



Ethical issues raised by new tests & treatments

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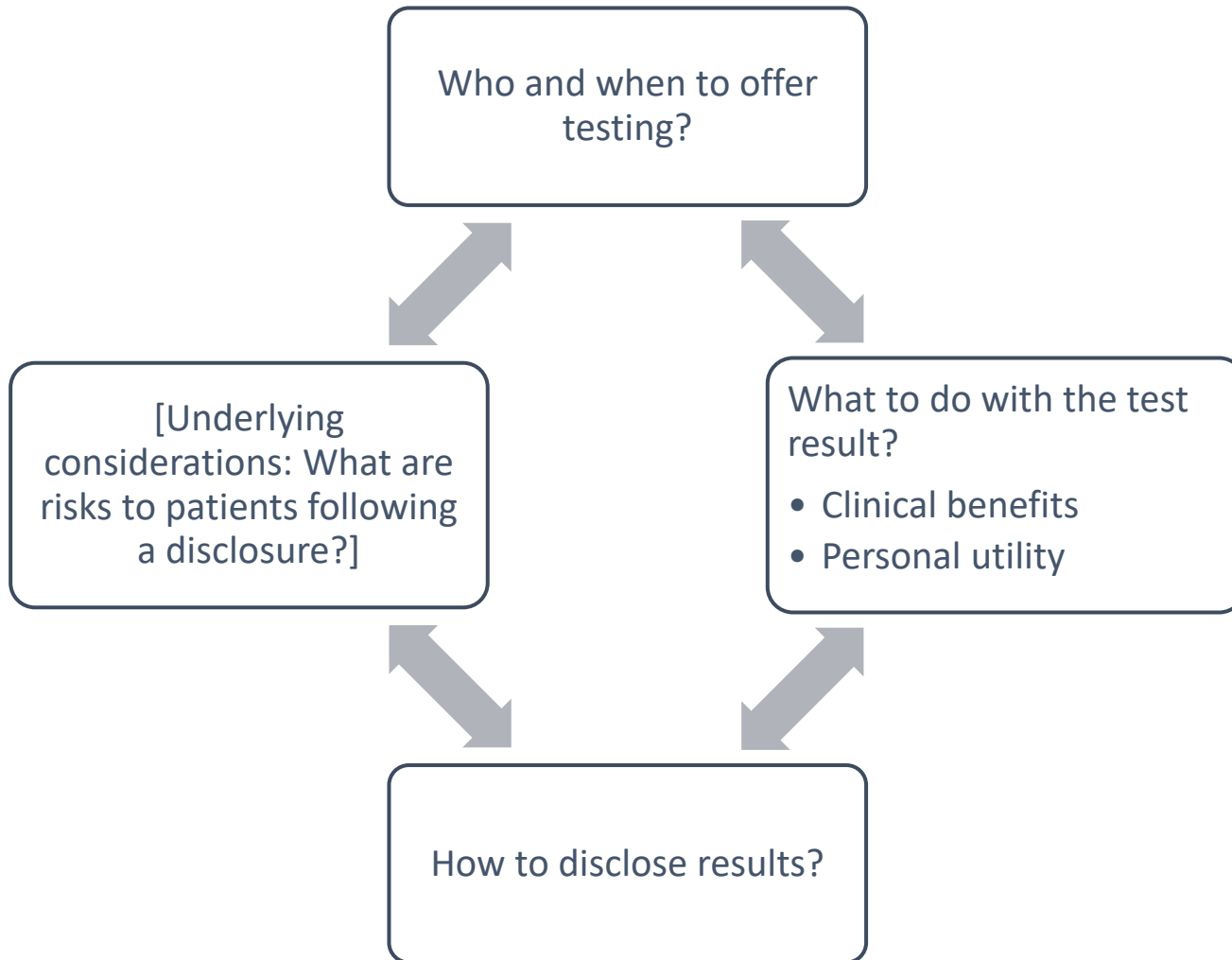


Three questions that underly an ethical analysis:

- 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:

Clinical management

- Confirmation
- Increased monitoring
- Treatment



Personal Utility

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



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 third-parties 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

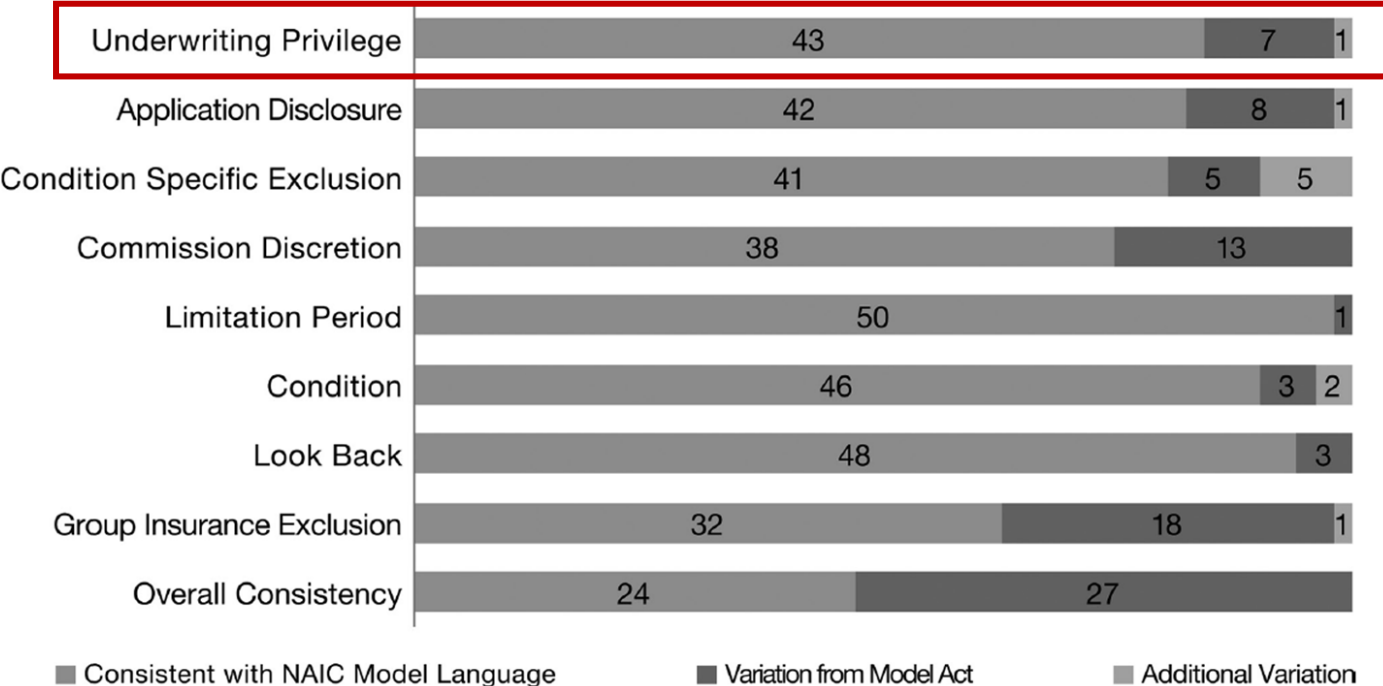
	Protection from employment discrimination		Protection from discrimination by health insurers		Protection from discrimination by life insurers		Protection from discrimination by long-term care insurers	
	Genetic markers	β -Amyloid biomarkers	Genetic markers	β -Amyloid biomarkers	Genetic markers	β -Amyloid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

^aThe 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.

^bAffordable 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.

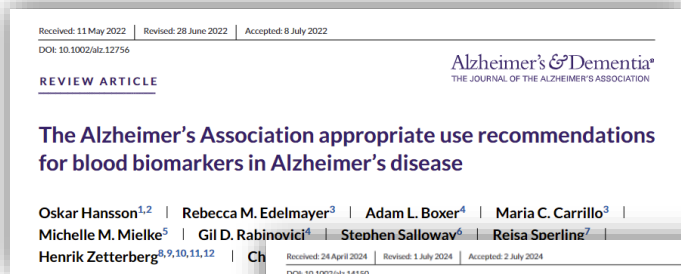
Long-term Care Insurance is a Major Gap

Figure 1
State Law Consistencies with the NAIC Model Act



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

Another perspective . . . Who NOT to test:



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

Alzheimer's & Dementia
THE JOURNAL OF THE ALZHEIMER'S ASSOCIATION

SHORT REPORT

Disclosure of elevated amyloid status is not associated with long-term suicidality in a preclinical AD trial

Joshua D. Grill^{1,2,3} | Rema Raman⁴ | Charlene Flournoy⁴ | Karin Ernstrom⁴ | Aimee Pierce⁵ | Amanda Smith⁶ | Paul Rosenber⁷ | Jeffrey Burns⁸ | Jason Karlawish⁹ | Paul Reisa Sperling¹¹ | David

Short Communication

Genetic and biomarker disclosure process in a memory and aging study

Inbal Mayan^{1,2}, He
Kim G Johnson⁷



RESEARCH ARTICLE |  Open Access | 

Disclosing genetic risk for Alzheimer's dementia to individuals with mild cognitive impairment

Kurt D. Christensen ✉, Jason Karlawish, J. Scott Robe
Elisabeth M. Wood, Thomas O. Obisesan, Lan Q. Le, L

First published: 22 March 2020 | <https://doi.org/10.1093/ndt/gfz001>

Alzheimer's & Dementia
THE JOURNAL OF THE ALZHEIMER'S ASSOCIATION

SHORT REPORT |  Open Access | 

Biomarker disclosure protocols in prodromal Alzheimer's disease clinical trials

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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BARRIERS TO DATA SHARING IN AD/ADRD RESEARCH*)

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