

World Molecular Imaging Society

Support for Beta Amyloid PET Imaging for the
Management of Dementia and
Neurodegenerative Disease

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Richard Wahl Disclosures

- **Employee** — The Johns Hopkins University
- **No industry funding on beta amyloid research.**
- **Consultant** — Nihon Medi Physics, Novelos
- **Research Grants** — Lantheus, Actinium Pharmaceuticals, GSK, Molecular Insight, RSNA, NCI, NIH
- **Licensed Patents** — GSK, Spectrum Pharmaceuticals, Naviscan PET Systems
- **Remunerated Speaking Engagements** — GE Health Care (unrelated to Amyloid Imaging), EORTC, KU Leuven, University of Copenhagen

WMIS Disclosures

- Tax-exempt 501(c)(3) dues-funded nonprofit organization.
- Membership open to all persons and organizations whose publication, education, manufacture or practice involves molecular imaging or its applications.
 - WMIS corporate members include General Electric, Siemens, and Avid Radiopharmaceuticals ,among others.
- WMIS receives industry grants and sponsorship to defray the costs of its annual meeting.
- WMIS sponsors the National Oncologic PET Registry (NOPR) with the American College of Radiology.



About WMIS

- International scientific educational organization with 1,000+ members
- Focus is on improving multimodal *in vivo* imaging and the utilization of quantitative molecular imaging in patient care
- Formed in 2011 through the merger of the Academy of Molecular Imaging (AMI) and the Society for Molecular-Genetic Imaging (SMI)
- Involved for many years in supporting CMS efforts to develop evidence-based coverage decisions on PET imaging
- AMI sponsored the original National Oncologic PET Registry in 2006, and WMIS sponsors both the NOPR 2009 and NOPR (NaF-PET) registries



Dementia Epidemiology and Impact: A Statistical Overview

- Dementia prevalence: $\sim 14,000/100,000$
 - $\sim 5\%$ of subjects age 70- 80 years
 - $\sim 24\%$ of subjects age 80-90 year
- ~ 3.4 million cases in USA (2007) (Neuroepidemiology 2007; 29: 125-132)
- ~ 5.4 million cases in USA today (Alzheimers Dement. 2012; 8:131-168)
- Annual costs (direct and indirect) $\sim \$150$ billion
- Dementia Subtypes:
 - AD (50%) / Vascular / DLB / FTD
- Routine clinical diagnostic accuracy $\sim 60\% - 80\%$

The Importance of Beta Amyloid PET

- At present, Alzheimer's disease pathology only can be inferred through the recognition of a characteristic phenotype
- By the time dementia is obvious, deficits often are so pervasive that the typical phenotype may be difficult to recognize
- Significant imaging advances now allow detection of the onset of Alzheimer's disease, tracking of its progression, and monitoring of treatment effects in patients (many of whom are in the Medicare population)
- Amyloid deposition in the brain is one of the most important pathological hallmarks of Alzheimer's disease
- Empowered with the knowledge of brain pathology, clinicians will be more likely to begin and maintain appropriate treatment

Why Diagnose FTD vs AD?

- Cognition does not benefit from symptomatic AD therapy (AChE inhibitor)
- Behavior may deteriorate on AChE inhibitors
- Antipsychotics not contraindicated
- Anti-amyloid therapy likely will have no benefit

Courtesy K. Frey U of Michigan



Clinical Consensus vs PET Diagnosis

Molecular Imaging Classification

Clinical Consensus Classification		AD	DLB	FTD
	AD	30	4	2
	DLB	2	10	2
	FTD	15	1	9

35% Discordance between Molecular and Clinical Diagnoses

Mild dementia MMSE ≥ 18
Burke JF et al. Brain 2011, 134:1647-1657

WMIS Supports Medicare Coverage of Beta Amyloid PET

- WMIS strongly supports coverage of beta amyloid PET as “reasonable and necessary” for the management of dementia and neurodegenerative disease
- Published research demonstrates that beta amyloid PET has a positive impact on physicians’ clinical decision making when evaluating patients for Alzheimer’s and other causes of cognitive decline
- Advantages of PET evaluation for dementia include:
 - Improved early diagnostic accuracy
 - Increased recognition of Alzheimer’s and other neurodegenerative dementias
 - Shorter time of ambiguity for patient, family, and physician
 - Facilitation of early treatment, leading to disease stabilization and improved quality of life

WMIS Supports the SNMMI/AA Draft Appropriate Use Criteria

- WMIS supports the SNMMI/AA Amyloid Imaging Taskforce draft Appropriate Use Criteria for beta amyloid PET
- CMS can establish reasonable limitations on beta amyloid PET that permit beneficiary access without encouraging overuse
- Beta amyloid PET should not be used for screening of asymptomatic patients or for evaluation of patients with no documentation of cognitive decline.
- Beta amyloid PET should not be used for patients who present with symptoms and clinical profiles that make their diagnosis clear and confident without the scan
- Should CMS nonetheless conclude that additional evidence is necessary, WMIS is prepared to assist CMS in developing and administering registries for the collection of practice-based observational data from the Medicare beneficiary population