Clinical Amyloid PET Imaging Comments to MEDCAC January 30, 2012

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Disclosures (Past 12 months)

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Financial Interests

- **Bioethics Advisory Board Member:** Lilly USA, LLC (<$10,000)
- **Consultant:** Bristol-Myers Squibb (<$10,000)
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Non-Financial Interests

- **Advisory Committee Memberships:**
  - Amyloid Imaging Taskforce, Society of Nuclear Medicine and Molecular Imaging (SNMMI) / Alzheimer's Association
  - PET Endpoints Workgroup, Alzheimer's Disease Neuroimaging Initiative (ADNI), Private Partner Scientific Board, The Biomarkers Consortium, Foundation for the National Institutes of Health (FNIH)
  - Brain Imaging Outreach Workgroup, SNMMI
  - Co-Chair, 3rd Party Payers for Alzheimer's Disease Treatment and Diagnosis Meeting, Alzheimer's Association Research Roundtable
  - Leader, Clinical Practice Workgroup, American Academy of Neurology (AAN) Geriatric Neurology Section
  - Alzheimer's Disease Technical Working Group, The Green Park Collaborative

Objectives

- Why amyloid PET imaging represents a significant advancement for patient care
- The importance of how imaging results are incorporated into clinical decision-making
- Examples of how PET amyloid imaging could improve outcomes

Why Amyloid PET Imaging Represents a Significant Advancement for Patient Care

- Quality dementia care is dependent upon accurate diagnosis
- Not having information about histopathology has been a major handicap in dementia care
- Autopsy has been the diagnostic “gold standard”
- Diagnosis based upon clinical history and examination alone has limited accuracy and is associated with high levels of diagnostic uncertainty, even among dementia experts

The Importance of How Imaging Results are Incorporated into Clinical Decision-Making

- The critical expertise is not with performing and interpreting the scan, but rests with the provider ordering the study.
- In no similarly serious disease is the gap wider between what is typically done in the community and in centers of clinical excellence than in dementia care.
- The potential for misapplication of amyloid PET imaging results has been the major concern of experienced clinicians

Potential for Overuse is Overblown

- In Utah, a single dementia specialty clinic
- In Utah: ~30,000 with AD, ~50,000 with dementia of all types, ~50,000 with MCI
- In about 5% family members or providers have sufficient concern or uncertainty to refer to a dementia specialist for evaluation
- In our specialty practice: ~20% very helpful, ~20% somewhat helpful, and ~60% unnecessary or inappropriate
- Thus we expect 2-3% of those with dementia and MCI would warrant amyloid PET imaging

Indiscriminate Use of Amyloid PET Imaging Would Lead to Frequent Misdiagnosis and Huge Cost

- Average primary care provider
  - Panel of 2000 patients
  - 45 with cognitive impairment
  - 24 with dementia, of which in only 8 is dementia recognized, much less evaluated
- Amyloid PET would be an impractical technology if primary care providers used it as their first (and perhaps easiest) response to a cognitive complaint in an elderly patient

Case 1: Change in medication and management

- 76 y.o. man, lawyer, developed paranoid schizophrenia in his 40s
- Although unemployed lived independently until 3 yrs ago when behavior deteriorated
- Psychiatrist diagnosed Alzheimer's disease
- Our evaluation – delusional, hallucinating, bifrontal and temporal encephalomalacia and gliosis due to head trauma – not AD
- If + amyloid PET – does have AD; doesn't qualify for state psychiatric services, continue AD drugs
- If – amyloid PET – psychiatric illness; must leave nursing home, more intensive psychiatric care, stop AD drugs

Case 2: Decrease Other Testing

- 70 y.o. man developed fever, diarrhea, severe weight loss and cognitive problems 3 yrs ago while in New Guinea – intestinal parasite
- Symptoms resolved except for dementia that is progressive; PCP dx -- unidentified tropical disease
- Our evaluation: CSF unremarkable, typical clinical, MRI, neuropsychological features of AD
- If + amyloid PET: does have AD; provider and patient consensus about diagnosis and management
- If - amyloid PET: not AD; stop AD drugs, may be able to stop or reverse progression, other testing warranted

Case 3: The Value of Knowing a More Definitive Diagnosis

- 86 y.o. professor, left MCA stroke in 2008; a fib treated with warfarin
- Symptoms of aphasia and hemiplegia completely resolved; but memory problems progressive; PCP diagnosis vascular dementia
- Our evaluation: non-focal exam, memory predominant deficits, visuospatial and language deficits – AD with stroke
- If + amyloid PET: AD and progressive course confirmed, willing to make life-altering decisions
- If – amyloid PET: not AD, if no further strokes no progression expected or need to make changes