

# Ethical issues raised by new tests & treatments

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## **Disclosures:**

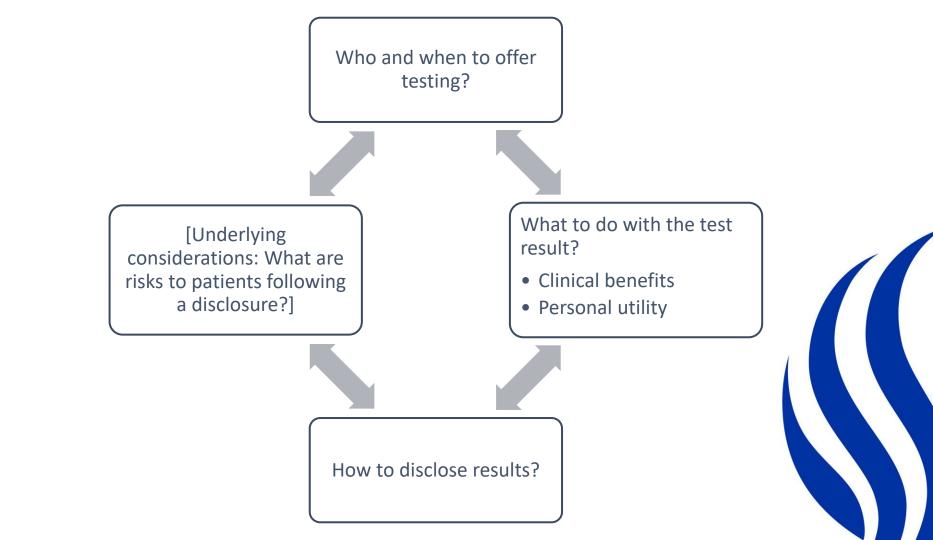
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  - Alzheimer's disease Data Initiative
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- Conflicts of Interest: None



# Three questions that underly an ethical analysis:

- Who and when to offer testing?
- What to do with the test result?
  - Clinical benefits
  - Personal utility
- How to disclose results?

[Underlying considerations: What are risks to patients following a disclosure?]



## Who and when to offer testing:

- Purpose
- Pre-test probability
- Testing platform
- Comorbidities
- Clinical staging



## What to do with the test results:

### <u>Clinical</u> <u>management</u>

- Confirmation
- Increased monitoring
- Treatment



### Personal Utility

- Advanced care
   planning
- Non-AD clinical decision-making
- Lifestyle
- Family/travel/emp loyment



## Is this information protected?

#### **Privacy:**

Intrusion into a person's information.

### Confidentiality:

Protection of the data to protect the individual.



#### Anti-Discrimination:

Protections against how thirdparties can use the information when making decisions about the individual.

# There are gaps within anti-discrimination protections

Table Summary of the scope of legal protections to prevent employment and insurance discrimination in persons who have either genetic markers or biomarkers for developing Alzheimer disease dementia

	Protection from employment discrimination		Protection from discrimination by health insurers		Protection from discrimination by life insurers		Protection from discrimination by long-term care insurers	
	Genetic markers	β-Amyloid biomarkers	Genetic markers	β-Amyloid biomarkers	Genetic markers	β-Amyloid biomarkers	Genetic markers	β-Amyloid biomarkers
Americans with Disabilities Act <sup>4,7</sup>	Uncertain <sup>a</sup>	Uncertain	No	Uncertain	No	No	No	No
Affordable Care Act <sup>6</sup>	No	No	Yes	Possible <sup>b</sup>	No	No	No	No
Genetic Information Nondiscrimination Act <sup>7</sup>	Yes	No	Yes	No	No	No	No	No

<sup>a</sup> The Equal Employment Opportunity Commission (EEOC) does not directly address genetic disposition. However, the EEOC has interpreted the 2008 amendment to the Americans with Disabilities Act to broaden the definition of disability in favor of coverage.

<sup>b</sup> Affordable Care Act provisions to limit discrimination in health insurance for persons with a preexisting condition start in 2014. Whether these provisions will apply to the concept of preclinical Alzheimer disease is uncertain—the analysis is complicated by the fact that preclinical biomarkers have yet to be validated and thus may not qualify as a preexisting condition.

## Long-term Care Insurance is a Major Gap

#### Figure I

#### State Law Consistencies with the NAIC Model Act

	Underwriting Privilege		43			7 1		
-	Application Disclosure		42			8 1		
Con	dition Specific Exclusion	41			5	5		
	Commission Discretion	38			1:	13		
	Limitation Period	50				1		
	Condition		46			3 2		
	Look Back		4	.8		3		
	Group Insurance Exclusion		32		18	1		
	Overall Consistency	24			27			
I	Consistent with NAIC Model Language			Variation from Model Act Additional Va				

The Proactive Patient: Long-term Care Insurance Discrimination Risks of Alzheimer's Disease Biomarkers Jadugus J. Aria, Ana M. Tjör, Benjamin J. Oster, and Jason Karlawish

### Another perspective . . . Who NOT to test:

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 Image: Content of the second secon

#### **REVIEW ARTICLE**

Alzheimer's & Dementia"

The Alzheimer's Association appropriate use recommendations for blood biomarkers in Alzheimer's disease

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Henrik Zetterberg <sup>8,9,10,11,12</sup>   Ch	Received: 24 April 2024 Revised: 1 July 2024 Accepted: 2 July 2024					
	POLICY FORUM	Alzheimer's & Dementia®				
	Considerations for widespread impleme	entation of blood-based				

Considerations for widespread implementation of blood-based biomarkers of Alzheimer's disease

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# 1. Benefits 2. FUTILITY

3. Harms 4. Justice

Scipion, et al. A Framework for futility of Alzheimer's disease biomarkers in "real world" patients.

# Disclosure: Need to shift to clinical disclosures

SHORT REPORT		Alzheimer's & Dementia* The JOURNAL OF THE ALZHEIMER'S ASSOCIATION	
	ated amyloid status is no ity in a preclinical AD tri		
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<sup>10</sup> EUBy and Company, Indianapolis, Indiana, U <sup>11</sup> Center for Alzhelmer Research and Treatment	<b>Abstract</b> Despite growing awarer ethical principles of rese for this disclosure in <i>A</i>	Disclosing genetic risk for Alz with mild cognitive impairme	cheimer's dementia to individuals ent
	biomarker and genetic r Alzheimer's Disease Res show high participant sa process and materials pro in the research setting.	Kurt D. Christensen 🔀 Jason Karlawish, J. Scott F Elisabeth M. Wood, Thomas O. Obisesan, Lan Q. First published: 22 March 2020   https://doi.org	Le, L NASSOCIATION Alzheimer's & Dementia <sup>®</sup> THE JOURNAL OF THE ALZHEIMER'S ASSOCIATION
			SHORT REPORT  Open Access  Open

Annalise Rahman-Filipiak 🔀 Corey Bolton, Joshua D. Grill, Ayda Rostamzadeh, Nathaniel Chin, Judith Heidebrink, Sarah Getz, Nicole R. Fowler, Allyson Rosen, Jennifer Lingler ... See all authors 🗸

## Summary & Future Research

- Ethical considerations are iterative and multi-dimensions
- Research is needed to take work done within research context and apply it to clinical care
- "Real world" patients may introduce new factors into the analysis



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**Alzheimer's disease Data Initiative** (INTERNATIONAL BARRIERS TO DATA SHARING IN AD/ADRD RESEARCH)

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