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2022 Virtual CE Summit

Early Identification and Treatment of Alzheimer's Disease: The Role of the Nurse Practitioner

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Disclosure:

Amy McLean, DNP, has no real or apparent conflicts of interest to report

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Learning Objectives

- Explain the pathophysiology and etiology of Alzheimer's disease (AD)
- List screening tools and patient-centered communication strategies to achieve early recognition and diagnosis of AD
- Review current evidence-based guidelines and newly approved disease-modifying drugs for treating patients with AD
- Describe how to evaluate the behavioral, safety, and functional needs of patients with AD as part of the care planning process
- Outline how to support patients and families using management strategies and tools to maintain optimal quality of life throughout the AD disease journey

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Overview of AD & the Role of Nurse Practitioners in Improving Patient Outcomes

Alzheimer's Disease Facts

- About 6.5 million people affected now in US
- By the year 2060, nearly 14 million Americans are projected to have AD
- Alzheimer's went from 6th to 7th top cause of death in the US (bumped by COVID-19 entering as 3rd in 2020)
- Black Americans are 2× as likely to have AD and Latino 1.5× as likely to have AD, as compared to White
- Estimated cost of $321 Billion in 2022 (by 2050, may reach 1 trillion)
- Caregivers of those living with dementia frequently report high levels of stress
- Over 50% of primary care providers caring for those living with Alzheimer's say their communities do not have enough dementia care specialists to meet patient demands
- During the COVID-19 pandemic, 17% increased deaths in AD and dementia

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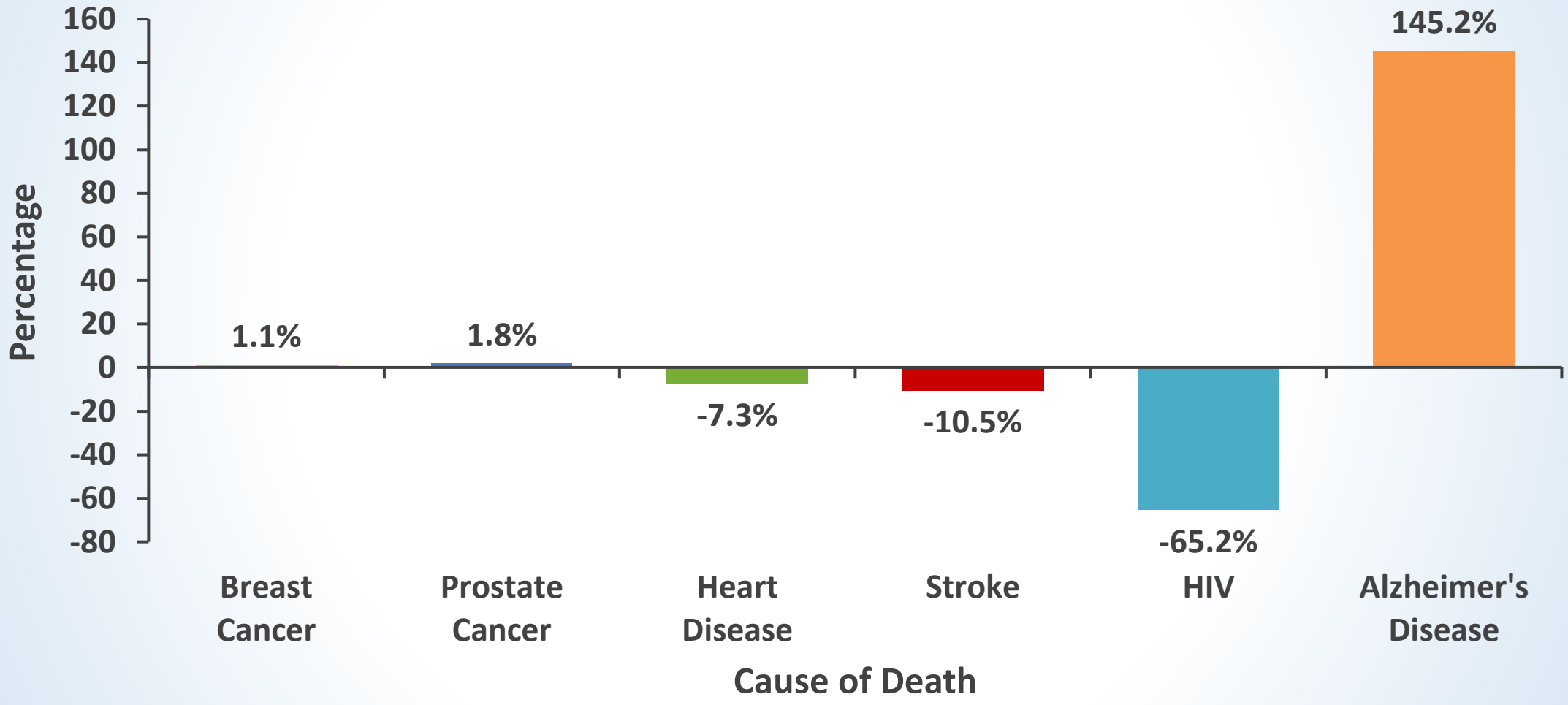
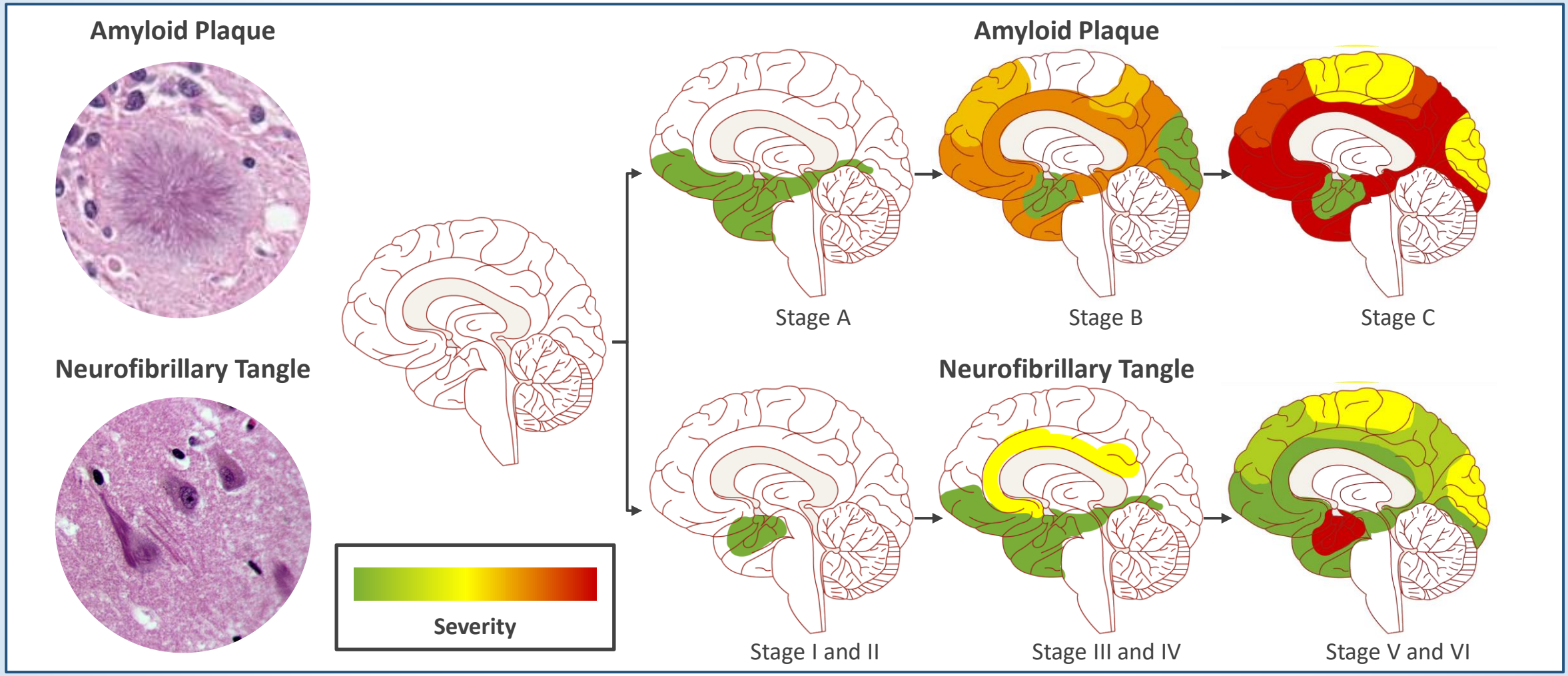
Percentage Changes in Selected Causes of Death (All Ages) Between 2000 and 2019

Figure 7



HIV, human immunodeficiency virus.
Created from data from the National Center for Health Statistics.

Current Understanding of AD Pathophysiology



Etiological Factors Associated With the Development of AD

Aging

- Older people are more likely to get Alzheimer's

Genetics

- Gene mutation (APP, PSEN1, PSEN2 genes) –early onset, rare.
- Chromosomal disorder: All Down Syndrome individuals develop AD – 3 copies of Chromosome 21 (APP gene)
- APOE4

Other modifiable factors

- Family history
- CV risk factors (diabetes, high BP, high cholesterol, lack of exercise, poor diet, smoking)
- Head injury
- Isolation/loneliness
- Hearing loss
- Excessive alcohol use
- Sleep issues (apnea, disrupted)
- Medications
- Depression

Environment

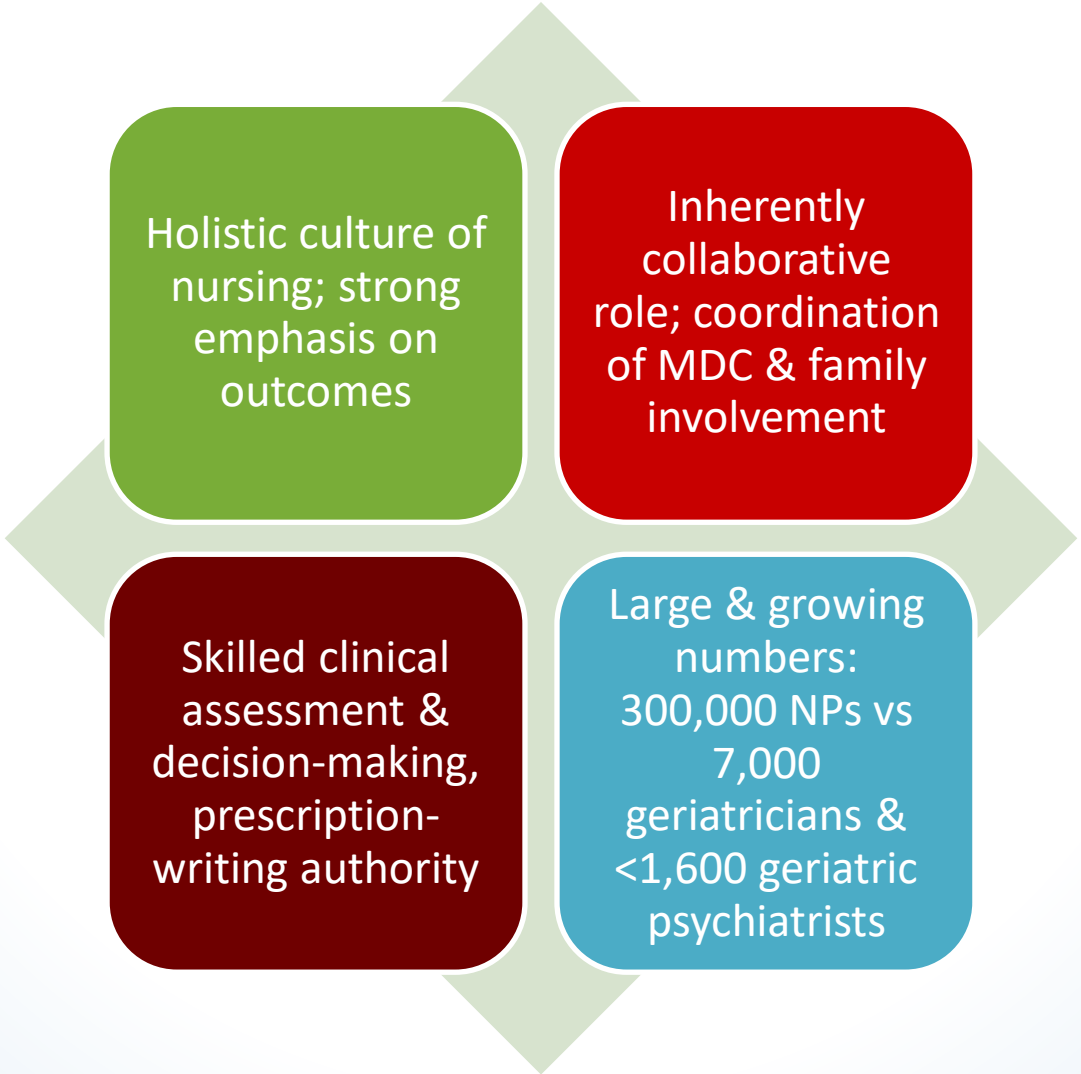
- Tobacco
- Smoke
- Pesticides
- Metals

CV, cardiovascular.

Duggal P, Mehan S. *J Alzheimer Dis Rep*. 2019;3:179-218.

The Key Role of Nurse Practitioners in AD Care

Nurse practitioners are well-situated to manage the complicated care required in AD



MDC, multidisciplinary care.

Reuben DB, Fulmer T. *Am J Geriatr Psychiatry*. 2021;29:527-529; Poghosyan L, et al. *Am J Geriatr Psychiatry*. 2021;29:517-526.

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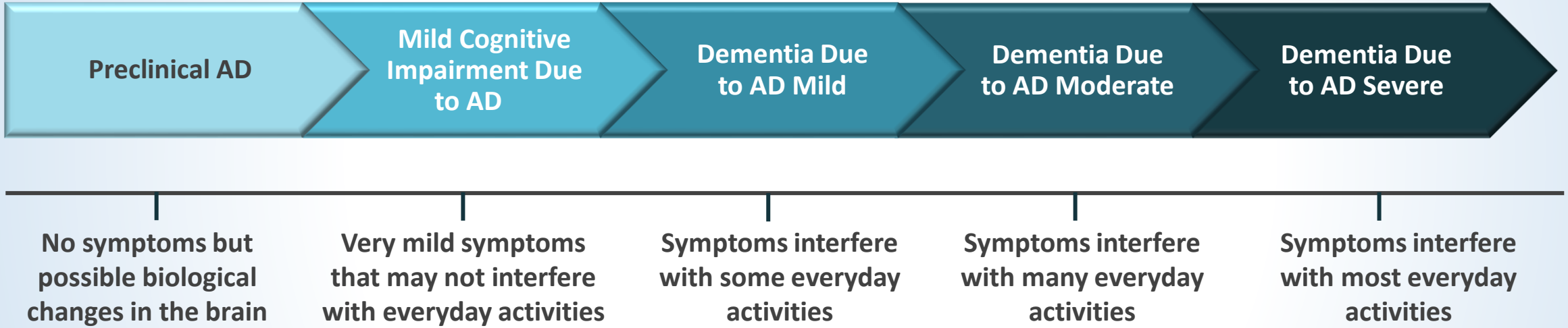
Early Recognition and Diagnosis of AD

The Progression of AD

Alzheimer's Disease (AD) Continuum*



"Please remember the real me when I cannot remember you." – Julie White

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Alzheimer's Association. 2022 Alzheimer's disease facts and figures. Available at: https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf

Cognitive Assessment and Care Planning

Detection of cognitive impairment during the Annual Wellness Visit

Cognitive assessment & care planning services

- Code **99483***
- Can use every 6 m
- Includes behavior, safety, & functional assessment

Assessment & Care Planning**

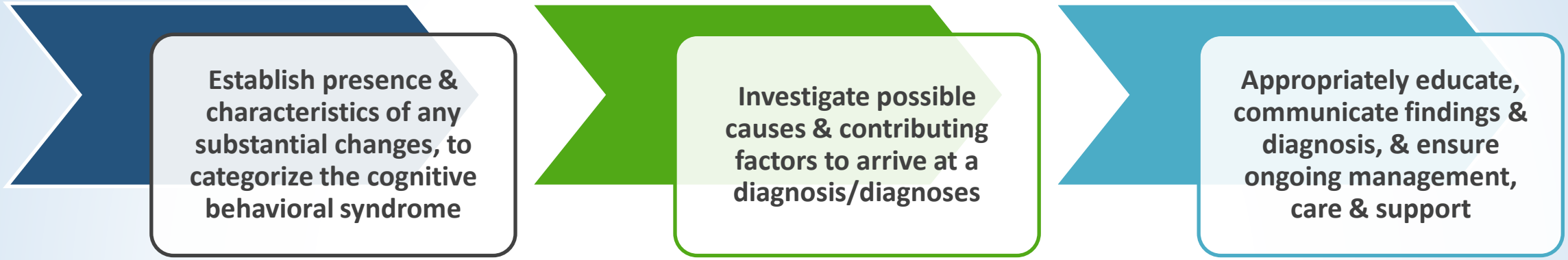
- Cognition-focused evaluation with pertinent history & examination
- Medical decision-making (moderate or high complexity)
- Functional assessment (eg, basic & instrumental ADLs), including decision-making capacity
- Standardized instruments for dementia staging (eg, FAST, CDR)
- Medication reconciliation, review for high-risk medications
- Evaluation for neuropsychiatric & behavioral symptoms (including depression) with standardized screening instrument(s)
- Evaluation of safety (eg, home), including motor vehicle operation
- Identification of caregiver(s), & their knowledge, needs, social supports, & willingness
- Development, update/revision, or review of an Advance Care Plan
- Written care plan with initial plans to address neuropsychiatric symptoms, neurocognitive symptoms, functional limitations, & referral to community resources as needed
- Typical duration: 50 min with patient and/or family or caregiver

*See the 2018 CPT manual for the full description and detailed instructions for code 99483; **Includes independent historian, in-office or outpatient, home, domiciliary or rest home setting.

ADLs, activities of daily living; CDR, clinical dementia rating; FAST, Functional Assessment Staging Test.

Alzheimer's Association. Cognitive assessment and care planning services. https://www.alz.org/careplanning/downloads/cms-consensus.pdf

2018 Alzheimer's Association Diagnostic Evaluation Clinical Practice Guideline



- **Core recommendations**
  - **Timely evaluation of ALL middle-aged or older individuals with cognitive, behavioral or functional changes**
  - Do not dismiss as "normal aging" without proper assessment
  - Involve a care partner (eg, family member or confidant) in evaluation
- **Assessment and testing approach**
  - Tailored & multitiered
  - History from someone who knows the patient well in addition to the patient

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Earlier Intervention in AD: From Patient Presentation to Treatment

STEP 1: Detect

Patient presentation

Patient & Family history

STEP 2: Assess/Differentiate

Blood test, neurologic & physical exams

Cognitive and functional assessments

Structural imaging

STEP 3: Diagnose

Access to biomarkers

Diagnose

STEP 4: Treat

Patient management

Recommended tests

STEP 1: Detect	STEP 2: Assess/Differentiate			STEP 3: Diagnose	STEP 4: Treat
• Patient history, family history • Caregiver perspective • Medical & disease history • Medication count • Lifestyle data (smoking, alcohol, exercise)	• Blood tests (full blood count, TSH, BG, serum B12, liver & renal function tests) • Genotyping • Neurologic exam • Physical exam	• **Cognitive:** AD8, IQCODE, MMSE, MoCA, Mini-Cog, or QRDs • **Functional:** A-IADL-Q, FAST, or FAW • **Behavioral:** GDS or NPI-Q	• MRI • FDG-PET*	• Amyloid PET • CSF Aβ42, p-tau & t-tau • CSF Aβ42/Aβ40	• Symptomatic treatments (eg, ACh inhibitors, NMDA receptor antagonist) • Lifestyle changes • Social work support • Clinical trial registries

Nonspecialists (eg, PCPs) — **Optimal referral window** — **Specialists (eg, memory clinics)**

A-IADL-Q, Amsterdam IADL Questionnaire; AD8, Ascertain Dementia 8-item Informant Questionnaire; BG, basal ganglia; FDG, fluorodeoxyglucose; GDS, Global Deterioration Scale; IQCODE, Informant Questionnaire on Cognitive Decline in the Elderly; MoCA, Montreal Cognitive Assessment; NPI-Q, Neuropsychiatric Inventory-Questionnaire; PCP, primary care provider; QRD, Quality Research in Dementia; TSH, thyroid-stimulating hormone.

Porsteinsson AP, et al. *J Prev Alzheimers Dis.* 2021;8:371-386.

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AD8

Remember, “Yes, a change” indicates that you think there has been a change in the last several years caused by cognitive (thinking and memory) problems	**YES, A Change**	**NO, No Change**	**N/A, Don’t Know**
Problems with judgment (eg, falls for scams, bad financial decisions, buys gifts inappropriate for recipients)			
Reduced interest in hobbies/activities			
Repeats questions, stories or statements			
Trouble learning how to use a tool, appliance or gadget (eg, VCR, computer, microwave, remote control)			
Forgets correct month or year			
Difficulty handling complicated financial affairs (eg, balancing checkbook, income taxes, paying bills)			
Difficulty remembering appointments			
Consistent problems with thinking and/or memory			
TOTAL AD8 SCORE			

Galvin JE, et al. *Neurology*. 2005;65(4):559-564.
Available at: https://penninstituteonaging.wordpress.com/2014/06/25/ad8galvin/

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Cognitive Assessment: Mini-Cog©

Step 1: Three Word Registration

Looks directly at person and say: "Please listen careful. I am going to say three words that I want you to repeat back to me now and try to remember. The words are (select a list of words from the version below). Please say them for me now." If the person is unable to repeat the words after three attempts, move on to Step 2 (clock drawing). The following and other word lists have been used in one or more clinical studies.[1-3] For repeated administrations, use of an alternative word list is recommended.

Version 1	Version 2	Version 3	Version 4	Version 5	Version 6
Banana	Leader	Village	River	Captain	Daughter
Sunrise	Season	Kitchen	Nation	Garden	Heaven
Chair	Table	Baby	Finger	Picture	Mountain

Step 2: Clock Drawing

Say: "Next, I want you to draw a clock for me. First, put in all of the numbers where they do." When that is completed, say: "Now, set the hands to 10 past 11."
Use preprinted circle (see next page) for this exercise. Repeat instructions as needed as this is not a memory test. Move to Step 3 if the clock is not complete within three minutes.

Step 3: Three Word Recall

As the person to recall the three words you stated in Step 1. Say, "What were the three words I asked you to remember?" Record the word list version number and the person's answers below.
Word List Version:
Person's Answers:

Scoring

Word Recall: (0-3 pts) — 1 pt for each word spontaneously recalled without cueing

Clock Draw: (0 or 2 pts) — Normal clock = 2 pts
Inability or refusal to draw a clock (abnormal) = 0 pts

Total Score: (0-5 pts) — Total score = Word Recall score + Clock Draw score

A total score <3 is indicative of dementia

A total score of <4 suggests the need for further evaluation

*A normal clock has all numbers placed in the correct sequence and approximately correct position (eg, 12, 3, 6, and 9 are in anchor positions) with no missing or duplicate numbers. Hands are pointing to the 11 and 2 (11:10). Hand length is not scored.

Cognitive Assessment: MMSE

Mini Mental State Examination (MMSE)

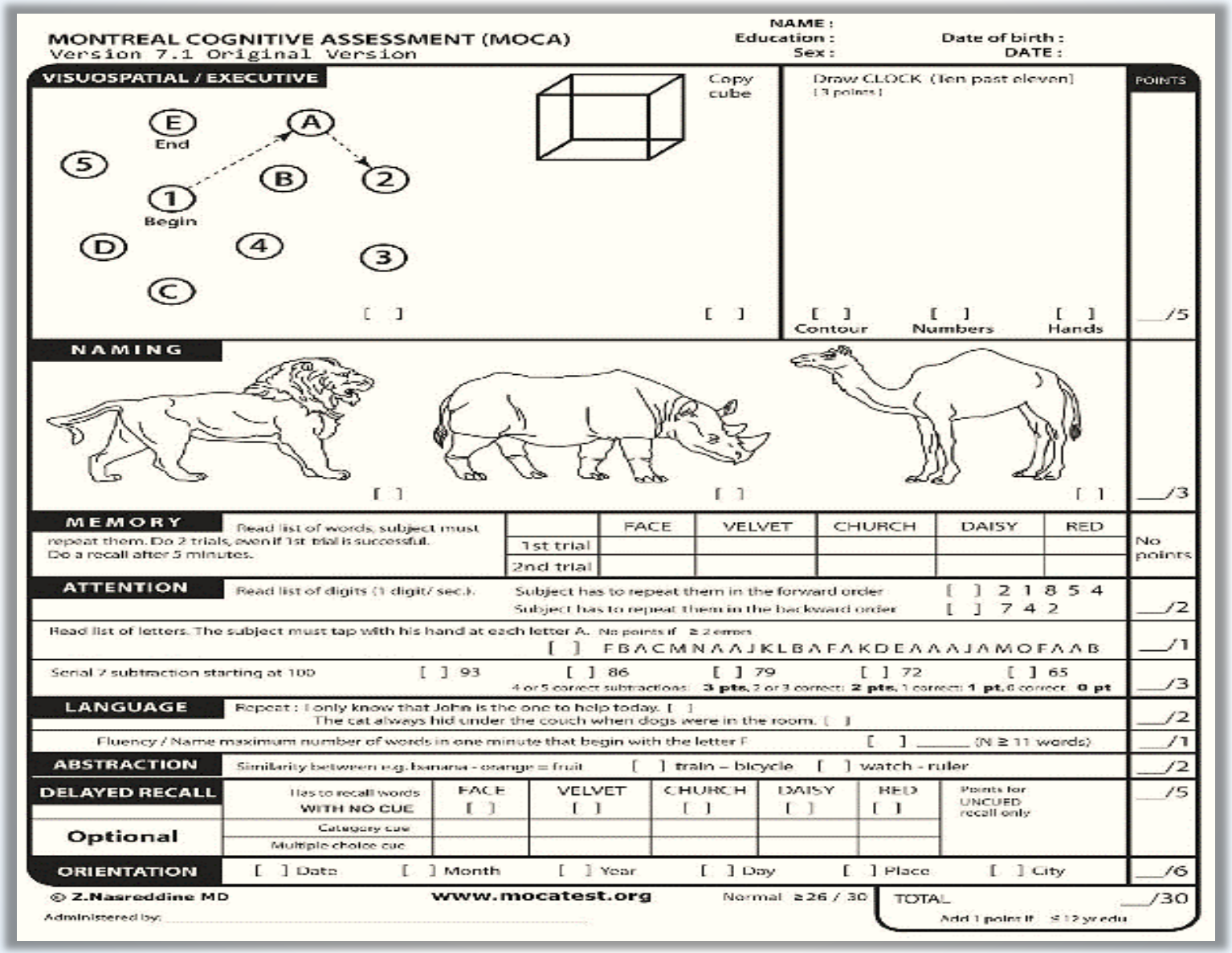
One point for each answer

ORIENTATION Year Season Month Date Time Country Town District Hospital Ward/Floor	...../ 5 ...../ 5	...../ 5 ...../ 5	...../ 5 ...../ 5
REGISTRATION Examiner names three objects (eg, apple, table, penny) and asks the patient to repeat (1 point for each correct. THEN the patient learns the 3 names repeating until correct).	...../ 3	...../ 3	...../ 3
ATTENTION AND CALCULATION Subtract 7 from 100, then repeat from result. Continue five times: 100, 93, 86, 79, 72, 65 (Alternative: spell "WORLD" backwards: DLROW).	...../ 5	...../ 5	...../ 5
RECALL Ask for the names of the three objects learned earlier.	...../ 3	...../ 3	...../ 3
LANGUAGE Name two objects (eg, pen, watch). Repeat "No if, ands, or buts". Give a three-stage command. Score 1 for each stage (eg, "Place index finger of right hand on your nose and then on your left ear"). Ask the patient to read and obey a written command on a piece of paper. The written instruction is: "Close your eyes". Ask the patient to write a sentence. Score 1 if it sensible and has a subject and a verb.	...../ 2 ...../ 1 ...../ 3 ...../ 1 ...../ 1	...../ 2 ...../ 1 ...../ 3 ...../ 1 ...../ 1	...../ 2 ...../ 1 ...../ 3 ...../ 1 ...../ 1
COPYING: As the patient to copy a pair of intersecting pentagons 	...../ 1	...../ 1	...../ 1
TOTAL:	...../ 30	...../ 30	...../ 30

SCORING: **24-30: no cognitive impairment**
18-23: mild cognitive impairment
0-17: severe cognitive impairment

Available at: https://oxfordmedicaleducation.com/geriatrics/mini-mental-state-examination-mmse/

MoCA



MONTREAL COGNITIVE ASSESSMENT (MOCA)
Version 7.1 Original Version

NAME :
Education :
Sex :
Date of birth :
DATE :

VISUOSPATIAL / EXECUTIVE — POINTS

Copy cube

E End, A, 5, B, 2, 1 Begin, D, 4, 3, C

[ ] [ ]

Draw CLOCK (ten past eleven) [3 points]

[ ] Contour [ ] Numbers [ ] Hands

/5

NAMING

[ ] [ ] [ ]

/3

MEMORY Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.

	FACE	VELVET	CHURCH	DAISY	RED
1st trial					
2nd trial					

No points

ATTENTION Read list of digits (1 digit/ sec.).

Subject has to repeat them in the forward order [ ] 2 1 8 5 4

Subject has to repeat them in the backward order [ ] 7 4 2

/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors

[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B

/1

Serial 7 subtraction starting at 100 [ ] 93 [ ] 86 [ ] 79 [ ] 72 [ ] 65

4 or 5 correct subtractions: **3 pts**, 2 or 3 correct: **2 pts**, 1 correct: **1 pt**, 0 correct: **0 pt**

/3

LANGUAGE Repeat : I only know that John is the one to help today. [ ]

The cat always hid under the couch when dogs were in the room. [ ]

/2

Fluency / Name maximum number of words in one minute that begin with the letter F [ ] _____ (N ≥ 11 words)

/1

ABSTRACTION Similarity between e.g. banana - orange = fruit [ ] train – bicycle [ ] watch - ruler

/2

DELAYED RECALL

	Has to recall words WITH NO CUE	FACE [ ]	VELVET [ ]	CHURCH [ ]	DAISY [ ]	RED [ ]	Points for UNCUED recall only
Optional	Category cue						
	Multiple choice cue						

/5

ORIENTATION [ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City

/6

© Z.Nasreddine MD www.mocatest.org Normal ≥26 / 30

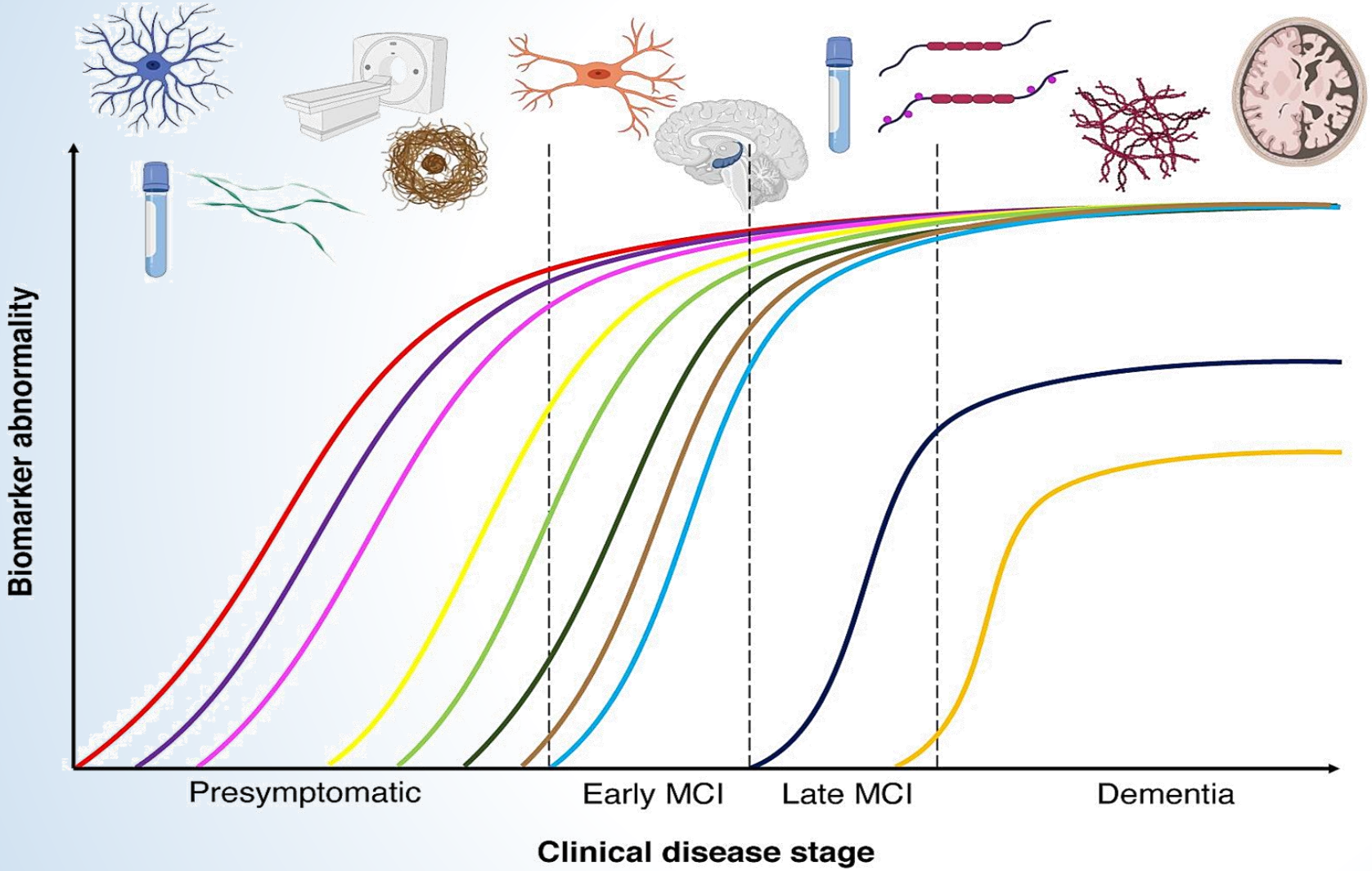
TOTAL /30

Add 1 point if ≤ 12 yr edu

Administered by:

Available at: https://gwep.usc.edu/moca-montreal-cognitive-assessment-test/

Biomarkers of AD Across Clinical Stages



Changes are occurring 10-15 years before symptom onset. Amyloid is the first detectable biomarker we can evaluate, rising quickly during the preclinical phase and plateauing by the time symptoms are present.

Bjorkli C, et al. *Front Aging Neurosci*. 2020;12:272.

Barriers to Achieving Early Diagnosis of AD

Patient/Family

- Health beliefs and literacy
- Attitudes toward AD
- Diagnostic stigma
- Cultural factors

Primary Care

- Knowledge among primary providers
- Time constraints
- Attitude toward dementia diagnosis
- Lack of familiarity with community resources
- Poor access to specialists
- Perceptions of limited efficacy of therapeutics

Health System

- Undersupply of specialists
- Inadequate health care payment models
- Low availability of community services
- Health care system fragmentation
- Lack of simple, definitive diagnostic testing
- Lack of treatment readily discerned as effective
- Reimbursement systems

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Piconet G, Geldmacher DS. *Practical Neurol.* 2018:51-52.

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Treatment Approach and Current Therapies

Traditional Treatments for Patients with AD

Drug Class	Drug	Indication	Common AEs
Anti-Aβ	Aducanumab	MCI or mild AD	• ARIA (can lead to fluid buildup or bleeding in the brain); headache, dizziness, falls, diarrhea, confusion
Cholinesterase inhibitor	Donepezil	Mild, moderate, & severe AD	• Nausea, vomiting, diarrhea, muscle cramps, fatigue, weight loss
	Rivastigmine	Mild, moderate, & severe AD	• Nausea, vomiting, diarrhea, weight loss, indigestion, muscle weakness
	Galantamine	Mild-to-moderate AD	• Nausea, vomiting, diarrhea, decreased appetite, dizziness, headache
NMDA antagonist	Memantine	Moderate-to-severe AD	• Dizziness, headache, diarrhea, constipation, confusion

Note: Combined ACh inhibitor and NMDA antagonist also available.

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AE, adverse event; ARIA, Amyloid-related imaging abnormalities.

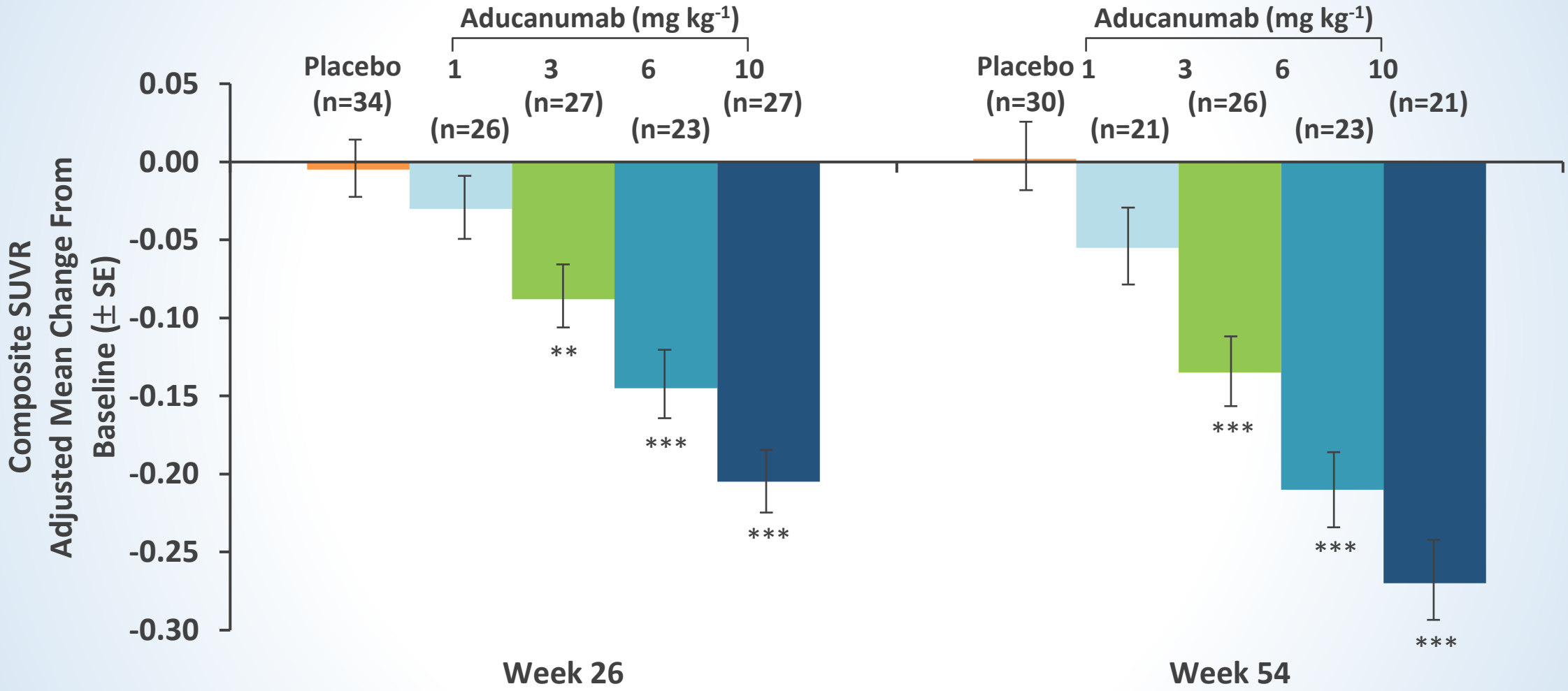
Overview of Aducanumab

- Human-derived antibody against Aβ
- First therapy targeting reduction of Aβ plaques
- IV-administered based on weight given over 1 hour Q4W
- Phase 1b data:
  - Treatment associated with β-amyloid plaque reduction on amyloid PET scans
  - Primary AE: dose-dependent ARIA-E (more common in APOE ε4 carriers)
- Phase 3 data:
  - In preplanned futility analysis, ENGAGE showed no significant changes in clinical outcomes, while EMERGE showed significant improvement in clinical outcomes vs placebo
  - Both trials showed significant β-amyloid reduction
  - Most common AE in both: ARIA-E (35% of aducanumab recipients)
- FDA approved in June 2021
  - First new approval for AD since 2003
  - Requirement for additional RCT to confirm clinical benefit
- CMS coverage currently limited to patients participating in CMS-approved or NIH-supported RCTs

CMS, Centers for Medicare and Medicaid Services; IV, intravenous; NIH, National Institutes of Health; Q4W, once every 4 weeks; RCT, randomized controlled trial.

Budd Haeberlein S, et al. *J Prev Alzheimers Dis*. 2022;9:197-210; Molano RV. *NEJM J Watch*. 2021; Sevigny J, et al. *Nature*. 2016;537:50-56.

Reduction of Plaques Associated With Aducanumab Treatment



Dose-response *P* <0.001 at weeks 26 and 54 based on a linear contrast test.

Sevigny J, et al. *Nature*. 2016;537:50-56.

Clinical Efficacy Outcomes (EMERGE and ENGAGE)

	ENGAGE			EMERGE		
	Week 78 Placebo Decline (N=545)	Week 78 Difference vs Placebo (%)* *P* Value		Week 78 Placebo Decline (N=548)	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	n=333 1.56	n=331 **-0.18 (-12%)** 0.2250	n=295 **0.03 (2%)** 0.8330	n=288 1.74	n=290 **-0.26 (-15%)** 0.0901	n=299 **-0.39 (-22%)** 0.0120
MMSE	n=332 -3.5	n=334 **0.2 (-6%)** 0.4795	n=297 **-0.1 (3%)** 0.8106	n=288 -3.3	n=293 **-0.1 (3%)** 0.7578	n=299 **0.6 (-18%)** 0.0493
ADAS-Cog 13	n=331 5.140	n=332 **-0.583 (-11%)** 0.2536	n=294 **-0.588 (-11%)** 0.2578	n=287 5.162	n=289 **-0.701 (-14%)** 0.1962	n=293 **-1.400 (-27%)** 0.0097
ADCS-ADL-MCI	n=331 -3.8	n=330 **0.7 (-18%)** 0.1225	n=298 **0.7 (-18%)** 0.1506	n=283 -4.3	n=286 **0.7 (-16%)** 0.1515	n=295 **1.7 (-40%)** 0.0006

ITT population excluding data collected after March 20, 2019; *Negative % means less progression in the treated arm; n = number of randomized and dosed subjects with endpoint assessment at Week 78.
Available at: www.fda.gov

Candidate Selection for Aducanumab Treatment

- **Evidence of MCI due to AD or mild AD dementia**
- **Amyloid status confirmed via PET scan or CSF biomarkers**
- **Brain MRI within 1 year before initiating aducanumab**
- **Stable CV, medical, and psychiatric status before initiating treatment**
- APOE4 genotyping is recommended due to increased risk for ARIA
- Concomitant cholinesterase inhibitors or memantine is acceptable
- Contraindications include pregnancy, anticoagulant use, or evidence of significant cerebrovascular disease on brain MRI, inability to complete MRI
- Involvement of specialists with expertise in these assessments may be required

Note: Bolded items are requirements for consideration of therapy.

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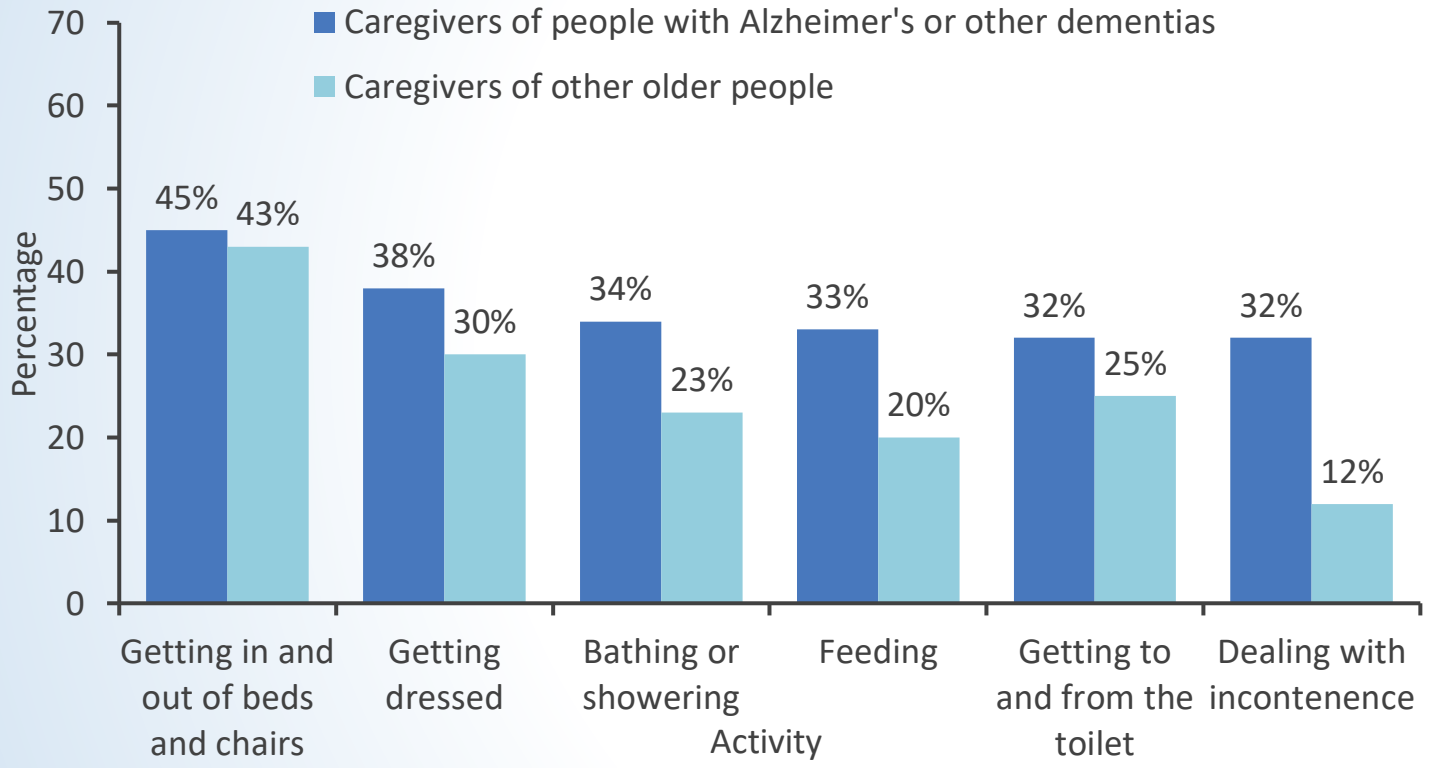
Improving Patient and Family QOL

Caregiver Impact of AD

Proportion of Caregivers of People With Alzheimer's or Other Dementias Versus Caregivers of Other Older People Who Provide Help With Specific Activities of Daily Living, United States, 2015



"Alzheimer's caregivers are heroes." *– Leeza Gibbons*

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Graph created from data from the National Alliance for Caregiving in Partnership with the Alzheimer's Association.

The Evolving Needs of Patients With AD and Their Family/Caregivers

	EARLY	MIDDLE	LATE
Patient	• Understanding of AD, its progression, & treatments • Psychological support to help cope with the diagnosis • Identification of personal goals • Maximizing independence & ability to live well • Finding a new balance	• Support in communication • Activities that provide meaning • Recognition of limitations (eg, driving)	• Appropriate support for changing physical needs: – Bladder function – Skin and body health – Infections and pneumonia – Food and fluids – Pain and illness • Late-stage care options
Family member/ caregiver	• Understanding of AD, its progression, & treatments • Understanding care partner role: – Maximizing patient independence & QOL; finding a new balance – Supporting medical needs • Understanding patient emotions • Self-care	• Ability to recognize behavior changes • Support in communication • Support of meaningful activities • Knowing patient limitations • Self-care	• Ability to recognize & address increasing physical needs • Knowledge of late-stage care options • Self-care

"Persons living with dementia are usually capable of more than we can imagine."
– Bob DeMarco

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Patient and Family/Caregiver Resources

ALZHEIMER'S ASSOCIATION® https://www.alz.org

Alzheimers.gov https://www.alzheimers.gov

NIH National Institute on Aging https://www.nia.nih.gov

AFA® ALZHEIMER'S FOUNDATION OF AMERICA https://alzfdn.org

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Support Tools

ALZHEIMER'S navigator®

alzheimer's association®

Alzheimer's Navigator®

Create a personalized caregiving action plan with tips and local resources.

alz connected®

ALZConnected®

Join other caregivers and people living with Alzheimer's to share concerns and advice on this online forum.

Community Resource Finder

Get connected with local resources, support groups, community programs and services in partnership with AARP.

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Alzheimer's Association. Online tools. Available at: https://www.alz.org/help-support/resources/online-tools

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Patient Case Study

Case Patient: Diagnosis of Early-Stage AD

- Kevin is a 79-year-old male, widowed and retired art professor, who reports difficulty remembering new information that has been getting worse over the past 18 months. Specifically, he reports frequently misplacing items, forgetting to pay bills, and missing appointments, as well as difficulty finding the right words when he speaks. He confides that he finds himself easily frustrated and feeling irritable much of the time.

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Patient Case Study Polling Questions

Case Question

What would be your first step for Kevin?

A. Involve a care partner in the evaluation
B. Administer cognitive assessments
C. Assure him that his symptoms are a part of “normal aging”

Case Question

- Kevin calls his son who joins the visit by speakerphone. His son confirms his father's previous accounts and further adds that his father has been asking the same questions and telling the same stories repeatedly. Based on the information you have so far, what type of assessments would you order for Kevin?

a) MoCA
b) PET
c) CSF
d) Genotyping

Case Question

- The results of Kevin's evaluation include a MoCA score of 24 and recall of 1/5 with MIS of 8/15, which collectively support a diagnosis of MCI due to probable AD. What factors would most strongly influence your decision regarding whether to recommend pharmacotherapy?

a) Degree of interference with daily activity
b) Patient goals
c) Current medications
d) Previous MRI findings

MIS, Memory Impairment Screen.

Case Question

What type of therapy would you be most likely to prescribe for Kevin?

A. A cholinesterase inhibitor
B. Memantine
C. Aducanumab

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Program Summary

Summary of Key Points

- Alzheimer's disease associated with substantial morbidity and mortality that affects millions of US adults, as well as their loved ones and caregivers.
- It is a condition characterized by a complex and multifactorial pathogenesis that remains challenging for clinicians to recognize, diagnose, and manage.
- Although traditional AD therapies are targeted at symptom control, many potentially disease-modifying treatments are currently under investigation.
- Indeed, the FDA has recently approved aducanumab, a therapy that has been shown to reduce beta-amyloid, one of the hallmarks of Alzheimer's disease.
- Given their role, nurse practitioners are particularly well-situated to aid in recognizing AD and manage the complicated care required by patients with AD.
- Moreover, nurse practitioners are highly suited to ensure strong emphasis on patient- and family-centered care throughout the disease course, which is essential to improving patient outcomes.

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Thank You!