Alzheimer’s Disease Centers Program updates

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Presented at ADC Directors Meeting, October 14, 2017, San Diego, CA
Congressionally mandated Centers of Excellence

Require a biennial report

ADCs were the first of the 6

- Alzheimer’s Disease Centers (1984)
- Claude D. Pepper Older Americans Independence Centers of Excellence (1989)
- Senator Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers (2001)
- National Institute on Minority Health and Health Disparities Centers of Excellence (2001)
- Rare Diseases Clinical Research Network (2003)
Important points:
• P30 Mechanism - no projects
• “In implementing these recommendations, NIA intends to provide increased resources to allow centers to expand core capacity that may be directed towards fulfilling particular recommendations.”
Thank you to Kelley Faber at NCRAD!!

- All the centers for getting these forms to Kelley
- NACC for their patience while we sort this out

Consent - not just an issue for GDS

- Identified issues that limit data sharing
- “Unrestricted” = ideal for sharing, but maybe not for other reasons: discuss
- “NPU” - Non-profit - restricts from commercial use, discuss reasoning
- “DS” - disease specific; which term to use:
  - aging, Alzheimer’s disease, neurodegenerative disease, neurologic disease, brain health, etc.
Supplements/revisions and timing

- Administrative supplements
  Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Admin Supp)

- Competitive Revision
  PAR-17-019

- Renewal applications - TBA

New committees and workgroups

- Imaging
  - Met at AAIC, sent summary – strong interest in trying to harmonize
  - Formed workgroup to discuss how and what to harmonize, led by Bill Jagust
  - Will have an open imaging meeting at next ADC meeting in April in LA
- Biomarkers – Doug Galasko, Les Shaw working on CSF harmonization
- Guidelines for External Advisory meetings and progress report tables – John Morris
- LBD Module – READY! Jim Galvin
- Spanish UDS – READY! Katya Rascovsky
- Latino listserv, Native American listserv, African American interest group
- Genetic Information
- Do you have an idea?
**Recommendation:** “Streamline as much as possible the standardized data collection to meet the scientific goals and promote increased opportunities for additional synergistic work. Analyze the Uniform Data Set to determine which variables provide the most meaningful contributions for AD and related dementias, while developing capacities to merge UDS requirements with local data collection scales and measures to enable enhanced longitudinal and cross-sectional research.”

- Strong interest from many to **streamline** the UDS to allow more local flexibility at ADCs.
- At the same time, it is important to continue to have some set of data that is both standard across the centers and scientifically useful. We also do want to consider the **existing investment** and **value of longitudinal data**.
- When the UDS was initially set up, a primary consideration was trying not to alter existing data collection at centers that had been collecting data for decades.
- Now, there are other important considerations, primarily, what will advance AD and ADRD research most rapidly and efficiently, while respecting participant burden concerns?
CMS Data Linkages to Cohort Studies: Claims + Rx

- Value of claims for treatment (Medicare Claims Covering Clinic and Hospital visits, Rx drugs)
  - Standardized format and nomenclature from all providers
  - High degree of accuracy and detail based on CPTs/HCPCs for treatment
    - Lack details of procedures
  - Longitudinal data permits assessment of initial and subsequent therapy
  - Coverage for about 65% of consented respondents (i.e. insured patient only/Medicare Advantage Data at this time is not available from CMS)
  - Captures information from all doctors/providers caring for patients
  - An accurate record of all prescriptions that were filled including dates of refills through Part D coverage
NIA Supports CMS Data Linkages Though a Contract with Acumen, LLC.

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<th>01</th>
<th>Beneficiary Demographics Data</th>
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<td>Verify survey participants' demographics information with Medicare and/or Medicaid information on participants' gender, age, and race/ethnicity.</td>
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<th>02</th>
<th>Diagnoses, Procedures, and Costs</th>
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<td>Gain insight into the diagnoses and procedures that survey participants have received under Medicare or Medicaid as well as the cost of those services.</td>
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<th>03</th>
<th>Dates of Health-Related Services</th>
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<td>Explore when participants received Medicare or Medicaid services to order those services across time.</td>
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<th>04</th>
<th>Prescription Drug Information</th>
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<td>Access information on the prescriptions that survey participants receive as well as the prescription costs covered by Medicare or the participant.</td>
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<th>05</th>
<th>Mental and Physical Assessments</th>
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<td>Incorporate mental and physical assessments of survey participants conducted by Medicare- and Medicaid-certified nursing homes as well as Medicare-certified home health agencies into your analysis.</td>
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<th>06</th>
<th>Provider-Related Information</th>
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<td>Use provider identifiers, geographic location, and, in the case of physicians, speciality codes to build a fuller picture of provider characteristics.</td>
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GUID = Global Unique Identifier

- Partnership with NINDS

- Enables data to be associated with a research participant without exposing or transferring the research participant’s personally identifiable information (PII).

- Random number not generated directly from PII.
  - It allows data about a research participant to be accumulated across projects over time, regardless of where and when that data were collected.
  - Enables a researcher to define a study population while supporting a research hypothesis, even if the data were not collected by the researcher.
  - Meets Federal data privacy standards.
National Strategy for Recruitment and Participation in Alzheimer’s Disease Clinical Research

- Led by NIA Office of Communication and Public Liaison in collaboration with the Alzheimer’s Association
- NAPA, 2011
  - Requires increase in enrollment in CT and other AD/ADRd research
  - Requires to increase enrollment specifically of diverse populations
- Three teams:
  - Local and diverse recruitment
  - National efforts
  - Capacity building
ABC-DS, Neurobiobank, Npath survey

- Survey results presented at Npath core meeting Friday night
- Looking for ways to improve ability to obtain autopsy on DS participants
- Also had long discussion about CLIA certification
- Separately, we will be putting together a small team to develop guidance for ADEAR, other staff when asked about donating a brain for research

www.nia.nih.gov/research/abc-ds
Request for Information (RFI): New Research Collaboration between the National Institute on Aging (NIA) and the Department of Veterans Affairs (VA) on Alzheimer’s Disease (AD) and Alzheimer's Disease Related Dementias (ADRD)

Notice Number: NOT-AG-16-083

Key Dates
Release Date: December 15, 2016
Response Date: January 16, 2017

- Insights on current organizational assets, strengths, and resources that would facilitate coordination and collaboration between NIA and the VA on AD and ADRD research (e.g., electronic medical records (EMR), biorepositories, co-location of VA and NIA AD Centers)
  - How the VA and NIH might leverage assets, strengths, and resources to support opportunities to collaborate and coordinate AD and ADRD research
- Current organizational barriers and challenges that prevent coordination and collaboration (between NIA and the VA) on AD and ADRD research
  - Suggestions for addressing or mitigating current barriers and challenges preventing effective research collaboration (between NIA and the VA) on AD and ADRD research
- AD and ADRD research questions and/or topics that could be addressed through a collaborative research partnership between the VA and NIH
- Other issues or concerns that could be considered and addressed in a collaborative research partnership between the VA and NIH on AD and ADRD research
Overarching goals from the recommendations

- Augment the capacity, utility and dissemination of resources of the network of ADCs
  - Leverage resources NACC, NCRAD, ADGC, etc.
  - Increase availability of data and samples
- Increase flexibility for innovation within ADCs
- Incentivize diversity across ADCs
- Enhance opportunities for collaborations across subsets of centers and outside ADC network
- Strengthen and modernize training opportunities
Additional slide for “New meeting format”

- This was not presented at the meeting, but several people asked about it afterward, so this slide is included for explanation.

- The session titled “Opportunities for Collaboration” replaced what had been the scientific session in previous meetings. While it is great to hear about the exciting science going on at different centers, we thought it would be good for people to talk about ideas for future cross-center collaboration and give others an opportunity to participate.

- We will be gathering feedback on this session and how to adapt it for future meetings.
Clinical Trials

- This slide also was not presented at the meeting, but NIA wanted to be sure everyone saw this.
- For updates on what falls under the definition of “clinical trials” please view this website: [https://grants.nih.gov/policy/clinical-trials/case-studies.htm](https://grants.nih.gov/policy/clinical-trials/case-studies.htm)
- Here is a relevant example:

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Case #18b: The study involves the recruitment of healthy volunteers and mild cognitive impairment patients who are administered a series of standard cognitive tasks while undergoing a brain scan or imaging procedure (e.g., fMRI). The purpose of administering these standard cognitive tasks (or behavioral tasks or presentation of stimuli) is to assess brain activity under standardized laboratory conditions and compare this activity between healthy individuals and mild cognitive impairment groups.

- Does the study involve human participants? Yes, the healthy volunteers and individuals with mild cognitive impairment are human participants.
- Are the participants prospectively assigned to an intervention? No, not in this context. The standard cognitive tasks and the fMRI are being performed to measure and describe brain activity, but not to modify it.

X This study is not a clinical trial.
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