Advisory Council on Alzheimer's Research, Care, and Services

Opportunities and Gaps

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P.L. 111 - 148, PATIENT PROTECTION AND AFFORDABLE CARE ACT

Sec. 4103: Medicare Coverage of Annual Wellness Visit Providing a Personalized Prevention Plan

- "Detection of any cognitive impairment" is specifically listed as an element in the law.
- Required as part of the AWV by the Centers for Medicare and Medicaid Services (CMS) Medicare.
- Effective 01/2011

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Detection of Any Cognitive Impairment
P.L. 111-148, Sec. 4103

- Assessment of an individual's cognitive function by direct observation, with due consideration of information obtained by way of patient report, concerns raised by family members, friends, caretakers, or others.

- Public commenters noted that this definition was vague and suggested adding a standardized screening tool.

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CMS Questions

- How should we detect any cognitive impairment?

- Is there an evidence-based assessment tool that could be used during the annual wellness visit?
  - sensitive and specific (to limit over-diagnosis)
  - applicable to Medicare beneficiary population
  - no cost
  - time to administer

- Are there recommendations on referrals and follow-up of individuals identified with cognitive impairment?
  - inappropriate and/or ineffective treatments

Courtesy of Joseph Chin, M.D.
CMS, Office of Clinical Standards & Quality
U.S. Department of Health and Human Services

Evaluation of Cognitive Screening Instruments

- "Detection of cognitive impairment" provision effective 1/2011

- February 23, 2011, NIH hosted a meeting with CMS and other federal agencies to discuss the new legislation and cognitive screening.

- On April 4, second meeting held with professional organizations and federal agencies to determine next steps.

- NIH recently completed a comprehensive review of over 140 published cognitive screening instruments.

- Next meeting (10/31/2011) scheduled to review instruments and make recommendations.

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Research

Opportunities and Gaps

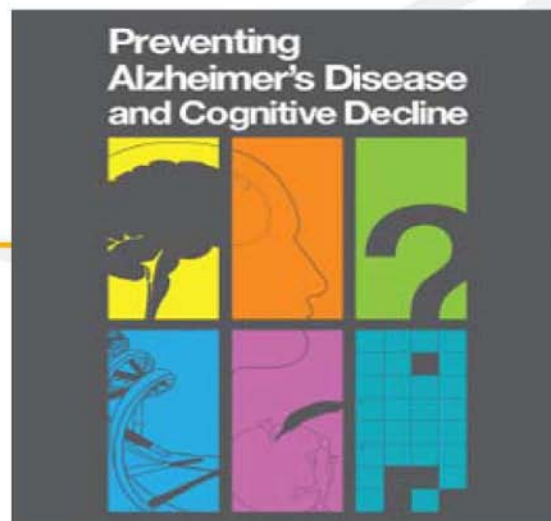U.S. Department of Health and Human Services

ADRD Federal Agencies
Research Planning, Priority Setting, and Evaluation

- Processes ensure that research programs and priorities are established, evaluated, and support the most promising research.

- Agencies' processes include:
  - Established peer-review/external expert reviews of research programs and funding opportunities
  - Participation in and sponsorship of research and state of the science conferences

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NIH State-of-the-Science Conference
Preventing Alzheimer's Disease and Cognitive Decline

Preventing Alzheimer's Disease and Cognitive Decline

April 26–28, 2010
Bethesda, Maryland

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Scientific Knowledge Gaps

- Firm conclusions cannot be drawn about the association of any modifiable risk factor with cognitive decline or Alzheimer's disease.

- Evidence is insufficient to support the use of pharmaceutical agents or dietary supplements to prevent cognitive decline or Alzheimer's disease.

- No "highly reliable consensus-based diagnostic criteria for cognitive decline, mild cognitive impairment and Alzheimer's," and available criteria at clinician level are not "uniformly applied," has been addressed.

  http://consensus.nih.gov/2010/alzstatement.htm

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Federally Funded Clinical Trials

- Over 40 active clinical trials (pilot and large scale) testing wide range of interventions
  - to prevent,
  - to slow, or treat AD and/or MCI,
  - to improve care delivery and patient/caregiver outcomes.

- Primary Prevention: of the 10 primary prevention trials, 2 are NIA-funded cognitive/AD measure add-ons to large NIH primary prevention trials that address a variety of other primary outcomes.

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ADRD FY 2011 Translational Research

Department of Veterans' Affairs

HX-11-014, Targeted Solicitation for Research Projects on Caregiver Programs and Practice to Improve Care Delivery for Veterans; Release date – March 31, 2011

http://vaww.research.va.gov/funding/docs/HSRD-HX-11-013.pdf

HX-11-013, Targeted Solicitation for Research Projects on Customizing Long Term Care Programs and Practice to Meet Veterans' Needs in the 21st Century; Release date – March 31, 2011

http://vaww.research.va.gov/funding/docs/HSRD-HX-11-014.pdf

Administration on Aging and National Institute on Aging Collaborations

PA-11-123, Translational Research to Help Older Adults Maintain their Health and Independence in the Community (R01); Release date- February 16, 2011

http://grants.nih.gov/grants/guide/pa-files/PA-11-123.html

PA-11-124, Translational Research to Help Older Adults Maintain their Health and Independence in the Community (R21), Release date- February 16, 2011

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http://grants.nih.gov/grants/guide/pa-files/PA-11-124.html

Reach

Resources For Enhancing Alzheimer's Caregiver Health

Supported by the National Institute on Aging and the National Institute on Nursing Research

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Promoting Adoption of REACH Interventions

- The Department of Veterans Affairs has implemented "REACH-VA" through its home health agencies

- Administration on Aging has used REACH in its Funding Opportunity Announcements as a model for its caregiving demonstration projects

- REACH-Hong Kong

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AoA New Research Programs for 2011

- "Accelerating Integrated, Evidence-Based, and Sustainable Service Systems for Older Adults, Individuals with Disabilities and Family Caregivers"

- "Creating Dementia Capable, Sustainable Service Systems For Persons With Dementia And Their Family Caregivers."

To develop and operate integrated long-term service and support systems that are dementia capable.

To ensure that older adults, individuals with disabilities and family caregivers have clear and ready access to a sustainable, integrated system that offers a comprehensive set of high quality, evidence-based services that can help them remain independent and healthy in the community.

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Dominantly Inherited Alzheimer Network (DIAN)

- Establish an international registry of mutation carriers and non-carriers from families with early onset AD

- Compare carriers and non-carriers to determine the chronology and order of imaging and biomarker changes that predict symptomatic AD

- Compare the clinical and pathological phenotypes of dominantly inherited AD with those of Late-Onset AD (LOAD) Study

- Maintain a publicly available resource of data and biospecimens

Sites: Washington Univ, B&W/MGH/Brown Univ, Columbia Univ, Indiana Univ, UCLA, ION/UCL, Australian Consortium

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Alzheimer's Disease Neuroimaging Initiative (ADNI) Public-Private Partnership

Abbott — alzheimer's association — NOVARTIS — Alzheimer's Drug Discovery Foundation — Eisai

élan — Genentech — GE — gsk GlaxoSmithKline — INNOGENETICS — Bristol-Myers Squibb — Bayer HealthCare — Johnson&Johnson

Lilly — MEDPACE — Pfizer — Roche — Schering-Plough — SYNARC — Wyeth

AstraZeneca UNITED KINGDOM

Private/Philanthropic + Public

FOUNDATION FOR THE National Institutes of Health

U.S. NATIONAL INSTITUTES OF HEALTH

National Institute on Aging

David Lee
Alison Drone

FDA

Neil Buckholtz

NIBIB, NINDS, NIMH, NIDA, NCRR, NINR

ADNI Executive Steering Committee			PI: Mike Weiner	Publications Core: BostonU: Green	Biostatistics Core: UCD: Beckett
PET Core: Berkeley: Jagust	MRI Core: Mayo: Jack	Clinical Core: UCSD: Aisen Mayo: Petersen	Administrative Core: UCSF Biomarkers Core: UPenn: Trojanowski/Shaw	Informatics Core: UCLA: Toga	Neuropathology Core: WashU: Morris

of Health and Human Services

57 Clinical Sites: ADNI PIs and Cores

8

Alzheimer's Disease (AD) Translational Research Initiative: From Drug Discovery to Clinical Trials
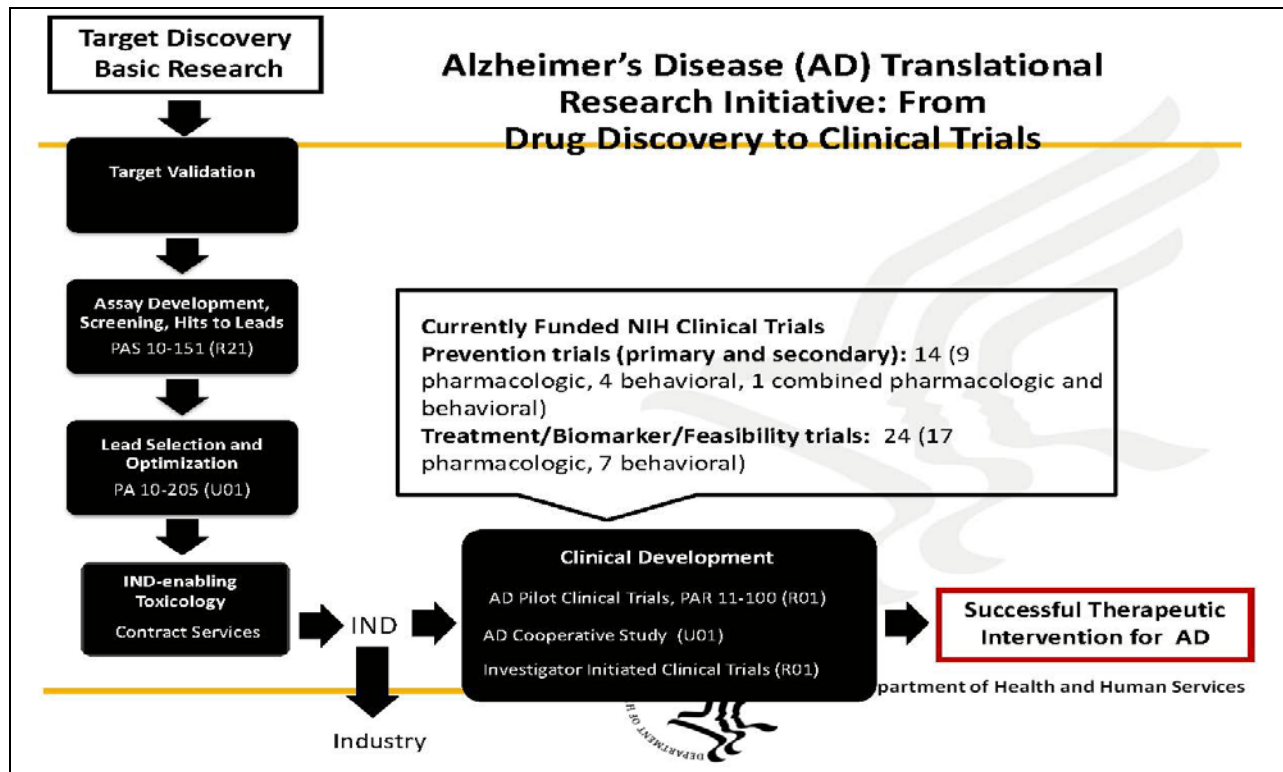
NIA-Alzheimer's Association Project to Redefine Diagnostic Criteria for Alzheimer's Disease

OVERALL GOALS

TO BETTER DEFINE THE NATURAL HISTORY OF ALZHEIMER'S DISEASE FROM ASYMPTOMATIC STAGES TO FULL BLOWN DEMENTIA

TO ATTEMPT TO RELATE THE CLINICAL SYMPTOMS, AS THEY EMERGE, TO THE UNDERLYING PATHOPHYSIOLOGY

TO USE PRESENT KNOWLEDGE TO BETTER DIAGNOSE THE DISEASE

TO DEFINE A RESEARCH AGENDA THAT WILL HELP TO EXTEND OUR KNOWLEDGE TO BETTER REACH THESE GOALS

Clinical Care

Opportunities and Gaps

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Identifying Gaps & Opportunities

- Potential for achieving program goals
- Service or project is supported by evidence
- Actionable
- Need not be specific to Alzheimer's disease

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Direct Clinical Services

- Effective early clinical recognition
- Initiating diagnostic testing early
- Appropriate clinical management

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Home & Community-based

- Case management services
- Personal Care/Unskilled Care and Respite Care
- Identifying & mitigating unsafe behaviors
  - home safety
  - driving
- Mobilizing health care benefits (e.g. hospice)
- Securing health care agents and care planning

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Education and Outreach for Patients, Families and Providers

- Health care provider training to enrich workforce skills
- Management options
- Case management to improve access and utilization of resources
- Patients and Families

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Long-Term Services and Supports

Opportunities and Gaps

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Opportunities and Gaps

Preliminary

- More information about individuals' and caregivers' use of services
- Dementia capable service systems
- Needs of special populations
- Training needs
- Outreach to individuals and caregivers

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Gaps and Opportunities: Examples

Gap	
Data	• LTSS data at both the federal and state levels are not readily available to ascertain the numbers of individuals with Alzheimer's who are receiving Medicaid home and community-based services.
Dementia-Capability	• Many programs or systems offering home and community-based services are not skilled at identifying people with dementia; knowledgeable about the kinds of services that help people with dementia and their caregivers; and/or capable of providing linkages to other organizations.

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Gaps and Opportunities: Examples

Gap	
Special Populations	• Most individuals with Down's Syndrome have deposits in their brains consistent with a diagnosis of Alzheimer's by the time they are 35-40 years of age. Dementia capable services for this "younger-onset" population are not widely available.
Training	• Physicians, nurses, allied health professionals, assessors, service coordinators, quality assurance staff, and direct care workers often lack specific training in how to identify dementia, the special needs of persons with dementia and their caregivers, the progression of the disease, the role of caregivers and how to support self-direction for this group.

Gaps and Opportunities: Examples

Gap	
Outreach	• Caregivers of persons with dementia are often reluctant to identify and seek treatment for depression. Awareness of available programs may help caregivers cope with behavioral health issues they experience.

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Discussion

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