

Dementia Diagnostic Clinic Network Spring Virtual Meeting

May 6, 2022

Continuing Education Credits

There will be 1.0 hour of continuing education (CEH) or 0.1 continuing education unit (CEU) available for the Most Difficult Case Conference. We do not have AMA or APA oversight for this training; hence, a CME credit is not available.

To request the continuing education credit (CEH/CEU), participants will need to:

1. complete the training evaluation by Monday, May 16, 2022
2. meet attendance verification criteria
 - use full name in online platform (double check your Zoom tile on the screen)
 - on individual computer
 - logged in during the Most Difficult Case Conference

Please note that telephone only attendees will not meet the above criteria.

The online platform attendance report will be used to verify participant attendance.

Disclosure and Attestation

The individuals in control of content for this educational activity have no relevant financial relationships that exist now or in the past 12 months.

This educational activity has received no commercial support.

Dr. Carlsson receives grant/research support from NIH/Lilly, NIH/Eisai, Department of Veterans Affairs, Alzheimer's Association/Foundation for NIH, the UW Department of Medicine, Bader Philanthropies, and the Louis A. Holland, Sr. Family.

Agenda

- | | |
|---|--|
| 1:00 p.m. Welcome
Cindy Carlsson, MD, MS | 2:45 p.m. National Alzheimer's Project Act (NAPA) Update
Cindy Carlsson, MD, MS |
| 1:10 p.m. Clinic Network Analysis
Maria Mora Pinzon, MD, MS | 2:55 p.m. Most Difficult Case Conference
Facilitator
Michael Malone, MD
Presenting Clinic
Marshfield Memory Disorders Clinic
Ekaterina Keifer, PhD
Sonja Blum, MD, PhD |
| 1:25 p.m. Overview of Aducanumab
Cindy Carlsson, MD, MS | Discussions
Danielle Dodson, MSW, LCSW
Victoria Williams, PhD |
| 1:35 p.m. Aducanumab Discussion
Breakout Room Discussions
Large Group Report-out and Discussion | 3:55 p.m. Closing Remarks
Cindy Carlsson, MD, MS |
| 2:05 p.m. BOLD Grant Care Planning Code Discussion
Kristen Felten MSW, APSW and Kathleen Smith | |
| 2:25 p.m. Clinic Network Progress and Updates
Cindy Carlsson, MD, MS | |

Clinic Network Analysis

Maria Mora Pinzon, MQ MS
Wisconsin Alzheimer's Institute



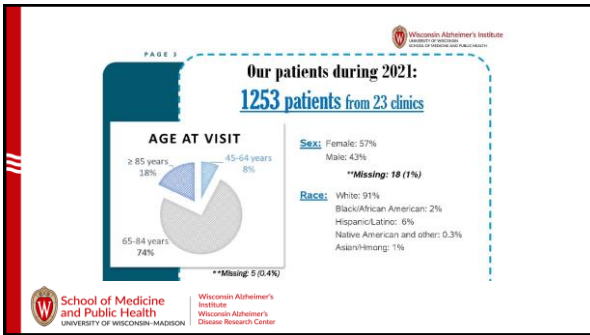
2018 – 2021



Clinics that submitted data in 2021

- Dane County Memory Clinic
- Essentia Health - Ashland Memory Clinic
- Gardeners Memory Center
- Lakeside Memory Clinic - Platteville
- Latino Generics Center Memory Clinic
- Marshfield Clinic - Eau Claire
- Marshfield Clinic - Menomonie Center
- Mayo Clinic Health System - La Crosse
- Mayo Clinic Health System Memory - Eau Claire
- Mills Balf Memory Assessment
- Monroe Clinic Memory Center
- NorthernWisconsin Memory Diagnostic Center
- Prosser Care Rands Memory Clinic
- Prosser Health Clinic - Cross Bay
- Rolland Area Senior & Assisted Living Clinic
- Senior Health Center - Wausau
- Southwest Health Center Memory Diagnostic
- Superior Health Memory Clinic
- The Memory Care Center - Neenah
- UW Health Geriatrics Clinic - East Madison
- UW Health Geriatrics Clinic - Foshburg
- UW Health Neurology Clinic - 600 Highland
- UW Health Specialty Clinic (Dau Point)

Thank You



Demographics of patients by year (2018—2021)

	2018 N=1,620	2019 N=1,166	2020 N=1,156	2021 N=1,253
Age				
20-44 years	0.4	0.2	0.1	0.4
45-64 years	8.1	9.7	6.8	7.5
65-84 years	70.1	69.8	73.5	74.1
>85 years	20.9	20.4	19.6	17.8
Gender				
Female	59.4	60.7	61.5	57.4
Male	40.0	39.3	39.0	42.0
Race/Ethnicity				
Black Non-Hispanic	1.3	2.8	1.0	1.4
Latino/Hispanic	1.1	3.3	4.1	5.0
Native American or Hawaiian	0.6	0.6	0.2	0.3
Other	1.7	1.2	1.1	1.4
White Non-Hispanic	94.9	91.6	93.9	90.7

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Quality Measures for MCI

The American Academy of Neurology Quality and Safety Measurement for Care of Patients with Memory Loss (MCI) is a voluntary public access MCI tool used in 2019 through 2020.

The complete description of these measures is available online at: <https://www.aan.com/quality-and-safety-measurement-for-care-of-patients-with-memory-loss>

In the article, the authors mention: "There is no mention in our use of a measure of risk, and despite our attempts to limit data collection efforts, several clinically relevant data points (e.g., family history, comorbidities) are missing from our data. We are currently working to address this data gap by adding family and other data to our data. They are expected to be available in our next update." "In the course of data use, the researchers should be made aware of the limitations of the data. Such limitations may be identified through periodic and other updates to our data."

The measures proposed include:

- Annual cognitive health assessment for patients with MCI and other
- Education and training of health care providers
- Cognitive and functional assessments for patients with MCI or memory loss
- MCI diagnosis disclosed and consented to patients with MCI
- Assessment and treatment of factors contributing to MCI
- Availability of cognitive medications for patients with MCI
- Education provided to care partners of patients with MCI

Quality Measure for MCI	2018 N=1,620	2019 N=1,166	2020 N=1,156	2021 N=1,253
Cognitive and Functional Assessment for Patients with MCI and Memory Loss				
Functional Assessment	95%	96%	95%	99%
MCI Diagnosis Disclosed and Consented on Treatment Options *				
Diagnosis disclosed	93%	96%	77%	88%
Education Provided to Care Partners of Patients with MCI				
Education provided	77%	78%	80%	95%

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Quality Measures — Dementia patients

Quality Measures Benchmark	2018 N=1,620	2019 N=1,166	2020 N=1,156	2021 N=1,253	National Average (2018—2021)
Q1. Diagnosis given					
Performance	84%	87%	88%	88%	n/a
Q2. Education and referral of caregivers to support services					
Performance	57%	59%	60%	71%	64.9%
Q3. Functional assessment					
Performance	97%	96%	98%	99%	79.5%
Q4. Behavioral screening & treatment					
Performance	75%	80%	87%	86%	77.5%
Q5. Safety screening & management					
Performance	84%	89%	91%	93%	68.3%
Q6. Driving evaluation & management					
Performance	78%	83%	84%	94%	n/a
Q7. Advanced care planning in record, and if not it was discussed					
Performance	92%	97%	97%	97%	n/a
Q8. Pain assessment & management					
Data Completeness	63%	73%	68%	75%	n/a

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Aducanumab

Overview, Breakout Rooms, and Group Discussion

- ## Aducanumab (Aduhelm)
- IgG1 monoclonal antibody against β -amyloid
 - June 7, 2021: FDA approved aducanumab under **accelerated approval pathway**, which requires:
 - substantial evidence of effect on an intermediate marker (amyloid removal)
 - reasonable likelihood of a meaningful clinical benefit
 - Phase 4 evidence for such a benefit to be gathered in a subsequent trial, after the marketing license has been granted

Participant Characteristics in Key Aducanumab Trials (EMERGE and ENGAGE)

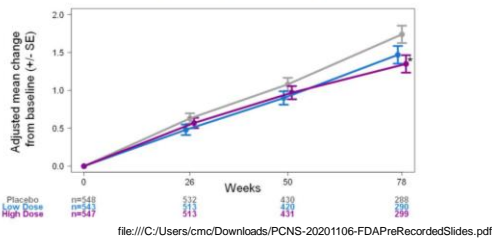
- mild cognitive impairment (MCI) or mild dementia due to Alzheimer's disease
- age 50-85 (mean 70-71)
- amyloid (+)
- EMERGE demographics of 1638 participants:
 - White 78%
 - Asian 7.8%
 - Black 0.7%
 - Hispanic or Latino 4.1%
 - Native American N=1

Cognitive and Functional Efficacy

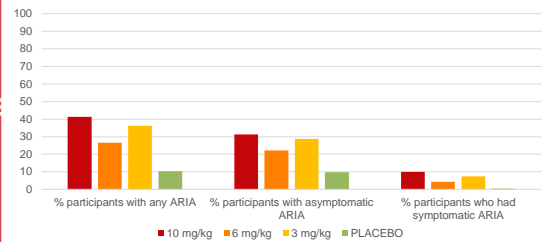
	ENGAGE		EMERGE	
	Week 78 Difference vs. Placebo p-value		Week 78 Difference vs. Placebo p-value	
	Low Dose (n=547)	High Dose (n=555)	Low Dose (n=543)	High Dose (n=547)
CDR-SB	NS	NS	NS	0.0120
MMSE	NS	NS	NS	0.0493
ADAS-Cog 13	NS	NS	NS	0.0097
ADCS-ADL-MCI	NS	NS	NS	0.0006

file:///C:/Users/cm/Downloads/PCNS-20201106-FDAPreRecordedSlides.pdf

EMERGE: Longitudinal Change from Baseline in CDR-SB



Amyloid-Related Imaging Abnormalities (ARIA) in EMERGE and ENGAGE Trials



Aducanumab: Appropriate Use Recommendations Update

Participant Features	Appropriate Use in Clinical Practice
Age	≥65 years or older patients meeting all other criteria for treatment may be considered candidates for aducanumab
Diagnosis	MCI due to AD or mild AD dementia
Cognitive status	Mild decline of cognitive skills or limited impairment of activities of daily living established by objective cognitive testing
Activity of daily living	Functional positive (PDI visual read) or CSF findings consistent with AD
Genetic testing	APOE genotype determined
Neurological examination	Non-AD neurological disorders excluded
Cardiovascular history	Stable cardiovascular conditions required
Medical history	Stable medical conditions required; patients with history of autoimmune disorders or seizures excluded
Psychiatric history	Stable psychiatrically
Chilling status	Patients with bleeding disorders or on anticoagulants excluded
Concomitant medications	Patients can be on standard of care with disease-modifying inhibitors and memantine
Laboratory studies	Normal serum creatinine (Cr) level, serum albumin (ALB), serum total protein and liver function tests, complete blood count, comprehensive urinalysis, uric acid and platelet count. Serum amyloid A (SAA) to monitor disease activity and response to therapy
Baseline MRI	None of the following: <ul style="list-style-type: none"> • Acute or subacute hemorrhage • Microhemorrhage • Cortical infarction larger than 1.5 cm • Infarction infarction larger than 1.5 cm • More than four microhemorrhages • More than one area of superficial edema
Informed consent	Extensive white matter disease indicative of ischemic injury Patient and care partner must understand the nature and requirements of therapy (e.g., monthly infusions to be performed individually) and the expected outcomes of therapy (e.g., monthly infusions to be performed individually)

AD = Alzheimer's disease; APOE = apolipoprotein E; MRI = magnetic resonance imaging; PDI = posterior cingulate intensity

Cummings J et al. J Prev Alz Dis 2022;2(9):221-230

Aducanumab: Appropriate Use Recommendations Update

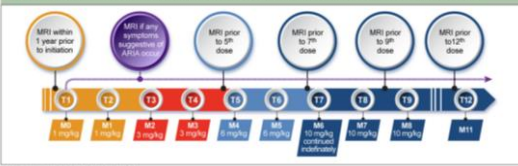
Table 3. Symptoms and signs consistent with ARIA that should trigger consideration of out-of-sequence MRI for patients receiving aducanumab

- Acute or subacute onset of new focal neurological signs or symptoms
- Headache
- Confusion/ altered mental status/ delirium/ disorientation
- Dizziness/ vertigo
- Nausea
- Vomiting
- Fatigue
- Blurred vision
- Vision disturbance/ impairment
- Gait disturbance
- Seizures

Cummings J et al. J Prev Alz Dis 2022;2(9):221-230

Aducanumab: Appropriate Use Recommendations Update

Figure 1. Schedule for aducanumab dosing and routine MRIs to monitor for the possible occurrence of ARIA

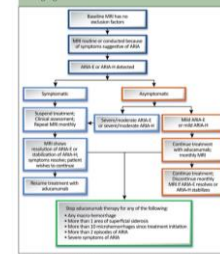


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Cummings J et al. J Prev Alz Dis 2022;2(9):221-230

Aducanumab: Appropriate Use Recommendations Update

Figure 2. Management strategy for detecting and managing ARIA



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Cummings J et al. J Prev Alz Dis 2022;2(9):221-230

CMS National Coverage Determination (NCD) of Aducanumab

- Incorporated 10,000 stakeholder comments and 250 peer-reviewed documents into determination
- Medicare will cover anti-amyloid monoclonal antibodies under coverage with evidence development (CED)
- CMS will provide enhanced access and coverage for people with Medicare participating in CMS-approved studies
- For drugs that FDA has not determined to have shown a clinical benefit (or that receive an accelerated FDA approval), Medicare will cover the drug and any related services (such as PET scans if required by trial protocol) for people with Medicare who are participating in these trials
- Decision is specific to individuals with a clinical diagnosis of MCI or mild dementia due to AD with confirmed presence of plaque

ICARE-AD Study

- study will follow 6,000 people on aducanumab for up to five years
- Goal of 1,000 African-American and Latino participants
- will include people with comorbid health conditions
- Data will be collected on cognition, function, neuropsychiatric symptoms, quality of life, caregiver burden, cost of dementia care, and safety, particularly ARIA
- no placebo, or other control group of any kind
- sponsored by Biogen but will rely on insurers and public funds to cover Aduhelm and other costs
- it will likely take up to 10 years

<https://www.alzforum.org/therapeutics/aduhelm>

ENVISION Study

- Anticipated to start May 2022
- Phase 4 confirmatory trial as required by the FDA
- will enroll 1,500 people with early AD
- randomized to drug or placebo for 18 months
- primary endpoint will be the CDR-SB
- Secondary endpoints: additional standard cognitive and functional measures, and amyloid and tau PET
- trial aims to recruit at least 18 percent of participants in the U.S. from black and Hispanic communities
- long-term extension will last up to four years
- Results are expected by 2026.

<https://www.alzforum.org/therapeutics/aduhelm>

Breakout Room Questions

For this discussion, disregard the cost and health insurance coverage issues.

1. What is the most significant positive/negative impact of aducanumab?
2. What is your healthcare system's biggest challenge(s) with aducanumab?
3. Did/does aducanumab change your practice? If so, how. If not, why not?
4. What are key resources/assistance that would facilitate the implementation of aducanumab or future therapeutics?



BOLD Grant Care Planning Code Discussion

Kristen Felten MSW APSWand Kathleen Smith
Wisconsin Department of Health Services



Clinic Network Progress and Updates

Cindy Carlsson, MD MS
Wisconsin Alzheimer's Institute



WAI Dementia Diagnostic Clinic Network Paper Published!

- Congratulations to Dr. Mora Pinzon, Ms. Krainer, and Dr. LeCaire for leading this effort!



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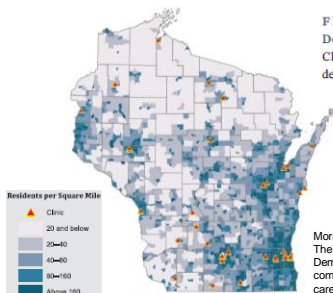
The Wisconsin Alzheimer's Institute Dementia Diagnostic Clinic Network: A community of practice to improve dementia care

Maria Mora Pinzon MD, MS^{1,2} | Judy Krainer MSW, LCSW, MBA¹ | Tamara LeCaire MS, PhD³ | Stephanie Houston BA¹ | Gina Green-Harris MBA^{1,2} | Nia Norriss MA, PhD² | Stacy Barnes PhD² | Lindsay R. Clark PhD^{2,3} | Corey E. Gibson PhD^{2,3} | Renee P. Horvath PhD² | Helen Kusun MS¹ | Will Buckingham PhD² | Nathaniel A. Chin MD^{4,5} | Sanjay Asthana MD^{2,3} | Sterling C. Johnson PhD^{2,3,6} | Art Wolkstein MD^{2,3,6} | Cynthia M. Carlsson MD, MS^{1,2,3}

WAI Dementia Diagnostic Clinic Network Paper Published!

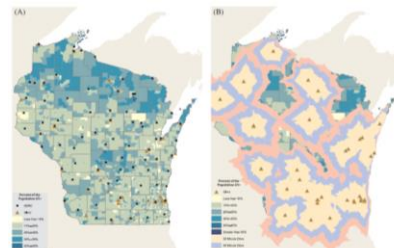
- Available through Open Access: <https://agsjournals.onlinelibrary.wiley.com/doi/10.1111/jgs.17768>
- Article describes:
 - Clinic Network structure
 - Educational format
 - Clinic characteristics
 - Characteristics of patients evaluated
 - Data collection
 - Future directions

FIGURE 1 Location of the WAI Dementia Diagnostic Network Clinics according to population density in the State of Wisconsin



Mora Pinzon M, Krainer J, LeCaire T, et al. The Wisconsin Alzheimer's Institute Dementia Diagnostic Clinic Network: A community of practice to improve dementia care. J Am Geriatr Soc. 2022;1-13. doi:10.1111/jgs.17768

Area of service of the WAI Dementia Diagnostics Network Clinics based on (A) % population 65+, and (B) driving time.



Mora Pinzon M, Krainer J, LeCaire T, et al. The Wisconsin Alzheimer's Institute Dementia Diagnostic Clinic Network: A community of practice to improve dementia care. J Am Geriatr Soc. 2022;1-13. doi:10.1111/jgs.17768

WAI Goals for Clinic Network for Coming Year

- Learn more about how to support Clinic Network clinical teams as we emerge from covid pandemic and staffing shifts
- Grow in our ability to provide hybrid educational offerings
- Take what we've learned from Clinic Network teams and seek out input from primary care providers about how to build practical dementia assessments into primary care clinics (several grants planned)
- Continue work on DICE training and academic detailing on management of behavioral and psychological symptoms of dementia – new grants planned

WAI Goals for Clinic Network this Year (cont'd)

- Partner with the Wisconsin Alzheimer's Disease Research Center on early student education efforts in dementia care (externship, clinical opportunities, research and public health projects)
- Continue to partner with Department of Health Services on fostering handoffs from DCS's to clinics for dementia evaluation
- Continue to brainstorm on how to better bring clinical trial opportunities to people throughout the state

Questions? Comments?

National Alzheimer's Project Act (NAPA) Update

Cindy Carlsson, MQ, MS
Wisconsin Alzheimer's Institute



History of National Alzheimer's Project Act (NAPA)

- Enacted January 4, 2011
- Act defines "Alzheimer's" as Alzheimer's disease and Alzheimer's disease-related dementias (AD/ADRD)
- Office of the Assistant Secretary for Planning and Evaluation (ASPE) becomes lead: April 2011
- First Advisory Council Meeting: September 28, 2011
- National Plan to Address Alzheimer's Disease first released: May 15, 2012



Upcoming 10-year Anniversary Highlights and Accomplishments

<https://aspe.hhs.gov/reports/national-plan-2021-update>

National Alzheimer's Project Act (NAPA)

Requires the Secretary of the U.S. Department of Health and Human Services (HHS) to establish the National Alzheimer's Project to:

- Create and maintain an integrated national plan to overcome Alzheimer's;
- Coordinate research and services across all federal agencies;
- Accelerate the development of treatments that would prevent, halt, or reverse the disease;
- Improve early diagnosis and coordination of care and treatment of the disease;
- Improve outcomes for ethnic and racial populations at higher risk;
- Coordinate with international bodies to fight Alzheimer's globally; and
- Create an Advisory Council to review and comment on the national plan and its implementation

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



Public

- 12 members representing:
 - 2 Patient advocates, including person living with dementia
 - 2 Caregivers
 - 2 Providers
 - 2 State and local government reps
 - 2 Researchers
 - 2 Voluntary health association representatives



Federal Government

- Department of Health and Human Services
 - Office of the Assistant Secretary for Planning and Evaluation
 - Indian Health Service
 - National Institutes of Health
 - Centers for Medicare & Medicaid Services
 - Agency for Healthcare Research & Quality
 - Administration for Community Living
 - Centers for Disease Control and Prevention
 - Health Resources and Services Administration
 - Food and Drug Administration
- Department of Veterans Affairs
- Department of Defense
- National Science Foundation

National Plan to Address Alzheimer's Disease

Goal 1: Prevent and Effectively Treat Alzheimer's Disease and Related Dementias by 2025

Goal 2: Enhance Care Quality and Efficiency

Goal 3: Expand Supports for People with ADRD and Their Families

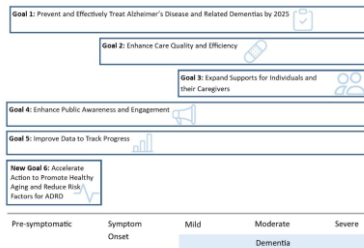
Goal 4: Enhance Public Awareness and Engagement

Goal 5: Improve Data to Track Progress

New Goal 6: Accelerate Action to Promote Healthy Aging and Reduce Risk Factors for ADRD

<https://aspe.hhs.gov/reports/national-plan-2021-update#goal-6>

National Plan to Address Alzheimer's Disease: 2021 Update



<https://aspe.hhs.gov/reports/national-plan-2021-update#goal-6>

How to Get Involved

- Join the NAPA Listserv: listserv@list.nih.gov
- Read through Clinical Care recommendations and think what ideas you have from your clinical practice: <https://aspe.hhs.gov/reports/national-plan-2021-update#intro>
 - What needs do you see in your patients and their caregivers? What policies are needed to address these concerns?
 - Where are there gaps in patient care?
 - What health disparities do you see in your patients? What ideas do you have for policies to promote health equity?
 - What do clinicians, communities, states, healthcare systems, and other stakeholders need to provide better treatment and care?
- Share your ideas through:
 - Contacting me at cmcarlss@wisc.edu
 - Preparing public comments for a NAPA meeting: napa@hhs.gov

Most Difficult Case Conference

Facilitator: Michael Malone, MD
Center for Senior Health and Longevity, Advocate Aurora Health
Presenting Clinic: Bateria Kefauver, PhD and Sonja Blum, MD, PhD
Marshfield Memory Disorders Clinic

Discussants:
Danielle Dodson, MSW, LCSW
Advocate Medical Group

Victoria Williams, PhD
UW-Health East Clinic and UW-Health Hospital and Memory Assessment Clinic



Closing Remarks

All participants will be emailed an evaluation link this evening, it is also in the Chat box. The continuing education credit for the Most Difficult Case Conference can only be requested through the evaluation survey. The evaluation survey has sections for both the Core Skills Training and for the Spring Clinic Network meeting. The evaluation survey will close Monday, May 16, 2022.

- Mark your calendars for the Virtual 20th Annual Update in Alzheimer's Disease and Related Dementias**
- Building Applied Skills in Dementia Care – Thursday, November 10, 2022
 - The 19th Annual Alzheimer's Disease Update – Friday, November 11, 2022
 - The Fall Clinic Network Meeting – Friday, November 11, 2022

Thank-you

