encounter any studies on disclosure of other biomarkers, including CSF-results or neuroimaging results. Although overall disclosure of APOE genotype seems safe, some concerns on the potential impact remain. While developing ethics guidelines, challenges concerned the development of a risk disclosure process across diverse geographical and cultural contexts, with a heterogeneous study population and different biomarkers. Important gaps remain in the evidence related to national and cultural differences in perceptions of AD risk, and differences between genetic and biomarkerbased risk information. The focus groups highlighted the importance of providing suggestions for courses of action following disclosure and the role of local primary and secondary care systems in shaping the long-term impact of risk disclosure. Conclusions: Disclosure of APOE seems relatively safe, but no data are available on the consequences of other biomarker disclosure. The combination of a longitudinal cohort study with proof of concept clinical trials poses several ethical challenges. Focus groups suggest a need for a focus on the post-disclosure period.

F4-02-03

## UNDERSTANDING THE IMPACT OF LEARNING AN AMYLOID PET SCAN RESULT: PRELIMINARY FINDINGS FROM THE SOKRATES STUDY

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Background: Progress in developing effective treatments to prevent cognitive impairment from AD requires clinical trials that study cognitively normal adults. Trials such as the Anti-Amyloid in Asymptomatic Alzheimer's disease (A4 Study) focus on enrolling persons with AD biomarkers, specifically, "elevated amyloid" as seen on a PET scan. The companion LEARN cohort study is enrolling persons whose PET scan shows "not elevated" amyloid. The Study Of Knowledge and Reactions to Amyloid TESting (SOKRATES) is studying a sample of A4 and LEARN participants to understand the experience of knowing this information. Methods: 85 persons in either A4 (50) or LEARN (35) were recruited from 9 sites to participate in a telephone interview to discover how they understood and appreciated their PET scan result, who they shared it with and how this sharing impacted on their relationships, and reported changes in behaviors or perceptions of health. Follow-up Interviews are being performed 9 to 12 months after the initial interview. Interviews are transcribed and analyzed by a multi-disciplinary team using qualitative methods that identify themes and patterns in themes. Results: As of 1 February 2016, 50 A4 participants completed a baseline interview. The presentation will show the results of their explanations of their amyloid PET scan result with attention to variations in meanings of "elevated" result. Conclusions: Data from the SOKRATES study showing how people interpret and reinterpret the results of their amyloid PET scan can inform the design and translation of educational and recruitment materials.

F4-02-04

## THE ALZHEIMER'S PREVENTION INITIATIVE (API) PROGRAM: GENETIC TESTING AND DISCLOSURE STRATEGIES

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Background: The Alzheimer's Prevention Initiative (API) is a collaborative funded by the NIH, philanthropy, and industry to conduct preclinical Alzheimer's disease (AD) trials in people who, based on age and genetics, are at elevated risk of developing AD symptoms. The API's Generation Study is enrolling apolipoprotein E (APOE) e4 homozygotes age 60-75. To support this and future trials, API established an interdisciplinary APOE Genetic Testing and Disclosure Committee whose aims include establishing an APOE genetic testing program to enrich referrals to studies, known as GeneMatch; updating APOE risk estimates; and evaluating disclosure of genetic risk and its impact. Methods: GeneMatch is a trial-independent program performing APOE genotyping in individuals age 55-75 to enrich referrals to prevention studies. GeneMatch uses buccal swab kits sent via mail and does not disclose APOE results to participants, either directly or inadvertently through referral to studies. Recruiting studies, however, may ask or invite individuals to learn their APOE results. The Generation Study includes standardized disclosure of AD risk by APOE genotype and the assessment of the psychological effects of genetic disclosure. A separate, investigator-initiated ancillary study, CONNECT 4 APOE, is examining the feasibility and efficacy of remote delivery (phone vs. real-time videoconferencing) methods for disclosing APOE results. Other investigator-initiated, ancillary studies examine the impact of APOE disclosure on objective and subjective cognitive functioning ("stereotype threat"), and its effect on families. Results: GeneMatch launched in 2015 and aims to enroll tens of thousands of participants. The Generation Study launched in November 2015; enrollment and genetic disclosure are ongoing. The CONNECT 4 APOE, Stereotype Threat, and Impact on Families ancillary studies will launch in 2016. Results from these efforts will be presented. Conclusions: GeneMatch is a key element of the API, facilitating enrollment into a range of research studies, including the Generation Study. Results from Generation Study's disclosure program and ancillary studies will help determine the effects of APOE disclosure across different modes of delivery and enhance appreciation of the psychosocial implications of high-risk results, with lessons for clinical practice and precision medicine, as well as future trials in genetically enriched populations.

## WEDNESDAY, JULY 27, 2016 FEATURED RESEARCH SESSIONS F4-03

JANUS: PREVENTION TRIALS IN ALZHEIMER'S DISEASE — LESSONS LEARNED AND MOVEMENT FORWARD

F4-03-01

COLLABORATION FOR ALZHEIMER'S PREVENTION (CAP): ADVANCING THE EVALUATION OF PRECLINICAL ALZHEIMER'S DISEASE TREATMENTS

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