

Update on Imaging Dementia-Evidence for Amyloid Scanning (IDEAS)

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Disclosures

IDEAS study is supported by:

- PET scans covered by U.S. Centers for Medicare and Medicaid Services
- Alzheimer's Association, American College of Radiology
- Avid Radiopharmaceuticals/Eli Lilly, GE Healthcare, Life Molecular Imaging

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- Associate Editor, JAMA Neurology

Outline

- **Overview of IDEAS study design and objectives**
- **Brief recap of Aim 1 results (patient management)**
- **Aim 2 analysis timeline (health outcomes)**
- **Secondary analyses**
 - Predictors of amyloid positivity
 - Demographics and outcomes in racial/ethnic minorities
 - Add-on studies

Outline (Cont.)

- **New IDEAS study approved by CMS 4/23/2020!**
 - Study design & aims

Single arm, multi-site, longitudinal study evaluating the clinical utility of amyloid PET in 18,295 Medicare beneficiaries with MCI or dementia meeting amyloid PET Appropriate Use Criteria (Johnson et al. 2013)

- Eligible patients referred for PET by dementia specialists
- PET performed with FDA-approved A β PET ligand
 - ^{18}F -florbetaben, ^{18}F -florbetapir, ^{18}F -flutemetamol
- **Aim 1: Impact of scan on management plan at 3 months**
- **Aim 2: Impact on major medical outcomes at 12 months**
- *The primary hypothesis is that, in diagnostically uncertain cases, amyloid PET will lead to changes in patient management, and these will translate into improved outcomes*

Inclusion/Exclusion Criteria

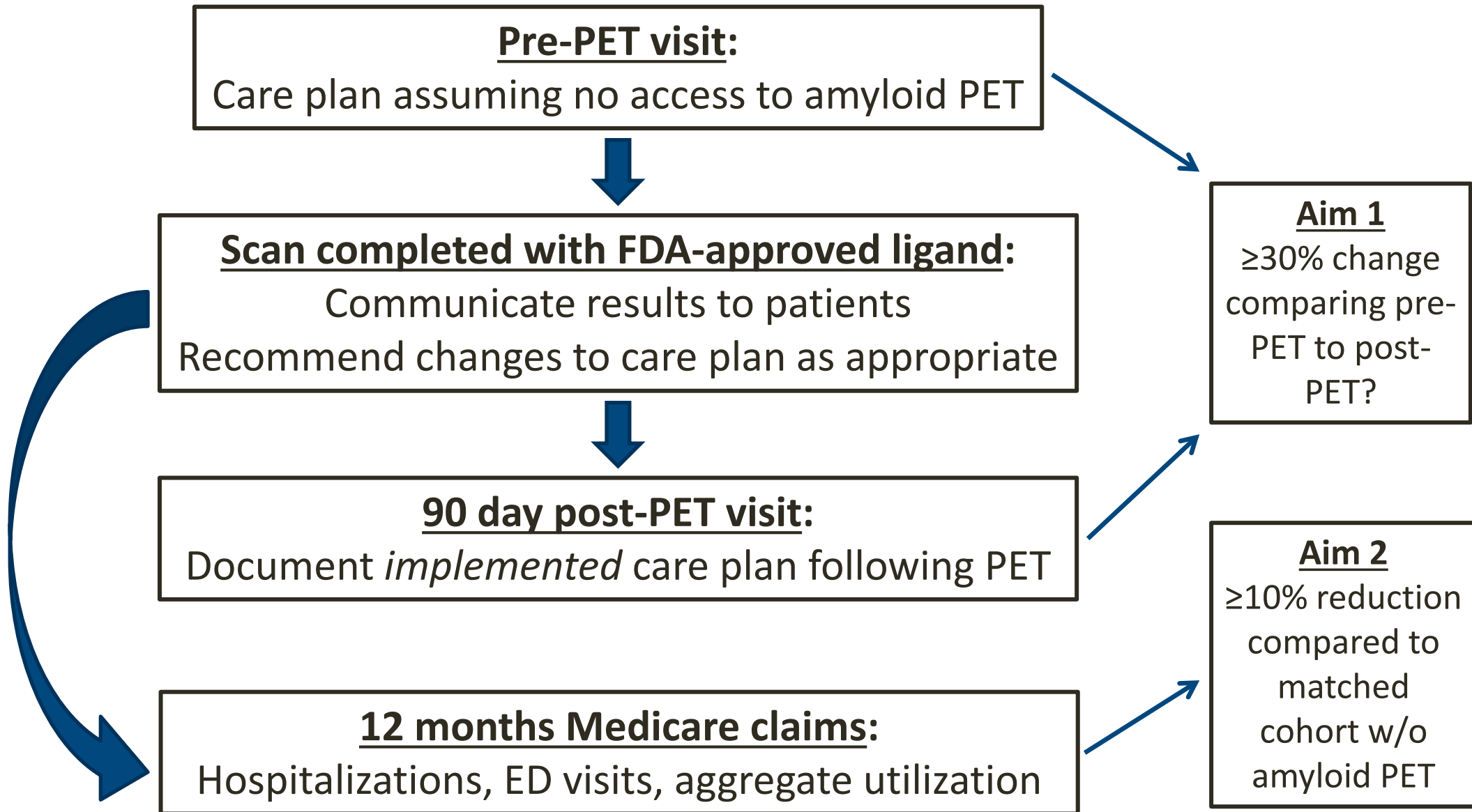
For complete list see: www.ideas-study.org

- **Primary Inclusion Criteria**

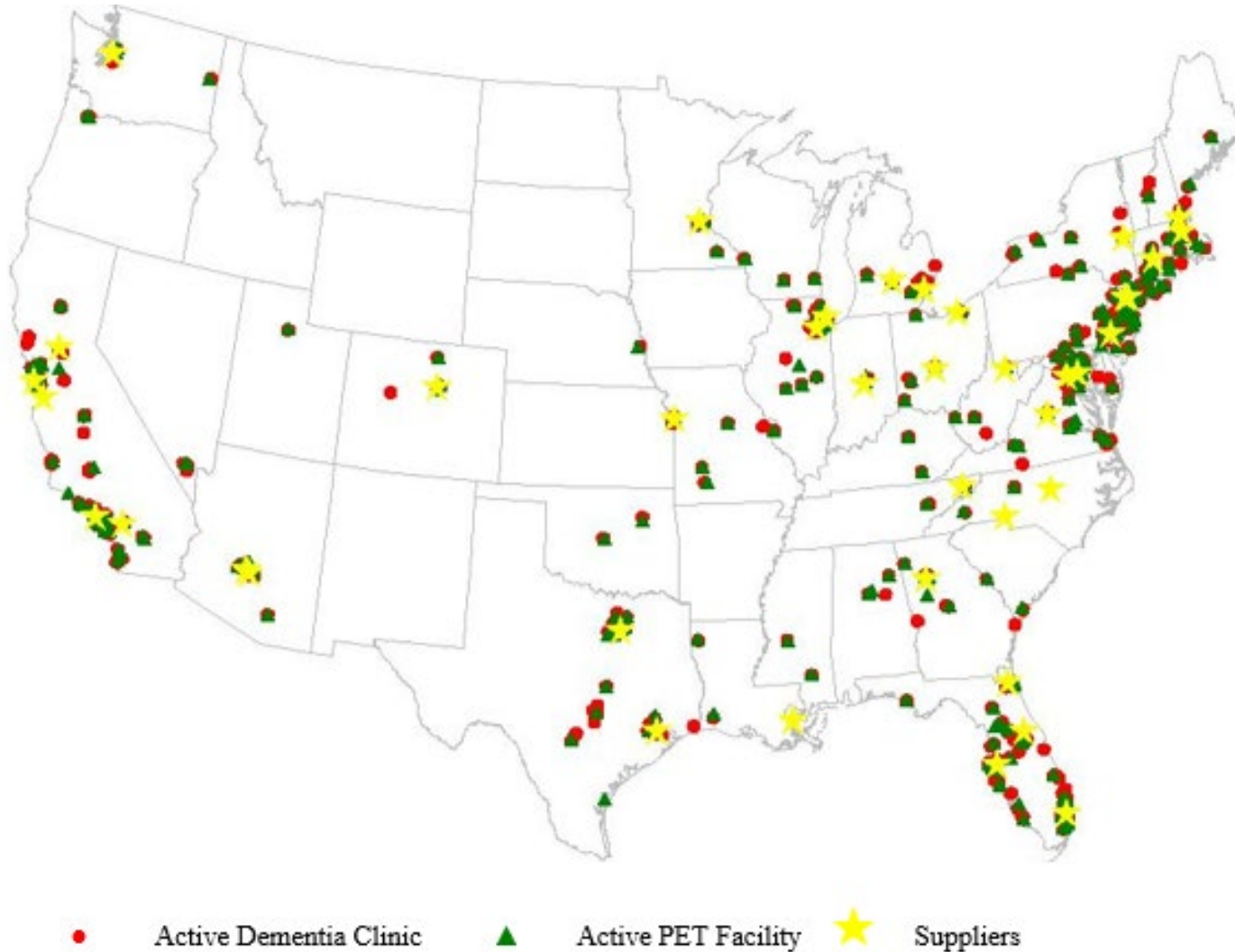
- Medicare beneficiary, age ≥ 65
- English or Spanish speaking (for purposes of consent)
- Meets Appropriate Use Criteria for amyloid PET
 - Objectively confirmed cognitive impairment (MCI/dementia)
 - Diagnosis uncertain after comprehensive evaluation by a dementia specialist (including labs and CT/MRI)
 - Knowledge of amyloid status expected to change management

- **Primary Exclusion Criteria**

- Amyloid status known, previous enrollment in anti-A β trial
- Knowledge of amyloid status expected to cause harm
- Life expectancy < 24 months based on medical co-morbidities
- Residence in a skilled nursing facility



IDEAS Study Network



595 dementia practices

79% private/group practice

946 dementia specialists

343 PET facilities

733 imaging specialists

18,295 scans completed

Feb 2016 – Feb 2018

Median age 75 (65-105)

60.4% MCI

39.6% dementia

PET A β +:

MCI 55.2%

Dementia 69.6%

JAMA | **Original Investigation**

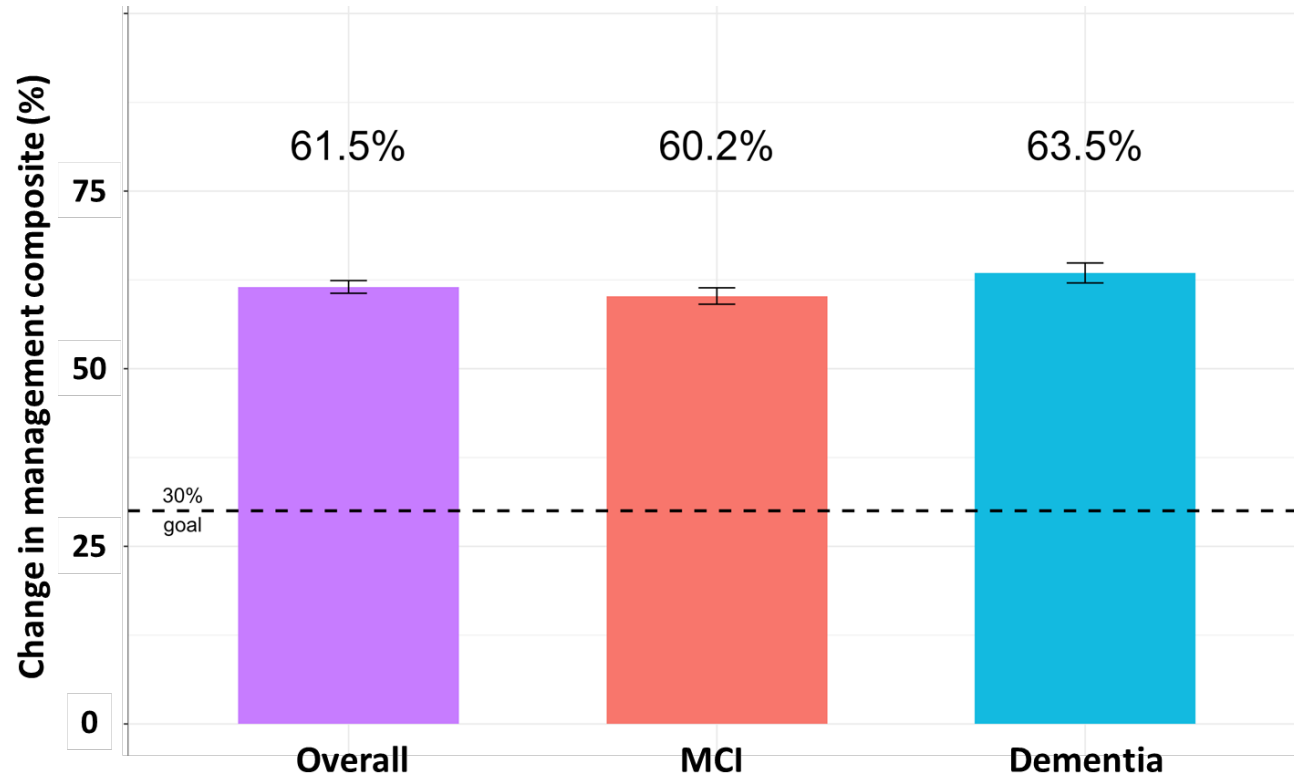
Association of Amyloid Positron Emission Tomography With Subsequent Change in Clinical Management Among Medicare Beneficiaries With Mild Cognitive Impairment or Dementia

Gil D. Rabinovici, MD; Constantine Gatsonis, PhD; Charles Apgar, MBA; Kiran Chaudhary, MS; Ilana Gareen, PhD; Lucy Hanna, MS; James Hendrix, PhD; Bruce E. Hillner, MD; Cynthia Olson, MBA; Orit H. Lesman-Segev, MD; Justin Romanoff, MA; Barry A. Siegel, MD; Rachel A. Whitmer, PhD; Maria C. Carrillo, PhD

JAMA 2019 321(13): 1286-1294

Amyloid PET Changes Patient Management (N=11,409)

Composite: AD drugs, non-AD drugs, counseling & referrals



Change in components:

AD drugs

MCI 43.6%, dementia 44.9%

Non-AD drugs

MCI 22.9%, dementia 25.4%

Counseling

MCI 24.3%, dementia 20.7%

Change in diagnosis

25.1% AD to non-AD

10.5% Non-AD to AD

Pre-PET dx was AD in 71.5% of PET-neg patients -> 10.2% post-PET

Aim 2: Approach and Endpoints

To assess the impact of brain amyloid PET on hospital admissions and emergency room visits in study patients (*amyloid PET-known*) compared to matched patients not in the study (*amyloid PET-naïve*) over 12 months

Primary Endpoint: determine if amyloid PET is associated with $\geq 10\%$ relative reduction in study patients compared to matched controls:

- Inpatient hospital admissions over 12 months
- Emergency room visits over 12 months

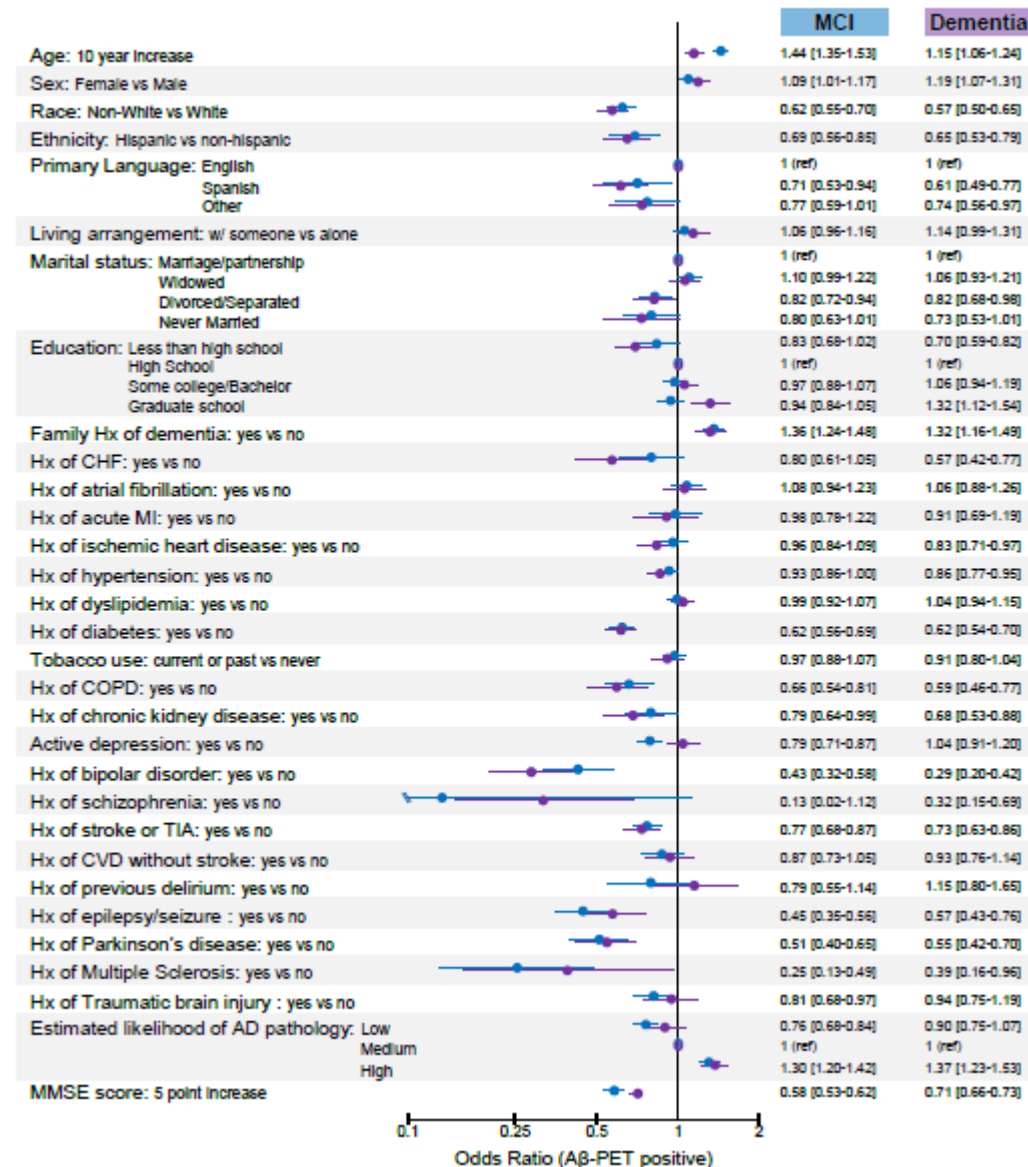
Secondary Endpoints:

- Preventable hospitalizations, aggregate resource utilization
- Associations between amyloid PET and health outcomes in:
 - A β -PET positive vs. A β -PET negative
 - MCI vs. dementia

Results expected in Summer 2020

Predictors of Amyloid Positivity

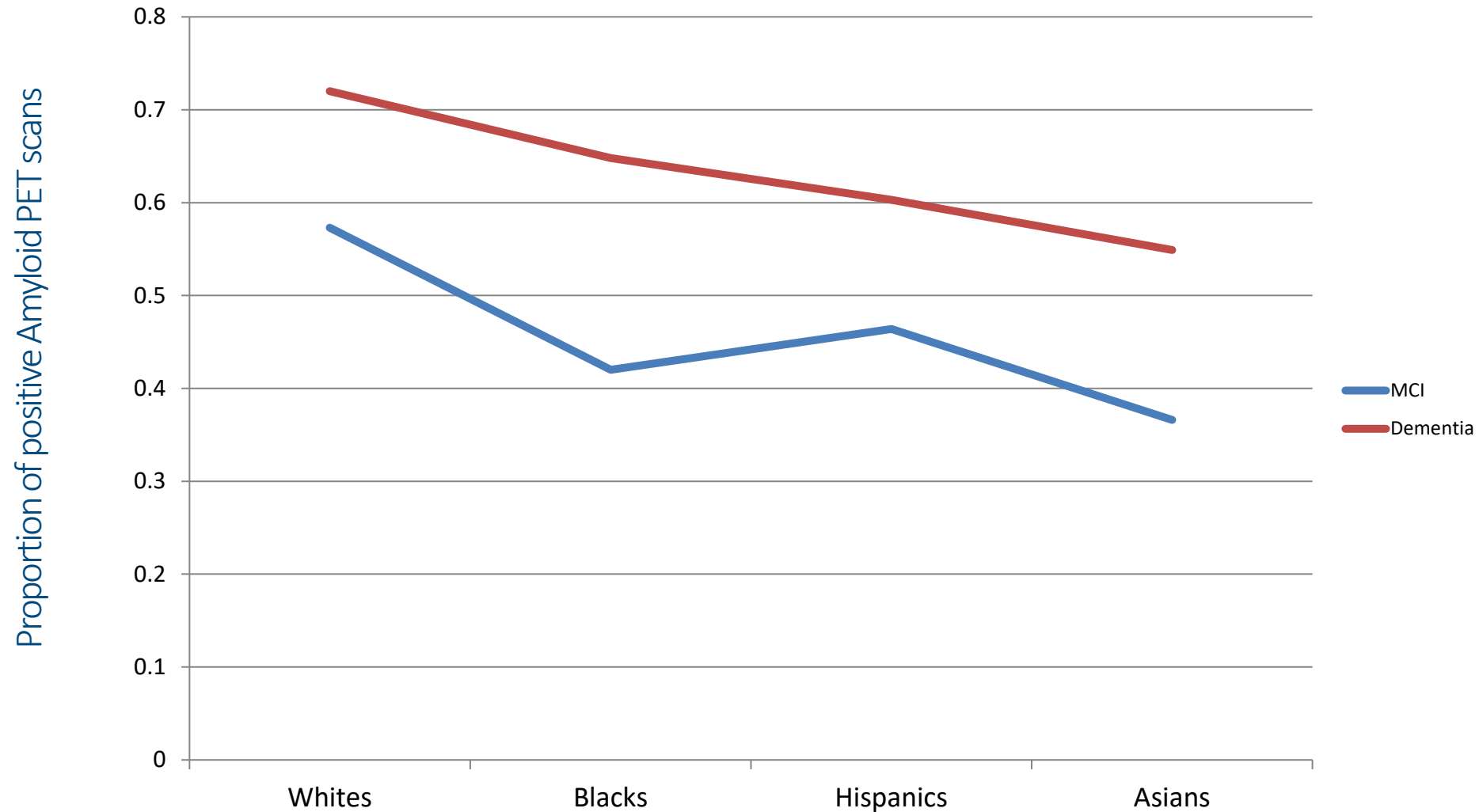
Lesman-Segev, La Joie et al.
in prep



Minorities in IDEAS: Window into Disparities in Dementia Care

- **Racial/ethnic minorities only 10.4% of participants**
 - 4.8% Hispanic, 3.4% Black, 1.8% Asian
- **Compared to Whites:**
 - All minorities more likely to have dementia
 - 52% Blacks, 56% Hispanics, 47% Asian, 37% Whites
 - More likely to have Medicare Advantage plan
 - Higher prevalence of diabetes (all), hypertension (Blacks)
 - Lower prevalence of family history of dementia

Lower Rates of PET-Positivity in Minorities vs. Whites

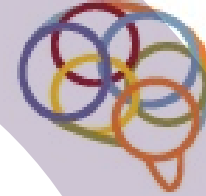




Genetic testing

PI: Taitiana Foroud, Indiana

N=1,946



BrainHealth
R E G I S T R Y

**Online cognitive testing
and questionnaires**

PI: Mike Weiner, UCSF

N=853

iDEAS
**Imaging Dementia—Evidence
For Amyloid Scanning**



Caregiver perspective

PI: Vince Mor, Brown

N=2,228

C₂N
Diagnostics

Plasma A β

N=697

New IDEAS: A Study to Improve Precision in Amyloid PET Coverage and Patient Care

- **Recruit diverse cohort of 7,000 Medicare beneficiaries**
 - At least 2,000 African-Americans/Blacks and 2,000 Latinx/Hispanics
 - Typical and atypical clinical presentations of AD
 - Early-onset and late-onset dementia
 - Biorepository (DNA and plasma) and image archive
- **Study approved by CMS 4/23/2020**
 - Hope to launch late summer/early fall 2020, COVID-19 permitting
 - Recruitment over 3 years

New IDEAS: Study Aims

- **AIM 1**: To compare 12-month claims-derived health outcomes in amyloid PET-positive versus amyloid PET-negative individuals presenting with MCI and dementia in the entire study cohort of diverse Medicare beneficiaries
- **AIM 2**: To describe the association of amyloid PET findings with changes in patient management and 12-month claims-derived health outcomes among Blacks/African Americans, Latinos/Hispanics and Whites/Caucasians presenting with MCI and dementia
- **AIM 3**: To describe the association of amyloid PET findings with changes in management and 12-month claims-derived health outcomes in individuals presenting with typical (progressive amnesic) versus atypical clinical presentations of MCI and AD dementia
- **ADDITIONAL OBJECTIVES**:
 - Establish biorepository of DNA, plasma
 - Collect and archive PET images

New IDEAS, New Leadership



Consuelo H. Wilkins, MD, MSCI
Vanderbilt University & Meharry Medical College



Peggy Dilworth-Anderson, PhD
University of North Carolina Chapel-Hill



Sid O'Bryant, PhD
University of N Texas



Robert Rissman, PhD
UC San Diego

Conclusions and Next Steps

- **IDEAS study provides strongest Phase IV data to date supporting the impact of amyloid PET on patient management**
- Aim 2 results on health outcomes required for coverage reconsideration, expected Summer 2020
- New IDEAS: coming soon to a PET scanner near you
- **IDEAS data as a resource to research community**
 - Data sharing requests reviewed by Research & Publications Committee
 - Data and images to be placed on Global Alzheimer's Association Interactive Network

Acknowledgments

IDEAS Steering Committee

Study Chairs

Gil Rabinovici, UCSF
Maria Carrillo, Alzheimer's Association
Peggye Dilworth-Anderson, UNC
Constantine Gatsonis, Brown
Bruce Hillner, VCU
Sid O'Bryant, University of North Texas
Barry Siegel, Washington University
Rachel Whitmer, UC Davis
Consuelo Wilkins, Vanderbilt/Meharry

Additional committee members

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Susan DeSanti, Life Molecular Imaging
Adam Fleisher, Avid/Eli Lilly
Meridith Johnson, GE Healthcare

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MITA - Sue Bunning

Biostatistics Center (Brown)

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Rajesh Makineni, Justin
Romanoff, Yunjie Song

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