NIA IMPACT COLLABORATORY
TRANSFORMING DEMENTIA CARE

The Clinical Implementation of Alzheimer's Disease Biomarkers

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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 and ask them at the end
- Want to continue the discussion? Associated podcast released about 2 weeks after Grand Rounds
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Disclosures

- O’Brien: No relevant disclosures

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- Fowler: No relevant disclosures

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Learning Objectives

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

- Understand the landscape of Alzheimer's disease (AD) biomarker testing
- Describe the potential clinical utility of plasma AD biomarkers
- Identify barriers to plasma AD biomarker implementation in specialist and non-specialist settings

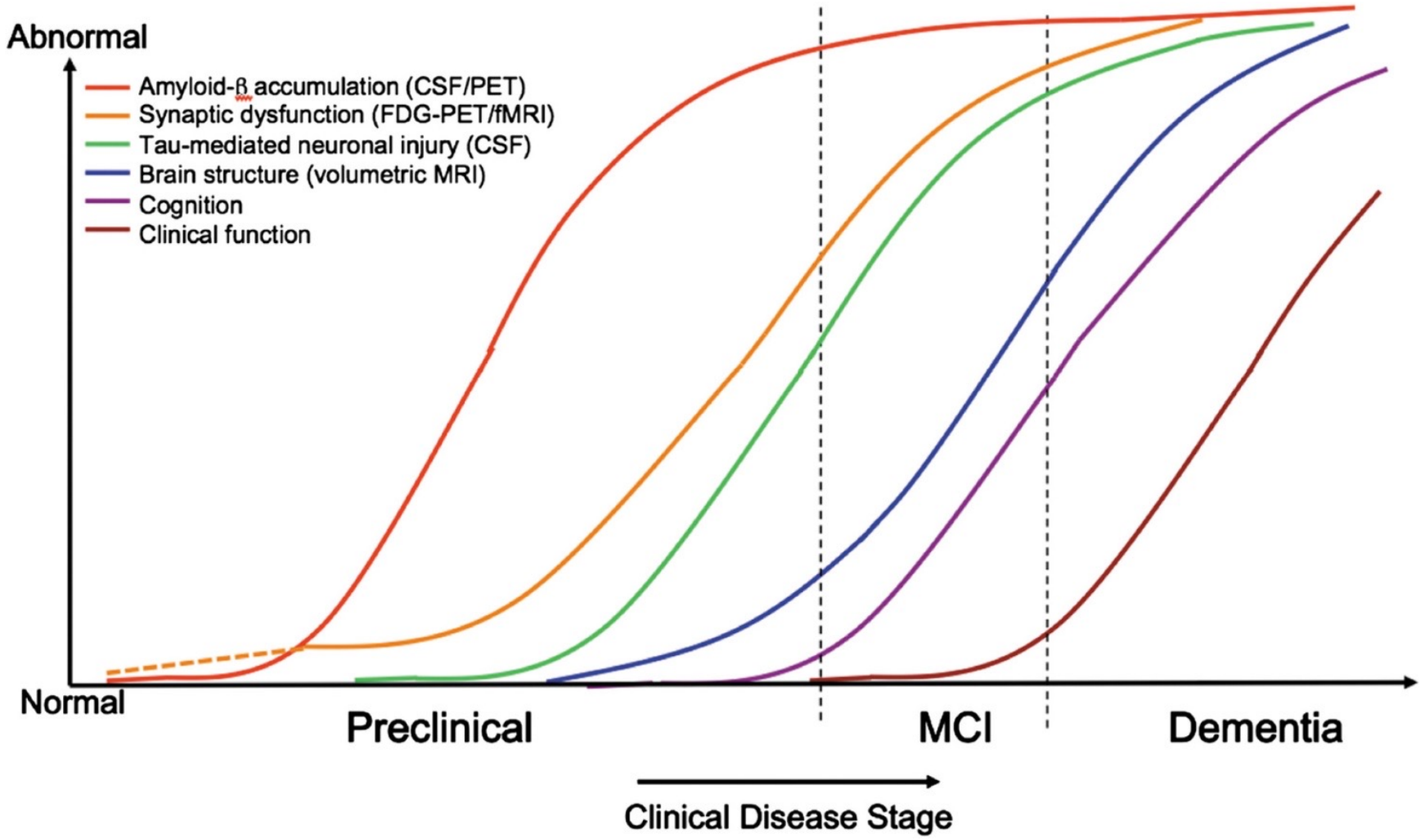
The biological definition of AD

- Historically, AD was a clinical diagnosis, confirmed at autopsy
- 2018 NIA-AA research framework describes the AT(N) classification of AD
  - Under revision
- AD biomarker tests allow for earlier identification of associated pathology

AT(N) profiles	Biomarker category	
A-T-(N)-	Normal AD biomarkers	
A+T-(N)-	Alzheimer's pathologic change	Alzheimer's continuum
A+T+(N)-	Alzheimer's disease	
A+T+(N)+	Alzheimer's disease	
A+T-(N)+	Alzheimer's and concomitant suspected non Alzheimer's pathologic change	
A-T+(N)-	Non-AD pathologic change	
A-T-(N)+	Non-AD pathologic change	
A-T+(N)+	Non-AD pathologic change	

Jack, *Alzheimers Dement*, 2018

Detecting AD pathology at earlier stages



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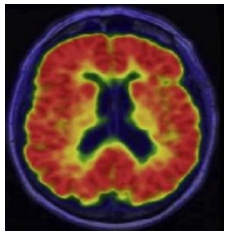
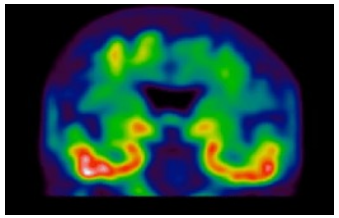
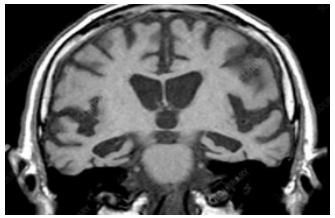
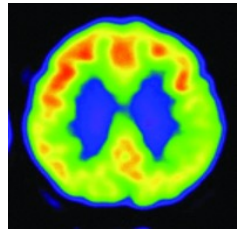
Sperling, *Alzheimers Dement*, 2011

Why are early evaluation and AD detection important?

- Access to therapeutics (e.g. lecanemab, donanemab)
- Individuals can participate more in care planning
- More opportunity to access treatment trials
- Identify other causes of cognitive impairment

AD biomarkers

Amyloid	Tau	Neurodegeneration
CSF Aβ42	CSF p-tau	CSF t-tau, NfL
Amyloid PET 	Tau PET 	MRI or FDG-PET  
Plasma Aβ42/Aβ40	Plasma p-tau	Plasma NfL

p-tau = phosphorylated tau; t-tau = total tau; NfL = neurofilament light chain

Advantages of plasma AD biomarkers

- Less invasive and less burdensome than CSF testing and PET
- Less expensive than PET imaging
- More accessible outside of specialist settings

Clinically available plasma AD biomarker tests*

- Quest AD-Detect: Aβ42/Aβ40, also available direct to consumer
- Precivity™
  - PrecivityAD: age, ApoE, Aβ42/Aβ40
  - PrecivityAD2: Aβ42/Aβ40, p-tau217/np-tau217
- LucentAD: p-tau181
- Labcorp: NfL, Aβ42/Aβ40, p-tau181, ATN profile

*None are FDA approved

Plasma Aβ42/Aβ40

Advantages

- Reduction in plasma Aβ42/Aβ40 seen with brain amyloid deposition

Challenges

- Less robust than spinal fluid measures
- Different performance depending on type of assay – immunoprecipitation mass spectrometry the best

Special considerations

- Can identify amyloid pathology in cognitively unimpaired

Benedet, *Alzheimers Res Ther* 2022; Janelidze, *JAMA Neurol* 2021; Palmqvist, *JAMA Neurol* 2019

Plasma phosphorylated tau (p-tau217, p-tau181, p-tau231)

Advantages

- Correlate with both cerebral amyloid plaques and tau tangles
- Elevated in AD but not other tauopathies (i.e. frontotemporal dementia)
- Performs similarly to PET and CSF biomarkers (p-tau217)
- Predict future cognitive decline and conversion to dementia from MCI
- Can monitor effects of anti-amyloid therapies in clinical trials

Challenges

- Different performance depending on variant and type of assay

Special considerations

- Can predict cognitive decline in cognitively unimpaired

Mattsson-Carlgren, *EMBO Mol Med* 2021; Palmqvist, *JAMA* 2020; Janelidze, *Nat Med* 2021; Cullen, *Nature Aging* 2021; Sims, *JAMA* 2023

Other emerging plasma biomarkers

Plasma neurofilament light chain (NfL)

- Nonspecific marker of brain cell injury; elevated in ALS, FTD, multiple sclerosis, HIV-associated neurocognitive dysfunction, parkinsonian disorders, and more modestly in AD

ATX(N) framework: Plasma glial fibrillary acidic protein (GFAP)

- Associated with brain amyloid (more so than CSF GFAP)
- Greater change in AD compared to non-AD neurodegenerative disease
- Elevated in mild traumatic brain injury and stroke

Bridel, *JAMA Neurol* 2019; Verberk, *Alzheimers Dement*, 2022; Hampel, *Nat Rev Neurol* 2021; Pereira, *Brain* 2021; Heller *J Neurol Neurosurg Psychiatry* 2020; Hansson, *Alzheimers Dement* 2022

Plasma AD biomarker performance varies across racial groups

Table 2. Unadjusted Mean and Covariate-Adjusted LSM Concentrations of Plasma and CSF Alzheimer Dementia Biomarkers and Ratios by Race

Biomarker	Unadjusted mean (SD)			Adjusted LSM (SE)[a]			
	African American participants	White participants	*P* value	African American participants	White participants	*P* value	Adjusted mean difference (95% CI)
Plasma							
Aβ42, pg/mL	10.35 (3.43)	9.12 (3.47)	.02	8.43 (0.47)	9.62 (0.39)	.04	−1.20 (−2.33 to −0.07)
Aβ40, pg/mL	160.68 (50.74)	186.79 (59.75)	.002	147.30 (9.28)	185.08 (7.67)	.001	−37.78 (−60.16 to −15.39)
p-tau$_{181}$, pg/mL[b]	17.99 (7.54)	21.78 (9.59)	.002	18.05 (1.05)	22.70 (1.20)	.004	−4.66 (−7.05 to −1.90)
Aβ42/Aβ40	0.07 (0.02)	0.05 (0.02)	<.001	0.06 (0.00)	0.05 (0.00)	.08	0.01 (0 to 0.01)
NFL, pg/mL[b]	11.19 (6.38)	13.41 (6.18)	<.001	12.06 (0.52)	13.64 (0.57)	.03	−1.58 (−2.83 to −0.19)

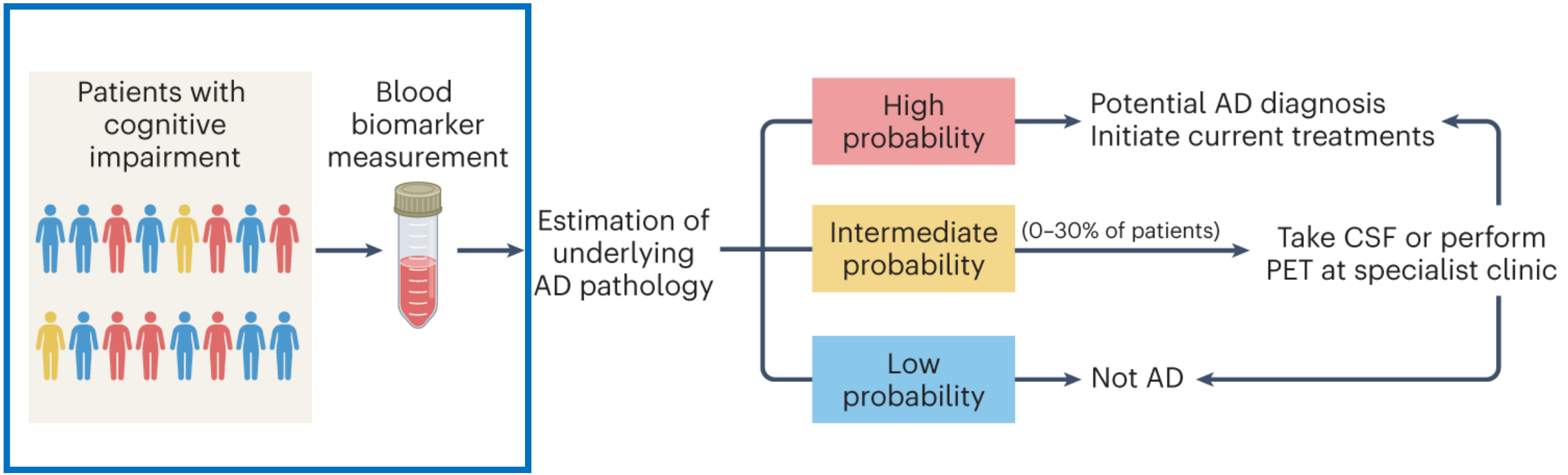
Model adjusted for age, sex, educational attainment, MoCA score, *APOE4*, hypertension, diabetes, and creatinine level

Hajjar, *JAMA Netw Open* 2022

Potential clinical uses of plasma AD biomarkers

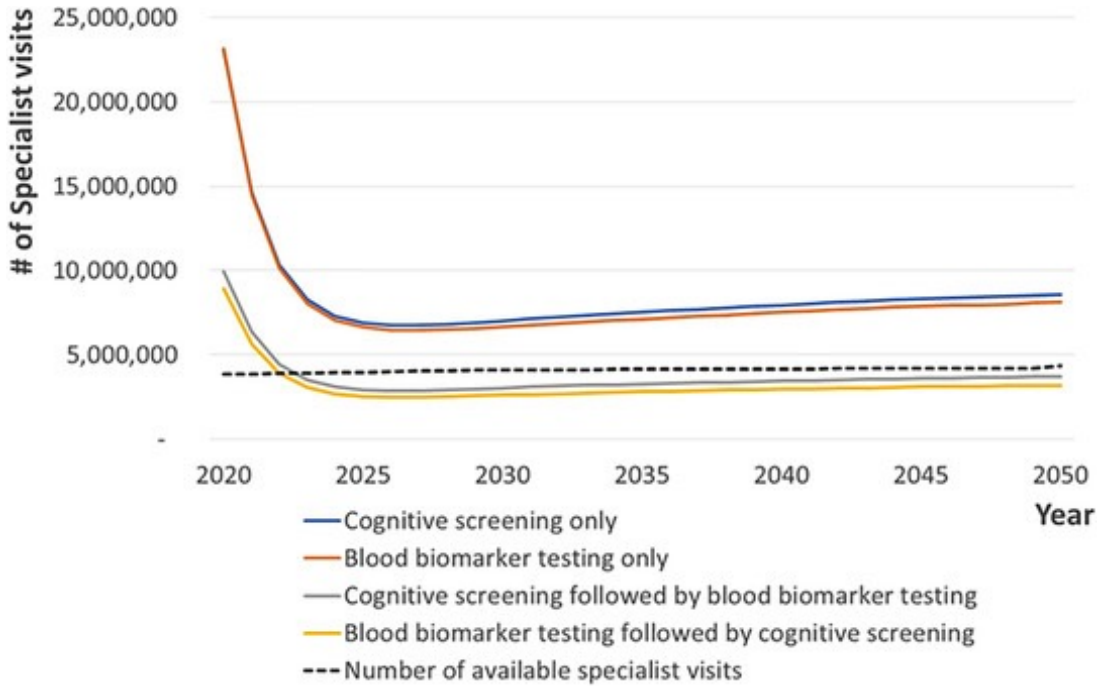
- Screening/case-finding in primary care
- Diagnostic step in specialty settings before amyloid PET or CSF testing
- Monitor response to anti-amyloid therapy

The role of plasma AD biomarkers

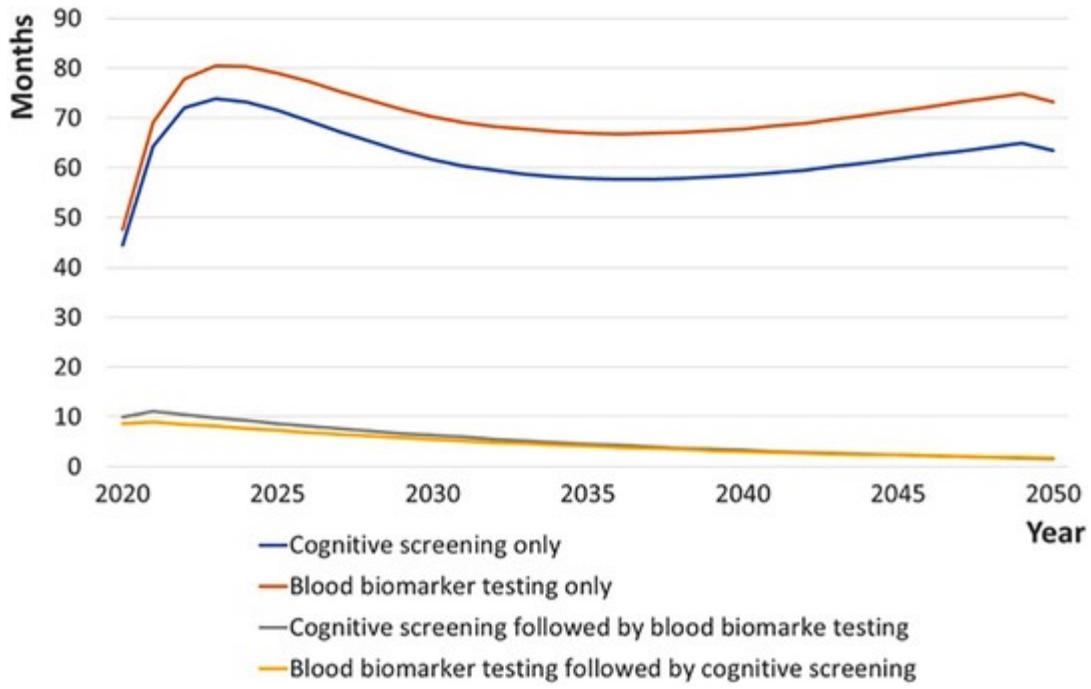


Hansson, *Nature Aging*, 2023

Potential impact of a plasma AD biomarker-based triage system in primary care



Annual demand for specialist visits



Average wait time to complete diagnostic process

Mattke, *Alzheimers Dement (Amst)* 2020

Challenges to detecting cognitive impairment and diagnosing AD in primary care

- Degree of comfort performing evaluation
- Concerns about burden to patient
- Doubts about usefulness of diagnosis/perception of limited treatment options
- Time constraints/competing priorities
- Lack of support/resources
- Language barriers

Bradford, *Alzheimer Dis Assoc Disord* 2009

Will clinicians use plasma AD biomarkers? Why or why not?

- Interviewed clinicians at Penn Medicine, University of Wisconsin, Wisconsin VA, and Wisconsin Alzheimer's Institute-Affiliated Dementia Diagnostic Clinic Network
  - General approach to cognitive evaluations
  - Knowledge and perceptions of plasma AD biomarkers
  - Used Diffusion of Innovations theory to evaluate aspects of plasma AD biomarkers that might impact their adoption
- Sixteen internal or family medicine providers, 8 geriatricians, 6 neurologists
- Fifteen with significant clinical experience in dementia diagnosis and care

Rogers, *Diffusion of innovations*, 1983

Clinician perspectives on use of plasma AD biomarkers

- Impact on medical and psychosocial management
- Impact on patient and family
- Patient characteristics
- Test attributes

O'Brien et al, in press

Impact on medical and psychosocial management

“It's very useful in terms of… care...advanced care planning… specifically for being able to start engaging support partners [with] surveillance for problem areas around finances and transportation…, in terms of really just life planning, ‘Is it reasonable for them just to be living alone?’” (131, geriatrician)

“They have cognitive impairment that impacts their day-to-day life. Then it becomes how do you manage it? Maybe I’m missing something but …what would be the benefit of doing the further testing? Until there are some therapeutic options that get informed by the testing, I’m not sure it’s overly beneficial.” (119, internist)

O’Brien et al, in press

Impact on patient and family

"I think number one is to openly talk about what people are afraid of to allow them to have some confidence and control so they can start addressing the things that are most concerning to them." (132, geriatrician)

"How would you feel if you got a positive test and you knew that…by the time you're at age 65, you're gonna be in bed drooling in a nursing home? Huge anxiety." (110, internist)

O'Brien et al, in press

Patient characteristics

“[I]f they were coming to me and already in a moderate or …moderately advanced stage of dementia, I'm not sure that I necessarily would.” (187, geriatrician)

“Anybody with a family history of dementia… you might even consider using that [in] everybody at age 65 or at a certain age… it could be figured out some age cutoff where we would catch it early enough to prevent it…” (117, internist)

O’Brien et al, in press

Test attributes

“[T]he cost on the healthcare system would be less…less invasive, probably less time away from their normal routine, bloodwork is just so much quicker, less potential radiation exposure...” (76, family medicine)

“The logistical issues with clinic workflow and patient volume… and all of that would be too much of a pain to deal with if the test wasn't sensitive or specific enough. I need a one and done.” (140, neurologist)

O’Brien et al, in press

Considerations for primary care

Factor	Exemplary quotes	Interventions to facilitate effective use
Interpretation	"[I]f this could be a dichotomous result…that would be perfect. If…there's some sort of risk spectrum…clear guidance as to the implications of the results on the patient's expected outcome, some clear way to communicate to the patient what it means." (75, family medicine)	• Explanation of test cutoff(s) in results report and implications for diagnosis and/or prognosis • Patient-friendly results disclosure aids
Guidelines	"[S]eeing recommendations for when to use the test and how to talk about it with patients would be helpful." (17, internist)	• Trainings and guidelines for appropriate use • Best practices and trainings for results disclosure
Resources	"If I don't have a good support system to help my patients deal with the fallout…I would be somewhat less likely to cooperate…probably a geriatrician, geriatric social worker. If it's a genetic test, a genetic counselor. (185, internist)	• Implement multidisciplinary care teams • Telehealth for remote supports in low-resource settings
Evidence	"I would feel empowered to [use the tests] if I had appropriate guidance and confirmation of clinical utility and evidence base from my trusted experts locally and nationally." (185)	• Educational materials containing test validation data • Studies of plasma AD biomarkers' clinical utility

O'Brien et al, in press

Study of the Utility and Impact of a p-Tau181 Alzheimer's Biomarker (SUIT-ABLE)

- Plasma p-tau181 biomarker made available at the Penn Memory Center
- Evaluate clinician diagnosis and diagnostic confidence pre- and post-test
- Assess change in management and impact on diagnostic practices
- Evaluate impact on patient and care partner pre- and post-disclosure
- Aim to enroll 120 participants

Pilot Study Testing the Feasibility and Acceptability of Using Plasma Biomarkers for Diagnosing Alzheimer's Disease in Primary Care: A Collaboration between IU Family Medicine, Internal Medicine & Geriatrics, and Neurology

Co-Is: Jared Brosch, MD (Neurology); Nicole Fowler, PhD, MHSA (Int Med & Geriatrics); Dustin Hammers, PhD (Neuropsychology); Deanna Willis, MD, Interim Chair, Family Medicine

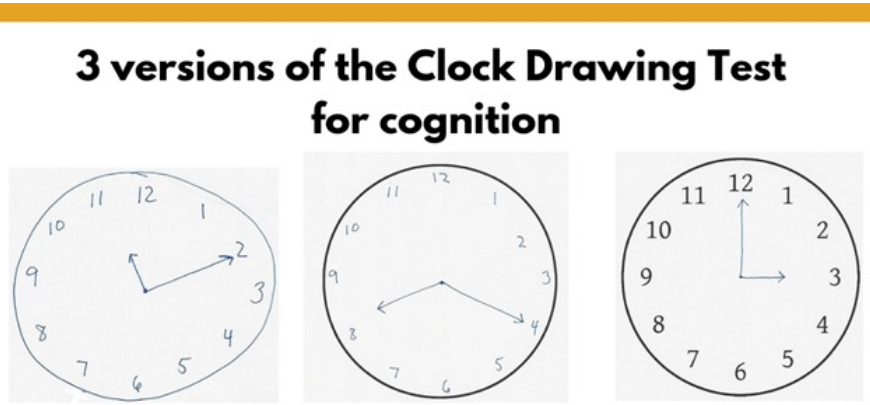
Background

- Primary care is the main “touch point” for people with Alzheimer’s disease (AD), MCI, or those at risk of developing AD.
- Identifying people with AD is critical for providing person-centered primary care.
  - Initiate interventions- Rx, models of care, HCBS
  - Health promotion
  - Safety
- Early detection is difficult in current primary care system.
  - No guidelines
  - No established workflows
  - Limited reimbursements

Background

Screening Tools

- Subjective cognitive complaints
- Clinical symptoms
  - Paper-Pencil (AD8, MiniCog, MoCA, MMSE, SLUMS, etc.)
  - Digital tools (CAMCI, Cognigram, Cognivue, Linus DCTClock, etc.)
- Biomarker tests for pathology
  - 6 clinically available blood-based biomarker tests for AD
  - 1 DTC blood-based biomarker tests for AD
  - CSF, PET
- They are infrequently used in primary care.
- Acceptability and feasibility and barriers and facilitators to using blood-based biomarkers in symptomatic primary care patients is unknown.



Methods

WHAT: 12-month pragmatic, embedded clinical demonstration project testing the implementation of a digital cognitive assessment (Linus Health DCTClock) in routine primary care for people ≥ 65 years old.

WHERE: 7 diverse, primary care clinics in central Indiana.

WHY: Is the system ready to integrate cognitive assessments into routine PC?

RESEARCH PILOT: What is the feasibility and acceptability of using blood-based biomarkers (C_2N Diagnostics, PrecivityAD® test) as part of the diagnostic process for Alzheimer's disease in primary care patients who *screen positive* on a digital cognitive assessment?

Measures

PATIENTS

- Consent, refusal, and ineligibility rates
- Usability of a Decision Guide (https://www.agreedementia.org/)
- Participation in disclosure

Pre and Post Disclosure:

- Concerns about Alzheimer's Disease
- Future Time Perspective Scale
- Impact of Event Scale
- Depression
- Anxiety

Outcomes

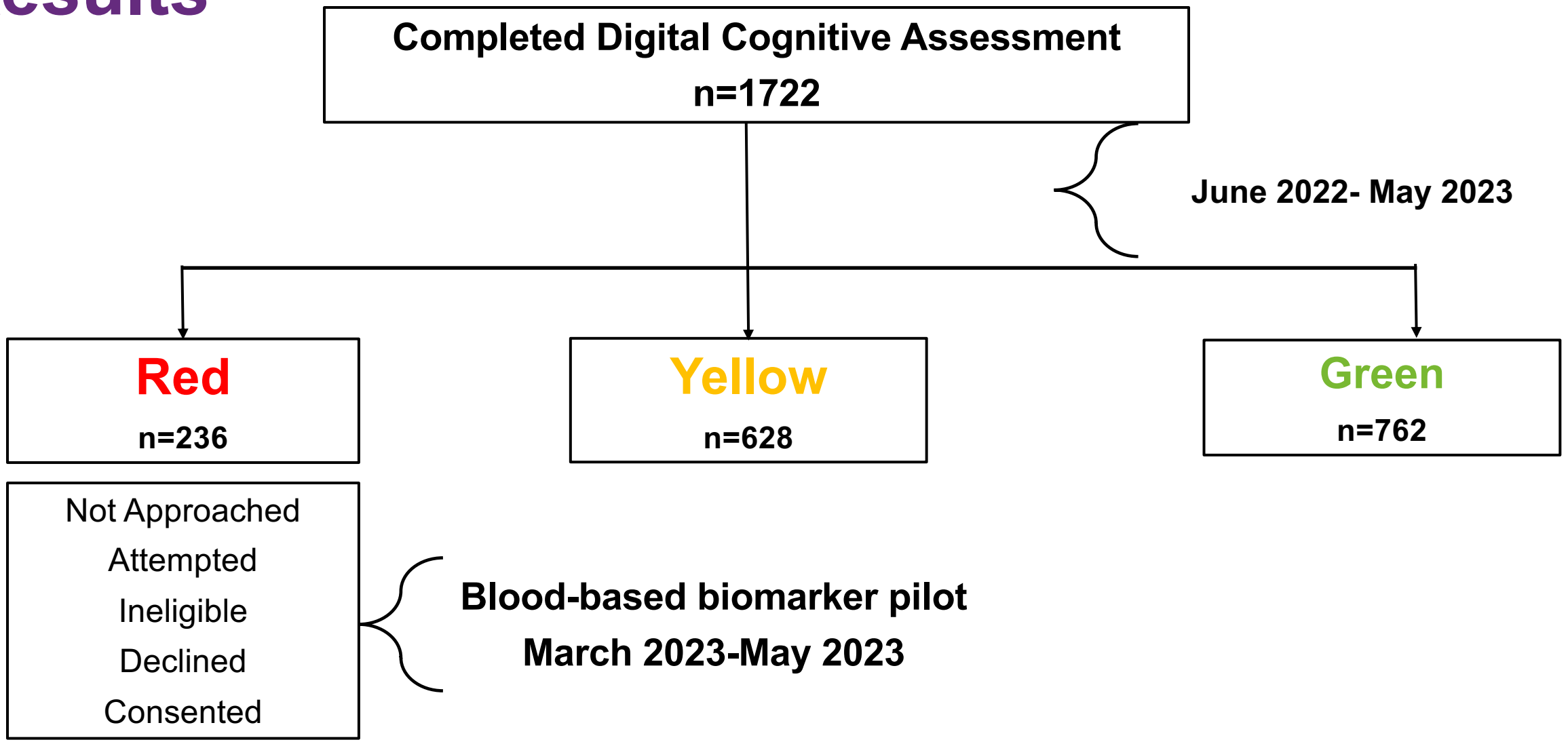
Follow-up behaviors (acceptance of referrals, testing, treatments), diagnoses.

Measures

PRIMARY CARE PROVIDERS

- Consent rate
- Participation in disclosure
- Clinical decision making (referrals to specialists, involvement of
- Brain Health Navigator, orders for testing, imaging, treatments)

Results


Completed Digital Cognitive Assessment
n=1722
June 2022- May 2023
Red
n=236
Yellow
n=628
Green
n=762
Not Approached
Attempted
Ineligible
Declined
Consented
Blood-based biomarker pilot
March 2023-May 2023

Results: Patients

Feasibility and Acceptability of Blood Based Biomarker Testing for AD in Primary Care							
	Not Approached	**Attempted**	**Ineligible**	**Declined**	**Agreed but no show to lab**	**Consented**	**Total**
Age, mean (SD)	75.9 (7.4)	76.3 (6.9)	80.1 (6.5)	76.1 (7.0)	69.9 (4.1)	75.6 (8.1)	76.2 (7.2)
Sex, n (%)							
Female	24 (43.6)	29 (46.0)	12 (57.1)	32 (51.6)	6 (66.7)	18 (69.2)	121 (51.3)
Male	31 (56.4)	34 (54.0)	9 (42.9)	30 (48.4)	3 (33.3)	8 (30.8)	115 (48.7)
Race, n (%)							
Asian	3 (5.4)	1 (1.6)	1 (4.8)	3 (4.8)	0 (0.0)	0 (0.0)	8 (3.4)
Black or AA	16 (29.1)	24 (38.1)	5 (23.8)	23 (37.1)	7 (77.7)	13 (50.0)	88 (37.3)
White	36 (65.5)	38 (60.3)	14 (66.7)	36 (58.1)	2 (22.2)	13 (50.0)	139 (58.9)
Other reported	0 (0.0)	0 (0.)	1 (4.8)	0 (0.0)	0 (0.)	0 (0.0)	1 (0.4)
Ethnicity, n (%)							
Hispanic	9 (16.4)	0 (0.0)	5 (23.8)	0 (0.0)	0 (0.0)	0 (0.0)	14 (5.9)
Non-Hispanic	46 (83.6)	63 (100.0)	16 (76.2)	62 (100.0)	9 (100.0)	26 (100.0)	222 (94.1)
Total	**55 (46.6)**	**63 (53.3)**	**21 (17.8)**	**62 (52.5)**	**9 (7.6)**	**26 (22)**	**236**

Results: Providers

	Provider Consented to Conduct Disclosure n=31 (53.5%)	Provider Did not Consent to Conduct Disclosure N=27 (46.5%)
Provider Completed a Results Disclosure	5 (26.1%)	NA
Provider Did not Complete a Results Disclosure	26 (83.9%)	27

NOTE: 45 Providers not approached

Results: Providers- Comfort with Disclosure

"I found the results helpful, but I didn't want to disclose because I did not know enough about it and I feel like someone who has been trained on [that] lab result would be a better a person, and if they are positive, I am going to send them to the neurology anyway." (Did not consent to disclose)

Results: Providers- Accuracy in PC populations

"You tell your patient that they are at risk of developing dementia, but do we really know what the sensitively and specificity is of these [blood] tests in [patient] populations with all kinds of different diseases?." (Consented to disclose but did not conduct a disclosure)

Results: Providers- Value of Biomarker Results

“Having a simple test that can be done on an iPad or something reproducible is great. I don't want to just be like, “*here's some more blood work than I’m throwing on because you can't even afford to be here and I'm trying to figure out what the cheapest way for you to even get just an A1C to make sure you're not dying”.* [Essentially] so having a screening test like the [DCA] does make me feel better. Having blood testing is a great next step to confirm or deny if anything's going on, but [it] just comes down to “*What do I do with that data afterwards?”..”* (Consented to disclose and conducted a disclosure)

Results

How well does the Decision Guide (DG) describe AD?

- 54% Excellent or Good

How well does DG describe why someone would want to get a blood test for AD?

- 92% Excellent or Good

How well does DG describe why someone would *not* want to get a blood test for AD?

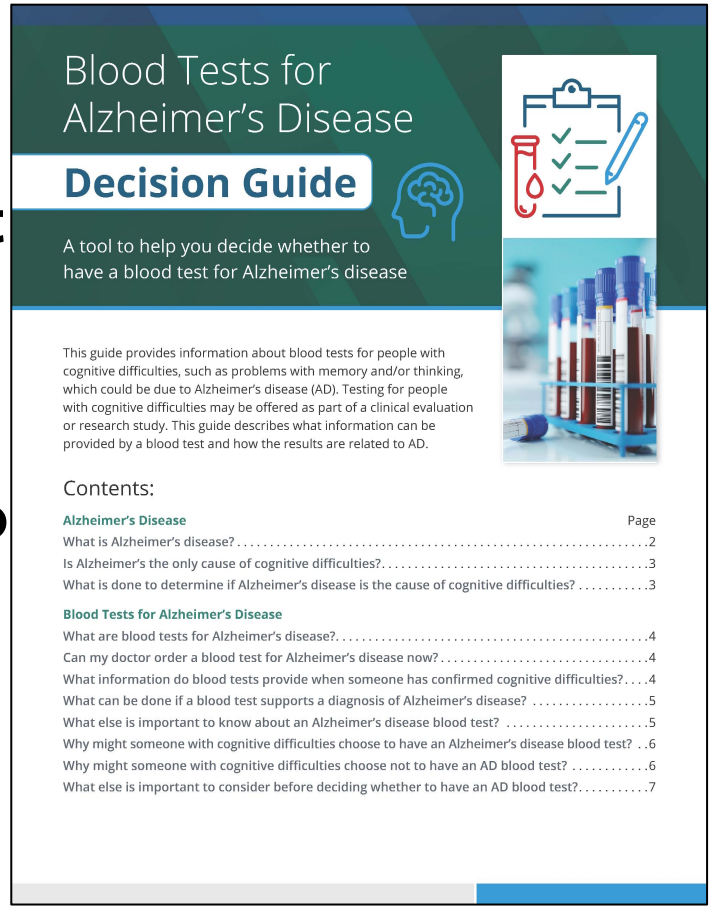
- 85% Excellent or Good

The amount of information presented in the DG.

- 85% Just Right

The DG was helpful when trying to decide whether to get a blood test for AD

- 85% Yes



Blood Tests for Alzheimer's Disease

Decision Guide

A tool to help you decide whether to have a blood test for Alzheimer's disease

This guide provides information about blood tests for people with cognitive difficulties, such as problems with memory and/or thinking, which could be due to Alzheimer's disease (AD). Testing for people with cognitive difficulties may be offered as part of a clinical evaluation or research study. This guide describes what information can be provided by a blood test and how the results are related to AD.

Contents:

Patient characteristics by Biomarker results

	Low Amyloid Probability Score*	Intermediate Amyloid Probability Score*	High Amyloid Probability Score*	P-value
Age, mean (SD)	71.7 (6.2)	78.0 (2.8)	81.6 (8.2)	0.009
Age category, n (%)				0.014
Age 65-69	8 (53.3)	0 (0.0)	1 (11.1)	
Age 70-74	1 (6.7)	0 (0.0)	2 (22.2)	
Age 75-79	4 (26.7)	1 (50.0)	0 (0.0)	
Age 80-84	2 (13.3)	1 (50.0)	2 (22.2)	
Age 85-89	0 (0.0)	0 (0.0)	3 (33.3)	
Age 90+	0 (0.0)	0 (0.0)	1 (11.1)	
Sex, n (%)				0.376
Female	12 (80.0)	1 (50.0)	5 (55.6)	
Male	3 (20.0)	1 (50.0)	4 (44.)	
Race, n (%)				0.002
Asian	0 (0.0)	0 (0.0)	0 (0.0)	
Black or AA	12 (80.0)	0 (0.0)	1 (11.1)	
White	3 (20.0)	2 (100.0)	8 (88.9)	
Area Deprivation Index, Median (25%, 75%)	72 (53, 85)	90.5 (84. 97)	62.5 (39, 78.5)	0.137
Total	**15**	**2**	**9**	**26**

**Amyloid Probability Score (APS) is a clinically validated algorithm integrating a ratio of plasma amyloid beta 42/40, ApoE & Age performed by C2N Diagnostics*

Patient Outcomes Post Biomarker Disclosure			
	Low Amyloid Probability Score, n (%)	**Intermediate Amyloid Probability Score, n (%)**	**High Amyloid Probability Score, n (%)**
Had disclosure conversation	15 (100)	1 (50)	8 (88.8)
Did not have a disclosure conversation	0	1 (50)	1 (11.1)
Incident ADRD diagnosis post disclosure	0	0	1 (11.1)
Prevalent MCI diagnosis	2 (13)	0	1 (11.1)
Incident MCI diagnosis post disclosure	0	0	2 (22.2)
ADRD medication initiated post disclosure	0	0	2 (22.2)
Referral to Neurology	0	0	8 (88.8)
Refused Neurology referral	-	-	1 (11.1)
Referral to Geriatrics	4 (26.6)	1 (50)	0
Referral to Neuropsychology	0	0	1 (11.1)
Referrals to Research	3	0	1

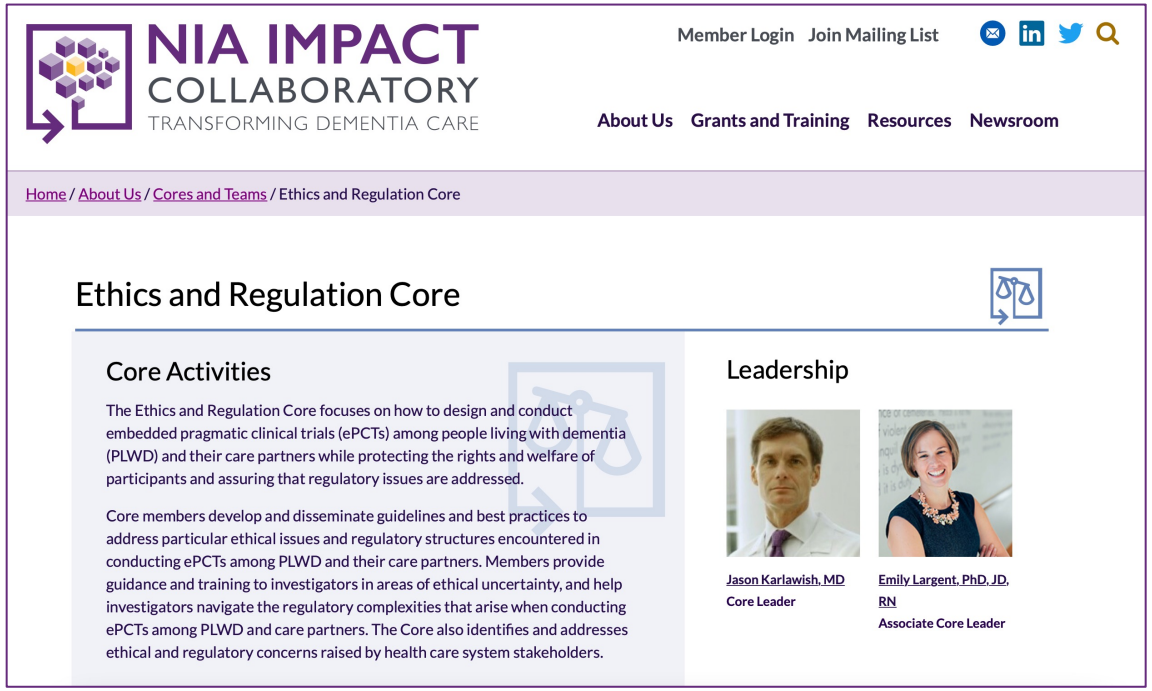
Pre- and Post-Biomarker Outcomes		
	Pre-Biomarker Collection (Baseline) n=26	**Post-Results Disclosure (2-4 weeks post) n=22**
Concerns About Alzheimer's Disease Dementia (CAADD), mean (SD)	18.4 (5.02)	14.22 (45.2)
CAADD score based on APS score, mean (SD)		
Low Amyloid Probability Score	17.7 (5.7)	12.84 (4.54)
Intermediate Amyloid Probability Score	16 (0)	9 (0)
High Amyloid Probability Score	18.12(3.9)	17.12 (5.5)
Future Time Perspective, mean (SD)	44.7 (9.8)	44.1(12.65)
Impact of Event Scale, mean (SD)	9.58 (13.02)	8.68 (10.43)
Subclinical subjective distress, n (%)	15 (57.7)	15 (68.18)
Mild subjective distress, n (%)	8 (30.7)	5 (22.73)
Moderate subjective distress, n (%)	1 (3.9)	2 (9.09)
Severe subjective distress, n (%)	2 (7.7)	0
No depression, n (%)	3 (11.5)	19 (86.3)
Mild depression, n (%)	4 (15.4)	3 (13.6)
Moderate and severe depression, n (%)	2 (7.7)	0
Missing PHQ-9	17 (65)	0
No anxiety, n (%)	4 (15.4)	21 (95)
Mild anxiety, n (%)	3 (11.5)	1 (5)
Moderate and severe anxiety, n (%)	1 (3.8)	0
Missing GAD-7	18 (69)	0

Research Implications

- 60% of symptomatic patients refused a blood test.
- 8% did not follow-up for the disclosure discussion.
- Disclosure in routine PC did not increase depression or anxiety, distress or concerns.
- 46% of PCPs declined to participate in the blood test disclosure discussion with their patients.
- Most patients agreed that a Decision Guide was helpful for them to decide to get a blood test.
- In this small sample of symptomatic PC patients, those who were older and white were more likely to have a high amyloid probability score.
- Low probability of amyloid was more likely to lead to Geriatrics referral, high to Neurology.

IMPACT Ethics & Regulation Core

- The ERC is available to consult with investigators on the use of AD biomarkers in ePCTs.
- Core members have experience:
  - Developing AD biomarker testing and disclosure protocols
  - Measuring outcomes of AD biomarker disclosure
  - Identifying clinical, ethical, legal, and social considerations re: AD biomarkers



Thank you

IMPACT Collaboratory Ethics & Regulations Core

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Questions?