



**NIA IMPACT**  
COLLABORATORY  
TRANSFORMING DEMENTIA CARE

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# Health-generated Data to Identify People Living with Dementia for IMPACT

*(Imbedded Pragmatic Alzheimer's and other Dementia Clinical Trials)*



## **Julie Bynum, MD, MPH**

Margaret Terpenning Collegiate Professor of Internal Medicine  
Division of Geriatric & Palliative Medicine, University of Michigan  
Vice Chair for Faculty Affairs  
Geriatric Center Associate Director for Health Policy & Research



**MICHIGAN MEDICINE**  
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# Housekeeping

- All participants will be muted
- Enter **all questions** in the Zoom **Q&A/chat box** and send to Everyone
- Moderator will review questions from chat box and ask them at the end
- Want to continue the discussion? Associated podcast released about 2 weeks after Grand Rounds
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# Learning Objectives

Upon completion of this presentation, you should be able to:

Understand the  
use of data to  
achieve pragmatic  
study aims

Identify strengths &  
challenges when  
using Healthcare-  
generated data  
(billing or electronic  
health record data)  
for participant  
identification

Identify threats to  
Health Equity and  
Generalizability  
related to choices  
about data use



# Pragmatic vs. Explanatory Trials

“**Pragmatic** randomized trial is undertaken in the “real world” and with usual care and is intended to help support a decision on whether to deliver an intervention.”

“**Explanatory** randomized trial is undertaken in an idealized setting, to give the initiative under evaluation its best chance to demonstrate beneficial effect.”



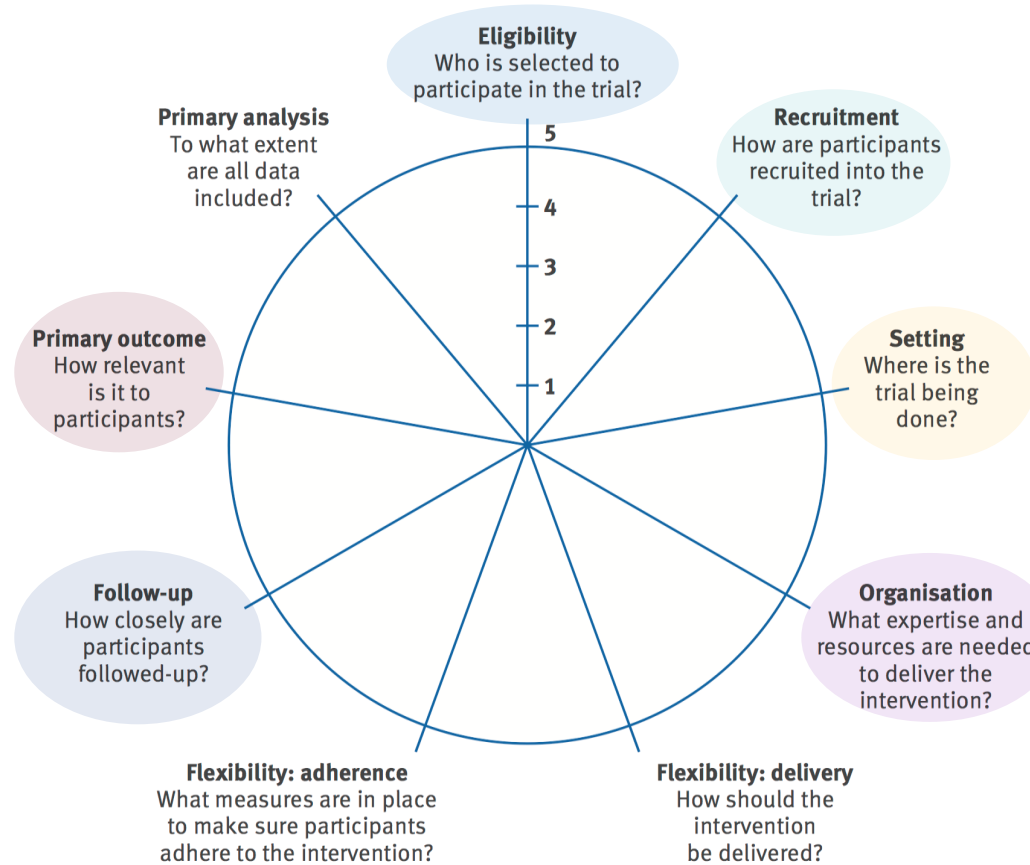
*What does this distinction mean for what and how data is used in a trial?*

# PRagmatic Explanatory Continuum Indicator Summary-2 Tool (PRECIS-2 Tool)

**Eligibility:** Who is selected to participate in the trial?

**Primary outcome:** How relevant is it to participants?

**Follow-up:** How closely are participants followed-up?



**Recruitment:** How are participants recruited into the trial?

**Setting:** Where is the trial being done?

**Organization:** What expertise and resources are needed to deliver the intervention?

# Healthcare-Generated Data

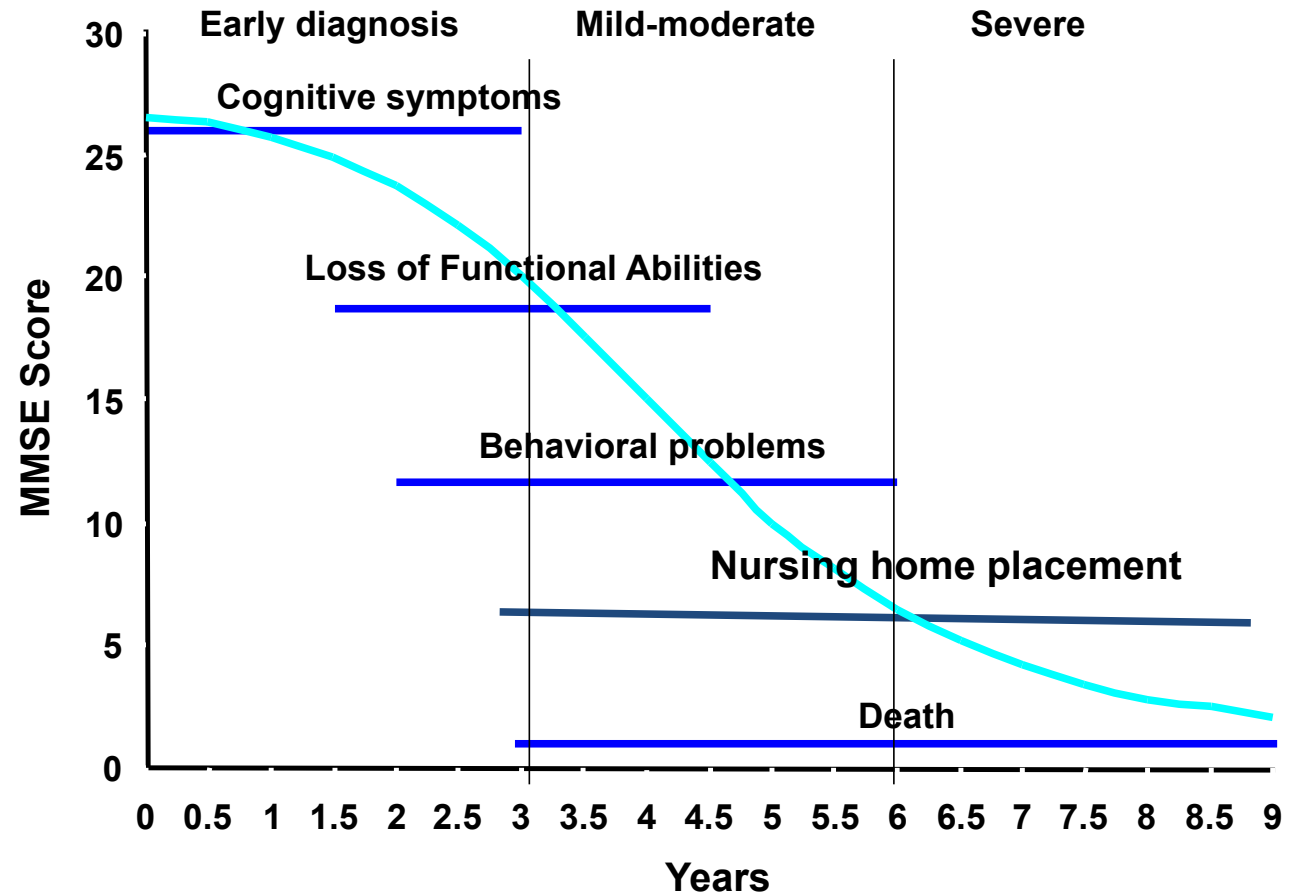
Data collected in the process of health care service delivery for payment or clinical record:

- ✓ Medicare Fee-for-Service (CMS)
- ✓ Medicare Advantage (CMS)
- ✓ Commercial Insurance (OPTUM, Sentinel/DRN, other payers)
- ✓ Medicaid (CMS, state)
- ✓ Minimum Dataset/OASIS (CMS)
- ✓ Electronic Health Record

# Eligibility: *Who is your target population?*

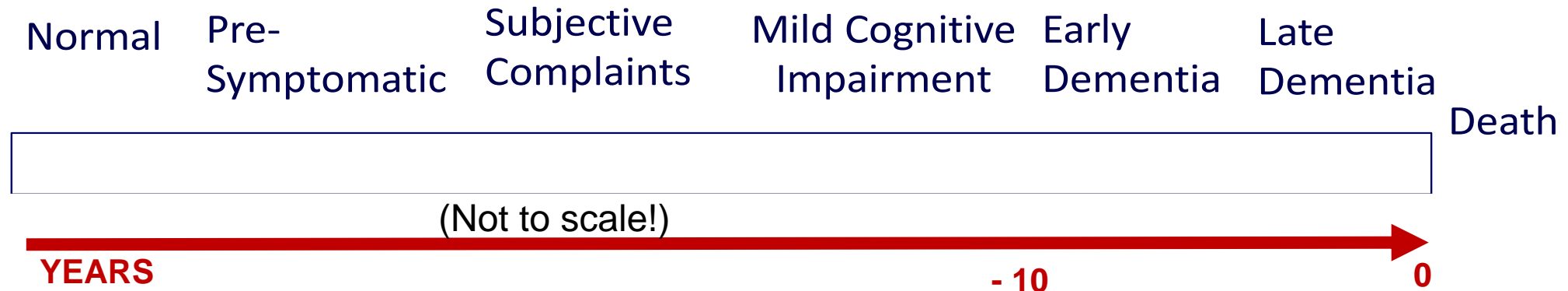
## What is meant by **People Living with dementia?**

*People living with an acquired syndrome of memory loss and other cognitive abilities serious enough to interfere with daily life.*

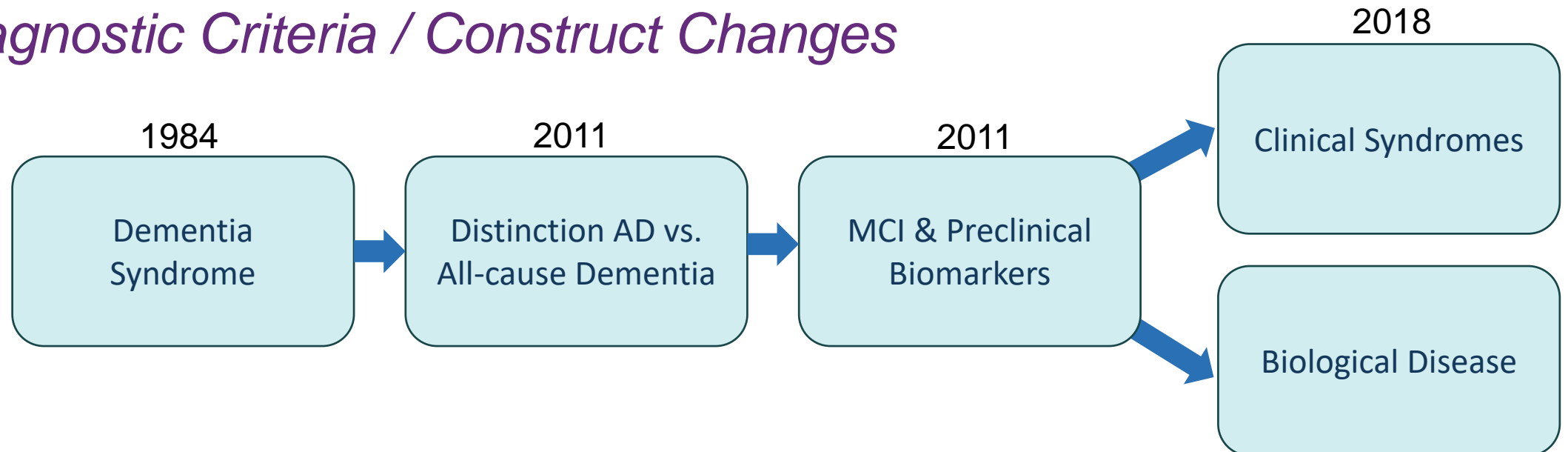


# TODAY: Conceptualization of Disease has changed over time

## A. Earlier Stages Now Recognized

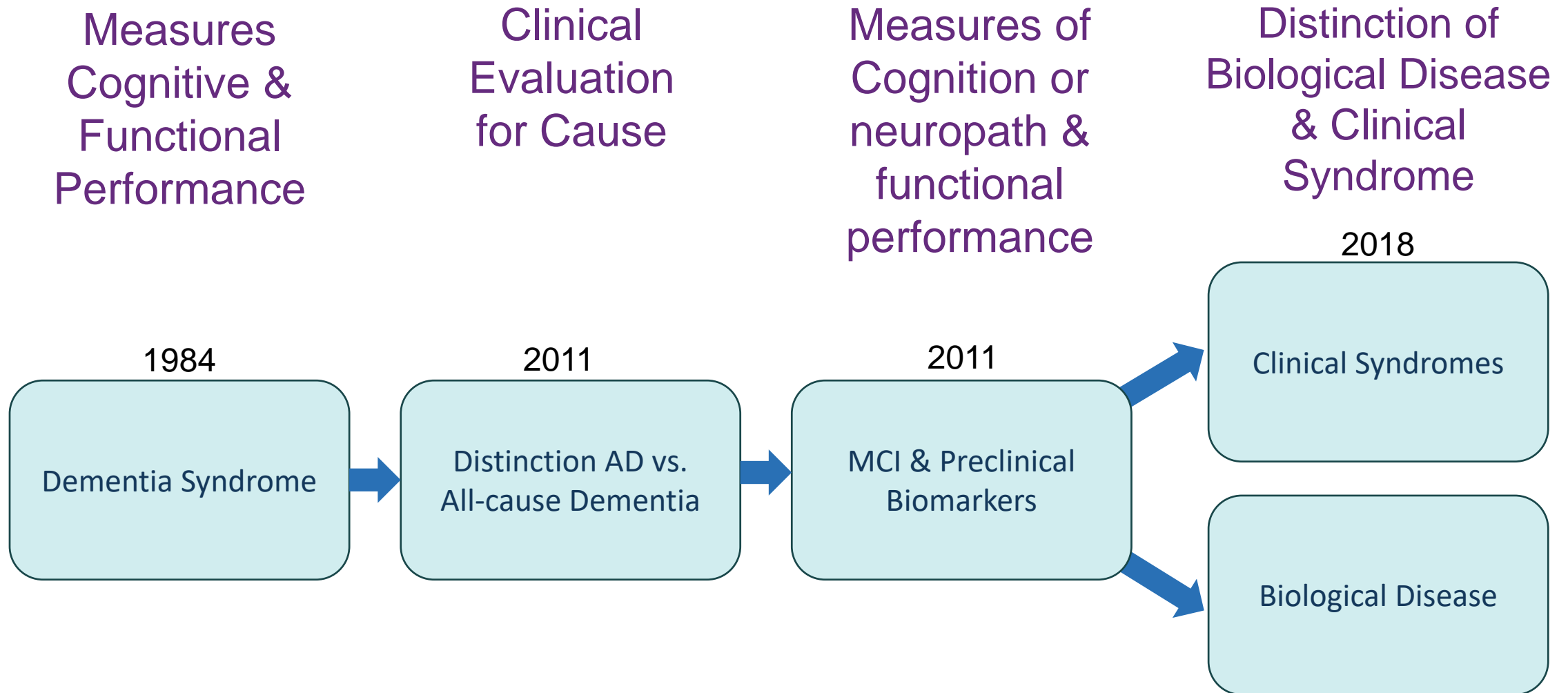


## B. Diagnostic Criteria / Construct Changes





# Target Disease Construct Determines Data Need



## Eligibility: Considerations for Target Population

- Does type of dementia matter?
  - Alzheimer's Disease
  - Vascular Dementia
  - Frontotemporal Dementia
  - Lewy Body Disease
  - Mixed forms
- Does severity/stage matter?
- Does presence of behavioral symptoms matter?
- Does whether cognitive impairment is due to a dementia matter?



What data elements  
are needed to  
identify your target  
population?

# Recruitment: *How will participants be identified?*

## Traditional Approach:

- One-by-One referral/volunteer
- Study Staff Collect Detailed Information

## Pragmatic Approach:

- Using existing data
- Often randomize by site rather than individual participant



How can the approach  
can be scalable to  
hundreds of sites for  
purposes of the study?

\*\*\*\*\*

What information will be  
available to use in "real  
world" when intervention  
is embedded into usual  
care?



## Setting: *Where will the intervention occur?*

Hospital

Emergency Room

Nursing home

Area Agency on Aging

Home Care Agencies

Clinic - primary care, specialty



What data sources already exist in the setting?

Does the data strategy integrate into the workflow, or will it require changing the workflow?



## Setting 2: *Which health care system?*

Academic medical center

Integrated Health System

Veteran's administration

Area Agency on Aging sites

Independent Nursing homes or part of a chain



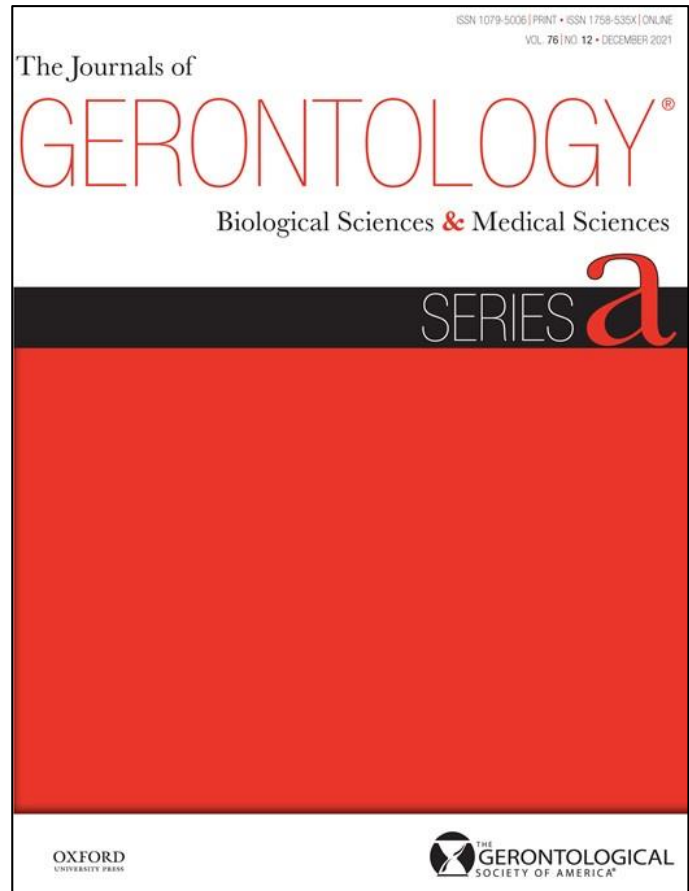
What is the system's readiness for using healthcare-generated data for research?

Does anything about the organizational strategy have impact on study generalizability?



# How important is diagnostic accuracy?

## Example of Participants Identified in Medicare Claims



### Validation of Claims Algorithms to Identify Alzheimer's Disease and Related Dementias

Ellen P McCarthy, Ph.D., MPH, Chiang-Hua Chang, Ph.D., MS, Nicholas Tilton, Ph.D, Mohammed U Kabeto, MS, Kenneth M Langa, MD, Ph.D, Julie P W Bynum, MD, MPH

*The Journals of Gerontology: Series A*, glab373, <https://doi-org.proxy.lib.umich.edu/10.1093/gerona/glab373>

### Identification Of Dementia In Recent Medicare Claims Data, Compared To Rigorous Clinical Assessments

Francine Grodstein, ScD ✉, Chiang-Hua Chang, PhD, Ana W Capuano, PhD, Melinda C Power, ScD, David X Marquez, PhD, Lisa L Barnes, PhD, David A Bennett, MD, Bryan D James, PhD, Julie P W Bynum, MD Author Notes

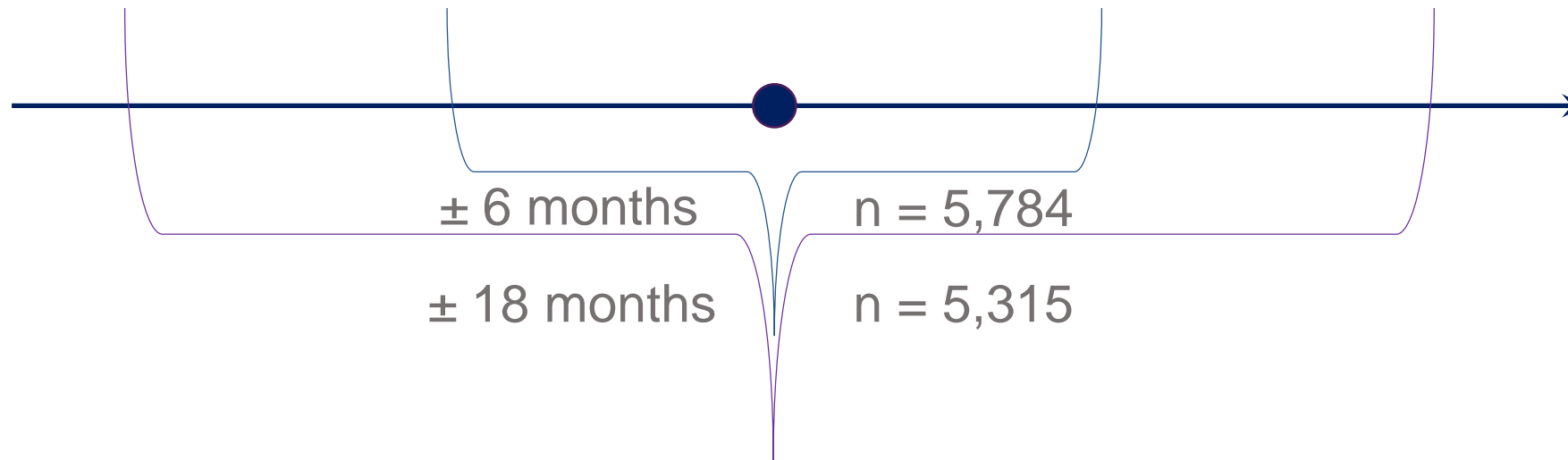
*The Journals of Gerontology: Series A*, glab377, <https://doi-org.proxy.lib.umich.edu/10.1093/gerona/glab377>

# Statement of the Problem

- Claims data routinely used to identify people with ADRD for multiple purposes: research, public health surveillance, payment policy, increasingly for pragmatic trials
- CCW algorithm based on Taylor 2009
  - ❖ Based on 1990s clinical practice and last validated on 2001 claims against ADAMS and requires 3 years of data
- Assess accuracy and validity based on more contemporary practice
  - ❖ Pragmatic trials require shorter reference or look back
  - ❖ Improve understanding of misclassification

# Health and Retirement Study Cohort, 2006-2012

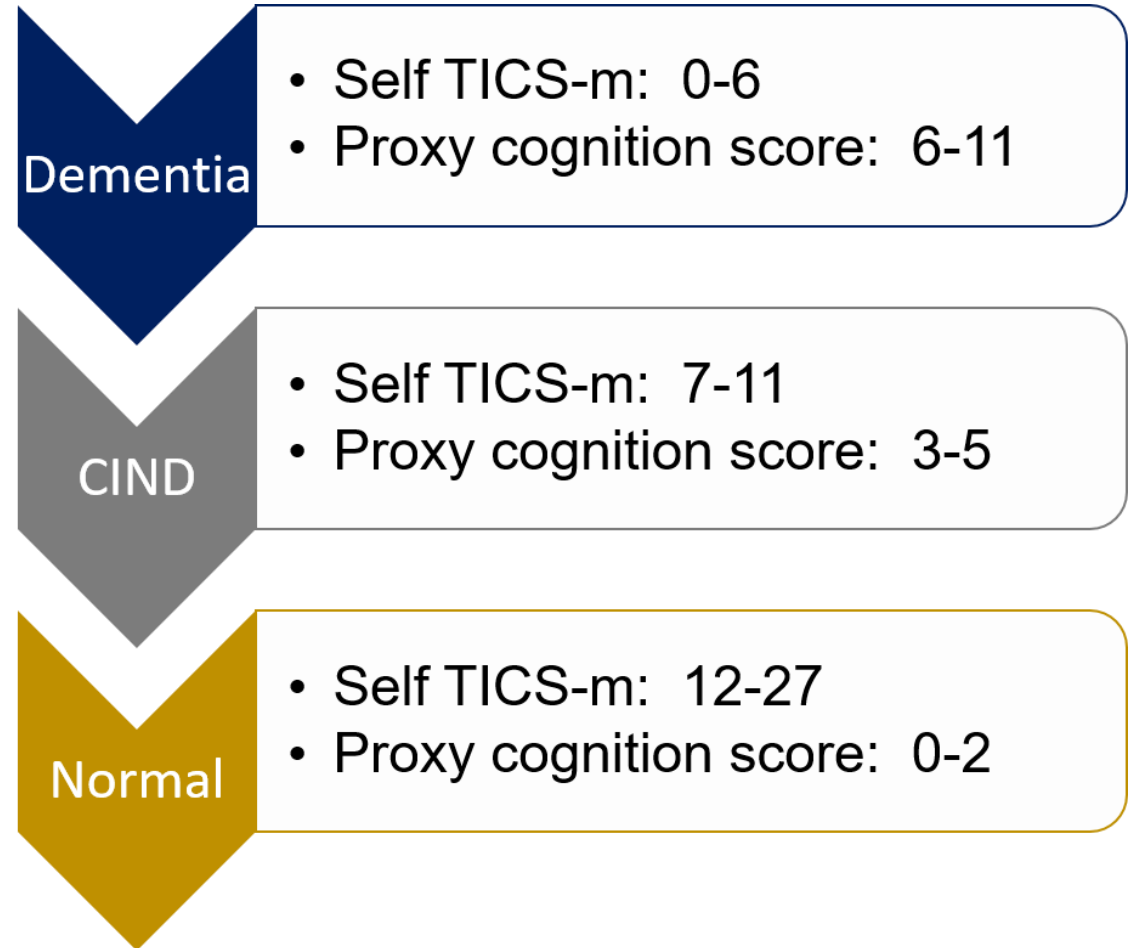
- Participants age  $\geq 65.5$  in 2012, continuously enrolled in Parts A & B fee-for-service
- Medicare enrollment and claims data 2010-2014 (last full year ICD-9)
  - 88% of participants consented to Medicare linkage
- Constructed 1-yr & 3-yr reference periods around 2012 interview date





# Reference Standard: HRS Cognitive Status

- Langa-Kebato-Weir method, cutpoints validated against ADAMS
  - Self: Modified TICS assessed immediate & delayed word recall, serial-7, and backward counting from 20
  - Proxy cognition score derived from proxy's assessment of participant's memory, difficulties with 5 IADLS, and interviewer rating of whether cognition was reason for proxy response



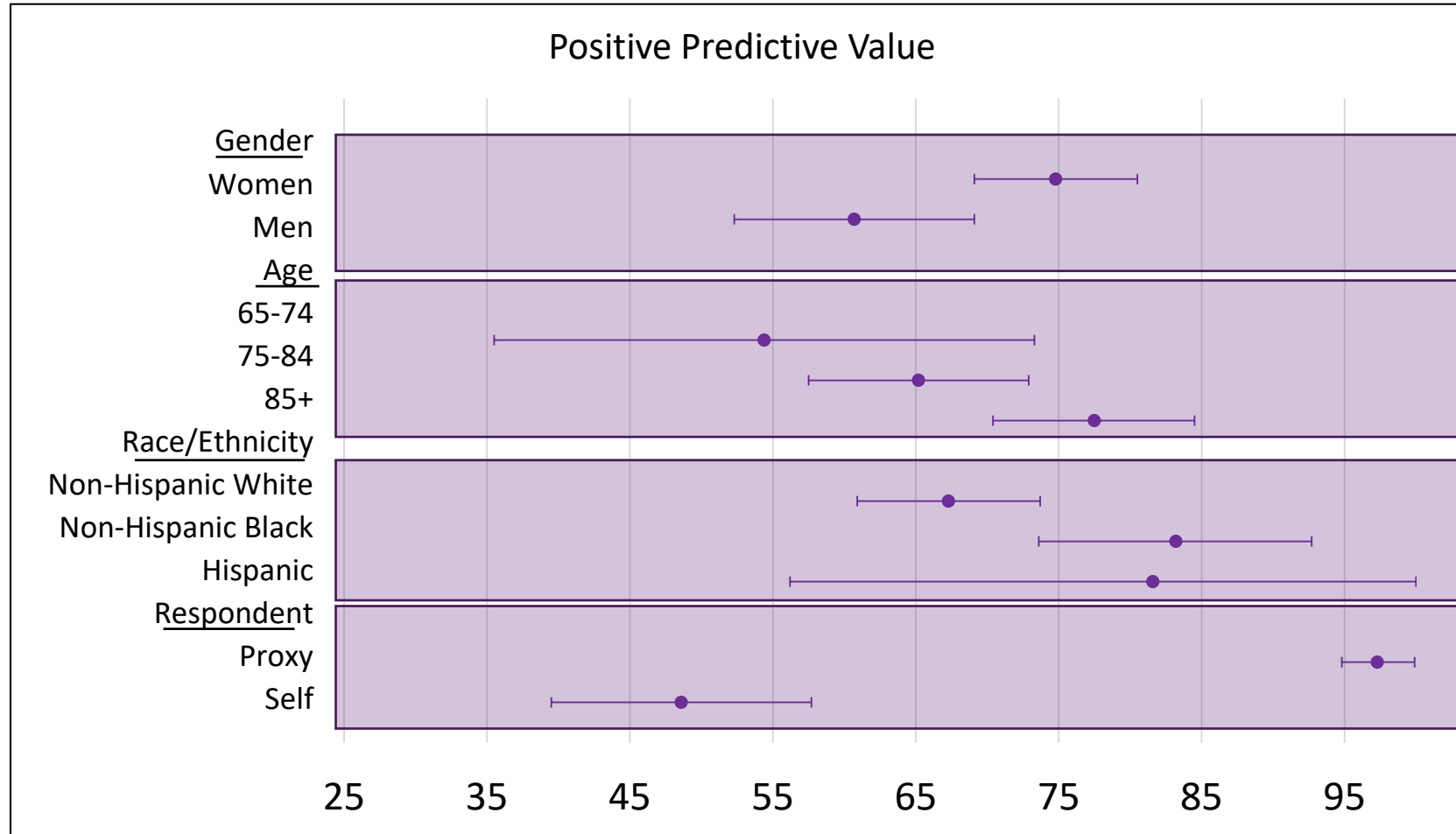
# ADRD Algorithms

3-years		1-year and 3-year	
CCW	<ul style="list-style-type: none"><li>• CCW ICD-9 Dx Codes</li><li>• Any claim inpatient, SNF, HHA, HOF, and</li><li>• Carrier claims<ul style="list-style-type: none"><li>• Types 71- 72 (non-DME)</li><li>• Excl. BETOS for DME &amp; ambulance</li></ul></li></ul>	Bynum E&M	<ul style="list-style-type: none"><li>• CCW <b>plus</b><ul style="list-style-type: none"><li>• 331.82: Lewy body dem</li><li>331.89: Cerebral ataxia</li><li>290.8: Senile psychosis NEC</li></ul></li><li>• Any inpatient, SNF, HHA, <b>hospice</b><ul style="list-style-type: none"><li>• HOF: <b>RHC, FQHC, &amp; CAH</b></li><li>• Carrier: Types 71-72 (non-DME) + <b>BETOS for E&amp;M</b></li></ul></li></ul>
			<ul style="list-style-type: none"><li>• CCW + <b>added codes</b></li><li>• Any claim inpatient, SNF, HHA, <b>hospice</b></li><li>• HOF &amp; Carrier claims<ul style="list-style-type: none"><li>• <b>2 claims &gt; 7 days</b></li><li>• HOF: <b>RHC, FQHC, CAS</b></li><li>• Carrier: Types 71-72 (non-DME)</li></ul></li></ul>

# PPV of Claims-Based Algorithms relative to HRS Cognitive Status

ADRD Algorithm	Positive Predictive Values (PPV)	Sensitivity	Specificity
CCW, 3-year	53.8 (49.4-58.2)	56.8	92.3
Bynum E&M, 3-year	56.2 (51.5-60.8)	52.2	93.5
Bynum Standard, 3-year	60.2 (55.2-65.1)	48.8	94.9
Bynum E&M, 1-year	64.5 (59.1-69.8)	35.4	97.1
Bynum Standard, 1-year	70.3 (65.0-75.6)	31.3	98.0

# Standard 1-Year Algorithm PPV by Subgroup



## Positive Predictive Value is:

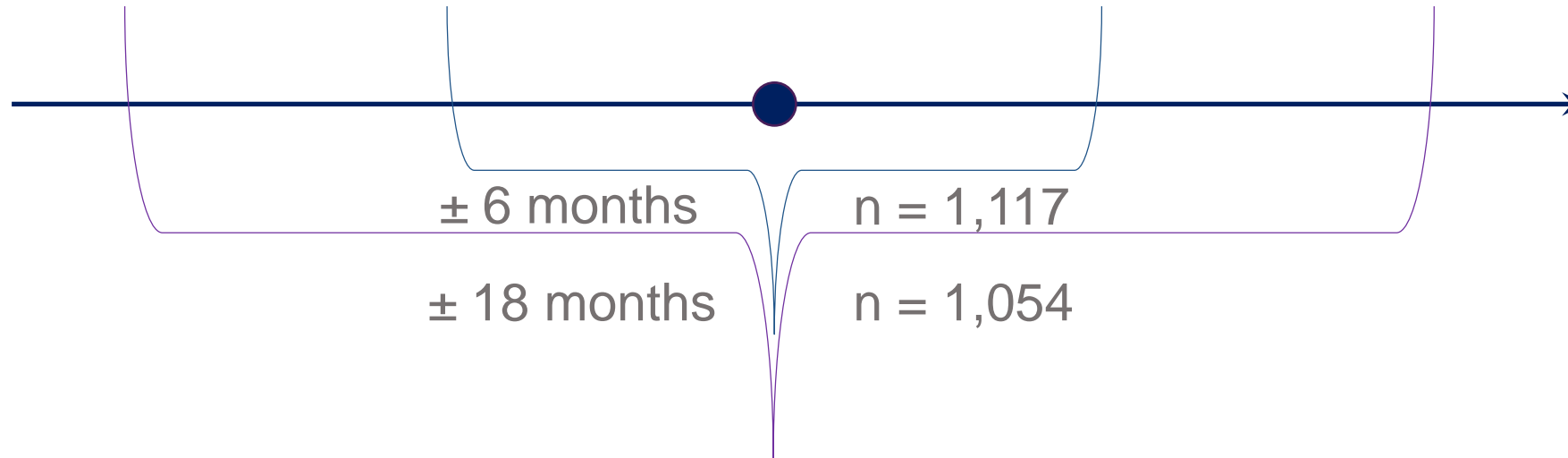
- Higher with older age
- Higher if person uses proxy in HRS
- Higher black or Hispanic (CI wide)

# Rush ADC Cohorts

- Participants in all 5 Cohorts\* age  $\geq 65$
- Medicare enrollment and claims data for year 2016
  - 84% of participants consented to Medicare linkage
  - 70% continuously enrolled in Parts A & B fee-for-service
- Constructed 1-yr & 3-yr reference periods around 2016 interview date

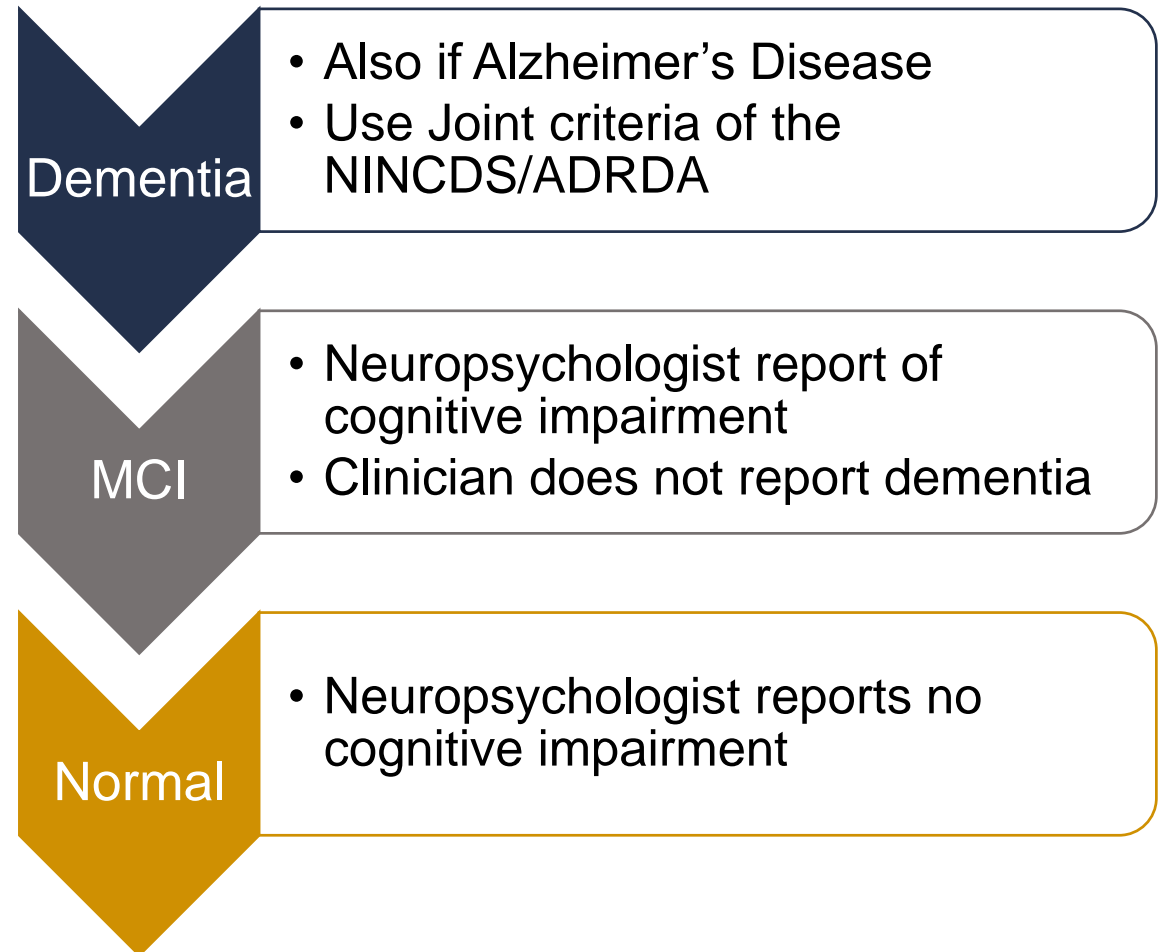
## \*5 Rush Cohort Studies

Religious Orders Study  
Rush Memory and Aging Project  
Minority Aging Research Study  
Rush African American Clinical Core  
Rush Latino Core



# Gold Standard: RADC Cognitive Status

- Annual, uniform, structured clinical evaluation harmonized across Cohorts
  - Neuropsychological and neurological evaluation
  - 18 cognitive tests
  - Severity rated across 5 domains
- Neuropsychologist blinded to sociodemographics renders clinical judgment on presence of dementia
- Experienced clinician reviews all data renders final clinical diagnosis



# ADRD Algorithm: Chose “Standard”

1 & 3-years	
Bynum Standard	• CCW + <b>added codes</b>
	• Any claim inpatient, SNF, HHA, hospice
	• HOF & Carrier claims
	• <b>2 claims &gt; 7 days</b>
	• HOF: <b>RHC, FQHC, CAS</b>
	• Carrier: Types 71-72 (non DME)

- Allowed both ICD-9 and ICD-10 codes
  - ICD-10 began Oct 2015
  - Note that all cases had ICD-10 dementia claims diagnoses on record
- Also ran same study in 2012 interview year

# PPV of Claims-Based Algorithm relative to RADC and HRS Cognitive Status

ADRD Algorithm	Comparator	Positive Predictive Values (PPV)	Sensitivity	Specificity
Bynum Standard, 1-year	RADC	58 (51-66)	64 (56-72)	93 (92-95)
Bynum Standard, 3-year	RADC	50 (43-56)	79 (73-86)	88 (86-90)
Bynum Standard, 1-year	HRS	70 (65-76)	31 (32-39)	98 (97-98)
Bynum Standard, 3-year	HRS	60 (55--65)	49 (46-52)	95 (94-96)

RADC Sample sizes: 1-year (n=1,184)  
3-years (n=1,054)

HRS Sample sizes: 1-year (n=5,784)  
3-years (n=5,315)



# Who are the False Positives?

DX in Claims	DX in Cohort Eval		
	Yes	No	Total
Yes	92	66	158
No	52	908	960
Total	144	974	1118

## Selected in, but no dementia

- Older
- More comorbidity
- More functional impairment
- Lower MMSE
- More MCI
- Frequent subjective complaints

False positives meet criteria for dementia in subsequent years:  
 @ 1 year 16%; @ 2 years 30%

	False Positives (N=66)	True Negatives (N=908)
Age	85 yrs	81 yrs
Male	24%	22%
White	78%	77%
Mean Education	16 yrs	17 yrs
MMSE	26.6	28.2
Subj Memory Concerns	51%	29%
Cohort DX MCI	72%	44%
ADL limitations, 3+	11%	5%
iADL limitations, 3+	34%	15%
Number Comorbidities	7	4
Hospitalized in year	59%	36%

$p < 0.001$

Grodstein, *Journal of Gerontology: Medical Science*, In Press

# Who are the False Negatives?

DX in Claims	DX in Cohort Eval		
	Yes	No	Total
Yes	92	66	158
No	52	908	960
Total	144	974	1118

Missed cases, with dementia

- More likely Non-White
- Less functional impairment
- But no difference in subjective complaints or education

	False Negatives (N=52)	True Positives (N=92)
Age	89	90
Male	suppressed	19
White	75	90
Mean Educ	16	17
MMSE	20	15.4
Subj Memory Concerns	41	45
ADL limitations, 3+	suppressed	48
iADL limitations, 3+	52	82
Number Comorbidities	4	5
Hospitalized in year	39	56

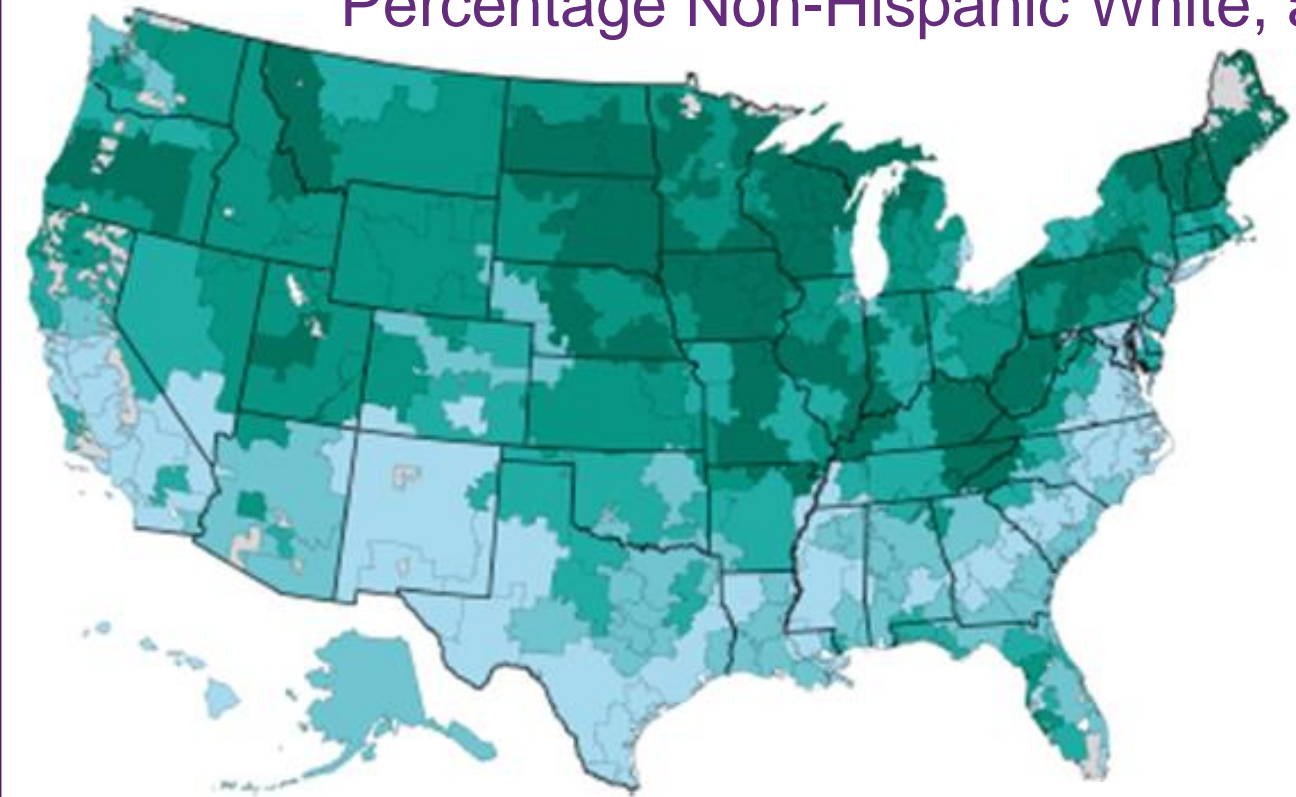
# Claims-based ADRD Diagnostic Accuracy

## Interpretation

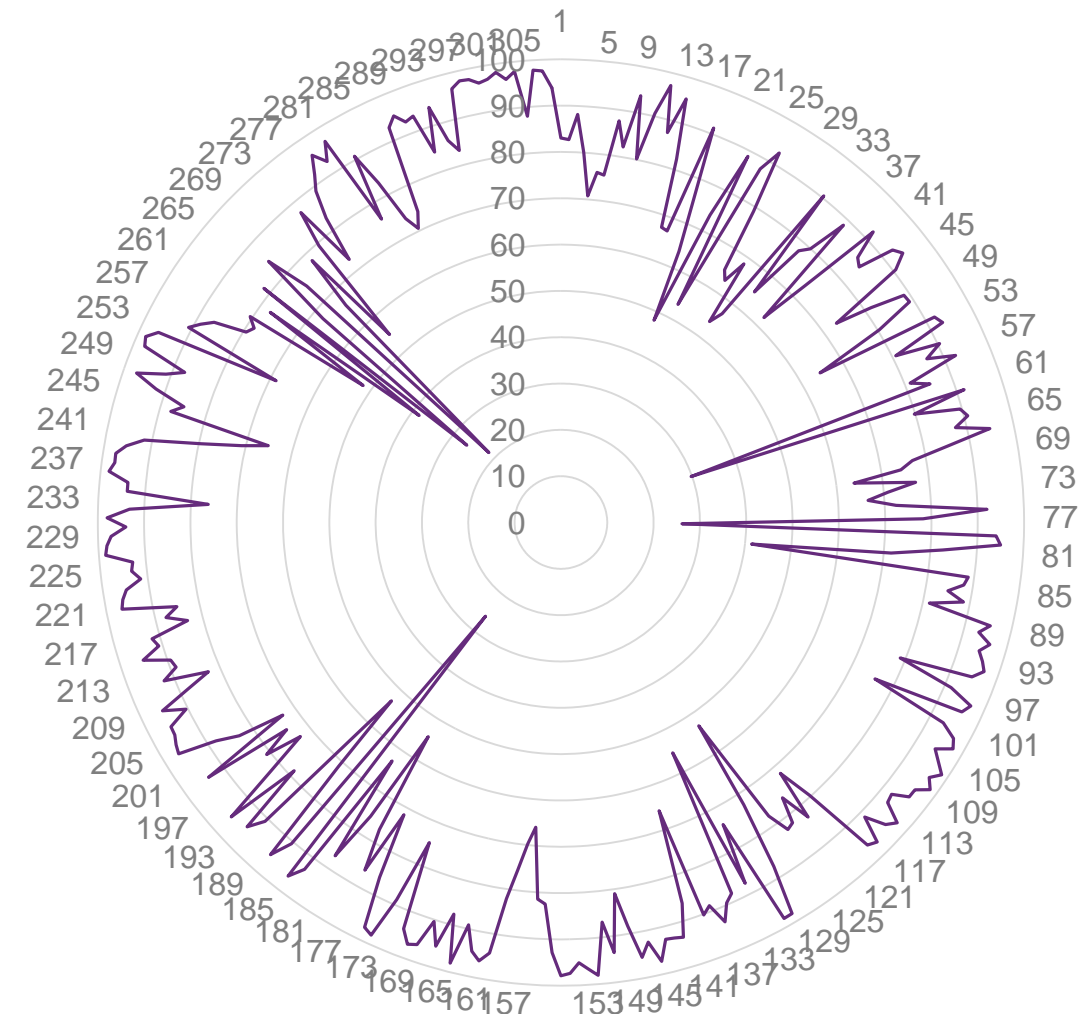
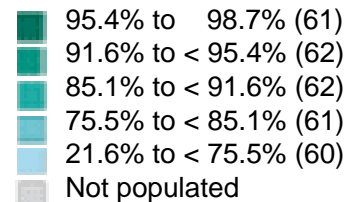
- Use of 1 year of data with algorithm like standardly used across many disease performs well. Appears worse with gold standard for comparison likely because our clinical diagnostic accuracy is not precise.
- Sensitivity is the weakness of claims data
- Certain subgroups when flagged with ADRD are more likely to be accurately identified (older, uses a proxy, Black race, more severe disease)
- False positives are not normal cognitively or functionally
- False negatives more likely to be non-White and less functionally impaired.

# How important is population representation?

## Geographic Distribution of FFS Medicare Percentage Non-Hispanic White, age 65+ by HRR (2012)



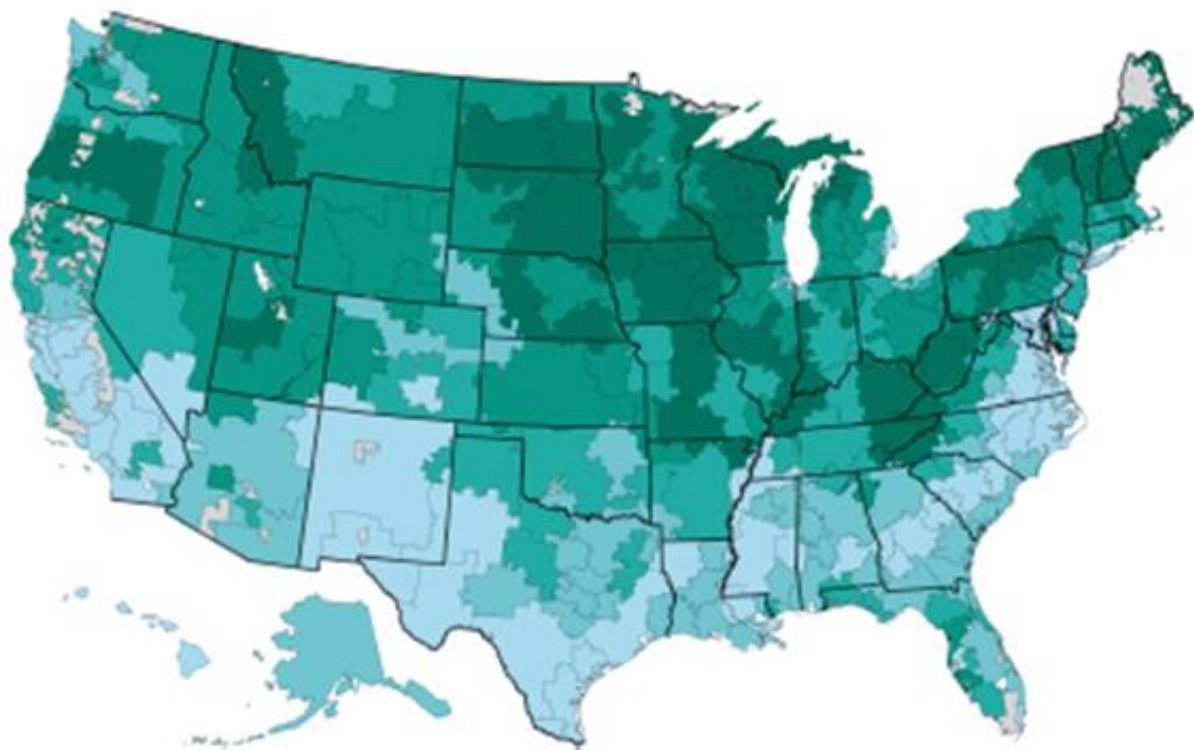
**Percent of Medicare Populations  
Comprising Non-Hispanic Whites  
By Hospital Referral Region (2012)**



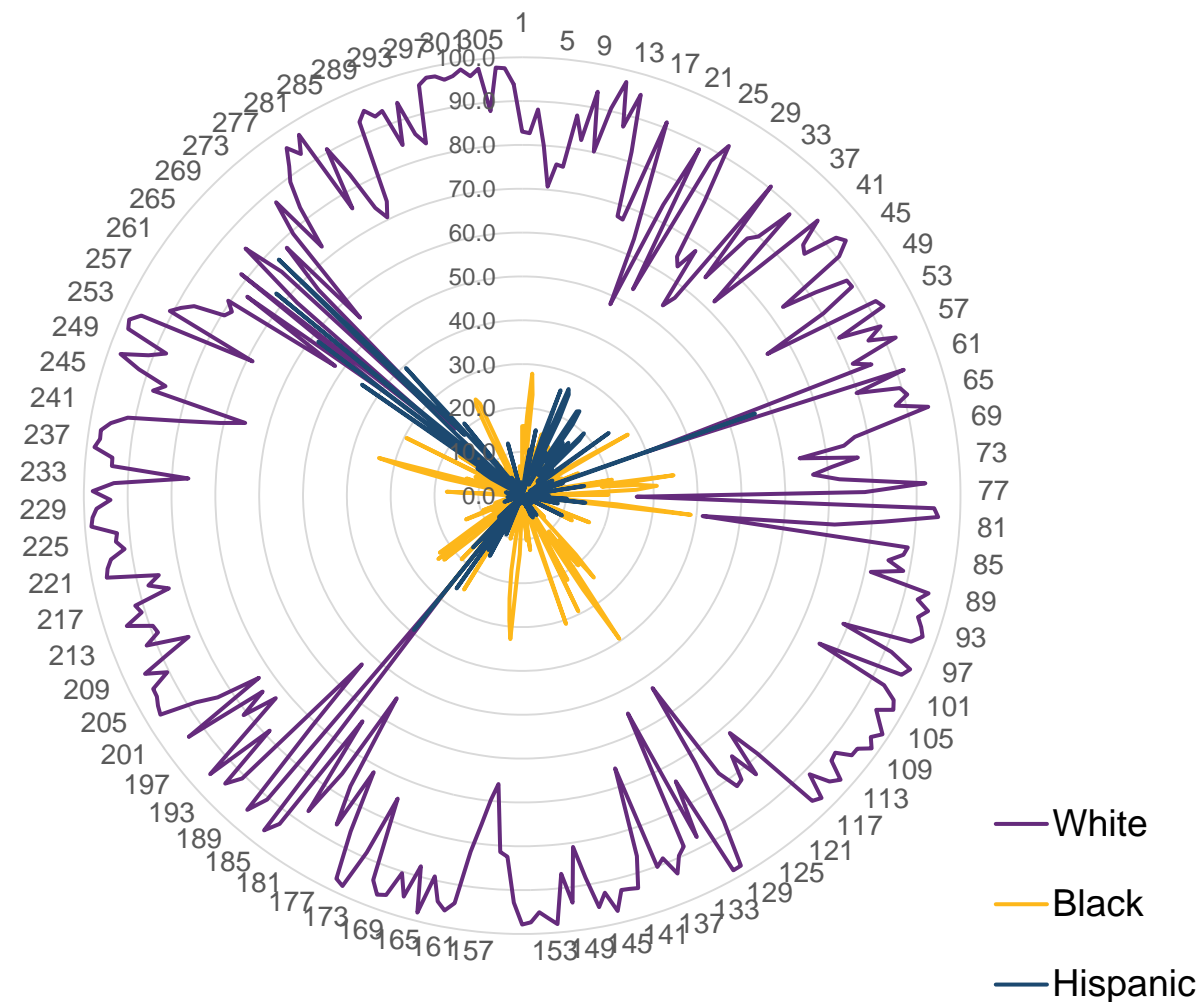
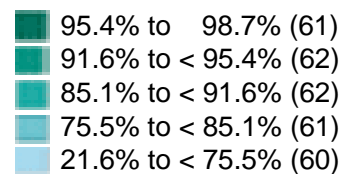
Source: Dartmouth Atlas

# Place Important for Representation

## Geographic Distribution of FFS Medicare Percentage by Race, age 65+ by HRR (2012)



**Percent of Medicare Populations  
Comprising Non-Hispanic Whites**  
*By Hospital Referral Region (2012)*



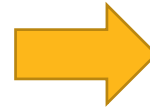


# Regional Data Created by Technical Data Core

## ADRD Cases identified in FFS Medicare 2018

### Methods

- ⑩ Age 65+
- ⑩ In Medicare Parts A & B (no HMO)
- ⑩ Algorithm in:
  - ⑩ McCarthy E.P et al (in press) Validation of Claims Algorithms to Identify Alzheimer's Disease and Related Dementias. *J. Gerontol.*
- ⑩ Based on zip code of residence



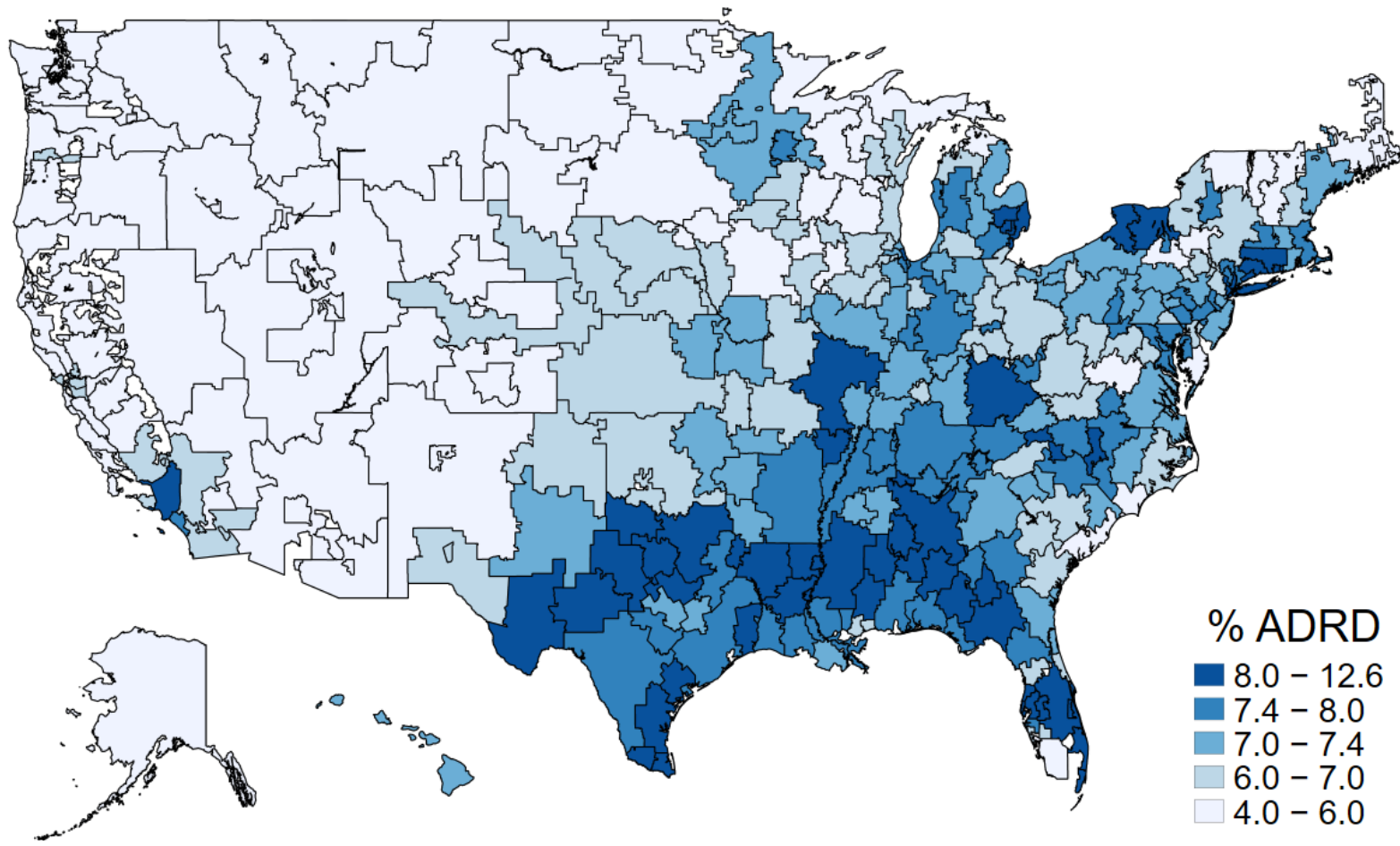
We identify the number of beneficiaries with diagnosed dementia by age, sex, race for each:

- ✓ State
- ✓ Hospital Referral Region (HRR)
- ✓ Hospital Service Area
- ✓ Primary Care Service Area

**NOTE:** We can query this data for investigators interested in knowing potential sample sizes



# Crude Proportion of Medicare FFS Benes, age 65+ with diagnosed dementia by HRR, 2018



Source: IMPACT TDC Analysis

## Informing health equity and generalizability

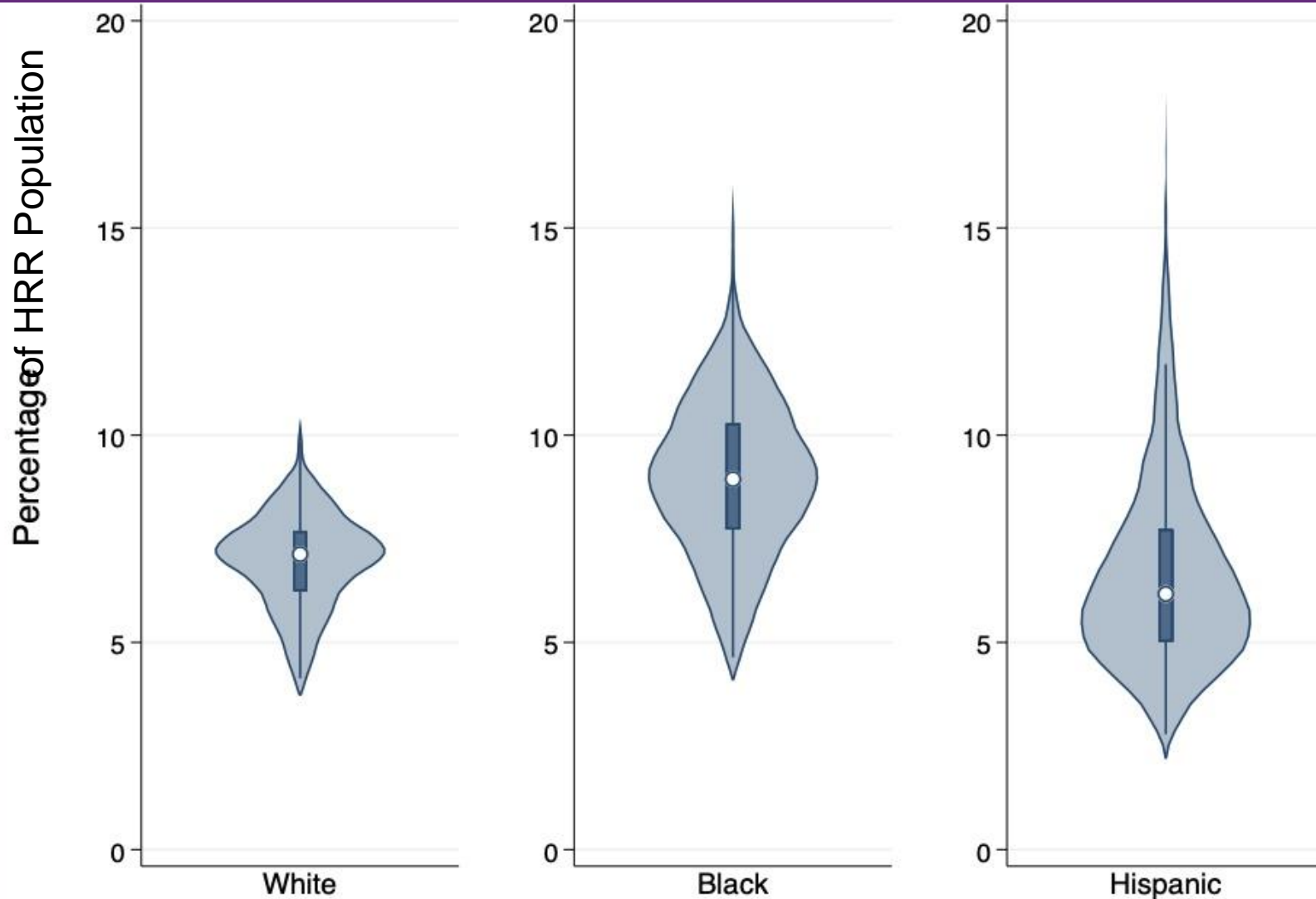
*Variation in diagnosed  
cases across place and  
race*

Why would proportion of  
population with ADRD be  
different across place?

❖ Warranted variation

❖ Unwarranted variation

# Proportion of Medicare FFS Beneficiaries age 65+ with diagnosed dementia by race, 2018



Source: IMPACT TDC Analysis

## Informing health equity and generalizability

*Variation in diagnosed cases across place and race*

- Epidemiological studies indicate higher risk in Blacks & Hispanics but result different using claims diagnosis
- Average proportion higher in Blacks than Whites
- Average proportion lower in Hispanics than White

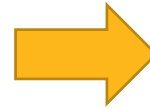


# Facility Data created by Technical Data Core

## ADRD Cases identified in FFS Medicare 2018

### Methods

- ⑩ Age 65+
- ⑩ In Medicare Parts A & B (no HMO)
- ⑩ Algorithm in:
  - ⑩ McCarthy E.P et al (in press) Validation of Claims Algorithms to Identify Alzheimer's Disease and Related Dementias. *J. Gerontol.*
- ⑩ Determine by facility number of people for each facility



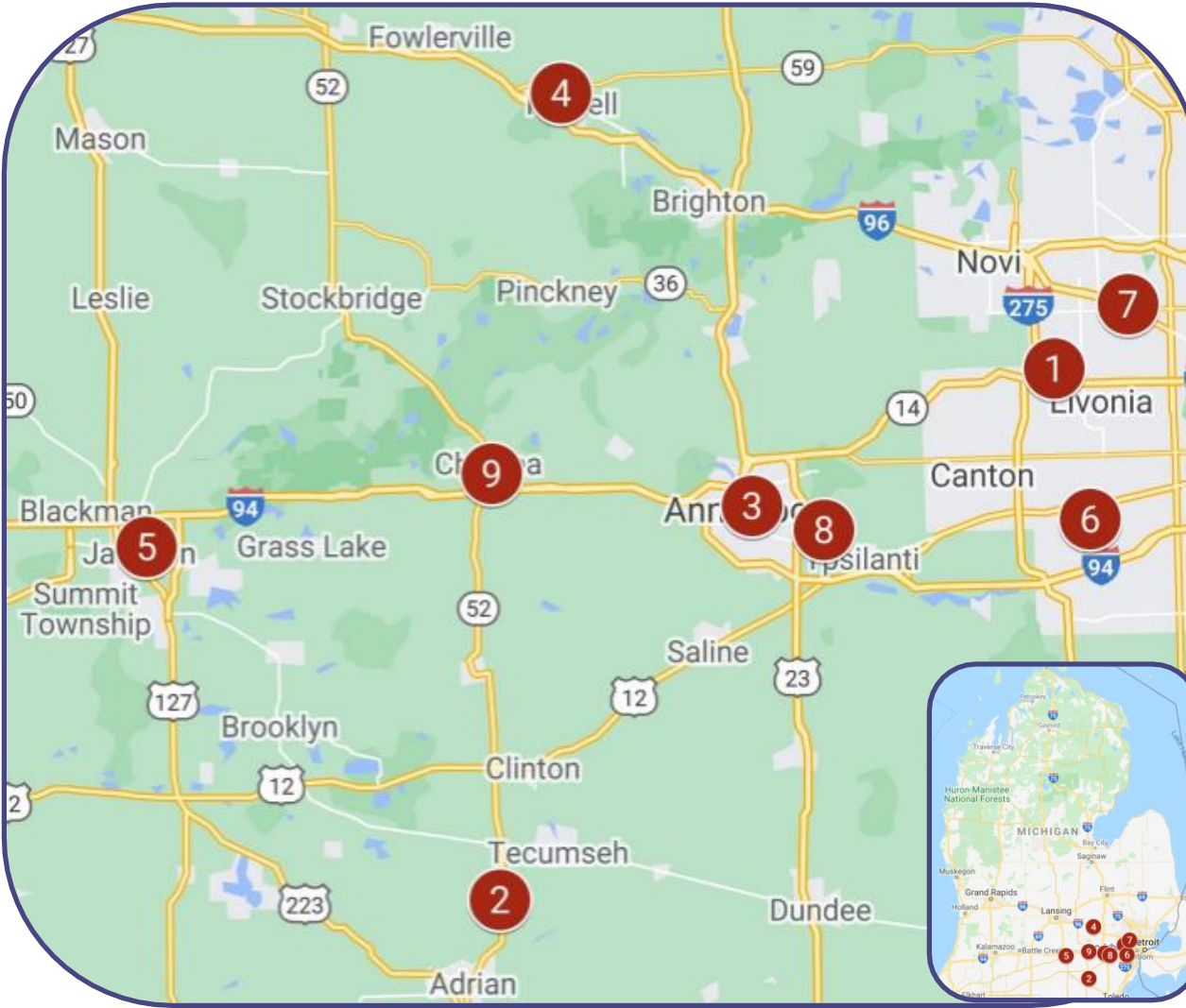
We identify the number of beneficiaries with diagnosed dementia by age, sex, race for each:

- ✓ Hospital
- ✓ Emergency Department
- ✓ Post-acute SNF Facility
- ✓ Long-stay Nursing Facility

**NOTE:** We can query this data for investigators interested in knowing potential sample sizes

# Informing health equity and generalizability

Variation in diagnosed admitted cases across settings



- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9

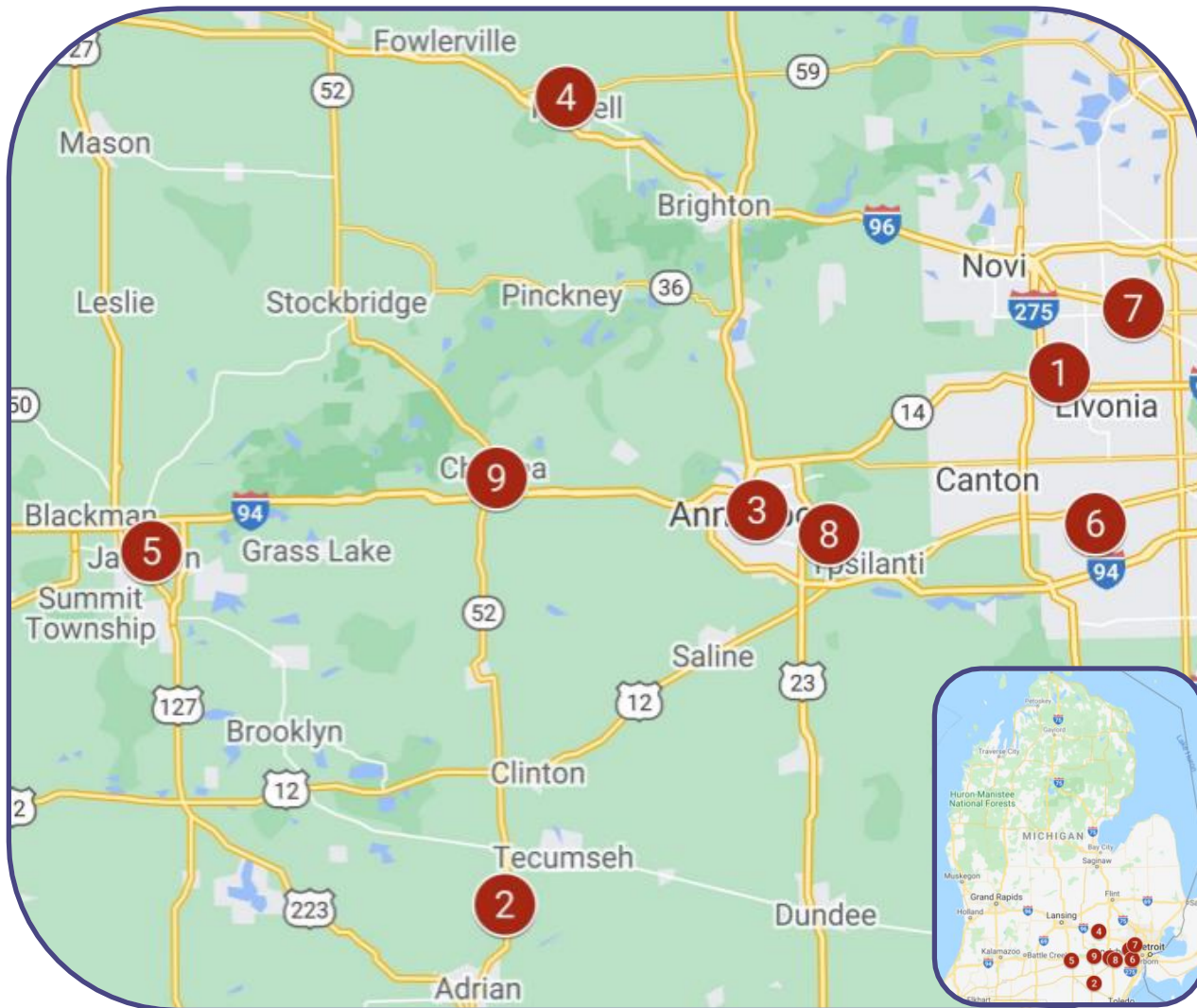
*Do patients with different characteristics seek or receive care in different sites within a setting?*

**EXAMPLE:** HRR 232 - Ann Arbor, Michigan

Source: IMPACT TDC Analysis

# Informing health equity and generalizability

Variation in diagnosed admitted cases across settings



HRR 232 - Ann Arbor, MI Hospital Label		Admits (n)	Percent Admits for Person with Dementia
1	St. Mary Mercy Hospital	6,130	31.9%
2	Promedica Charles and Virginia Hickman Hospital	1,197	22.5%
3	University of Michigan Health System	9,411	12.5%
4	St. Joseph Mercy Livingston Hospital	1,262	21.5%
5	Henry Ford Allegiance Health	5,977	17.8%
6	Beaumont Hospital – Wayne	1,927	33.8%
7	Beaumont Hospital – Farmington Hills	4,240	37.2%
8	St. Joseph Mercy Hospital	9,215	20.5%
9	St. Joseph Mercy Chelsea	1,588	16.9%

**EXAMPLE:** HRR 232 - Ann Arbor, Michigan

**Source:** IMPACT TDC Analysis

# Medicare Claims for Participant Identification

## Strengths

- Participants and non-participants included
- Uniform data elements allow use same algorithm across sites with ease
- Uniform data use agreement across all sites if CMS source
- Validated algorithms



## Weaknesses

- Inherent biases and equity issues present in usual care
- Depends on quality of diagnosis in usual care
- Managed care?  
Encounter data not yet validated
- Issues of timeliness are dissipating with VRDC





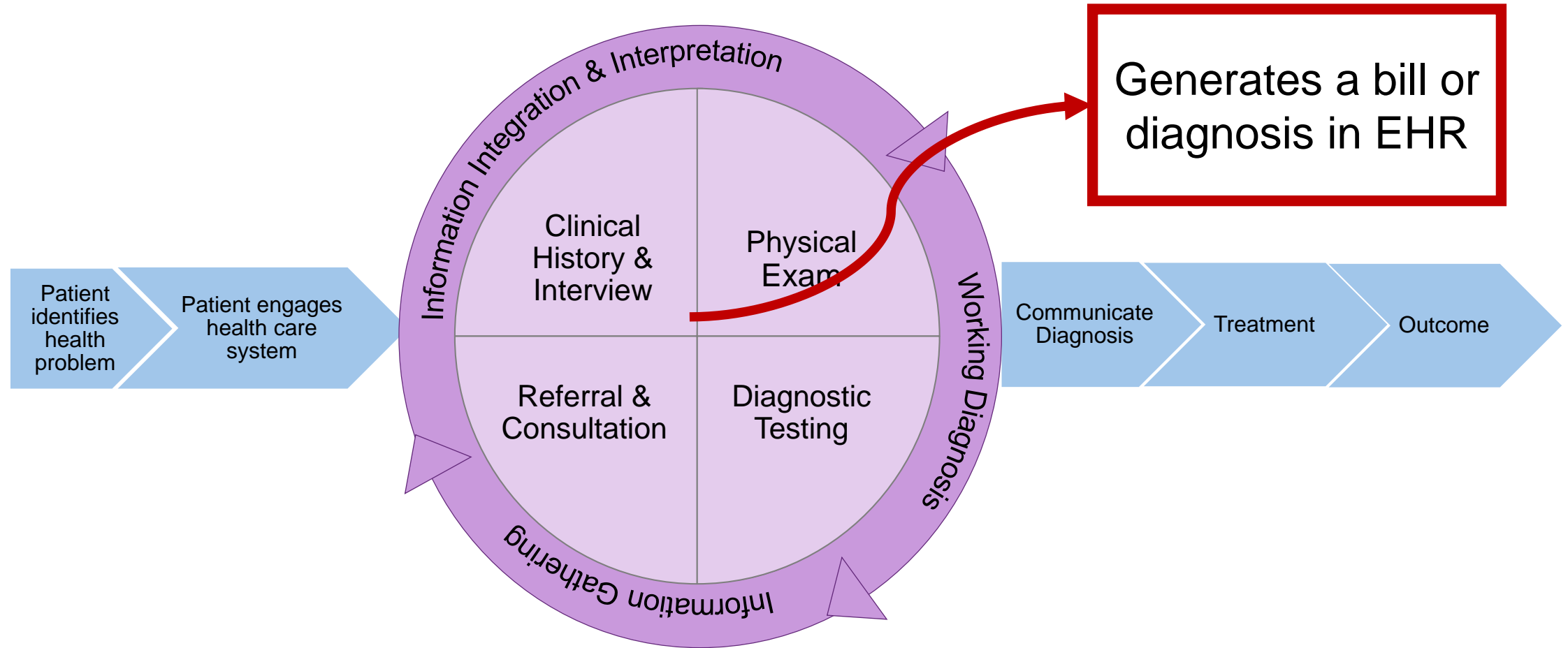
# Electronic Health Records: Panacea or Pandora?

## Comparison to claims:

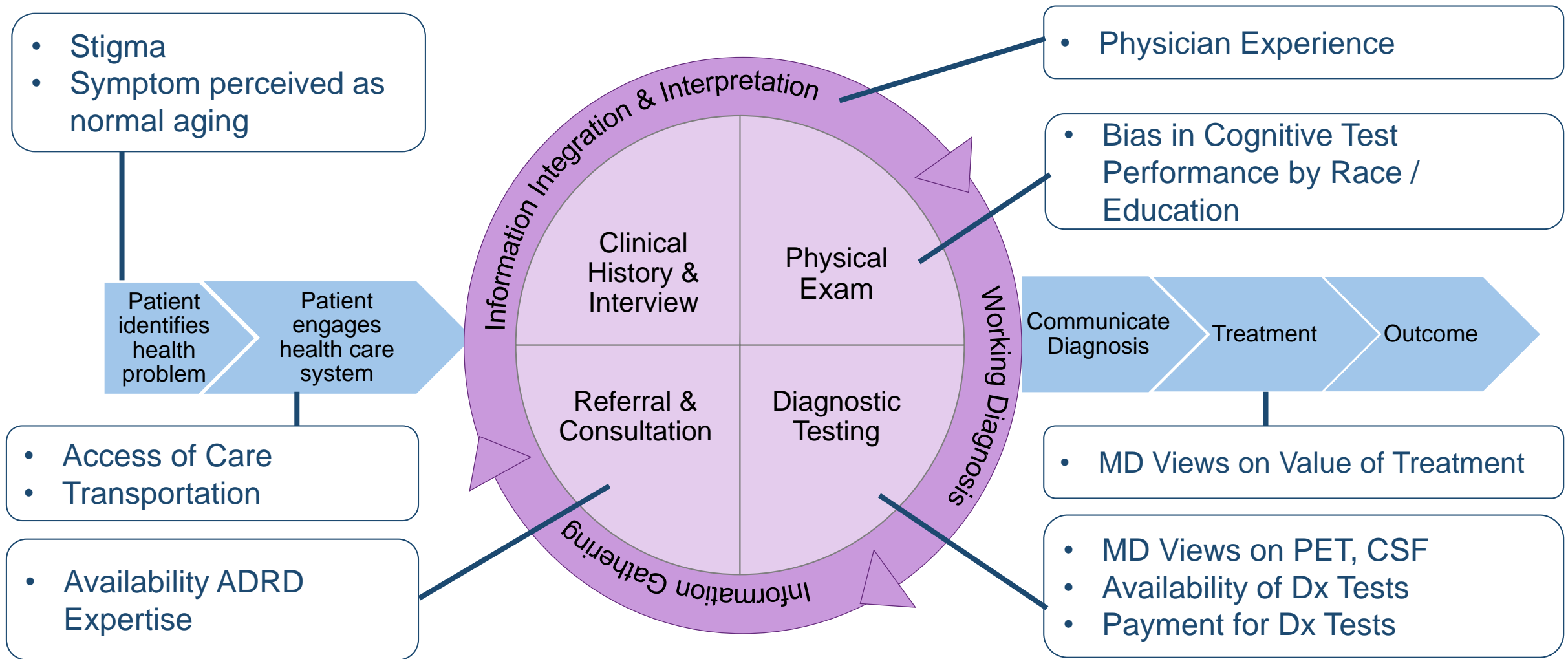
- Contains all payers and ages
- Same inherent biases and quality of diagnosis quality
- Typically need permission each site or system separately



# Process of Obtaining a Diagnosis



# Many Challenges Obtaining a Diagnosis



# Electronic Health Record and Health Equity

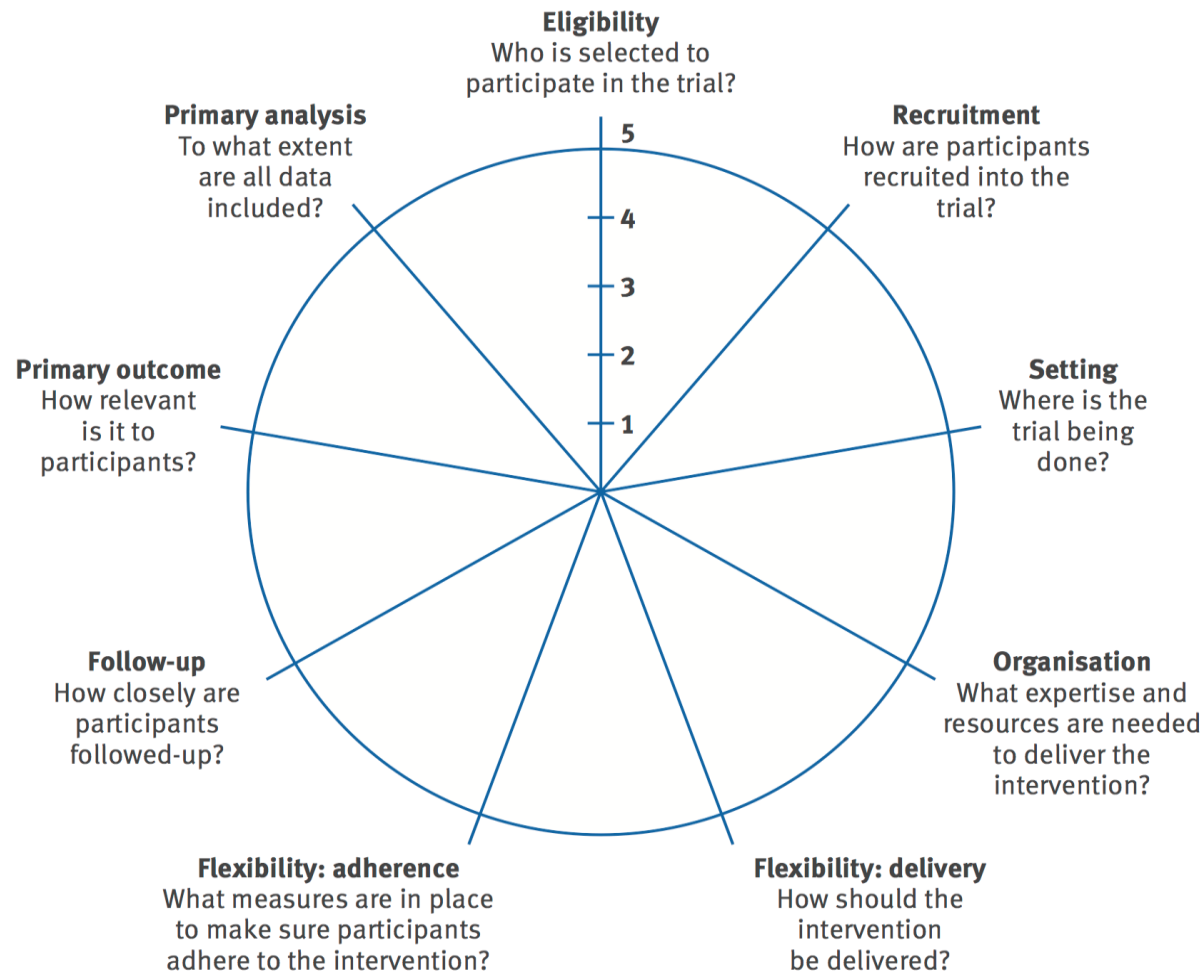
*Many discussions, publications, workshops on how data itself and how it is processed can induce inequities*

## New algorithms & validation

- Access to unstructured data elements creates opportunity for new methods of identification (text, ML)
- Algorithms typically validated against billing diagnoses
- Validation of algorithms not available across sites, must be evaluated at each site



# Electronic Health Record



## Organization:

What are the capabilities of your planned organization to do this data work? And what does it mean for future dissemination?

## Follow-up/Outcomes:

Opportunity to use functions in EHR for monitoring recruitment, delivery, adherence, and person-centered outcome collection

# Closing

- Healthcare-generated data in pragmatic trial design can enhance scalability and intervention application in the "real world."
- Dependency on billing and EHR data for identification of subjects presents limitations for accuracy of case identification and detail in characteristics which need to be considered as trade-offs in the design.
- Consider how inherent bias in underlying data, the settings chosen, analytic methods used (such as ML) can contribute to creating health equity challenges.

# Thanks

## Team at Michigan

Chiang-Hua Chang

Jason Mann

Slim Benloucif

Megan Jensen

Mark Iskandar

Pil Park

Jonathan Martindale

Clare Kolevar

## TDC Executive C'ee

David Dorr (OHSU)

Julie Lima (Brown)

Ellen McCreedy (Brown)

David Meyers (Brown)

Vinod Vydiswaran (Mich)

Richard Platt (Harvard)

Liaisons – Vince Mor &  
Ellen McCarthy

## Collaborators

Ellen McCarthy (Harvard)

Nicholas Tilton (Mich)

Mohammed Kabeto (Mich)

Ken Langa, MD (Mich)

Francine Grodstein (Rush)

Ana Capuano (Rush)

Lisa L Barnes (Rush)

David A Bennett (Rush)

Bryan D James (Rush)



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**Questions?**