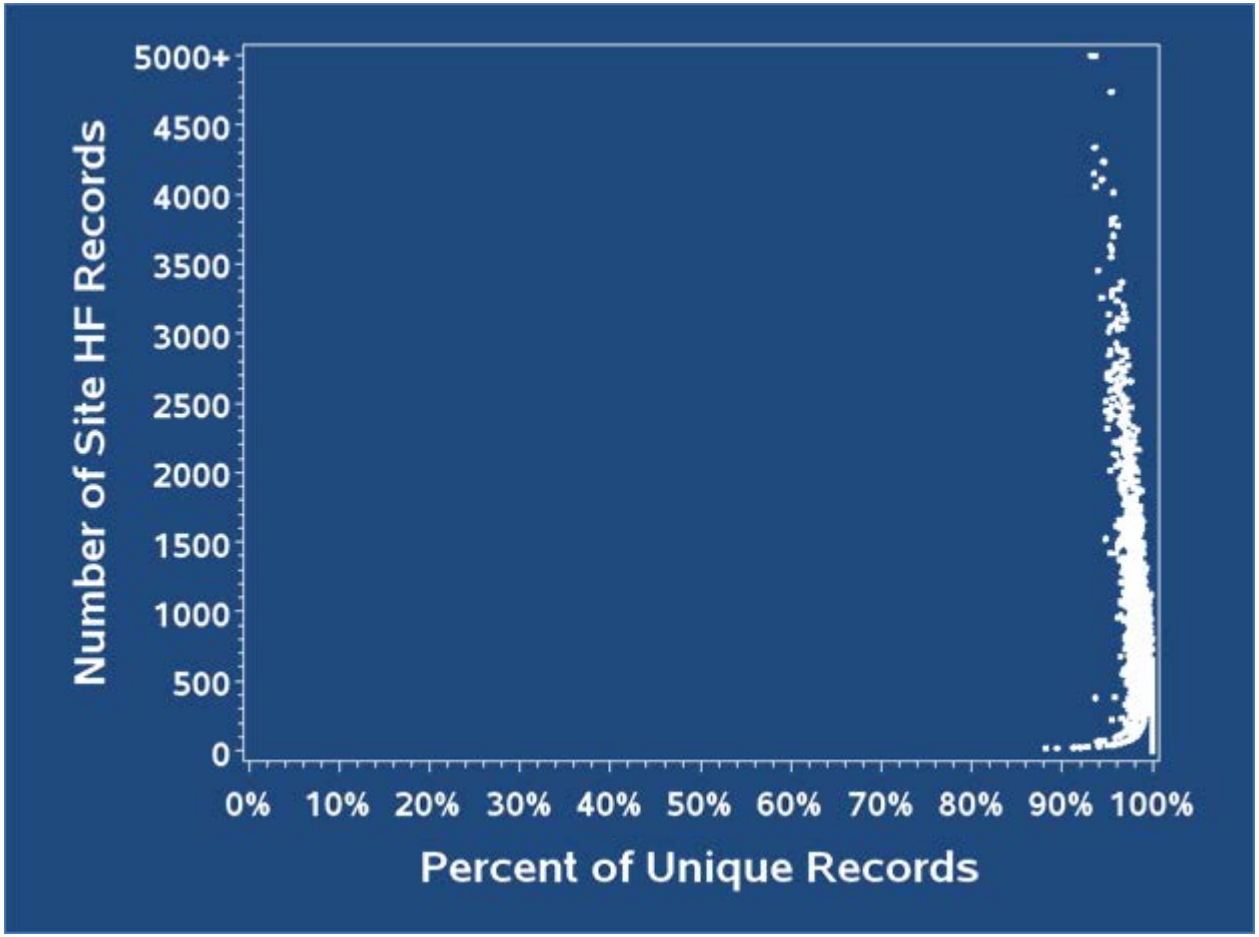
Admit±1d Discharge Age Sex



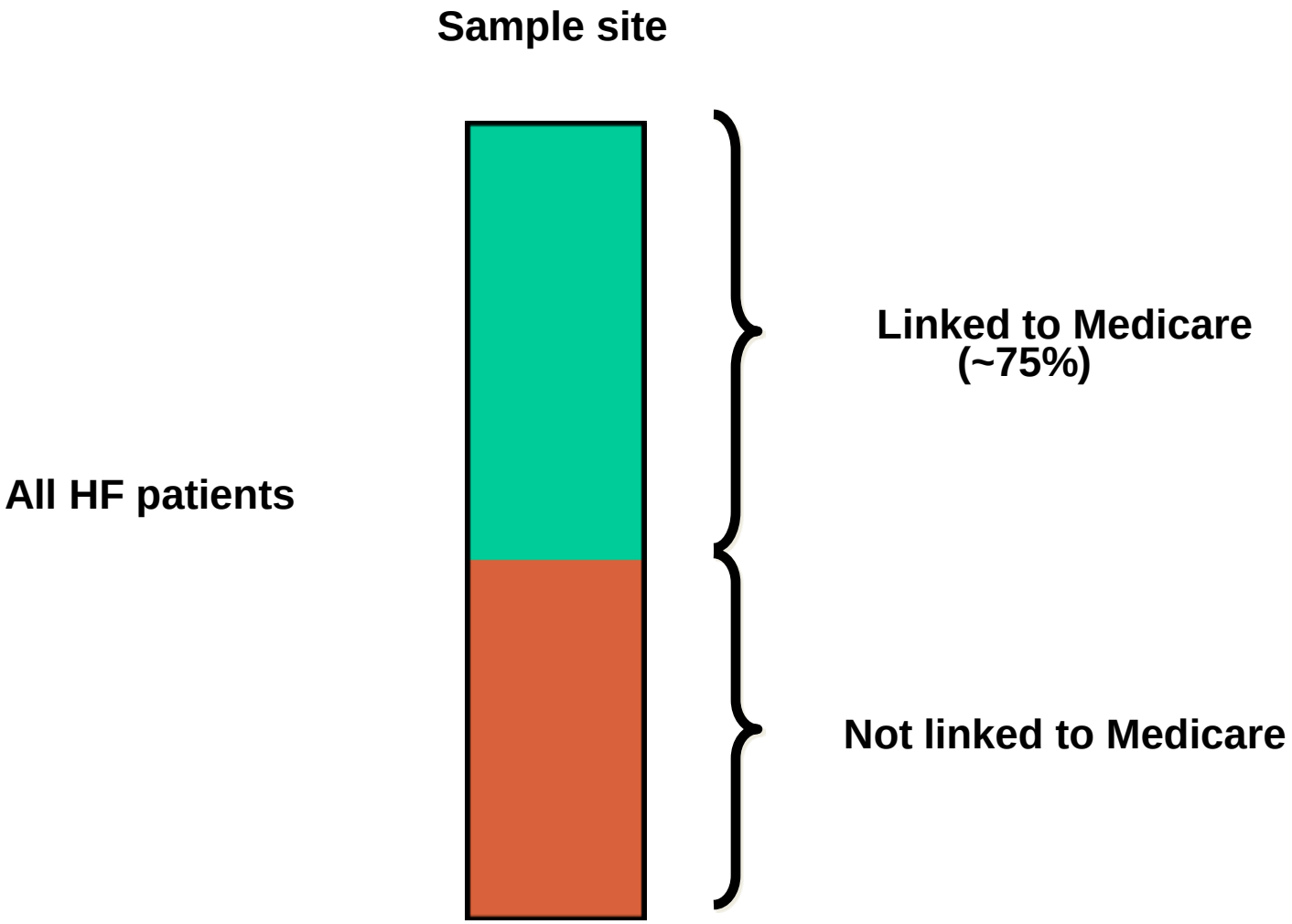
Percent of Unique Records within Sites

2007 Medicare HF Records

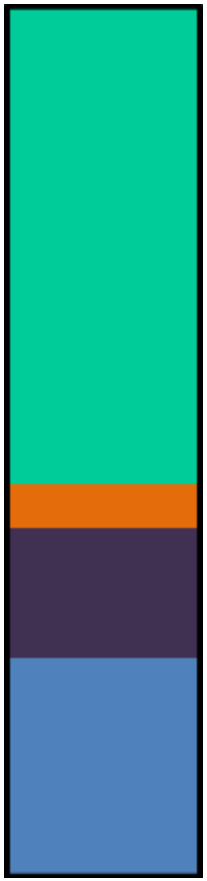
Admit Discharge Age±1y Sex



Why Might Registry Records not Link to Medicare?



Why Might Registry Records not Link to Medicare?



In Medicare claims, but…

- Inconsistent coding of procedures or diagnoses
- Inconsistent service dates or patient info

Not in Medicare claims due to…

- Medicare as secondary payer
- Medicare managed care enrollment
- 23-hour stay
- Age
- VA hospital (site-level)

Why Stop at Inpatient Medicare Data?

Medicare data

Mortality
(or censoring)

Inpatient

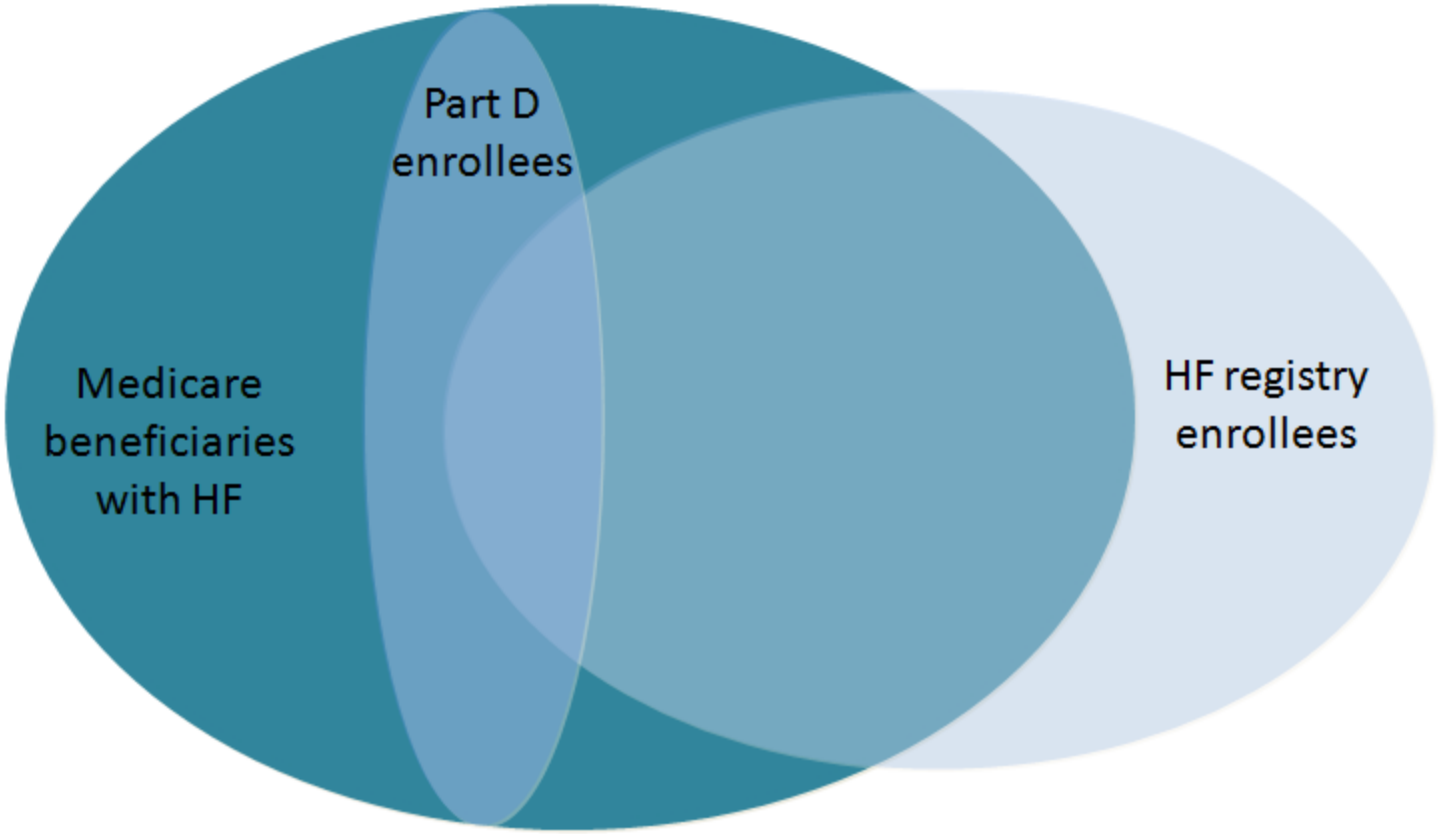
Outpatient / Physician

Part D

Benefits of Linkage with Part D

- Platform for comparative effectiveness, safety given rich clinical detail (registry, epi cohort) and longitudinal medication exposures (Part D)
- Medication transitions from inpatient to outpatient settings
- Improved confounder adjustment

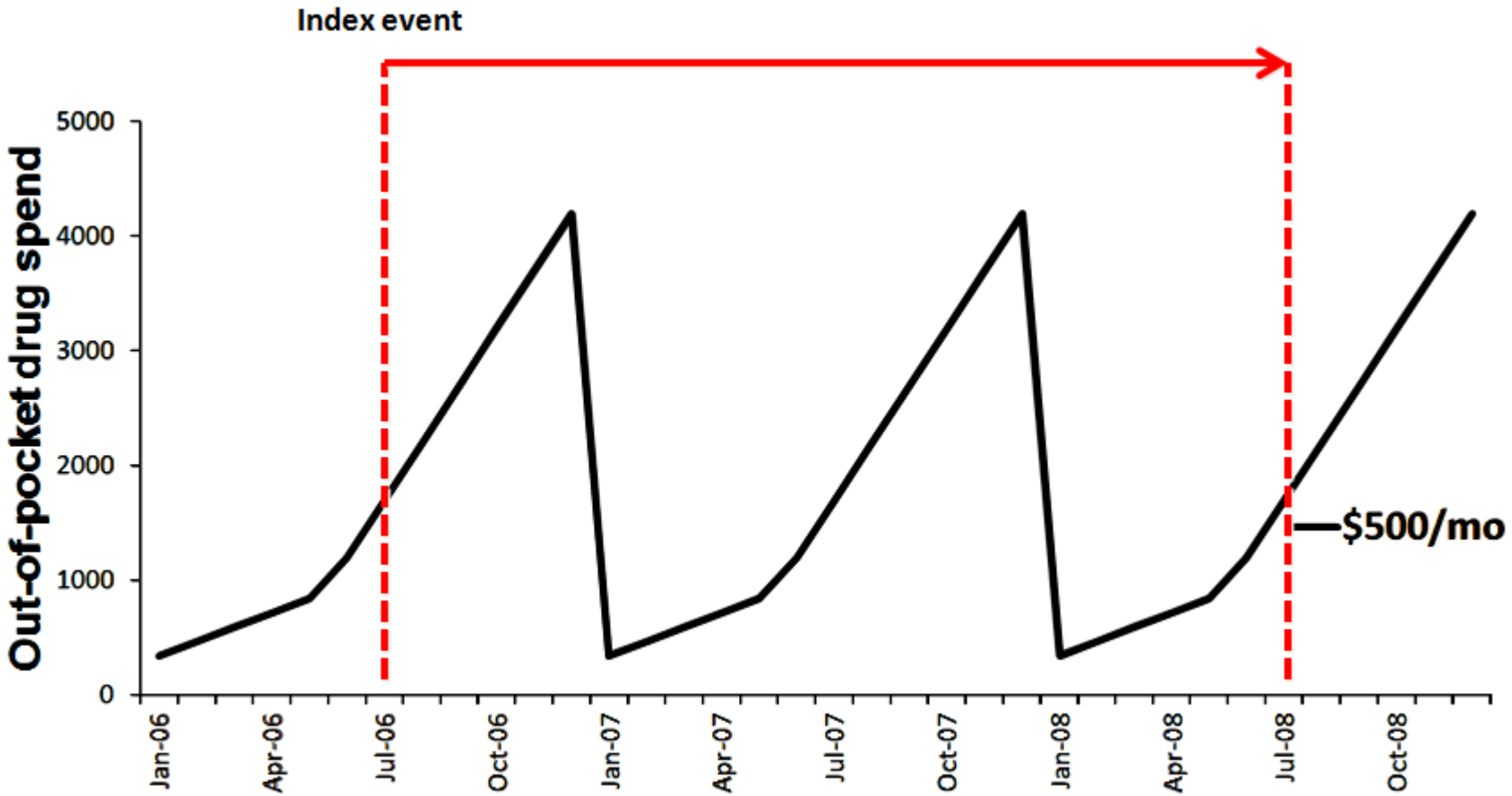
Challenges of Linkage with Part D: Sample Size



Challenges of Linkage with Part D: The Donut Hole

- Potential for multiple exposures
- Analytical complexities
- Unknown effect on adherence

Exposure to the Part D Coverage Gap



Analytical Approaches to the Coverage Gap

- Exposure prior to or concurrent with cohort entry
  - Dichotomous variable
- Exposure after cohort entry
  - Time-varying covariate in time-to-event models
  - In other models???

Challenges of Linkage with Part D: Disagreements Between Data Sources

- Registries record intention, claims record filled prescriptions
  - Neither captures exposure

Drug in…	Registry	
Part D	*Yes*	*No*
Yes	77.5%	9.2%
No	22.5%	90.8%

Challenges of Linkage with Part D: What We Don't Know

- Medication exposures during institutional stays (hospitalizations, post-acute SNF stays)
- Over-the-counter meds
- Walmart effect ($4 scripts)

Challenges of Linkage with Part D: Selection Bias

- Beneficiaries select their Part D plan
  - Variable premiums
  - Cost sharing
  - Formulary coverage
  - Pharmacies
- Beneficiaries can switch during the calendar year
  - Pre-2006: Monthly switching
  - 2006: Switching between January and June
  - 2007 onward: Switching between January and March

In Summary…

- Linkage of registries with Part D is possible
- Many design and analysis issues to consider
- If used thoughtfully, data have the potential to yield important insights about use and effectiveness in the real world

Differences in the Characteristics of Medicare Beneficiaries with Heart Failure According to Enrollment in the Medicare Part D Prescription Drug Benefit

Zubin J. Eapen, MD

Disclosures

"I, Zubin Eapen, declare no conflicts of interest or financial interests in any product or service mentioned in this presentation, including grants, employment, gifts, stock holdings, or honoraria."

Background

- The need for comparative effectiveness studies is a national priority because efficacy studies for drug approval enroll highly selected patients
- As the leading cause of readmission for Medicare beneficiaries, heart failure (HF) is responsible for 37% of annual Medicare spending
- Overall pharmaceutical spending similarly represents a significant cost to Medicare by comprising more than a fifth of annual spending

Background

- Pharmaceutical spending by Medicare has increased since 2006 when the Medicare prescription-drug benefit (Part D) was implemented
- Part D has resulted in greater access to prescription medications and, consequently, greater costs – $45.5 billion in 2008 alone
- The population of Part D enrollees with HF and their medication regimens have not been described

Objectives

- Compare patient-level characteristics of beneficiaries diagnosed with heart failure who are and are not enrolled in stand-alone Medicare Part D plans
- Describe medications prescribed to Medicare beneficiaries diagnosed with heart failure who are enrolled in a Medicare Part D plan

Methods

Data Sources

- Medicare claims and Part D event data for a nationally representative 5% sample of CMS beneficiaries

Study Cohorts

- Annual cohorts (for 2006 and 2007) of beneficiaries having prevalent CHF January 1st of the cohort year

Exposure of interest

- Enrollment in a Part D prescription medication plan. Part D enrollment was determined as of January 1 of cohort year using the annual Part D denominator files

Methods

Inclusion Criteria

- Beneficiaries with CHF reported as a diagnosis (ICD-9-CM codes 428.x, 402.x1, 404.x1, or 404.x3) in any position on a single inpatient claim or at least 3 outpatient/carrier claims during prior year (e.g. in 2005 for 2006 cohort)
- Patients who were enrolled in Medicare FFS for the entire prior year
- Age ≥66 (to allow one prior year of enrollment and claims) as of January 1st of the cohort year

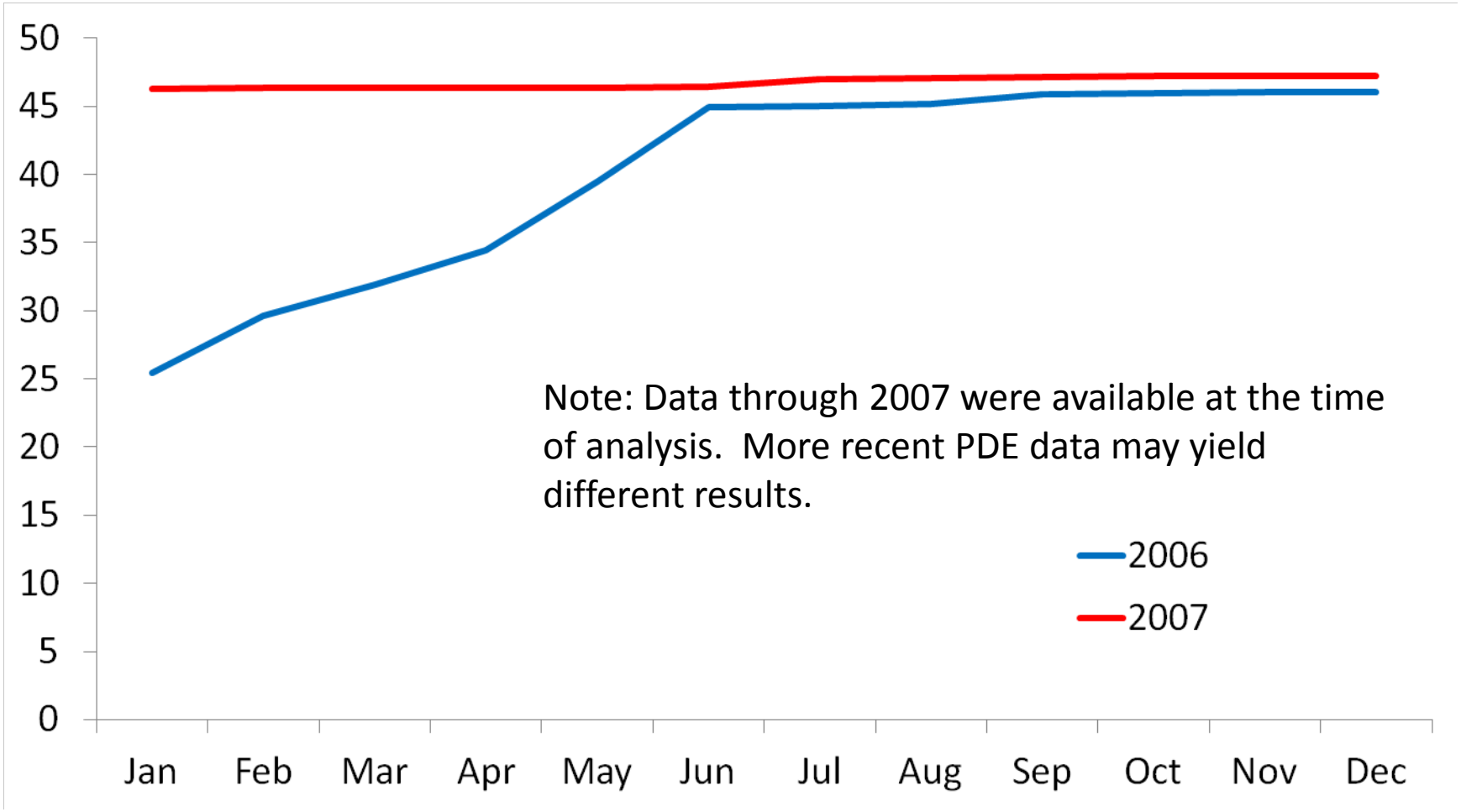
Methods

Analysis

- We compared demographics and comorbidities of patients enrolled to those not enrolled in a Part D plan.
- We determined the most frequent drug prescriptions for Part D enrollees with HF

Part D Enrollment Trend

FFS Beneficiaries (N ~ 1.5m)



Baseline Characteristics

Variable	2006		2007	
	Not Part D Enrolled	Part D Enrolled	Not Part D Enrolled	Part D Enrolled
N	55,252	35,883	36,510	50,834
Demographics				
Age, mean (SD), years	80.1 (7.6)	80.7 (8.2)	80.1 (7.4)	80.7 (8.1)
Gender, Male	26,447 (47.9%)	11,083 (30.9%)	19,087 (52.3%)	17,242 (33.9%)
Race				
White	48,818 (88.4%)	28,261 (78.8%)	32,499 (89.0%)	41,369 (81.4%)
Black	3,678 (6.7%)	4,522 (12.6%)	2,237 (6.1%)	5,448 (10.7%)
Other/Unknown	2,756 (5.0%)	3,100 (8.6%)	1,774 (4.9%)	4,017 (7.9%)

*p values for all comparisons are <.001

Baseline Characteristics

Variable	2006		2007	
	Not Part D Enrolled	Part D Enrolled	Not Part D Enrolled	Part D Enrolled
N	55,252	35,883	36,510	50,834
Medicare Info				
State buy-in	1,713 (3.1%)	19,419 (54.1%)	208 (0.6%)	19,808 (39.0%)

*p values for all comparisons are <.001

Baseline Characteristics

Variable	2006		2007	
	Not Part D Enrolled	Part D Enrolled	Not Part D Enrolled	Part D Enrolled
N	55,252	35,883	36,510	50,834
Comorbidities				
Coronary heart disease	40,606 (73.5%)	25,026 (69.7%)	27,172 (74.4%)	35,960 (70.7%)
Diabetes mellitus	24,093 (43.6%)	18,197 (50.7%)	16,381 (44.9%)	25,156 (49.5%)
Hypertension	49,589 (89.8%)	32,619 (90.9%)	33,175 (90.9%)	46,599 (91.7%)
Chronic obstructive pulmonary disorder	28,058 (50.8%)	18,960 (52.8%)	18,509 (50.7%)	26,534 (52.2%)
Cerebrovascular disease	17,350 (31.4%)	12,714 (35.4%)	11,745 (32.2%)	17,734 (34.9%)

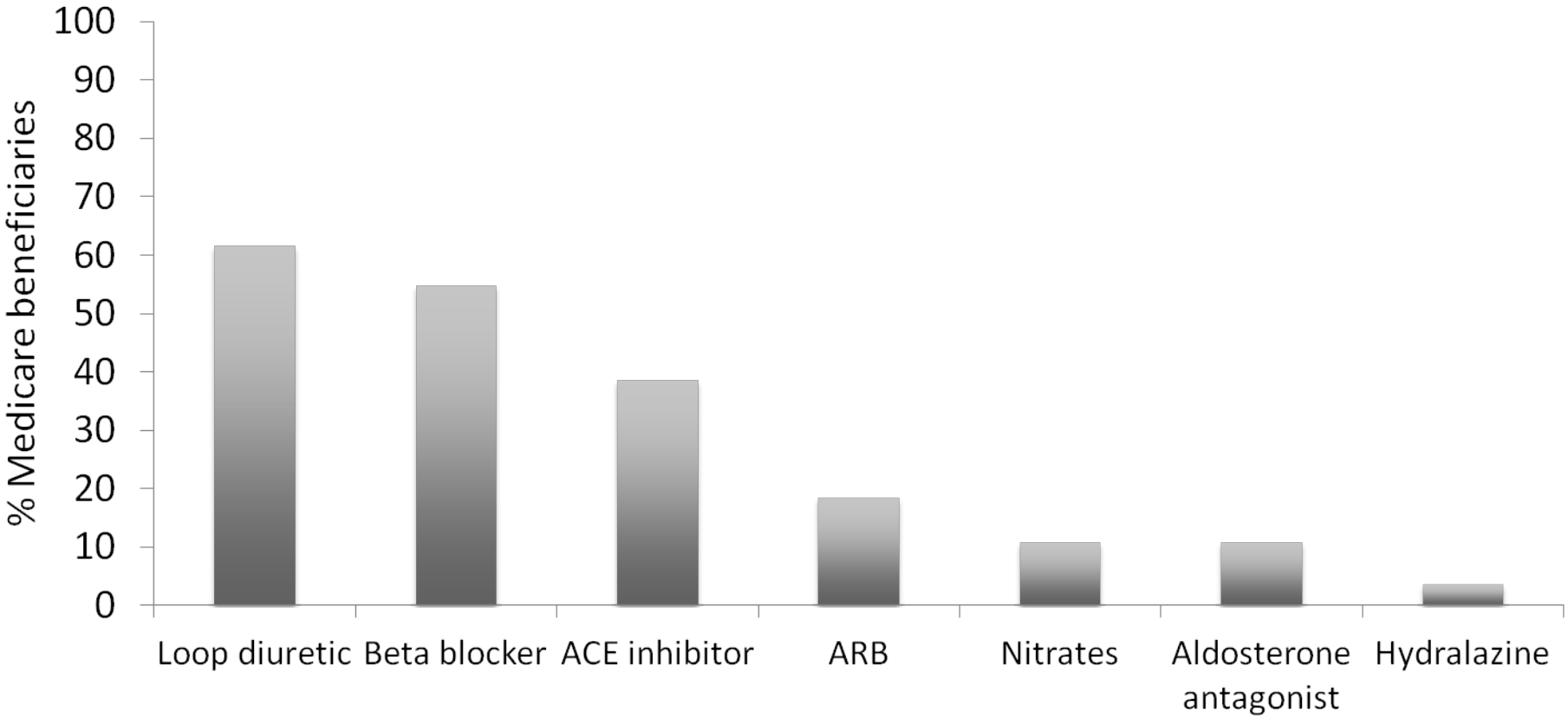
*p values for all comparisons are <.001

Baseline Characteristics

Variable	2006		2007	
	Not Part D Enrolled	Part D Enrolled	Not Part D Enrolled	Part D Enrolled
N	55,252	35,883	36,510	50,834
Comorbidities				
Cancer	10,213 (18.5%)	5,134 (14.3%)	7,165 (19.6%)	7,775 (15.3%)
Dementia	5,013 (9.1%)	7,016 (19.6%)	3,327 (9.1%)	8,461 (16.6%)
Myocardial infarction	12,988 (23.5%)	7,436 (20.7%)	8,565 (23.5%)	10,787 (21.2%)
Peptic ulcer disease	2,462 (4.5%)	2,021 (5.6%)	1,549 (4.2%)	2,530 (5.0%)
Peripheral vascular disease	20,079 (36.3%)	14,779 (41.2%)	13,708 (37.5%)	20,861 (41.0%)

*p values for all comparisons are <.001

Are HF Patients Receiving the Right Medications?



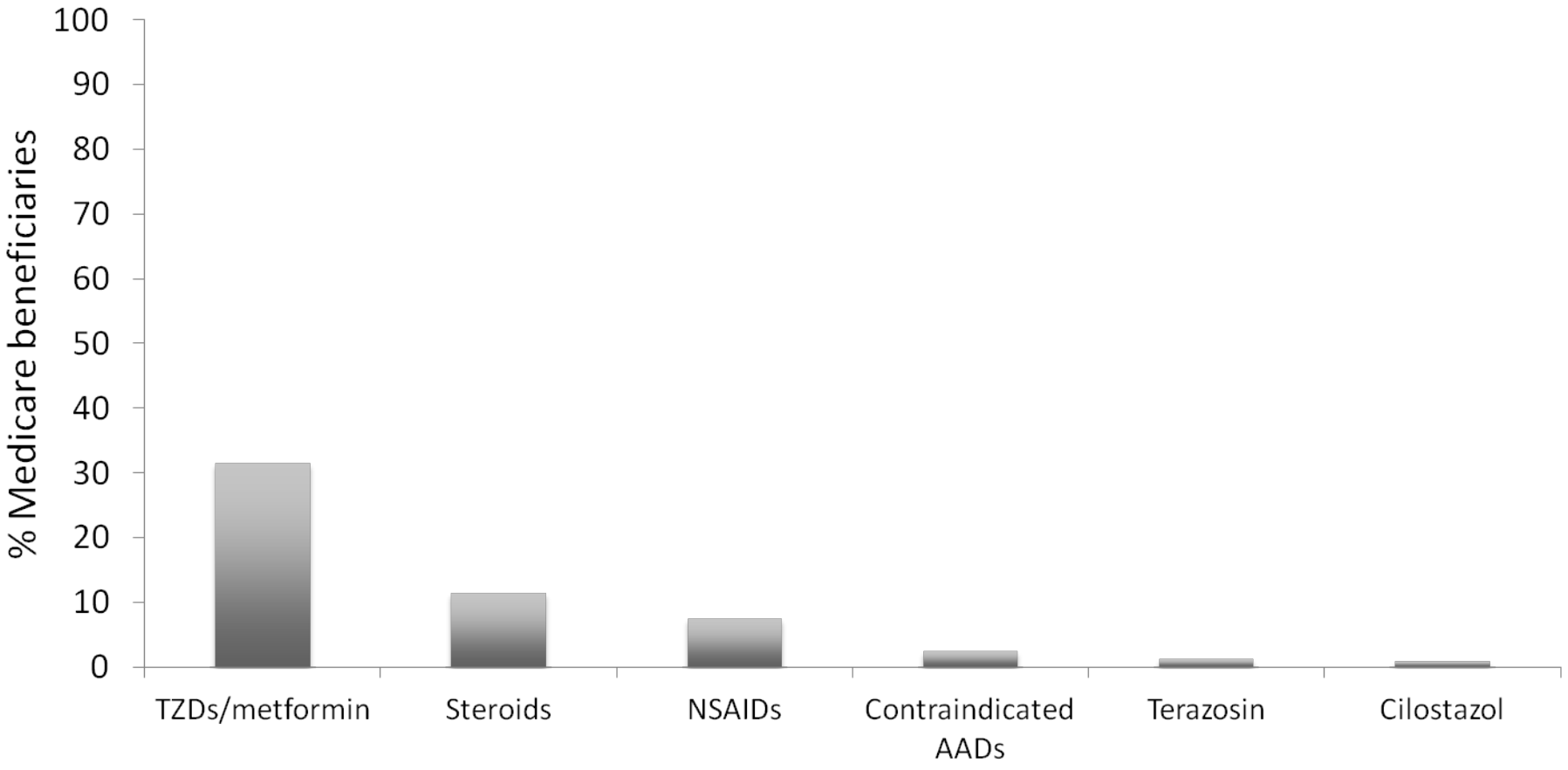
n= 45,543

Beneficiaries with a Prescription for Each Medication Class

	2006	2007
Indicated/Potentially indicated		
Loop diuretic	19,882 (61.4%)	28,089 (61.7%)
Beta blocker	16,046 (49.6%)	24,959 (54.8%)
ACE inhibitor	12,532 (38.7%)	17,610 (38.7%)
Statin	11,435 (35.3%)	18,192 (39.9%)
Warfarin	7,087 (21.9%)	11,024 (24.2%)
Digoxin	6,929 (21.4%)	9,333 (20.5%)
Angiotensin receptor blocker	5,726 (17.7%)	8,402 (18.4%)
Antiplatelet agent (excl. aspirin)	5,306 (16.4%)	7,615 (16.7%)
Nitrates	3,921 (12.1%)	4,955 (10.9%)
Aldosterone antagonist	3,370 (10.7%)	4,806 (10.8%)
Hydralazine	1,000 (3.1%)	1,625 (3.6%)

- Between January and April of the cohort year (denominator = beneficiaries)

Are HF Patients Receiving the Wrong Medications?



n= 45,543

Beneficiaries with a Prescription for Each Medication Class

	2006	2007
Contraindicated		
Diabetes medication (thiazolidinediones, metformin)	10,476 (32.4%)	14,366 (31.5%)
Corticosteroids	3,493 (10.8%)	5,221 (11.5%)
NSAIDs	2,744 (8.5%)	3,418 (7.5%)
Contraindicated antiarrhythmics (sotalol, disopyramide, mexiletine, flecainide, propafenone, quinidine)	666 (2.1%)	1,079 (2.4%)
Terazosin	371 (1.1%)	578 (1.3%)
Cilostazol	323 (1.0%)	431 (0.9%)

- Between January and April of the cohort year (denominator = beneficiaries)

Most Frequent “Other” Drug Prescriptions

Generic name	2007
Potassium chloride	16,325 (35.8%)
Levothyroxine sodium	10,075 (22.1%)
Hydrocodone / acetaminophen	7,039 (15.5%)
Isosorbide mononitrate	5,775 (12.7%)
Omeprazole	5,362 (11.8%)
Levofloxacin	4,729 (10.4%)
Azithromycin	4,119 (9.0%)
Ciprofloxacin	3,725 (8.2%)
Propoxyphene / acetaminophen	3,662 (8.0%)
Diltiazem	3,661 (8.0%)

Conclusions

- Part D enrollees in this analysis tended to have fewer comorbidities and were more likely to be female and black
- Part D enrollees in this analysis were more likely to have a portion of their Medicare Part A and B premiums paid for by the state (state buy-in), a potential indicator of low-income status
- Medicare beneficiaries with HF in this analysis differ significantly according to enrollment in Part D prescription drug plans and represent a population underrepresented in clinical efficacy trials

Conclusions

- Utilization of evidence-based, guideline-driven therapies for HF among Part D enrollees is low
- Studies with Part D claims data linked to a clinical registry may inform clinical practice as to the effectiveness of drug therapy in real-world settings

Assessments

Assessment Question 1

Inpatient registries may be linked with Medicare claims data using:

Social Security number, birth date, and gender

Hospital site and beneficiary name and address

Dates of service, date of birth, and hospital site

Medical record number, birth date, gender, and hospital site

Assessment Question 2

Inpatient registries linked with Part D prescription drug event data provide the capability to assess:

Time of initiation of a medication newly prescribed at discharge

Post-discharge adherence to all medications

Agreement between medication list at discharge and medications filled in outpatient settings

1/A and 3/C

All of the above

Questions?

Contact information

For more information please contact:

Lesley Curtis
lesley.curtis@duke.edu

Zubin Eapen
zubin.eapen@duke.edu

Presentation Evaluation

Please get your ARS Response Card ready