Wisconsin Alzheimer's Disease Research Center
UNIVERSITY OF WISCONSIN
SCHOOL OF MEDICINE AND PUBLIC HEALTH

Disclosing biomarker status: Considerations when working with individuals from historically marginalized communities

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Disclosing Biomarker status

- Frame our discussion
  - Today - disclosures in individuals with cognitive symptoms; e.g., dementia/MCI
- Discussion of controversies
- In addition to AD-relevant disclosure, look for guidance from other disciplines
- Considerations when working with historically marginalized groups

Disclosing Biomarker status

- Why is it controversial?
  - Understanding of what "positive status" means still emerging (e.g., for MCI)
  - Predicting the future
- As an expert: Ask yourself, what you believe about biomarker status (in context of cognitive impairment)
- Once FDA approved florbetapir, ADNI investigators indicated support for disclosure (Shulman et al. 2013)

Disclosing Biomarker status

- Why is it controversial?
  - What solutions can we provide
- As an expert: Ask yourself,
  - What do you believe about value of preclinical (MCI) and clinical diagnosis
  - What is your opinion about treatment options
  - What do you believe about prevention strategies

Effects of Disclosure in Cognitively normal

- Bemelmans et al. (2016) *Psychological, behavioral and social effects of disclosing AD biomarkers to research participants: a systematic review.* Alz Res and Therapy (8)46
  - Included *APOE*e4 as a biomarker
  - All 17 papers included – *APOE*e4 disclosure
  - Multiple papers from REVEAL
  - Original REVEAL sample 152/162 White
- J Burns et al (2017) *Safety of disclosing amyloid status in cognitively normal older adults*. Alzheimer's and Dementia; 13.
  - N=97 (all but 3 were Caucasian)

Disclosing of Biomarker status

- Acknowledge those who have examined biomarker disclosure (in cognitively healthy individuals)
- Overall:
  - Most tolerated disclosure
    - Disclosure done with a structured protocol
  - Strongest support for harm
    - Objective and subjective cognitive changes after disclosure
    - Some distress related to test results

Other frameworks

- Cancer
  - HT Lynch et al. (2006) Patient responses to the disclosure of BRCA mutation tests in hereditary breast-ovarian cancer families. Cancer and Genetics and Cytogenetics; 165(2).
  - CV Fernandez et al. (2003) Disclosure of the right to research participants to receive research results; Cancer; 97.

Why/Why not Disclose?

- May create unwarranted psychological harm (understanding is emerging)
- Create stigma: insurance, employment, fatalism
- Significant time investment

Why/Why not Disclose?

- Fundamental right to self determination
  - Guard against paternalism
- You can get an amyloid scan clinically
- For communities historically marginalized
  - Transparency is paramount
  - Lack of transparency erodes trust

Full disclosure

- My bias:
  - Study participants are partners in this work

Another Bias:

We are asking the wrong question:

➢ Ask not whether we should disclose.

➢ Rather we should ask how we best ascertain participant’s preference for disclosure.

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even after penicillin was proven an effective treatment

Suggested Solution

- Plain language disclosure about level of certainty/uncertainty of findings
  - Background/significance section of your funding proposal
- Trained, experienced communicators
- Establish participant’s preference for disclosure/nondisclosure
- When understanding still emerging: maintain contact after study visits

Considerations for URG Participants

Provide feedback in a responsible and transparent manner

- Disclosure would increase trust
- Need enough participation to make informed statements
- Must engage URG communities
- Increase participation

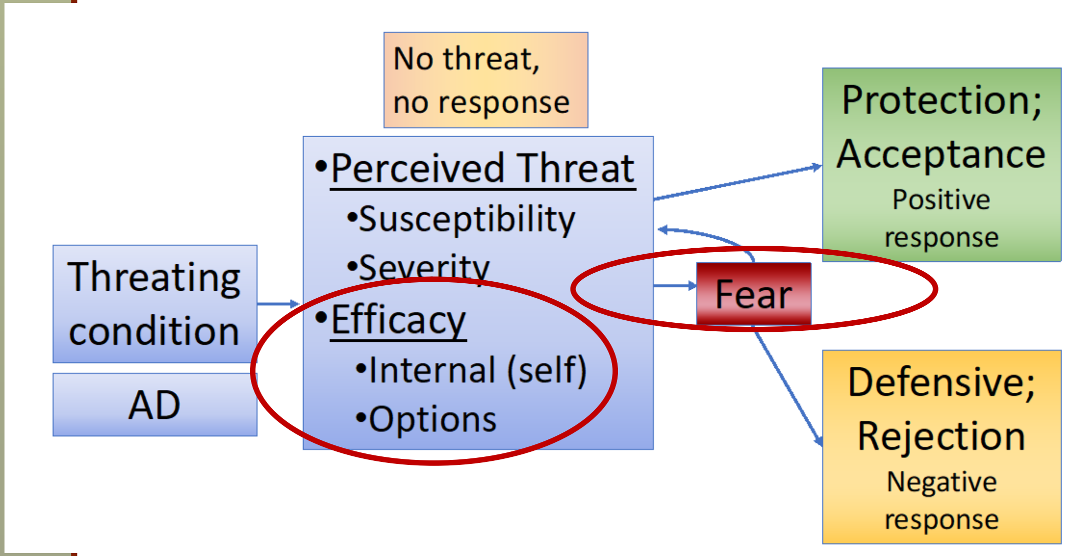
In addition to consulting from a CAB

- Use a Model of decision to guide our discussions

Exploring the decision to seek risk information in African Americans

Asked about decision to be screened for MCI

- ✓ Build self-efficacy – especially awareness of what one can do to address risk
- ✓ Make sure fear is realistic
- ✓ Trust in institutions/providers can mitigate fear
- ✓ Trust is transmitted through relationships



No threat, no response

- <u>Perceived Threat</u>
  - Susceptibility
  - Severity
- <u>Efficacy</u>
  - Internal (self)
  - Options

Threating condition

AD

Fear

Protection; Acceptance
Positive response

Defensive; Rejection
Negative response

Flowers Benton et al (in submission)

Suggested Solution

- Need to understand better the perspective of under-represented groups
- Proposed project to investigate
  1) What influences intention to participate in biomarkers studies
  2) What are the consequences of disclosure

Thank you for your attention

Questions and Comments?

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