The Impact of Beta-amyloid Imaging on Diagnosis and Intended Patient Management

Dr. Mark Mintun, Chief Medical Officer
Avid Radiopharmaceuticals
(A wholly owned subsidiary of Eli Lilly and Company)
CMS MEDCAC, 1/30/13

Answers That Matter.

Disclosure

Dr. Mark Mintun, MD, is Chief Medical Officer and a full time employee of Avid Radiopharmaceuticals (Avid), a wholly owned subsidiary of Eli Lilly and Company (Lilly).

Lilly owns the New Drug Application (NDA) for Amyvid (Florbetapir F 18 Injection).

Agenda

Alzheimer’s Disease – The Role of Beta-amyloid and Challenges with Diagnostic Accuracy

Brief Summary of Amyvid Registration Trials

The Potential of Beta-amyloid Imaging to Impact Patient Diagnosis and Management

Summary

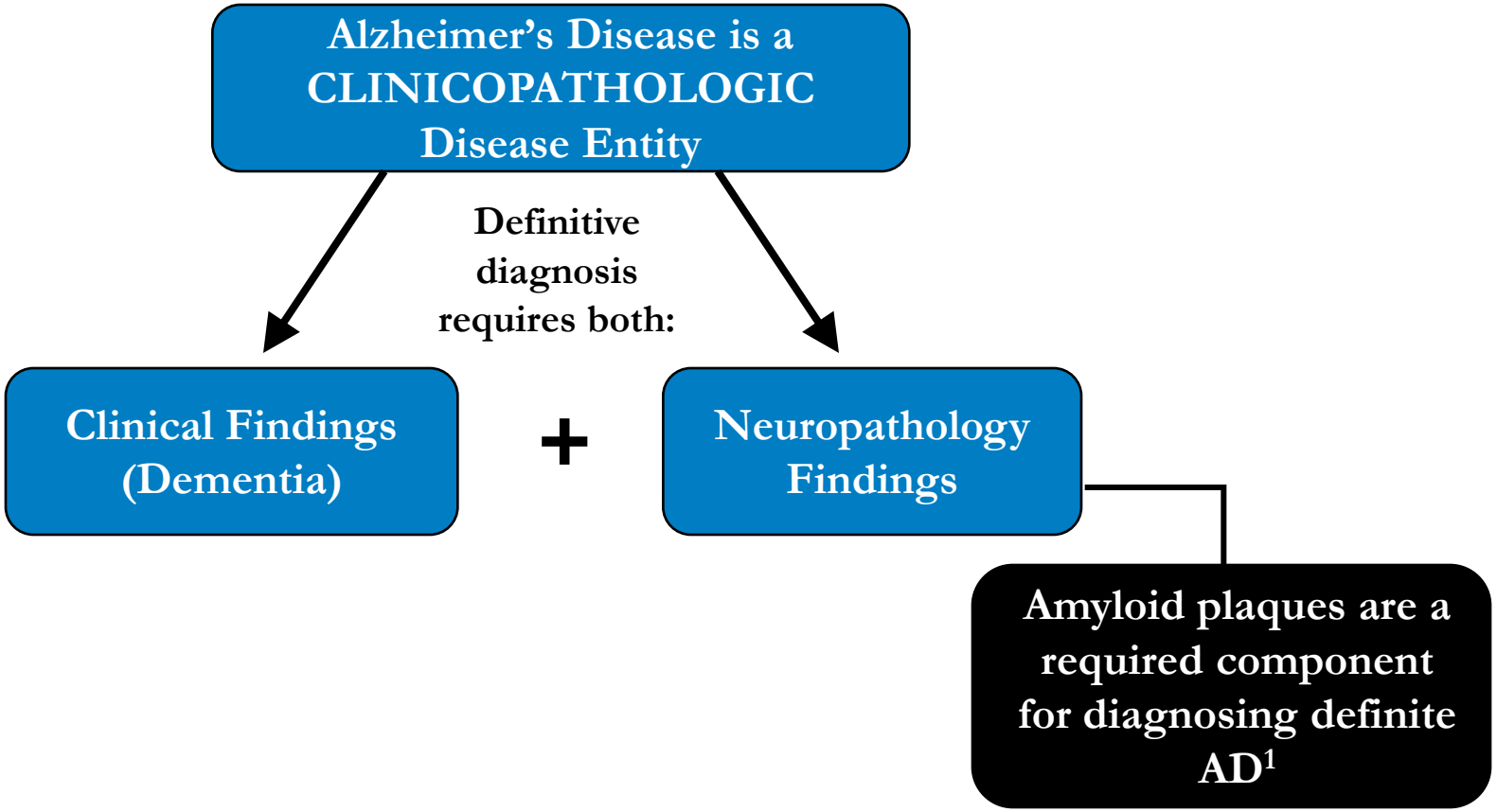
NAPA – A National Call to Action

The National Alzheimer's Project Act[1] (NAPA) represents a call to action across the agencies within Health and Human Services (HHS), including CMS, to encourage and make available improved means by which providers can diagnose and care for their patients afflicted with Alzheimer's disease and other forms of cognitive impairment.

[1] U.S. Department of Health and Human Services, 2012.

Alzheimer’s Disease – The Role of Beta-amyloid and Challenges with Diagnostic Accuracy

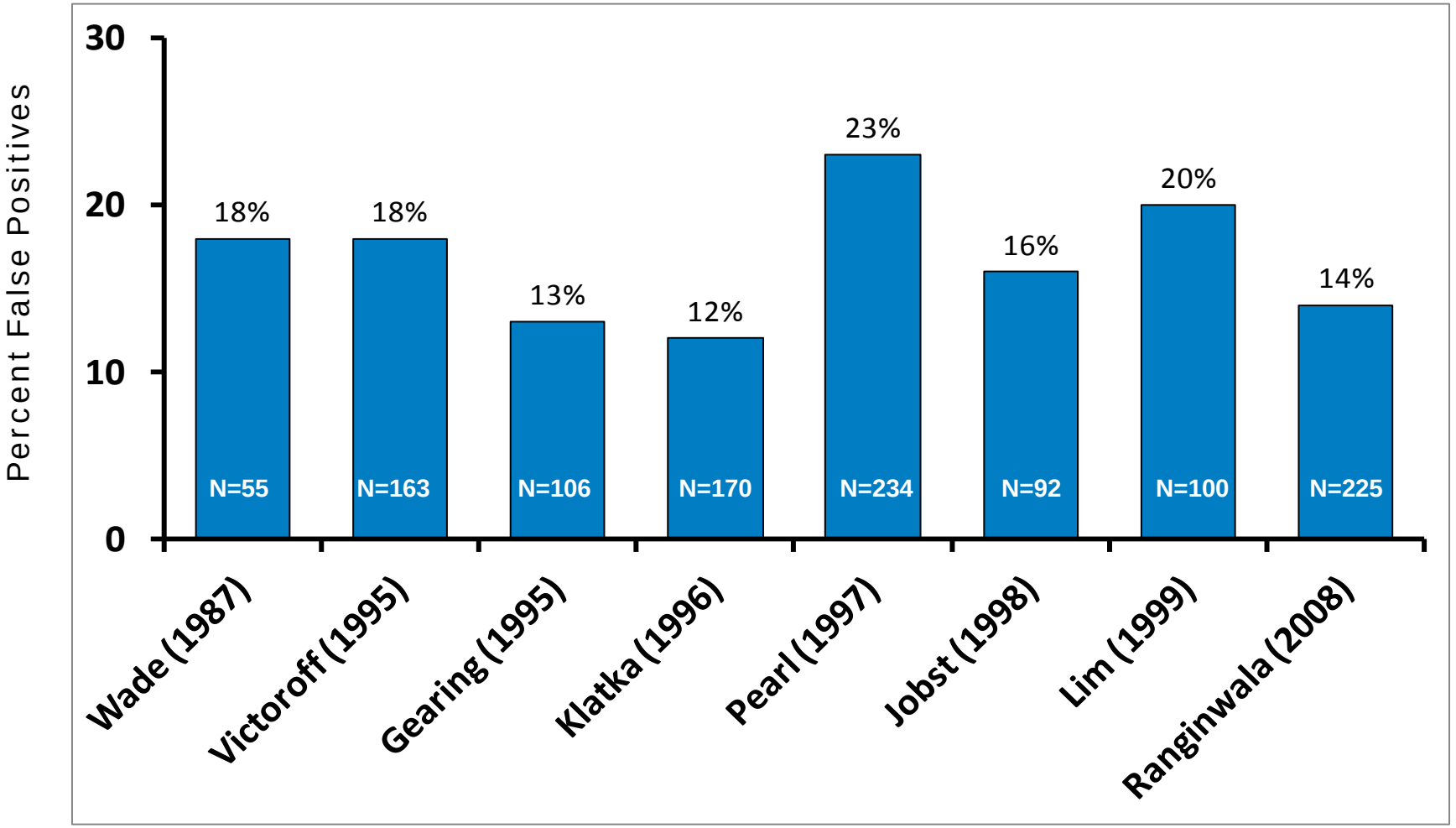
Definitive Diagnosis is Currently Only Possible with Pathological Examination



Highest level of diagnostic certainty ante-mortem is "Probable AD"
Currently, definitive diagnosis is only possible post-mortem

[1] Standaert DG, 2001.

False Positive Rates of Clinical Diagnosis Range from 12% to 23% in Pathological Studies



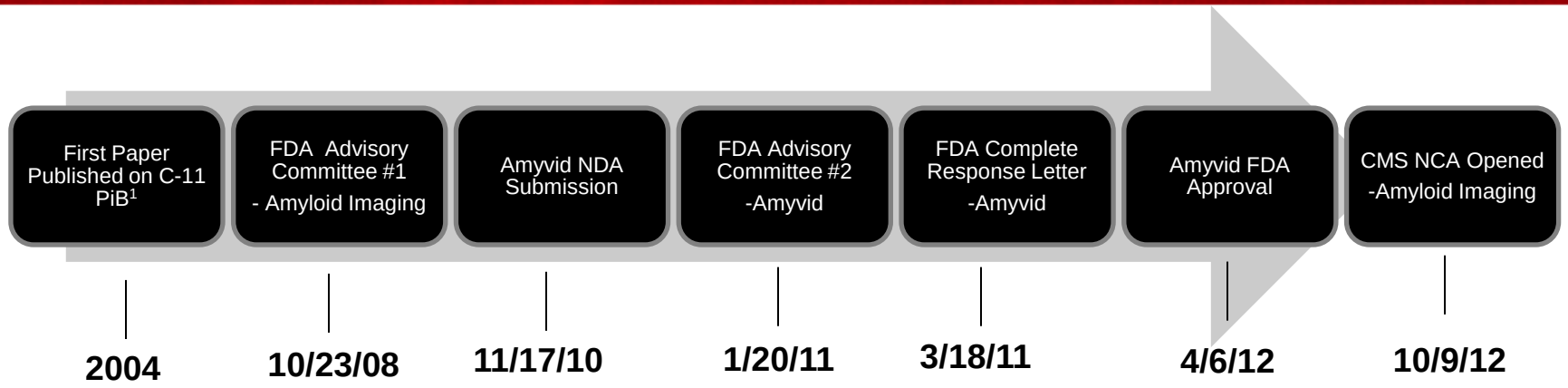
Highlighted Implications of Uncertain or Incorrect Diagnosis

Acetylcholinesterase inappropriate for patients with frontotemporal dementia (FTD)	Lack of consistent evidence for efficacy of acetylcholinesterase inhibitors in FTD[1]	Acetylcholinesterase inhibitors can lead to exacerbation of behavioral symptoms in patients with FTD (particularly those with behavioral variant)[2]
Uncertainty about presence of AD could delay diagnosis of potentially treatable causes of dementia	Patients with coexisting vascular disease and AD may not receive an aggressive trial of a cholinesterase inhibitor[3]	Treatment for depression, hydrocephalus, alcohol dependence syndrome, metabolic disease, epilepsy, or delirium could all be delayed[4]
Value of Knowing to Patient and Family	Impacts of delayed detection can include: " …missed opportunities to prevent falls and injuries, including potentially fatal injuries; [and]…delays in planning for future functional declines."[5]	

[1] Kerchner et al., 2011.
[2] Mendez et al., 2007.
[3] Kavirajan and Schneider, 2007.
[4] Hejl et al., 2002.
[5] 2012 Alzheimer's disease facts and figures.

Brief Summary of Amyvid Registration Trials

Beta Amyloid Imaging Milestones



✓**Long history of evidence beginning with C-11 PiB**

✓**Amyloid imaging would be clinically useful (e.g., a negative scan makes AD an unlikely diagnosis)**

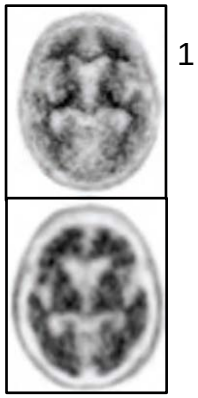
✓**The available data support the approval of Amyvid conditional on the implementation of a training program that demonstrates accuracy and consistency**

✓**FDA evaluated 3 Amyvid clinical studies that examined images from healthy adult subjects as well as subjects with a range of cognitive disorders**

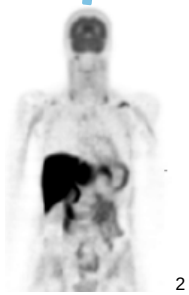
[1] Klunk et al., 2004.

Amyvid Development Timeline

Phase I (A01-A04) → **Phase II*** → **Phase III**



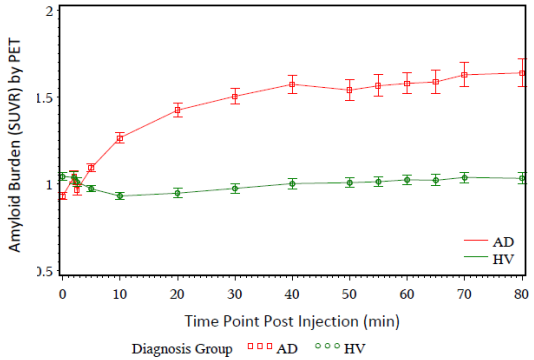
1



2

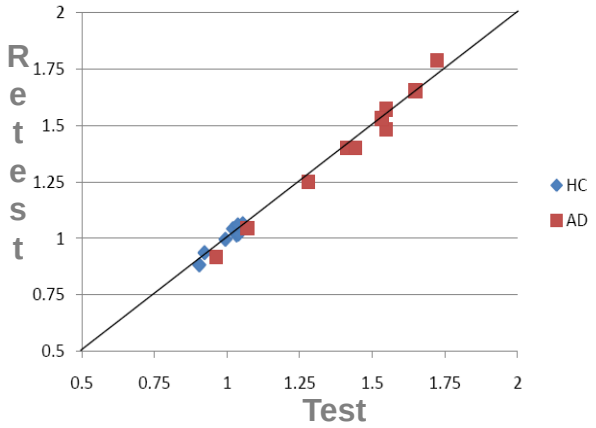
3 mCi
vs
10 mCi

Time Course of ^{18}F-AV-45
SUVR - Cortical Regions to Cerebellum



Differentiate AD from HC
Relationship to pathology
risk factors:

- ApoE ε4
- Age
- Cognitive Scores



- 3 clinical studies
- Demonstrate the ability to effectively estimate beta amyloid plaque density
- High inter-reader reproducibility

[1] Idealized images representative of difference between AD and HC in Wong et al., 2010.
[2] Data combined from Wong et al., 2010 and Joshi et al., 2012.

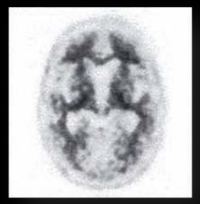
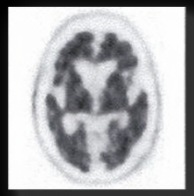
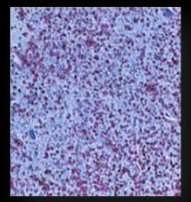
Study 1 (A07): Image to Autopsy (part I)

Design[1]

Comparison of premortem Amyvid images to the findings from a postmortem brain examination

Results[1]

- Statistically significant correlation between median Amyvid PET scan scores and percentage of cortical amyloid burden seen at autopsy (r=0.78; *P*<0.0001)

Negative Amyvid PET Scan[2]	Pathology Result (IHC)[2]	Positive Amyvid PET Scan[2]	Pathology Result (IHC)[2]
			
Low Amyvid uptake in cortical gray matter	No evidence of amyloid plaques	High Amyvid uptake in cortical gray matter	High levels of amyloid plaques

[1] Amyvid (Florbetapir F 18 Injection) full Prescribing Information; 2012.
[2] 2012 Data on file, Lilly Research Laboratories, AMY20120725.

Study 2 (A16): Image to Autopsy (part II)[1]

Design

- Assessed performance characteristics (sensitivity and specificity) among subjects with a postmortem amyloid neuritic plaque density truth standard
- All readers underwent in-person training, 5 readers interpreted scans using a binary visual read methodology

Results

- Using the majority interpretation, **96% sensitivity and 100% specificity** for the presence or absence of moderate to frequent amyloid plaques were achieved in patients with autopsies performed within 1 year of imaging (n=46)
- In the complete data set (patients autopsied within 2 years of imaging, n=59), **92% sensitivity and 100%** specificity were achieved

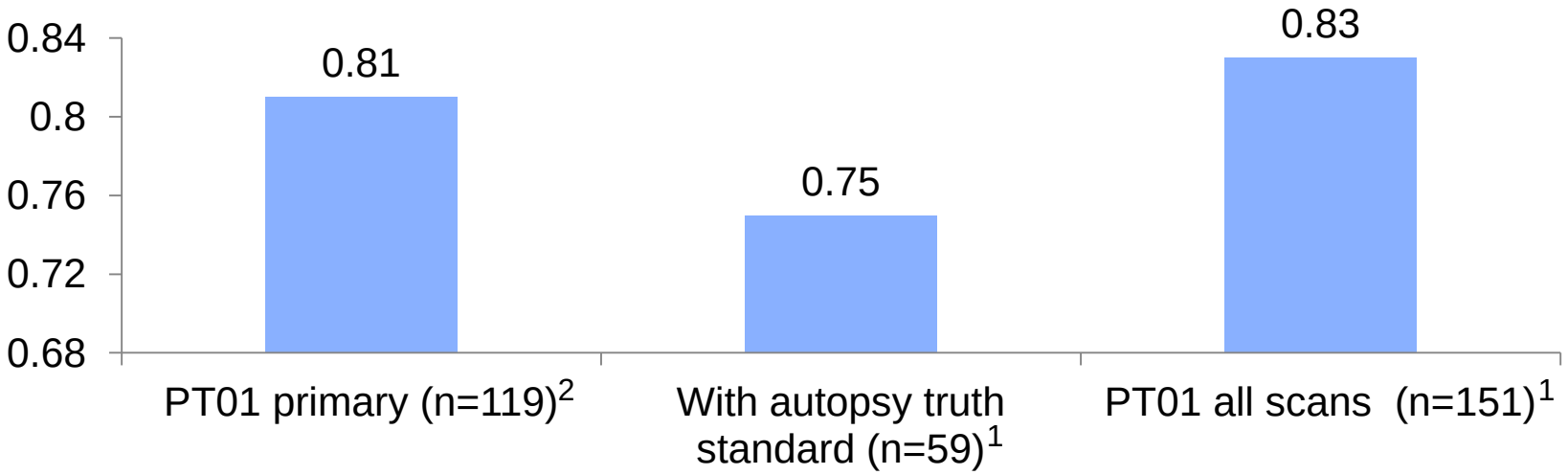
[1] Amyvid (Florbetapir F 18 Injection) full Prescribing Information; 2012.

Study 3 (PT01): Design[1]

- Additionally, inter-reader and intra-reader image interpretation reproducibility was assessed among all the subjects, including subjects who lacked a postmortem truth standard
- Assessed performance characteristics (sensitivity and specificity) among subjects with a postmortem amyloid neuritic plaque density truth standard
- Before image interpretation, all readers underwent electronic media-based training
- 5 readers interpreted scans using a binary visual read methodology
- 151 subjects: 92 subjects who did not undergo autopsy (truth standard) in addition to 59 patients (same population from Study 2) with autopsy data were studied

[1] Amyvid (Florbetapir F 18 Injection) full Prescribing Information; 2012.

Study 3 (PT01): Fleiss' Kappa Shows High Inter-reader Reproducibility



- Fleiss' kappa for inter-reader agreement (n=5 readers), using binary reads:
  - 0.81 (95% CI:0.75 to 0.87) using primary data set (n=119),
  - 0.83 (95% CI, 0.78-0.88 for all images (n=151).
    - Note, the lower bound of the 95% CI for both of the results exceeded the pre-specified success criterion of 0.64 (95% CI lower bound >0.58).
  - 0.75 (95%CI: 0.67 to 0.83), in the all-autopsy (Study A16) population (n=59)

Fleiss' kappa=the degree of agreement among multiple readers over that which would be expected by chance.

[1] Amyvid (Florbetapir F 18 Injection) full Prescribing Information; 2012.
[2] Avid Radiopharmaceuticals. Clinical Study Report ^{18}F-AV-45-PT01. 3 Oct 2011.

High Sensitivity and Specificity Were Shown Across Both Methods of Reader Training

Amyvid Scan Results by Reader Training Method,
All Autopsied Patients (n=59)[1]

	In-Person Training (Study 2)	Electronic Media Training (Study 3)
Median sensitivity (of individual readers)	92% (69-95%, range)	82% (69-92%, range)
Median specificity (of individual readers)	95% (90-100%, range)	95% (90-95%, range)

Amyvid Scan Results by Reader Training Method,
Patients Who Went to Autopsy Within One Year of Imaging (n=46)

	In-Person Training (Study 2)[2]	Electronic Media Training (Study 3)[3]
Median sensitivity (of individual readers)	96% (75-100%, range)	89% (75-100%, range)
Median specificity (of individual readers)	94% (89-100%, range)	94% (89-100%, range)

[1] Amyvid (Florbetapir F 18 Injection) full Prescribing Information; 2012.
[2] Avid Radiopharmaceuticals. Clinical Study Report ^{18}F-AV-45-A16. 3 Oct 2011.
[3] Avid Radiopharmaceuticals. Clinical Study Report ^{18}F-AV-45-PT01 3 Oct 2011.

Adverse Reactions Reported in Amyvid Clinical Trials[1]

Adverse Reactions	Amyvid N (% of Patients)
Headache	9 (1.8%)
Musculoskeletal pain	4 (0.8%)
Fatigue	3 (0.6%)
Nausea	3 (0.6%)
Anxiety	2 (0.4%)
Back pain	2 (0.4%)
Blood pressure increased	2 (0.4%)
Claustrophobia	2 (0.4%)
Feeling cold	2 (0.4%)
Insomnia	2 (0.4%)
Neck pain	2 (0.4%)

N=496

[1] Amyvid (Florbetapir F 18 Injection) full Prescribing Information; 2012.

Amyvid FDA Approved Indication[1]

INDICATION

Amyvid is indicated for Positron Emission Tomography (PET) imaging of the brain to estimate β-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's Disease (AD) and other causes of cognitive decline.

A negative Amyvid scan indicates sparse to no neuritic plaques and is inconsistent with a neuropathological diagnosis of AD at the time of image acquisition; a negative scan result reduces the likelihood that a patient's cognitive impairment is due to AD. A positive Amyvid scan indicates moderate to frequent amyloid neuritic plaques; neuropathological examination has shown this amount of amyloid neuritic plaque is present in patients with AD, but may also be present in patients with other types of neurologic conditions as well as older people with normal cognition.

Amyvid is an adjunct to other diagnostic evaluations.

Limitations of Use

- A positive Amyvid scan does not establish a diagnosis of AD or other cognitive disorder
- Safety and effectiveness of Amyvid have not been established for
  - Predicting development of dementia or other neurologic condition
  - Monitoring responses to therapies

Warnings and Precautions

- Image interpretation errors (especially false negatives) have been observed.
- Radiation risk: Amyvid, similar to all radiopharmaceuticals, contributes to a patient's long-term cumulative radiation exposure. Ensure safe handling to protect patients and health care workers from unintentional radiation exposure.

[1] Amyvid (Florbetapir F 18 Injection) full Prescribing Information; 2012.

The Potential of Beta Amyloid Imaging to Impact Patient Diagnosis and Management

The Potential to Impact Patient Diagnosis and Management

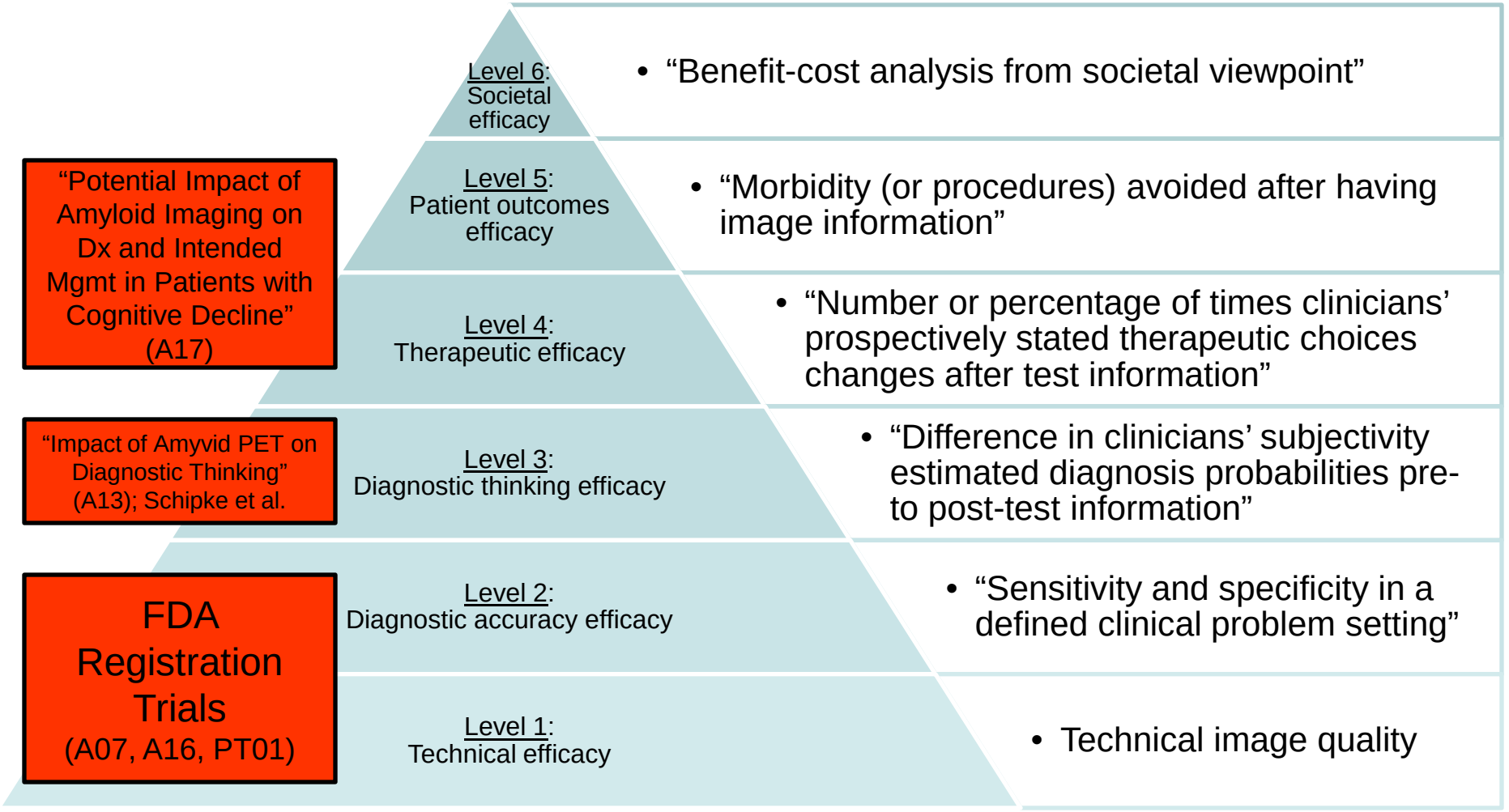
- Recent SNMMI/AA Draft Appropriate Use Criteria[1] reinforce potential value with key studied populations, including patients with the following characteristics:
  - A cognitive complaint with objectively confirmed impairment
  - Alzheimer's disease as a possible diagnosis, but when the diagnosis is uncertain after a comprehensive evaluation by a dementia expert
  - Knowledge of the presence or absence of beta-amyloid pathology is expected to increase diagnostic certainty and alter management

- Both retrospective and prospective studies indicate the appropriate use of beta-amyloid PET can change both patient diagnosis and intended management[2]

[1] Summarized from Preamble to Draft Appropriate Use Criteria posted for public comment at the time of slide submission to CMS. Electronically retrieved December 12, 2012. Available online at http://www.alz.org/research/funding/amyloid_imaging_task_force.asp.

[2] A13, A17, and Schipke et al. studies; described in greater detail in following slides.

Scientific Framework for the Evaluation of Diagnostics[1]



[1] Fryback and Thornbury , 1991.

A13 Study: Impact of Amyvid PET on Diagnostic Thinking[1]

Design

- Selection of case vignettes from Phase 2 study
- 50% of cases amyloid negative – 50% positive
- Three academic neurologists :
  - Reviewed each case
  - (44 cases x 3 reviewers = 132 total cases)
  - Made dx and created tx plan
  - Reviewed PET scan and interpretation
  - Made final diagnosis treatment plan

Limitations

- Hypothetical rather than actual diagnosis
- Intended rather than actual (observed) management plan
- Open design, scan information obtained for all cases.
- No confirmation of outcome absent scan

Results

ECRP Physician	Total number of cases reviewed (44 cases x 3 reviewers = 132 total cases)	Cases where pre-PET Dx was inconsistent with PET N(%)	Cases where Dx changed after viewing PET N(%)	% cases with Dx change when initial diagnosis was inconsistent with PET 95% CI	P-Values
Overall	132	78 (59%)	66 (50%)	85% (80-100%)	<0.0001

[1] Avid Radiopharmaceuticals. Clinical Study Report ^{18}F-AV-45-A13. 4 Nov 2011; publication forthcoming.

Impact of Florbetaben on Diagnostic Thinking and Intended Change In Patient Management[1]

Physicians reported an anticipated impact on their patient management of probable AD patients in 89% of the cases (108 of 121) as compared to 35% of the controls (28 of 80).

Impact rated as either “strong” or “some” in approximately 2 out of 3 probable AD patients

83% change of confidence – an increase or a decrease in the original diagnosis – was observed within probable AD cases (101 of 121)

Design and Limitations:

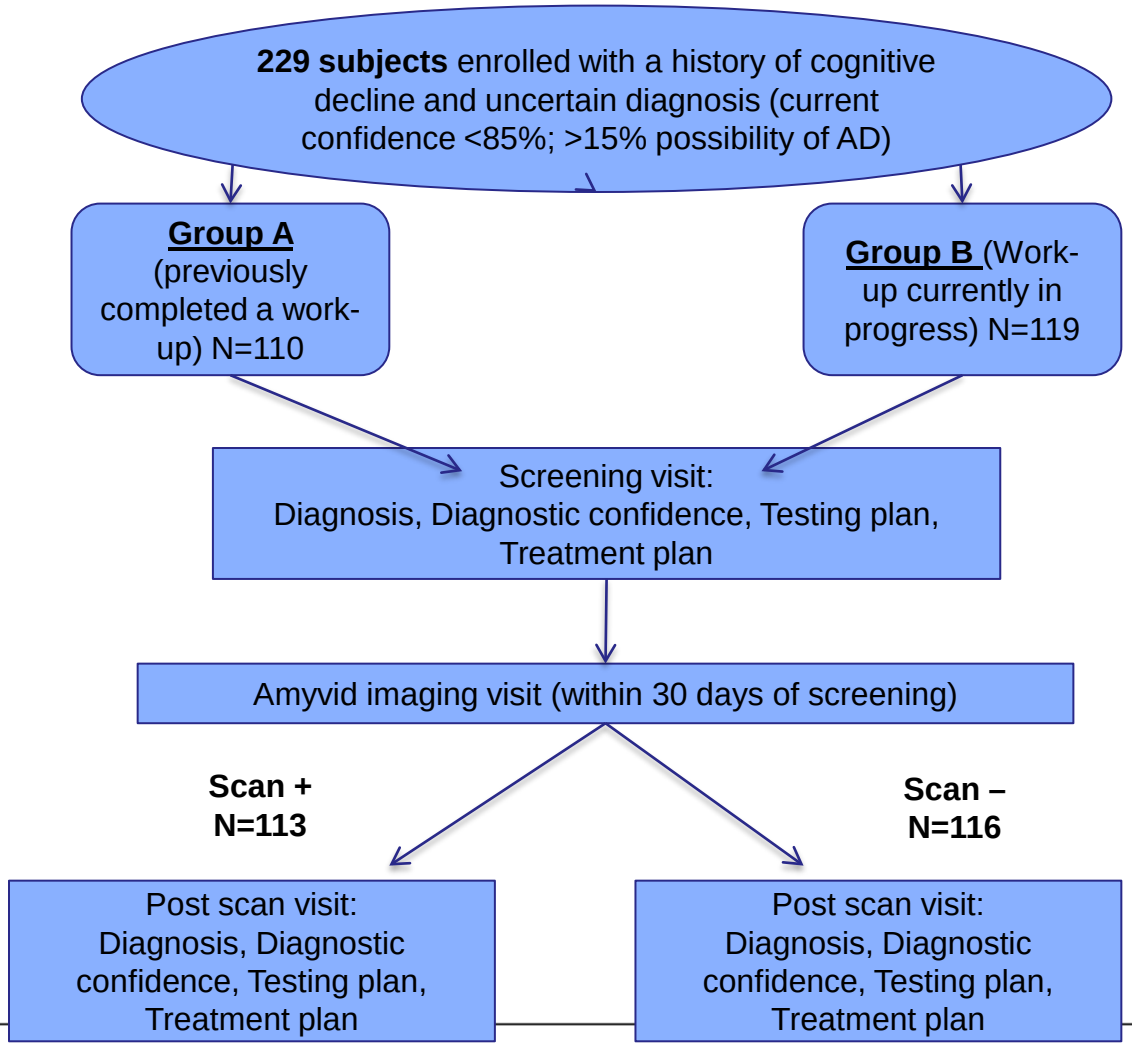
Voluntary physician questionnaire add-on to multicenter, five country phase IIb trial; study participants were limited to patients diagnosed with probable AD or healthy controls; limited number of subjects prevented stratification of findings by country

In 100% of probable AD cases with a ***negative*** PET scan (n=22), physicians reported a decrease in confidence in their original diagnosis

In 78% of probable AD cases with a ***positive*** PET scan (n=77), physician reported an increase in confidence in their original diagnosis

[1] Schipke et al., 2012

A17: Potential Impact of Amyloid Imaging on Diagnosis and Intended Management in Patients with Cognitive Decline[1]



Limitations

- Changes in management were hypothetical due to pre-market initiation of trial
- Physicians were largely memory disorder experts, experienced with diagnosis
- Scan was read centrally by experts

[1] Grundman et al., 2012

A17: Amyvid PET Impact On Diagnostic Thinking[1]

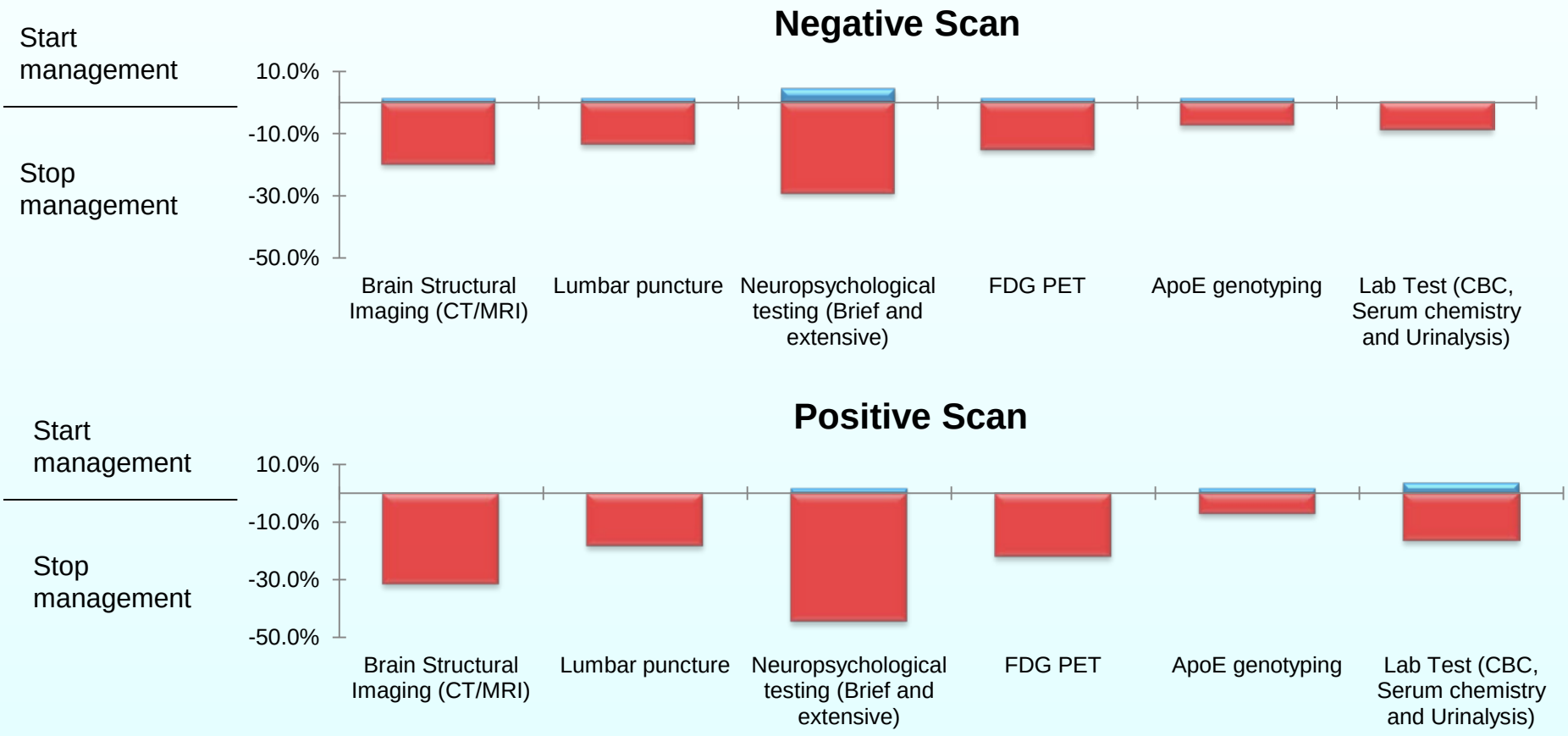
After receiving the results of an Amyvid PET scan:

- **Physicians changed their reported diagnosis in 54.6% of the cases** (125/229; 95% CI: 48.1% to 60.9%)
- **Physicians diagnostic confidence increased by an average of 21.6%** (n=84; 95% CI: 18.3% to 24.8%)

Pre-Scan Diagnosis	Post-Scan Diagnosis			Change
	Syndromic	Due to AD	Not due to AD	
Scan -				
Syndromic (n=74)	41(55.4%)	0(0.0%)	33(44.6%)	**33 (44.6%)**
Etiology due to AD (n=33)	22 (66.7%)	1 (3.0%)	10 (30.3%)	**32 (97.0%)**
Not due to AD (n=9)	1 (11.1%)	0 (0.0%)	8 (88.9%)	**1 (11.1%)**
Scan +				
Syndromic (n=48)	1(2.1%)	47(97.9%)	0(0.0%)	**47(97.9%)**
Etiology due to AD (n=53)	0 (0.0%)	53 (100.0%)	0 (0.0%)	**0 (0.0%)**
Not due to AD (n=12)	0 (0.0%)	12 (100.0%)	0 (0.0%)	**12 (100.0%)**

[1] Grundman et al., 2012

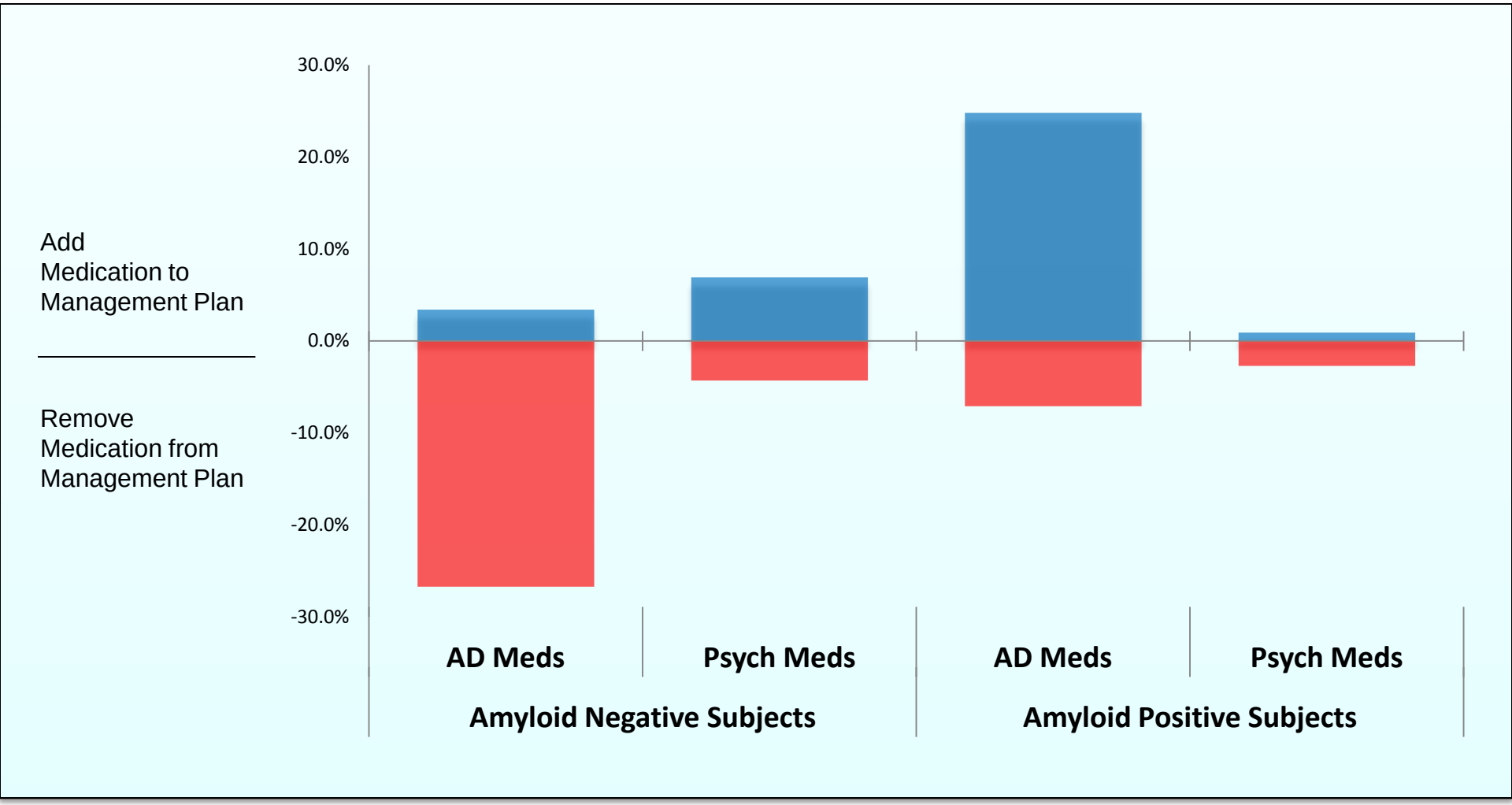
A17: Impact of Amyvid on Intended Change In Patient Management, for Subjects Whose Workup Was in Progress at Time of Enrollment in Study (n=119)[1]



Across all study subjects (N=229), 86.9% of all cases had at least one change in their intended management plan following the Amyvid PET scan

[1] Grundman et al., 2012

A17: Change In Intended Medication Plan After Receiving Amyvid Scan Results, All Study Subjects (n=229)[1]



[1] Grundman et al., 2012

Summary

Summary

- The National Alzheimer's Project Act (NAPA) calls for prioritization of diagnostics and treatments within this space
- The Alzheimer's Association/SNMMI draft guidelines identify clear patient populations for appropriate and beneficial use of beta-amyloid PET scans
- Innovative diagnostic technology must be evaluated in the appropriate policy and scientific contexts
- Beta-amyloid imaging is accurate and reliable, with compelling negative predictive value
- Multiple studies suggest the ability for beta-amyloid imaging to impact the diagnosis and intended management of Medicare patients

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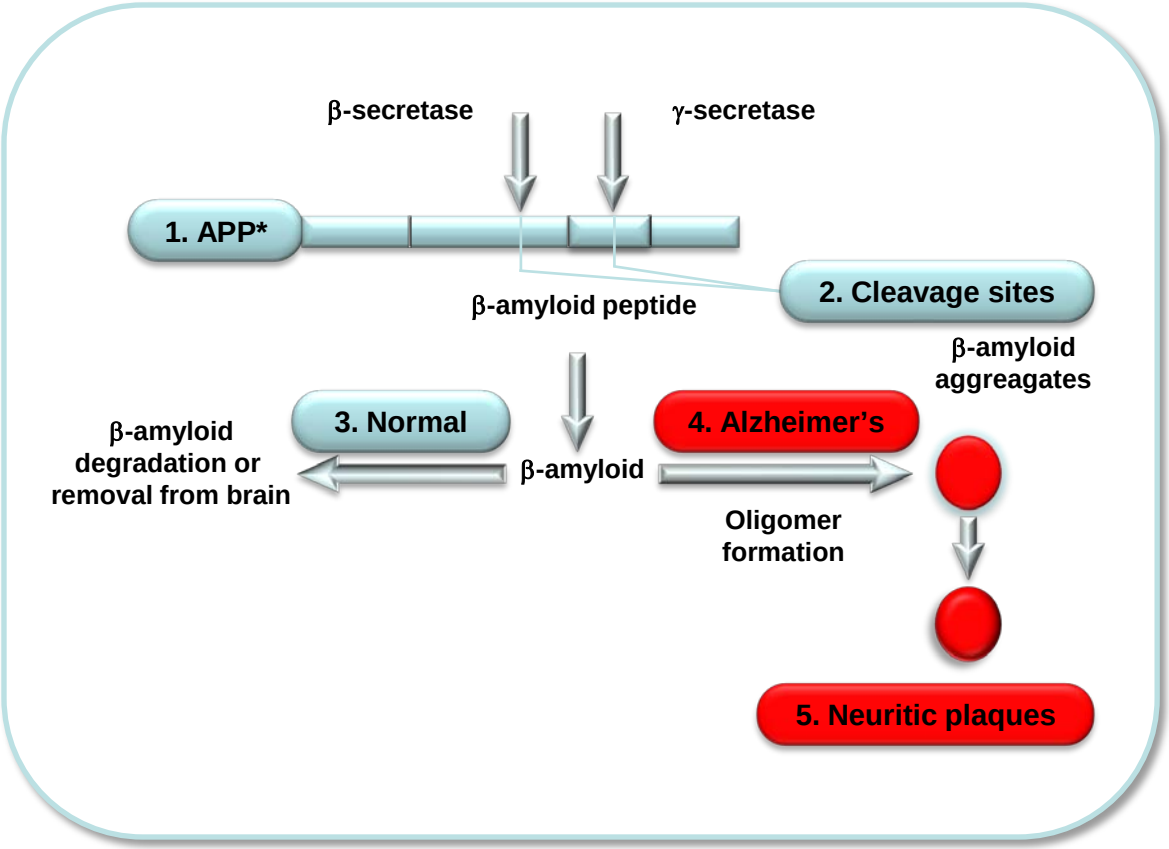
Backup Slides

The Role of Beta Amyloid[1]

- Although the etiology of Alzheimer's disease is unknown, the soluble Aβ peptide is a major constituent of the beta amyloid plaques (a neuropathological hallmark of Alzheimer's disease).

- There is increasing support for the "amyloid cascade" hypothesis, in which the initiating event in AD is an imbalance between the production and clearance of beta-amyloid in the brain. The imbalance results in an increase in various forms of soluble and insoluble beta-amyloid peptide. One or more of these soluble forms is neurotoxic, eventually resulting in synaptic dysfunction and neuronal loss and ultimately depositing as insoluble plaque.



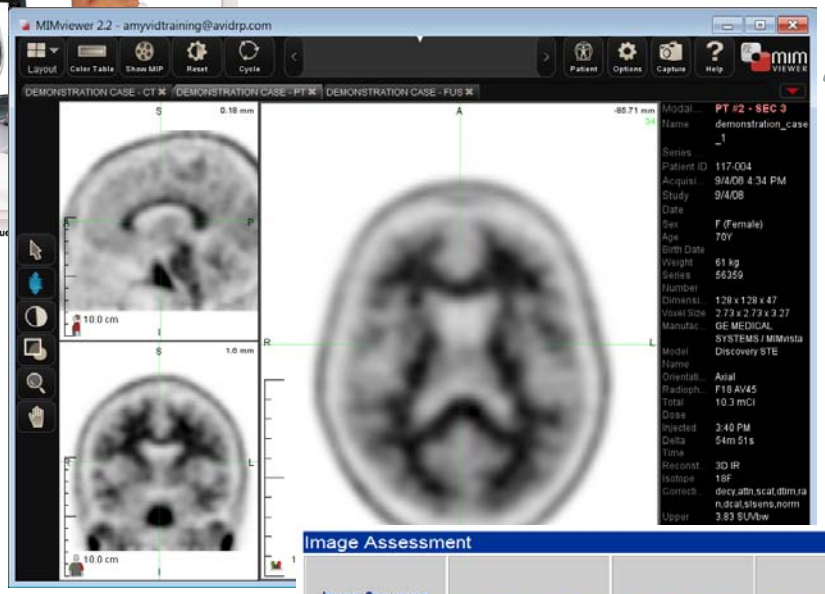
*APP=amyloid precursor protein.

[1] Standaert et al., 2011; Blennow et al., 2006; Simon et al., 2009.

Study 3 (PT01): Reader Training Program Validation

Physician completes e-based Training

Physician interprets Amyvid Scans in clinical setting (Aβ+, Aβ-)



Interpretation results captured electronically & analyzed

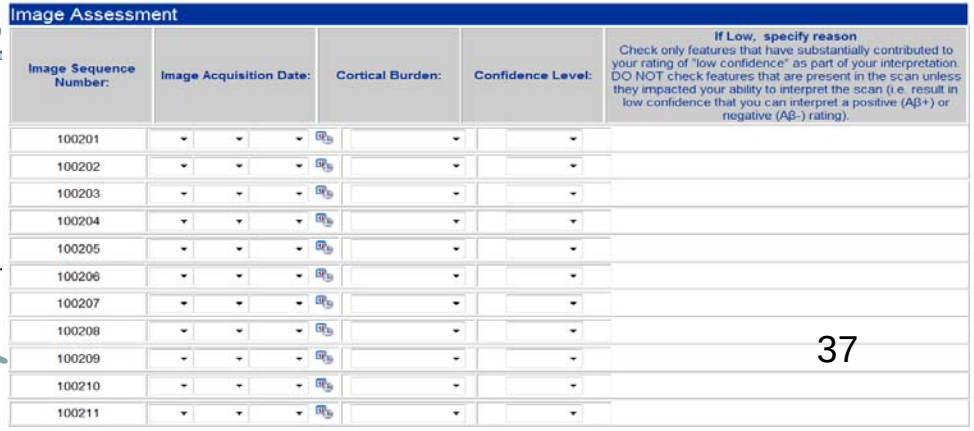


Image Assessment

Image Sequence Number:	Image Acquisition Date:	Cortical Burden:	Confidence Level:	If Low, specify reason Check only features that have substantially contributed to your rating of "low confidence" as part of your interpretation. DO NOT check features that are present in the scan unless they impacted your ability to interpret the scan (i.e. result in low confidence that you can interpret a positive (Aβ+) or negative (Aβ-) rating).
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