Updates from the Genetic & Biomarker Disclosure Workgroup
An overview and update
May 2, 2019

ADC Administrators meeting

Neelum T. Aggarwal, MD
Carey Gleason, PhD, MS
Work Group Co-Chairs

Genesis of this work

- Recognized the need for guidelines for programs considering disclosure of genetic, biomarker and risk data
- ADC program to provide leadership
- Guidelines should:
  - Provide accurate information on risk
  - Be clear on limits of our understanding
  - Be offered in plain language
  - Be relevant to specialists, primary care physicians, and people with and at risk for dementia

Review of Work Group Aims

Aim1: *Organize and critically evaluate the existing research* regarding Genetics and Biomarkers, and their use in *dementia risk prediction*

Aim 2: Using findings from Aim 1 to improve messaging and training

a) *Improve and standardize messaging regarding genetic and biomarker risk and disclosure practices* to patients, research and clinical trial participants and the lay public, along with primary care physicians and specialists treating these individuals

b) Develop innovative educational programming focusing on the role of *health literacy, culture, ethnicity and care access to guide disclosure* of biomarker and genetic status

Aim 3: Develop programming and best practices

a) Guide the development of an ongoing *multi-modal educational program* that includes community partners in the design and execution of the content, programming and dissemination activities

b) Integrate best practices for engaging *underserved/under-represented* communities in Genetic and Biomarker research

Tasks of Each Subcommittee to Achieve Aims

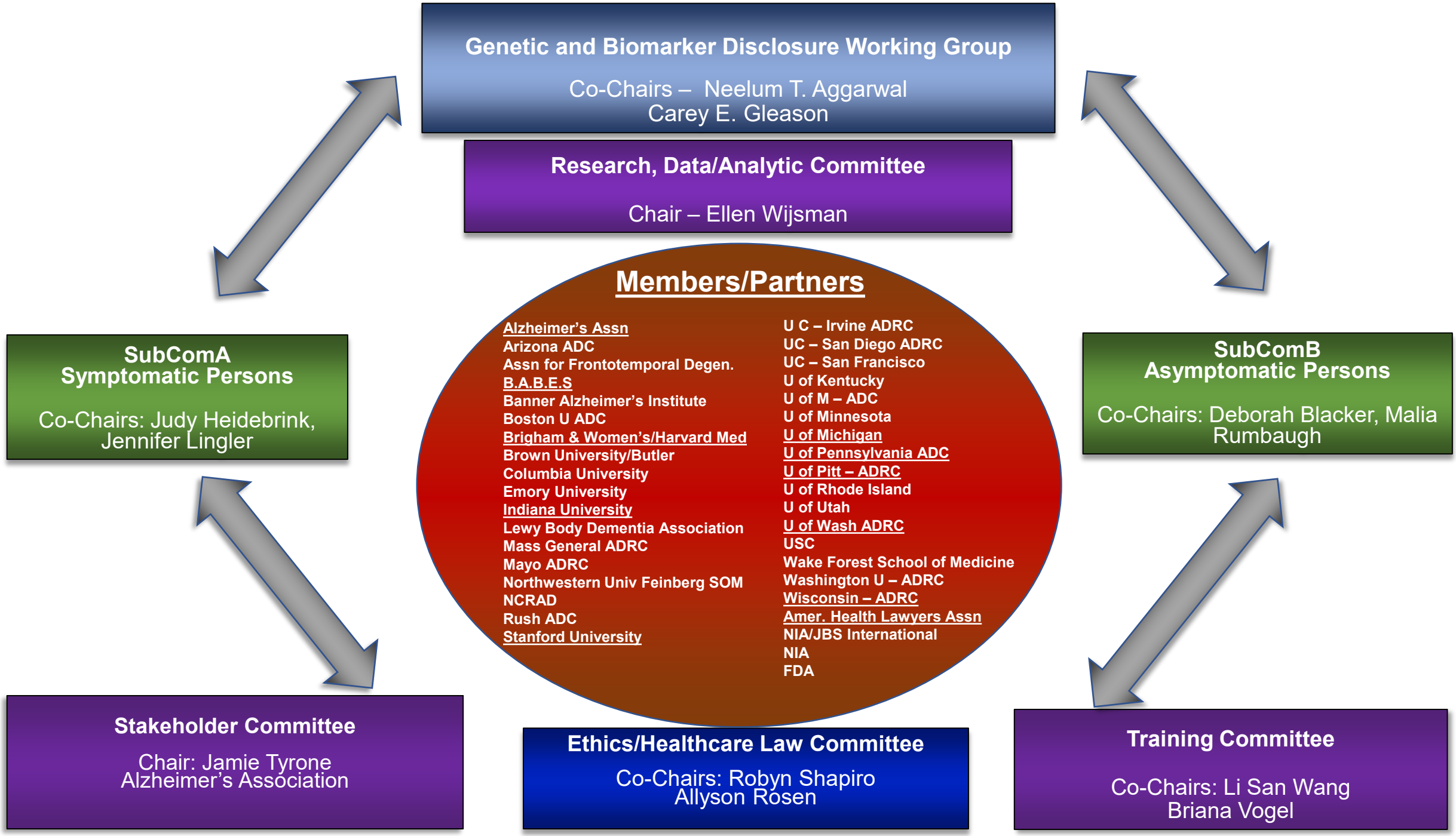
A. Disclosure with Symptomatic individuals
   - Focus on best practices for disclosure with persons who already have cognitive decline or diagnosis

B. Disclosure with Asymptomatic individuals
   - Focus on best practices for disclosure with persons who do not have a diagnosis or experiencing cognitive decline

C. Ethics/Healthcare Law
   - Review of existing law and ethics surrounding disclosure practices and make recommendations for future needs

D. Stakeholder
   - Engage patients and families, clinical trial participants, allied associations, members from AD and related Dementia Associations (LBD, AFTD, Alz Association) for recommendations on disclosure

E. Training Subcommittee
   - Assemble diverse group of trainees to identify gaps in education and training programs on issues related to disclosure

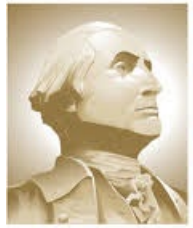

Genetic and Biomarker Disclosure Working Group
Co-Chairs – Neelum T. Aggarwal
Carey E. Gleason
Research, Data/Analytic Committee
Chair – Ellen Wijsman
Members/Partners
Alzheimer's Assn
Arizona ADC
Assn for Frontotemporal Degen.
B.A.B.E.S
Banner Alzheimer's Institute
Boston U ADC
Brigham & Women's/Harvard Med
Brown University/Butler
Columbia University
Emory University
Indiana University
Lewy Body Dementia Association
Mass General ADRC
Mayo ADRC
Northwestern Univ Feinberg SOM
NCRAD
Rush ADC
Stanford University
U C – Irvine ADRC
UC – San Diego ADRC
UC – San Francisco
U of Kentucky
U of M – ADC
U of Minnesota
U of Michigan
U of Pennsylvania ADC
U of Pitt – ADRC
U of Rhode Island
U of Utah
U of Wash ADRC
USC
Wake Forest School of Medicine
Washington U – ADRC
Wisconsin – ADRC
Amer. Health Lawyers Assn
NIA/JBS International
NIA
FDA
SubComA
Symptomatic Persons
Co-Chairs: Judy Heidebrink, Jennifer Lingler
SubComB
Asymptomatic Persons
Co-Chairs: Deborah Blacker, Malia Rumbaugh
Stakeholder Committee
Chair: Jamie Tyrone
Alzheimer's Association
Ethics/Healthcare Law Committee
Co-Chairs: Robyn Shapiro
Allyson Rosen
Training Committee
Co-Chairs: Li San Wang
Briana Vogel

Who Are Our Stakeholders?

LBDA
LEWY BODY DEMENTIA ASSOCIATION

Banner Alzheimer's Institute

AHLA
American Health Lawyers Association


THE GEORGE WASHINGTON UNIVERSITY
WASHINGTON, DC

DEPARTMENT OF HEALTH & HUMAN SERVICES • USA
FDA

Quest Diagnostics™

alzheimer's association®

AFTD
The Association for Frontotemporal Degeneration
FIND HELP·SHARE HOPE

B.A.B.E.S.
"BEATING ALZHEIMER'S BY EMBRACING SCIENCE"

University of Kentucky

NORTHWESTERN UNIVERSITY
FEINBERG SCHOOL OF MEDICINE

UNIVERSITY OF MIAMI

THE UNIVERSITY OF UTAH

Who are our Stakeholders? (cont'd)

Patient Advocates and Dementia Experts

Jamie Tyrone (B.A.B.E.S)
Anand Pathak (FDA)
Angela Taylor (Lewy Body Dementia Association)
Bonnie Wheaton
Susan Hahn (Quest)
Debbie Fenoglio
Donna Roscoe (FDA)
Emily Rogalski (Northwestern)
Karen Larimer
Susan Blanton (University of Miami)
Jessica Langbaum (Banner Alzheimer's Institute)
Keith Fargo (Alzheimer's Association)
Mandi Pratt-Chapman (George Washington University)
Martin Nava (Alzheimer's Association)
Rey Martinez (Alzheimer's Association)
Robyn Shapiro (American Health Lawyers Association)
Sadie Gabler (University of Utah)
Sharon Denny (Association for FTD)
Shoshana Bardach (University of Kentucky)

Individuals Living with Dementia and Care Partners

Cynthia Huling Hummel
Jeff Borghoff
Jim Taylor
Kate Callahan
LuPita Gutierrez Parker
Rod Blough

ADC Survey Development

Workgroup Aim 2

"Improve and standardize messaging regarding genetic and biomarker risk and disclosure practices to patients, research and clinical trial participants and the lay public, along with primary care physicians and specialists treating these individuals"

Activity to Achieve Aim 2: Survey Development

Focus on ADC and site disclosure practices for various research results - genetics, biomarkers, neuroimaging

Survey Questions anchored to each site's longitudinal cohort studies

Survey Domains

- —Whether or not result is returned, to whom, with what frequency

- —Reasons why sites do / do not disclose results
- —Perceived benefits for participants
- —Perceived barriers (e.g., financial costs)

- —Processes involved in results disclosure
- —What modality, which professionals?

Approach Taken

- Draft survey developed by both Symptomatic and Asymptomatic Subcommittee members
- Survey–addresses the issue of returning individual-level research results, including genetic and biomarker findings, to participants in ADC studies – shared with the Stakeholder Committee leader and Alzheimer's Association co-facilitators.
- Asymptomatic Subcommittee representatives included two specific questions regarding the survey:

  Q1: Are there other reasons that participants would want their individual research results which are missing from the survey?

  Q2: Are there any other questions we should be asking the ADCs about disclosure of biomarker and genetic test results?

- **April 22, 2019:** Stakeholder Committee leader and Alzheimer's Association co-facilitators disseminated the survey and prompts to Stakeholder Committee members for review.

Approach Taken

- **April 25th, 2019:** Scott Roberts of Asymptomatic Subcommittee presented the survey on a Zoom call to the Stakeholder Committee.
- As explained, the survey will be completed by an ADC's Clinical Core Leader and is intended to get a better understanding of what occurs in research settings that involve people living with cognitive impairment where genetic and bio-marker information is collected.

- Stakeholder Committee members offered feedback on the two specific questions they had received in advance, in addition to a larger discussion about the survey's purpose, usability, limitations, and the collection and reporting of genetic and bio-marker information in general.

Next Steps for ADC Survey

- Review and discuss input from Stakeholders at Subcommittee meetings
- Edit and modify survey as deemed appropriate
- Disseminate Survey to all ADC's and Clinical Core Leaders
  - Timeline: Beginning of June 2019
- Share survey results with ADC's and Stakeholder Committee after results are tabulated for feedback
- Develop modified survey that will focus on genetic and biomarker disclosure practices directed to a diverse group of physicians their clinical teams and physician organizations

Next Steps for Stakeholder Committee

- May 23rd, 2019 (tentative): Presentation from Symptomatic Persons Sub Committee
- June 27th, 2019 (tentative): Presentation from Ethics/Healthcare Law Committee

Calendar invitations to Stakeholder members and presenting Subcommittee members will be sent once dates are confirmed.

Impact of WG activities to the ADC Program-Considerations

- Institutional Practices and their approach to genetic and biomarker disclosure
  - Impact on Administrators
  - How to incorporate disclosure practices in overall consent forms, sub study and biorepository consents?
- Informed Consent
  - Impact on Clinical Core and staff
  - Recognition that participants want to know disclosure
  - What is potential impact of disclosure?
- Recruitment and retention
  - Impact on ORE Core and staff
  - What information are people obtaining elsewhere, how they are obtaining this, and how to integrate with ADC activities?
- Process for disclosure
  - If disclosed: who, how, when and where?
  - What materials will be available to support disclosure?

How can Administrators be involved?

- Join Zoom meetings
- Join a sub-committee
- Help with assuring that implementation aligns with Center processes
- Other thoughts?

Thank you for your Attention

Questions? Comments?

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