RUSH

Excellence is just the beginning.

Rush System for Health

Diagnostic Testing, Biomarkers & Pathophysiological Testing

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Prepared For

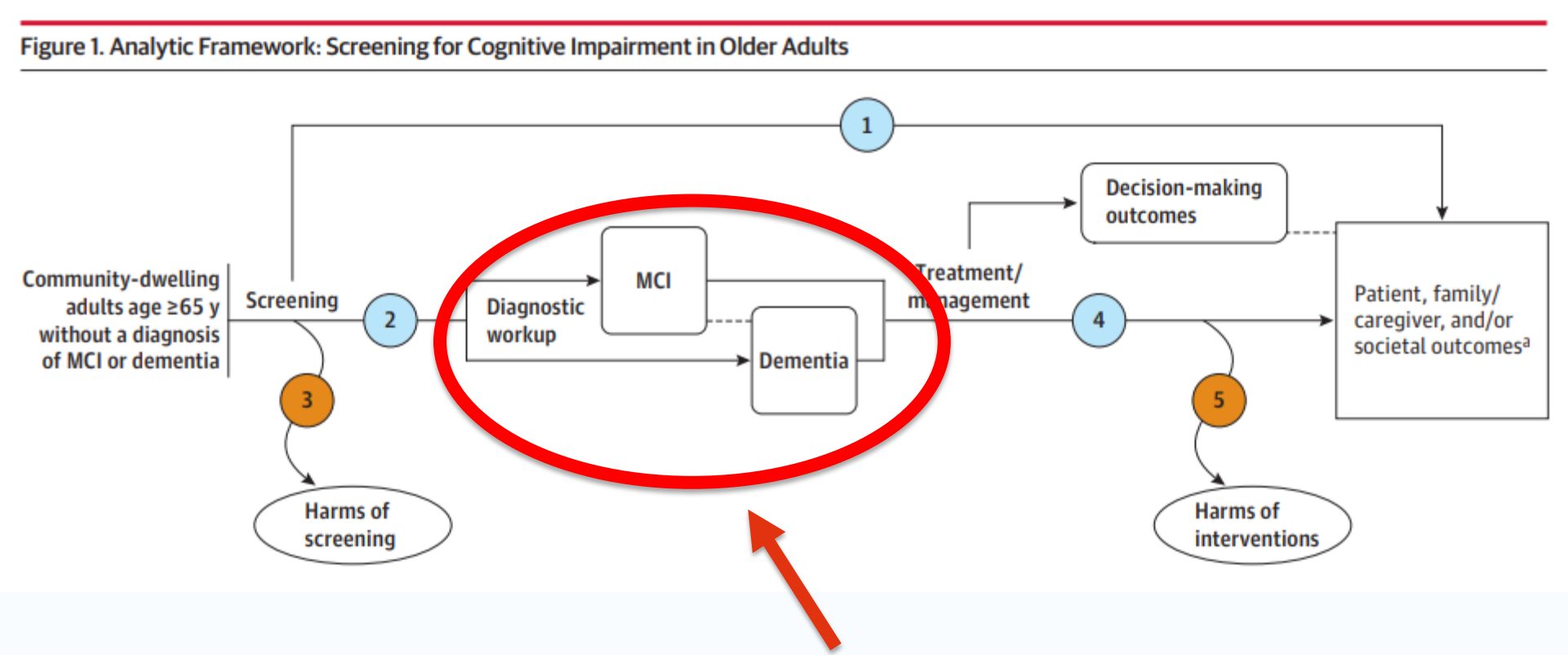
SIU Medicine 2023 Brain Aging Conference
March 10, 2023
Springfield, Illinois

Disclosures

I report

- no relevant disclosures to the content of this presentation;
- being the site principal investigator or sub-investigator for clinical trials for which his institution (Rush University Medical Center) is compensated [Amylyx Pharmaceuticals, Inc., Athira Pharma, Inc., Edgewater NEXT, Eli Lilly & Co., Inc., and Genentech, Inc.];
- being a non-compensated board member of the Alzheimer's Association -- Illinois Chapter until 2021;

The US Preventive Services Task Force Analytic Framework



Source: Patnoude, et al. *JAMA*. 2020;323(8):757-763. doi:10.1001/jama.2020.0435

The Rational Clinical Evaluation

THE RATIONAL CLINICAL EXAMINATION

CLINICIAN'S CORNER

Does This Patient Have Dementia?

Tracey Holsinger, MD
Janie Deveau, MD
Malaz Boustani, MD, MPH
John W. Williams, Jr, MD, MHS

Context While as many as 5 million individuals in the United States have dementia, many others have memory complaints. Brief tests to screen for cognitive impairment could help guide dementia diagnosis.

Objective To review the literature concerning the practicality and accuracy of brief cognitive screening instruments in primary care.

CLINICAL SCENARIO

Ms A, an 81-year-old retired nursing instructor who is recently widowed and lives alone, arrives in your office. She is accompanied by her daughter who decided to miss work and attend the appointment because she wanted you to know that her mother has become increasingly forgetful during the past 6 months. The patient is misplacing her glasses and keys more often, and she complains of difficulty sleeping and poor concentration. You must address whether the memory complaints are indicative of a dementia or if she has anxiety, depression, or is merely noting poorer recall associated with normal aging.

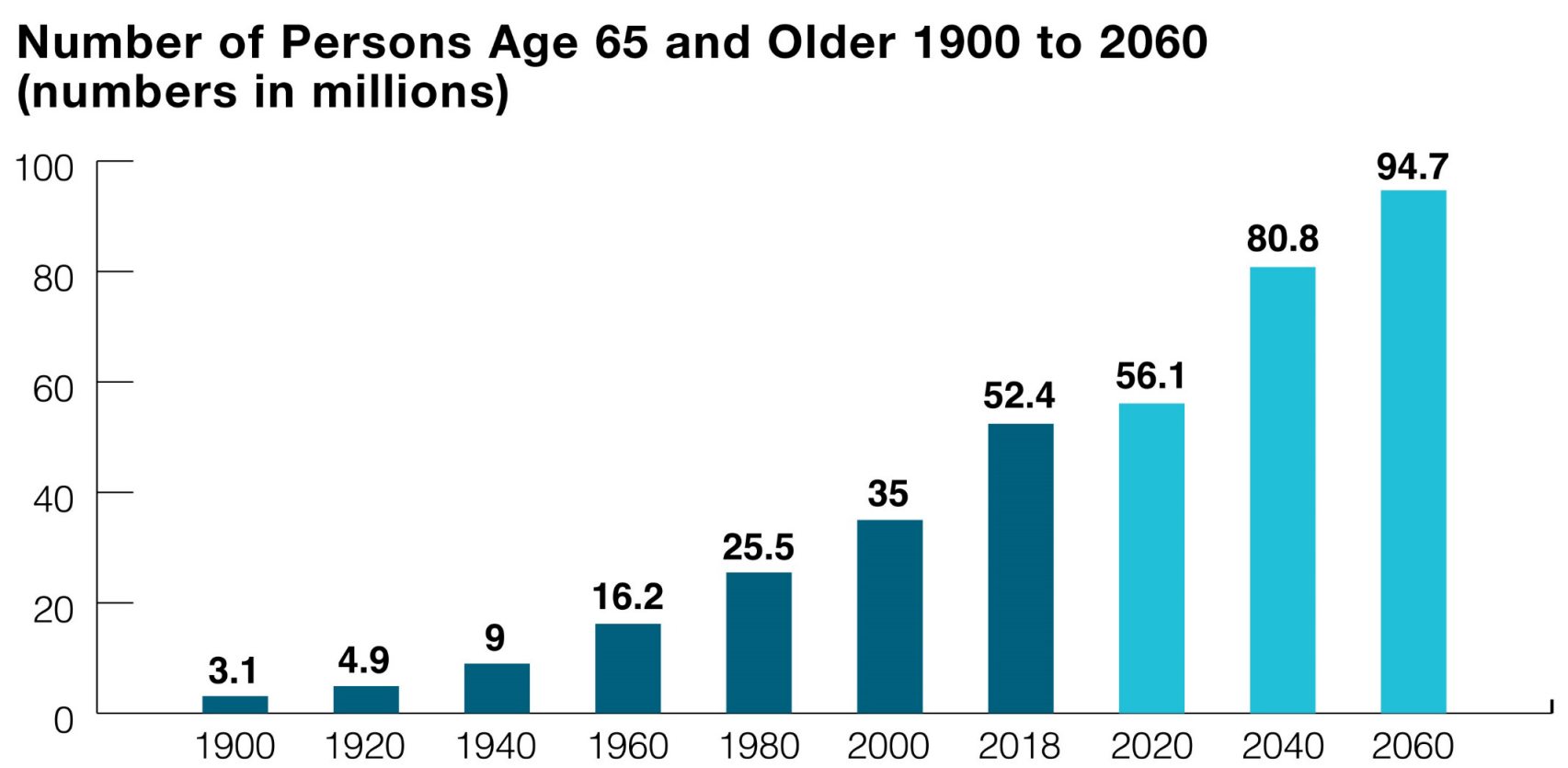
JAMA. 2007;297:2391-2404

Learning Objectives

- How do we make an early diagnosis of dementia in primary care now
- What are the limitations to making an early diagnosis
- Where are we in new tool development for an early diagnosis
- What are potential innovations on the horizon

Why focus on early diagnosis in primary care?

The Denominator – Persons over age 65 at Risk



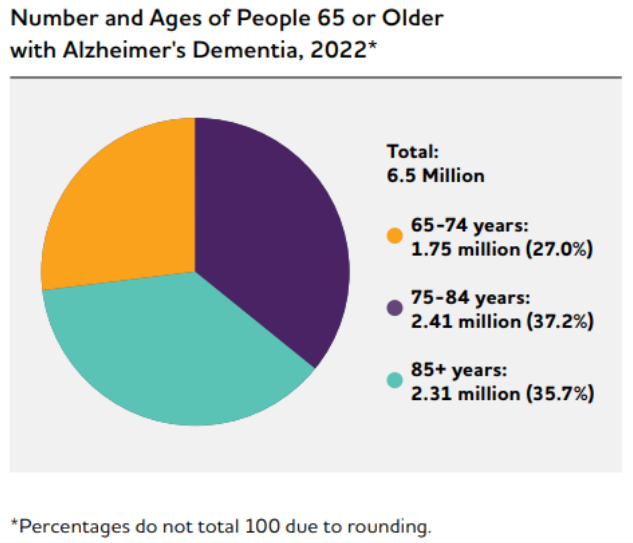
Note: Increments in years are uneven. Lighter bars (2020, 2040, and 2060) indicate projections.

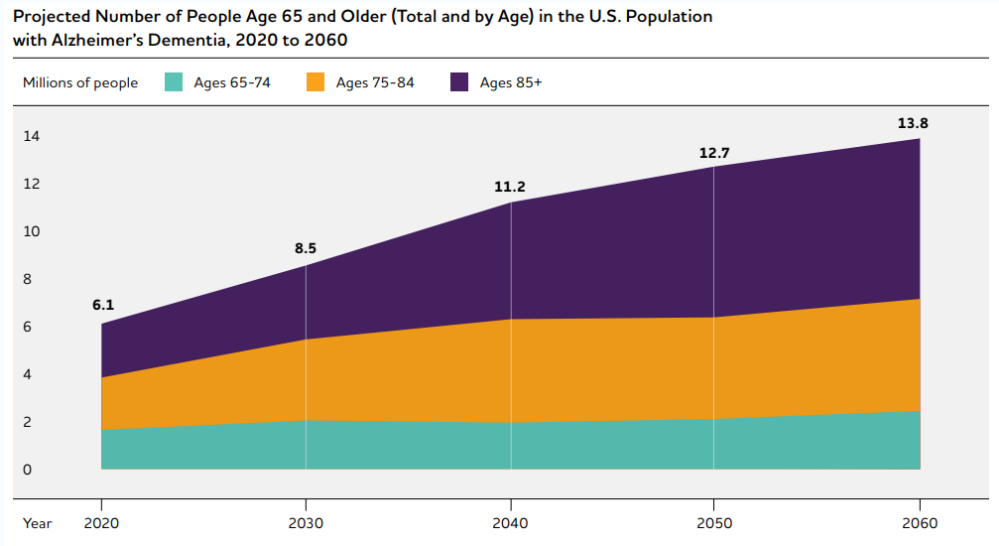
Source: U.S. Census Bureau, Population Estimates and Projections

Source: http://www.aoa.gov/AoARoot/Aging_Statistics/Profile/index.aspx

The Problem of Cognitive Loss (United States)

- In 2022, an estimated 6.5 million Americans have Alzheimer's disease.
- Alzheimer's disease and related disorders are the third most costly disease state behind heart disease and cancer in the United States.





RUSH

2023 BRAIN AGING CONFERENCE
ROADMAP TO BRAIN HEALTH

Alzheimer's Association. 2022 Alzheimer's Disease Facts and Figures. Alzheimers Dement 2022;18.

The Problem of Alzheimer's (Illinois)

Prevalence

NUMBER OF PEOPLE AGED 65 AND OLDER WITH ALZHEIMER'S

Year	TOTAL
2020	230,000
2025	260,000

ESTIMATED % CHANGE

13%

Caregiving (2021)

383,000
Number of Caregivers

$8,806,000,000
Total Value of Unpaid Care

21.4% % of caregivers with depression

483,000,000
Total Hours of Unpaid Care

53.5% % of caregivers with chronic health conditions

16.7% % of caregivers in poor physical health

Health Care

HOSPICE (2017)

9,795
# of people in hospice with a primary diagnosis of dementia

18%
% in hospice with a primary diagnosis of dementia

HOSPITALS (2018)

1,624
# of emergency department visits per 1,000 people with dementia

23.4%
dementia patient hospital readmission rate

MEDICAID

$1.787B
Medicaid costs of caring for people with Alzheimer's (2020)

23.1%
projected change in costs from 2020 to 2025

MEDICARE

$30,672 per capita Medicare spending on people with dementia (in 2021 dollars)

Alzheimer's Association. illinois-alzheimers-facts-figures-2022.pdf.

The Problem of Confusion/Memory Loss (Illinois)

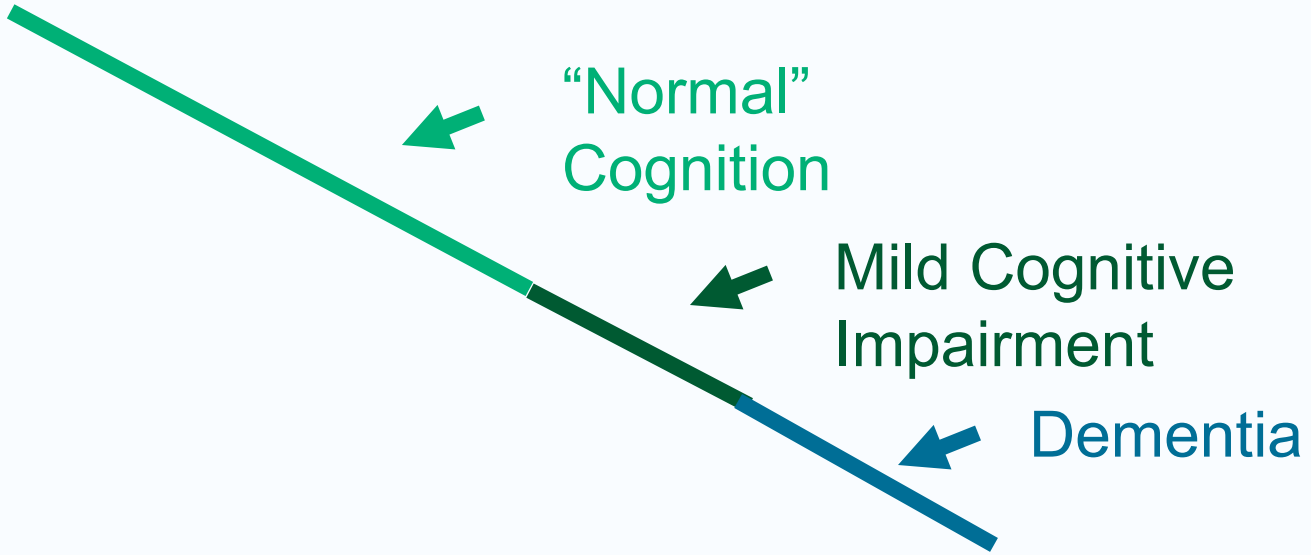
In 2013, based on the increased confusion or memory loss (ICML) module of the Centers for Disease Control and Prevention Behavioral Risk Factor Surveillance Study (BRFSS)

- 1.2 million households (not residential care facilities) reported having someone with ICML (of those, 5% with a person living with Alzheimer's dementia and 12% with a person living with a related dementia)
- 37% of persons with ICML reported restricted social, work, or household activities as a result of the cognitive changes.
- 68% of persons with ICML reported never talking with a health care provider about their cognitive and functional concerns.

https://dph.illinois.gov/content/dam/soi/en/web/idph/files/publications/burden-update-healthy-brain-initiative.pdf

How to get aligned on some basic concepts?

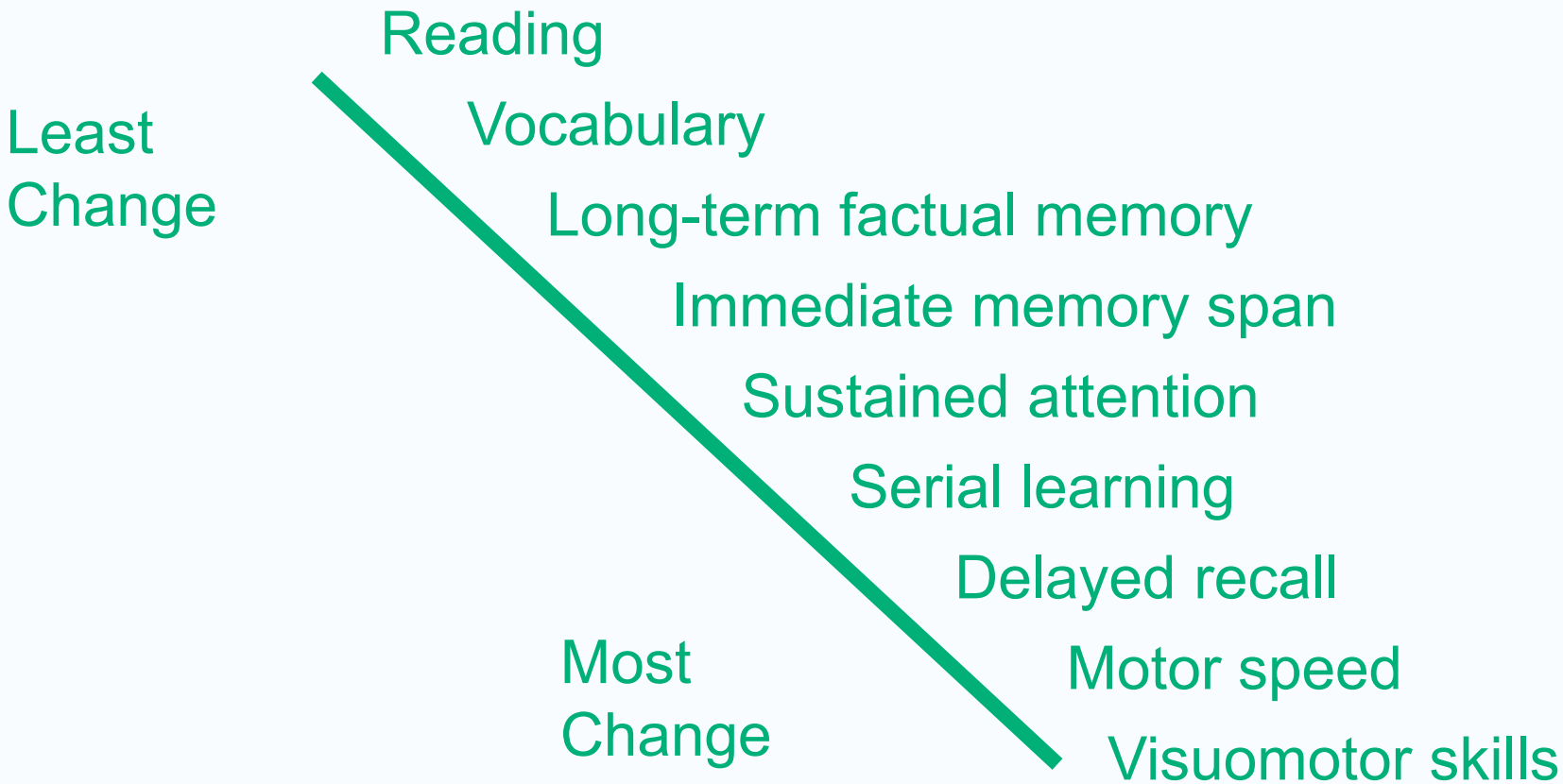
What We Know about Cognitive Decline?



Dementia is part of the Cognitive Spectrum

JAMA. 2019;322(16):1589-1599. doi:10.1001/jama.2019.4782

“Normal” Cognition with Aging



Ashman TA, Mohs RC, Harvey PD. Cognition and Aging. In Principles of Geriatric Medicine and Gerontology, 4th Ed.

Mild Cognitive Impairment (MCI)

- Subjective complaint of memory difficulty
- Objective memory impairment
- Normal other cognitive function
- No functional loss
- No dementia

mith GE, Waring SC. Archives of Neurology.
8

Dementia

What are the types of dementia?

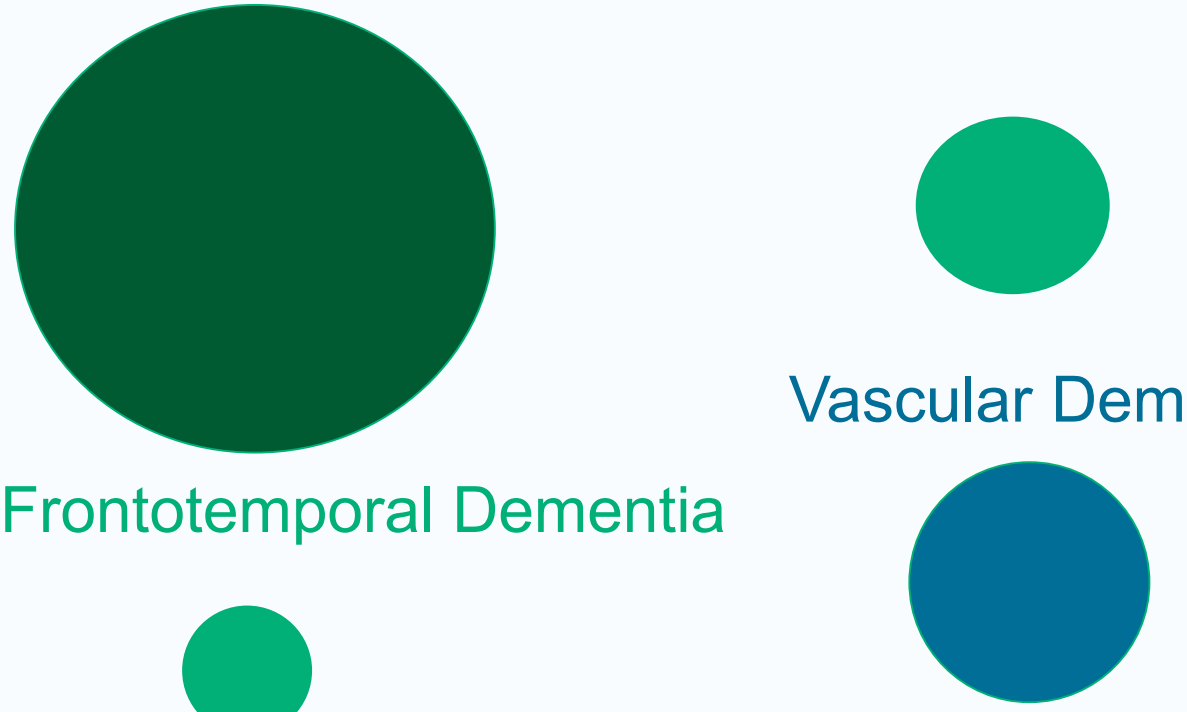
There are many types of dementia (with mixed dementia being the most common. The four most common neurodegenerative types are:

Alzheimer's Disease

Lewy Body Dementia

Vascular Dementia

Frontotemporal Dementia



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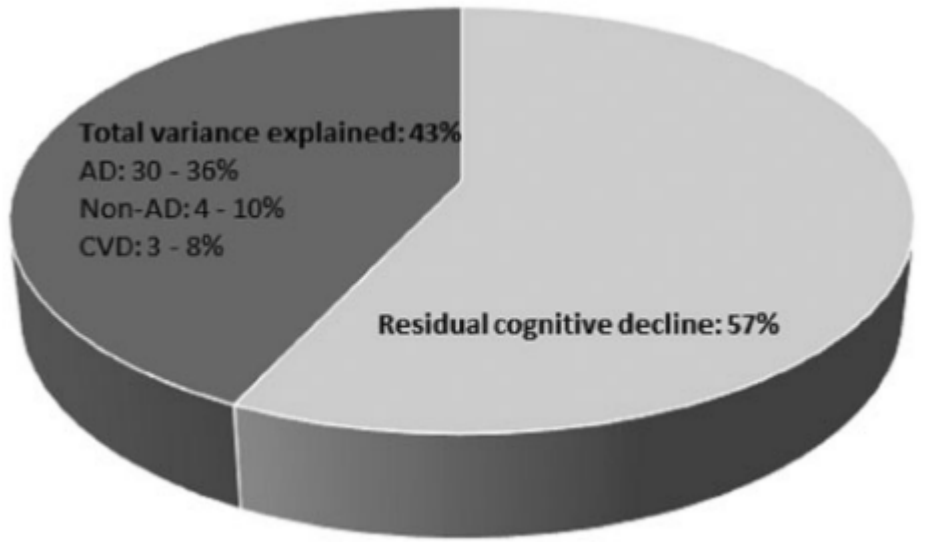
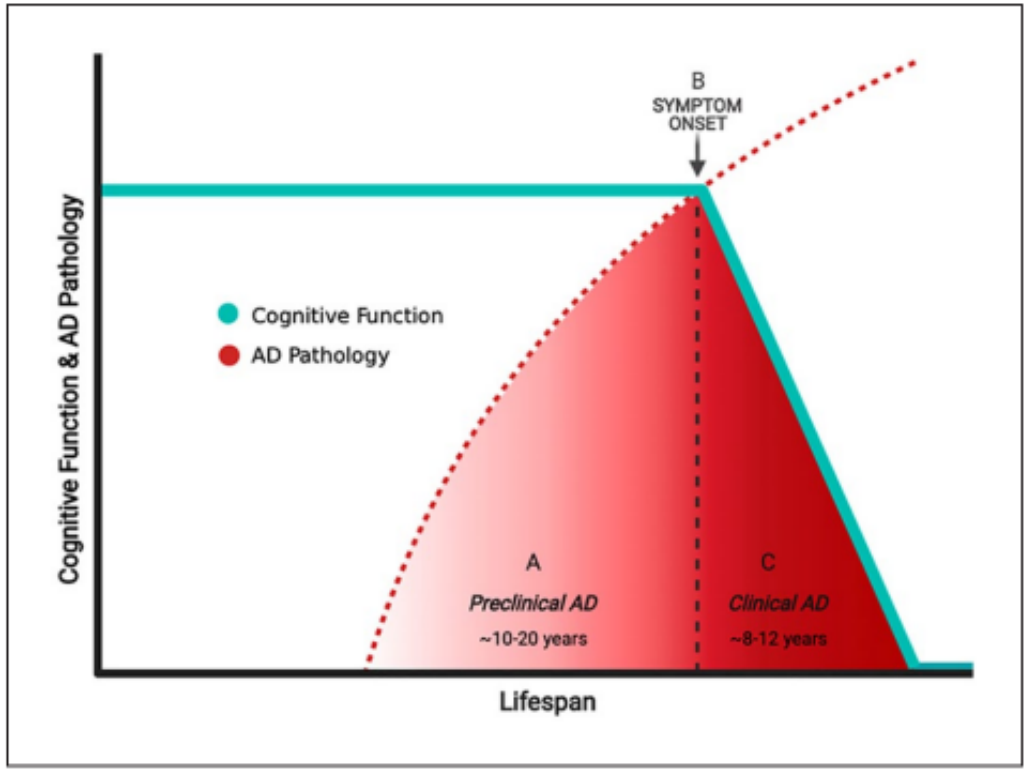


In the same person, many of the brain changes associated with each type can co-exist and may not explain all cognitive decline

BRAIN 2021: 144; 2166–2175

How to detect dementia early in primary care?

Early Dementia Diagnosis – The Ideal



Journal of Primary Care & Community Health
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DOI: 10.1177/21501319221141178
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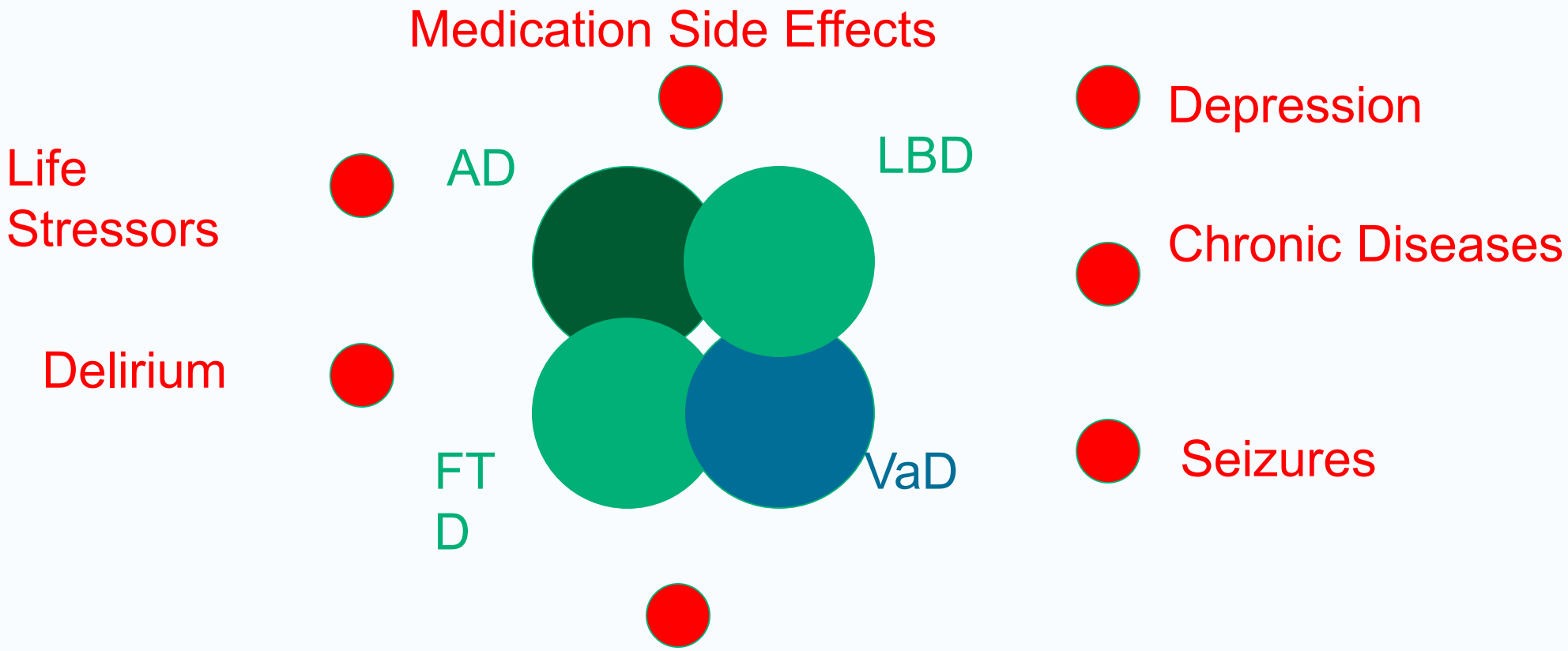
SAGE

Alzheimer Disease Biomarkers in Clinical Practice: A Blood-Based Diagnostic Revolution

Madeline M. Paczynski[1] and Gregory S. Day[2]

How Do We Evaluate Cognitive Loss Concerns?



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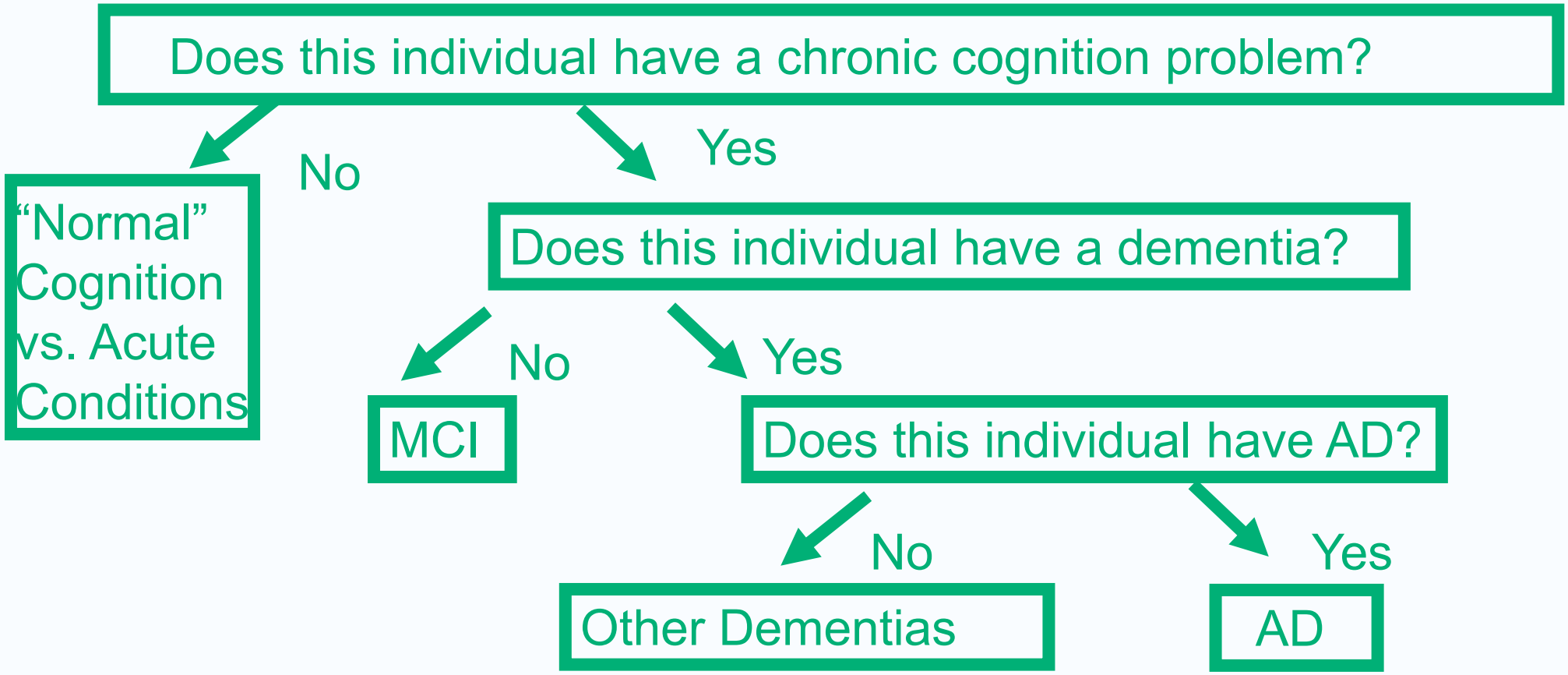


The Key Person-Centered Quality Check

- Did the Health Care Provider Inquire and Listen?
  - History, history, and more history
  - Need corroboration from another source & Push for timeline
  - Memory History of Present Illness
  - Memory Review of Systems
  - Depression Screening
  - Functional Assessment
  - Medication Review

Required information	Example questions for the patient and/or informant
Medical history	Has the patient had any recent illnesses? Has the patient recently had any head injuries? Has the patient used any medications recently that could cause memory loss? Has the patient used or been exposed to any illicit drugs? Is there a history of epilepsy?
Risk factors	Is there a history of dementia within the family?
	Does the patient have any other medical conditions, such as cardiovascular disease or obesity?
	Is the patient a smoker or ex-smoker?
Cognitive and behavioral changes	What does a typical day look like for you (the patient)? Has the patient noticed they are forgetting things or misplacing items recently? Has the patient noticed any changes to their mood or felt helpless recently? Has the patient had any issues with finances?
Physical	Has the patient had any falls recently? Has the patient noticed any issues with their balance?
Other	Does the patient have any vision or hearing problems? Is there anything else the patient or caregiver is concerned about?

Galvin JE, Sadowsky CH, NINCDS-ADRDA. Practical guidelines for the recognition and diagnosis of dementia. J Am Board Fam Med 2012;25:367–82.

Key Tips to Early Dementia Diagnosis

Use HI/BL (human intelligence/brain learning)

- Keep eyes and ears open to signals
- Find the ‘canary in the coal-mine’
- Use the reflection point provided by the Annual Wellness Visit

- Inquire and listen
- Use a three-question algorithm
- Focus on function

- Remember horses and zebras

Instrumental Activities of Daily Living

Do you need assistance with:

Transportation
Medications
Finances
Grocery shopping
Cooking
Housecleaning
Telephone use

Adapted from Lawton MP, Brody EM. Assessment of older people: self-maintaining and instrumental activities of daily living. Gerontologist. 1969. 9. 179-86.

Basic Activities of Daily Living

Do you need assistance with:

Transferring out of bed
Walking
Grooming (brushing teeth, dressing)
Toileting (maintaining continence)
Bathing
Feeding

Adapted from Katz S, Ford AB, Moskowitz RW. Studies of illness in the aged. The index of ADL: a standardized measure of biological and psychosocial function. JAMA 1963. 185. 914-9

Depression -- SIGECAPS

S = Sadness and sleep difficulty

I = Interest decline

G = Guilty Feelings

E = Energy level decline

C = Concentration decline

A = Appetite change

P = Psychomotor agitation or retardation

S = Suicidal Thoughts

Other Evaluation Steps

- Physical Exam
  - Vitals (Blood pressure, pulse, weight)
  - Cognitive Assessment via Testing
    - One example is Mini-Mental State Examination
  - Neurologic Exam
    - Looking for parkinsonian features
    - Looking for stroke features

Laboratory & Imaging

-- CBC, BMP, TSH, B12 (RPR as needed)

-- Imaging study (CT vs MRI) (Looking for large strokes and masses)

Features for Dementia Causes

What are the limitations to making an early diagnosis of dementia in primary care?

Barriers to Early Dementia Diagnosis

Barriers for Patients and Families

- Fear of diagnosis
- Stigma
- Assuming changes part of normal aging
- Lack of self-awareness of disease process
- Ability to access care services
- Ability to afford diagnosis and treatment

Barriers for Health Care Providers

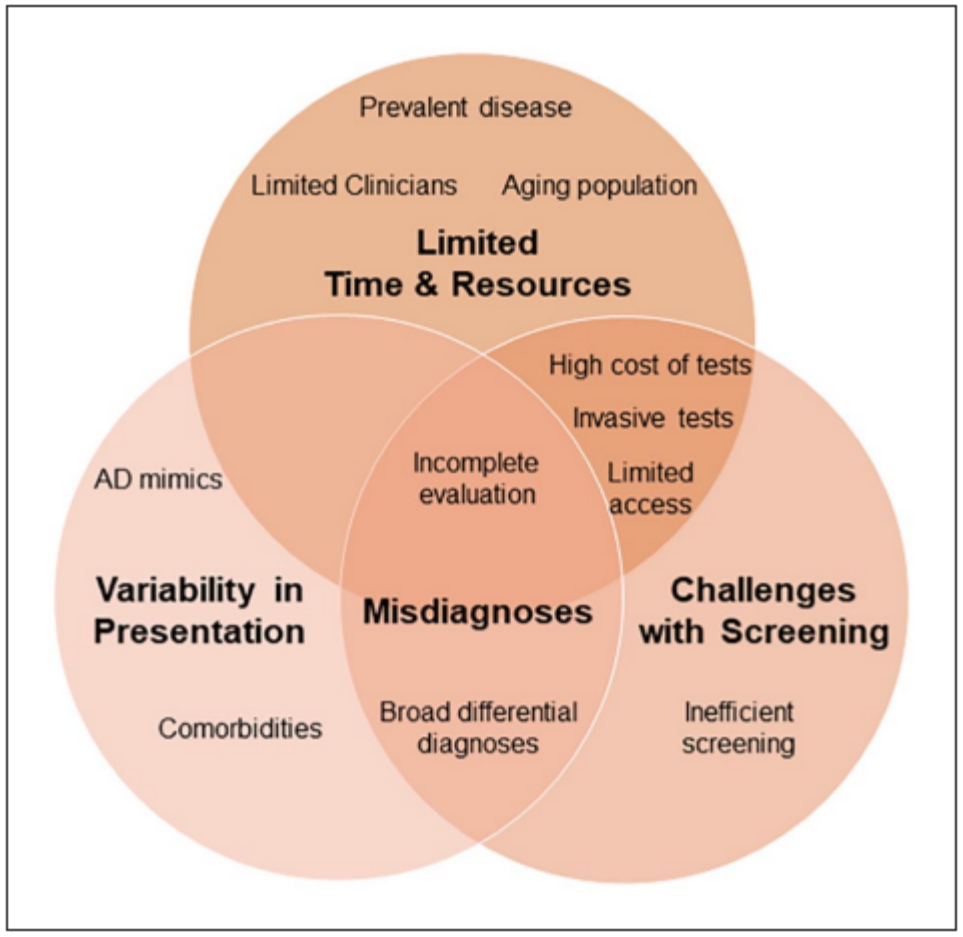
- Difficulty Recognizing Symptoms
- Practice Constraints
- Nihilistic Attitudes

Barriers for Community Services Providers

- Lack of coordination of service providers

Medicina **2022**, *58*, 906. https://doi.org/10.3390/medicina58070906

Barriers to Early Dementia Diagnosis



Alzheimer Disease Biomarkers in Clinical Practice: A Blood-Based Diagnostic Revolution

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SAGE

Madeline M. Paczynski[1] and Gregory S. Day[2]

Where are we in tool development for early diagnosis of dementia in primary care?

Imaging and Cerebro-Spinal Fluid biomarkers

Current Alzheimer's Disease Biomarkers

	Abnormality	Pathology
MRI		
Regional anatomy	Decreased volume of hippocampus and other temporal lobe structures	Tissue loss and neurodegeneration
PET		
^{18}F-fluorodeoxyglucose PET	Decreased uptake in posterior cingulate-precuneus and temporoparietal cortex	Glucose hypometabolism and neurodegeneration
^{11}C-PiB and fluorinated tracers for amyloid PET*	Increased cortical retention	Deposition of β-amyloid in the cortex
CSF measures		
Aβ42 or Aβ42:Aβ40	Decreased concentration or ratio	Abnormal metabolism of β-amyloid
Total tau and hyperphosphorylated tau	Increased concentration	Neuronal damage and accumulation of tau pathology; hyperphosphorylated tau is more specific for Alzheimer's disease neurodegeneration

Tau-PET is still under development and, therefore, is not included. PiB=Pittsburgh compound. Aβ=fibrillar β-amyloid.
*Using tracers such as florbetapir, flutemetamol, and florbetaben.

***Table 1*: Biomarkers for the diagnosis of Alzheimer's disease**

Lancet Neurol 2017; 16: 661–76

State of Validation of Alzheimer biomarkers

	Phase 1: preclinical exploratory studies; PA	Phase 2: clinical assay development for Alzheimer's disease pathology					Phase 3: retrospective studies using longitudinal data available in repositories						Phase 4: prospective diagnostic accuracy studies					Phase 5: disease burden reduction studies; PA
		PA	SA1	SA2	SA3	SA4	PA1	PA2	SA1	SA2	SA3	SA4	PA	SA1	SA2	SA3	SA4	
MRI medial temporal atrophy*	Full	Full	Part	Full	Full	Full	Full	PE	Part	Part	Part	NA	NE	NE	NE	NE	NE	NE
^{18}F-fluorodeoxy-glucose PET	Full	Full	Full	Full	Full	Part	Full	Part	PE	Part	Part	PE	NE	PE	NE	PE	NE	NE
^{11}C-PiB and fluorinated tracers for amyloid PET†	Full	Full	Part	Full	Part	Part	Full	Part	NE	Part	Part	PE	NE	NE	NE	NE	NE	NE
CSF measures (Aβ42 or Aβ42:Aβ40 or total tau and hyperphosphorylated tau)	Full	Full	PE	Full	Part	Part	Full	Part	Part	Part	Part	PE	PE	NE	NE	NE	NE	NE

PA=primary aim. SA=secondary aim. Full=Phase fully achieved (no need to collect further evidence). Part=Phase partly achieved (studies available but replication or completion is required). PE=only preliminary evidence available. NA=not applicable. NE=no evidence available. PiB=Pittsburgh compound. Aβ=fibrillar β-amyloid. *Assessments represent the least developed level between visual and volumetric medial temporal atrophy. †Using tracers such as florbetapir, flutemetamol, or florbetaben.

***Table 4*: State of completion of biomarkers development in Alzheimer's disease for the five phases in the strategic roadmap**

Lancet Neurol 2017; 16: 661–76

What are potential innovations on the horizon?

Blood Biomarkers in Primary Care

Potential Scenario

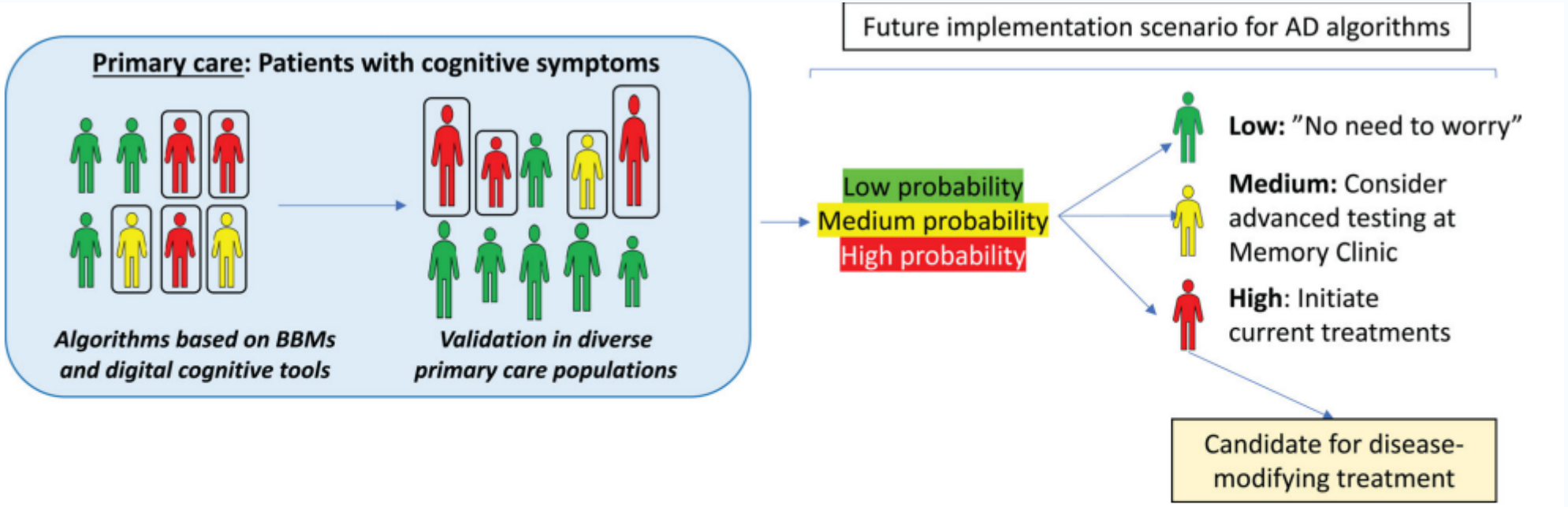


FIGURE 2 Potential future use of blood-based biomarkers in primary care. In primary care we need easy and accurate methods to be able to identify different underlying neurodegenerative diseases in patients with cognitive complaints. Ideally blood-based biomarkers together with clinical assessments could be used to determine the patient-level probability of having a neurodegenerative disease like Alzheimer's disease (AD), which would improve patient management, including decisions regarding treatment or referrals to specialized clinics. However, it is very important that novel diagnostic algorithms (based on blood-based biomarkers) are prospectively validated against relevant reference standards in large and diverse primary care populations before implementation in clinical practice

Alzheimer's Dement. 2022;18:2669–2686.

Current State and Issues

The Alzheimer's Association appropriate use recommendations for blood biomarkers in Alzheimer's disease

Oskar Hansson[1,2] | Rebecca M. Edelmayer[3] | Adam L. Boxer[4] | Maria C. Carrillo[3] | Michelle M. Mielke[5] | Gil D. Rabinovici[4] | Stephen Salloway[6] | Reisa Sperling[7] | Henrik Zetterberg[8,9,10,11,12] | Charlotte E. Teunissen[13]

- Potential Candidates
  - plasma Aβ42/Aβ40
  - p-tau181, p-tau217, p-tau231
  - plasma NfL
  - plasma GFAP

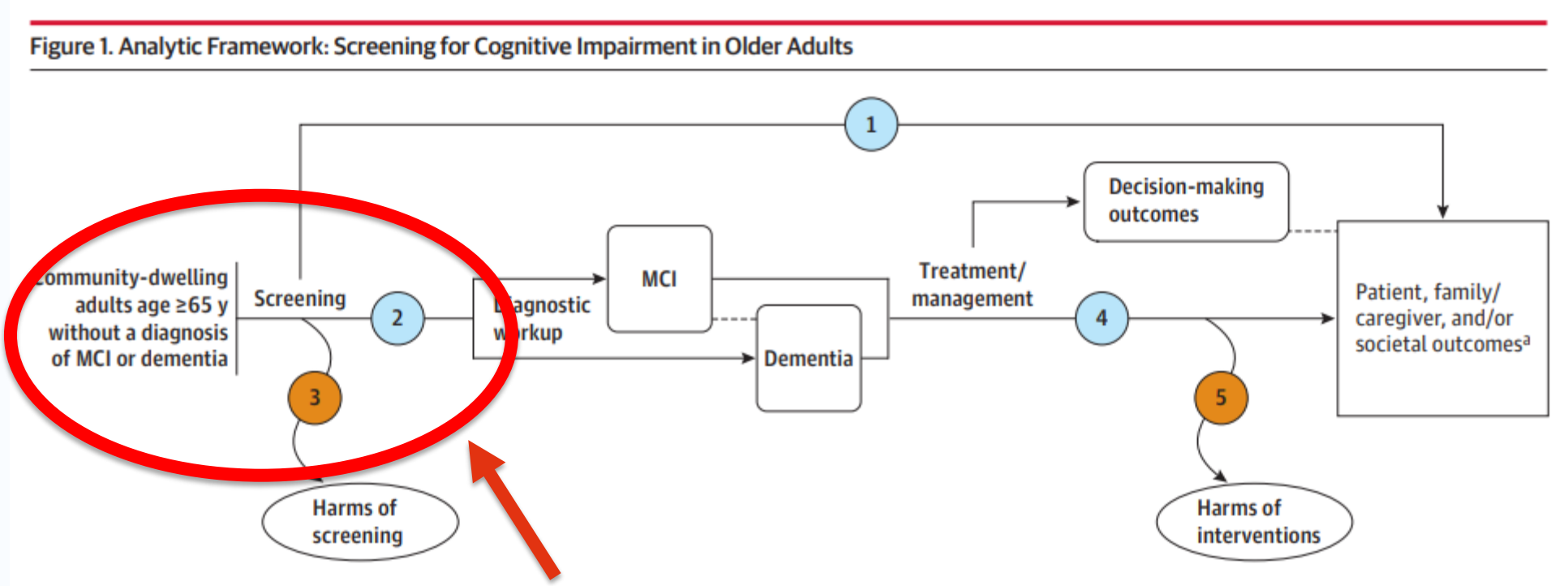
Issues

- No studies have extensively evaluated blood-based biomarkers in primary care settings.
- Prevalence in primary care lower than in specialty clinics
- Population more heterogenous and with more comorbidities
- Evaluations needed for accuracy and change in management

Alzheimer's Dement. 2022;18:2669–2686.

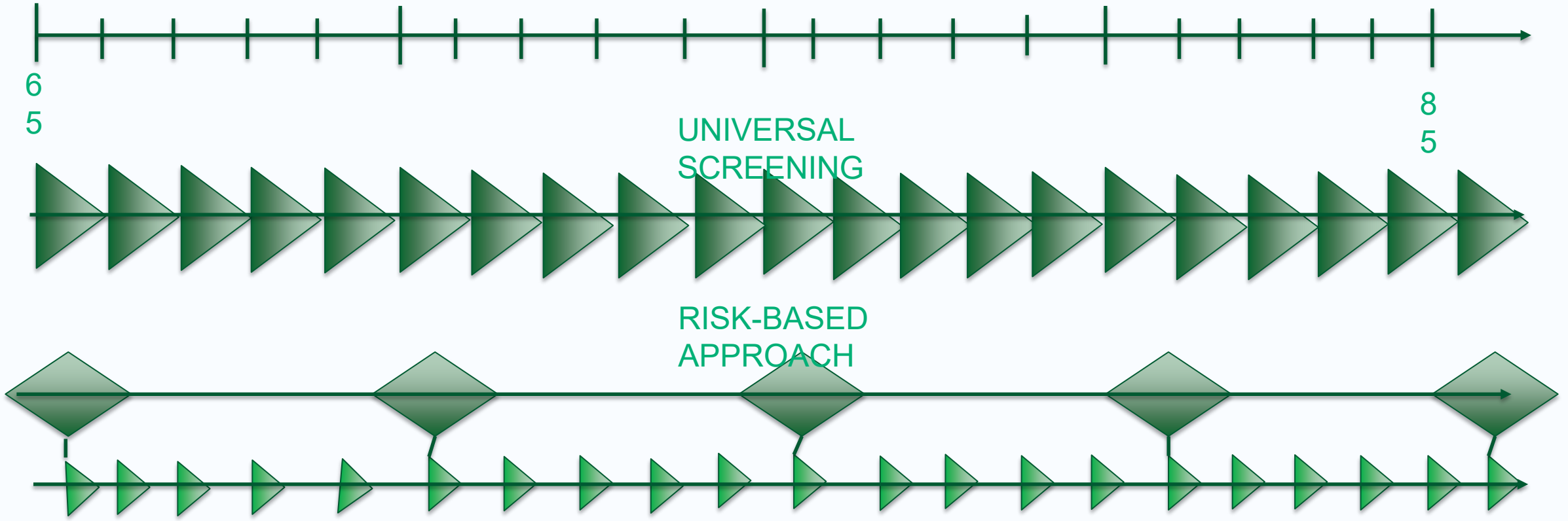
Risk Prediction Modelling

The US Preventive Services Task Force Analytic Framework

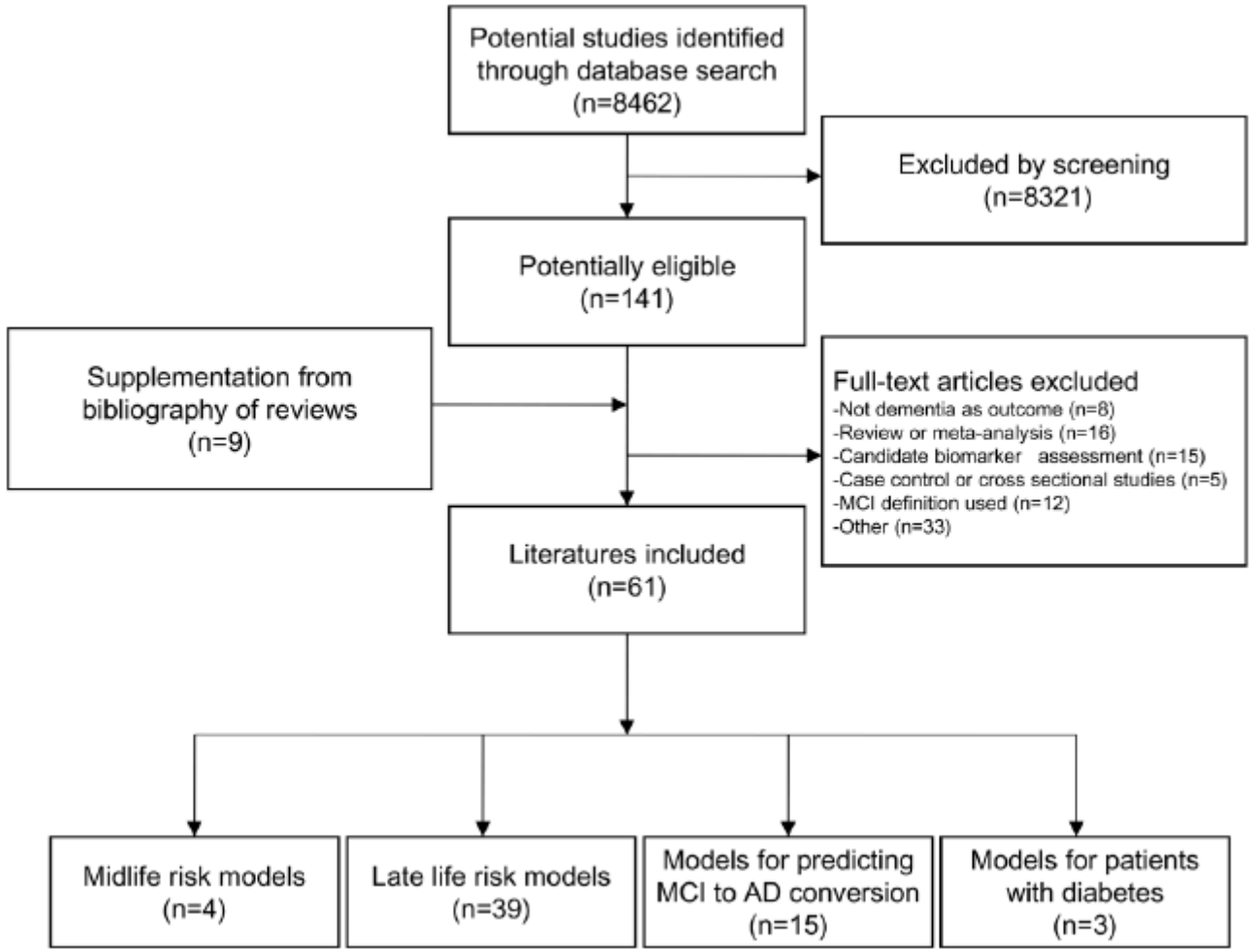


Source: Patnoude, et al. *JAMA*. 2020;323(8):757-763. doi:10.1001/jama.2020.0435

Universal Screening vs. Risk-Based Approach



Systematic Review of Risk Prediction Models



Hou X-H, *et al*. *J Neurol Neurosurg Psychiatry* 2019;**90**:373–379. doi:10.1136/jnnp-2018-318212

Systematic Review of Risk Prediction Models (Primary Care)

15 Walters K, Hardoon S, Petersen I, *et al*. Predicting dementia risk in primary care: development and validation of the Dementia Risk Score using routinely collected data. *BMC Med* 2016;14:6.

25 Jessen F, Wiese B, Bickel H, *et al*. Prediction of dementia in primary care patients. *PLoS One* 2011;6:e16852.

26 Barnes DE, Beiser AS, Lee A, *et al*. Development and validation of a brief dementia screening indicator for primary care. *Alzheimers Dement* 2014;10:656–65.

Hou X-H, *et al*. *J Neurol Neurosurg Psychiatry* 2019;**90**:373–379. doi:10.1136/jnnp-2018-318212

Dementia Screening Indicator

Do you think your patient may have cognitive impairment based on:

☐ your observations ☐ concerns of patient ☐ concerns of family or others

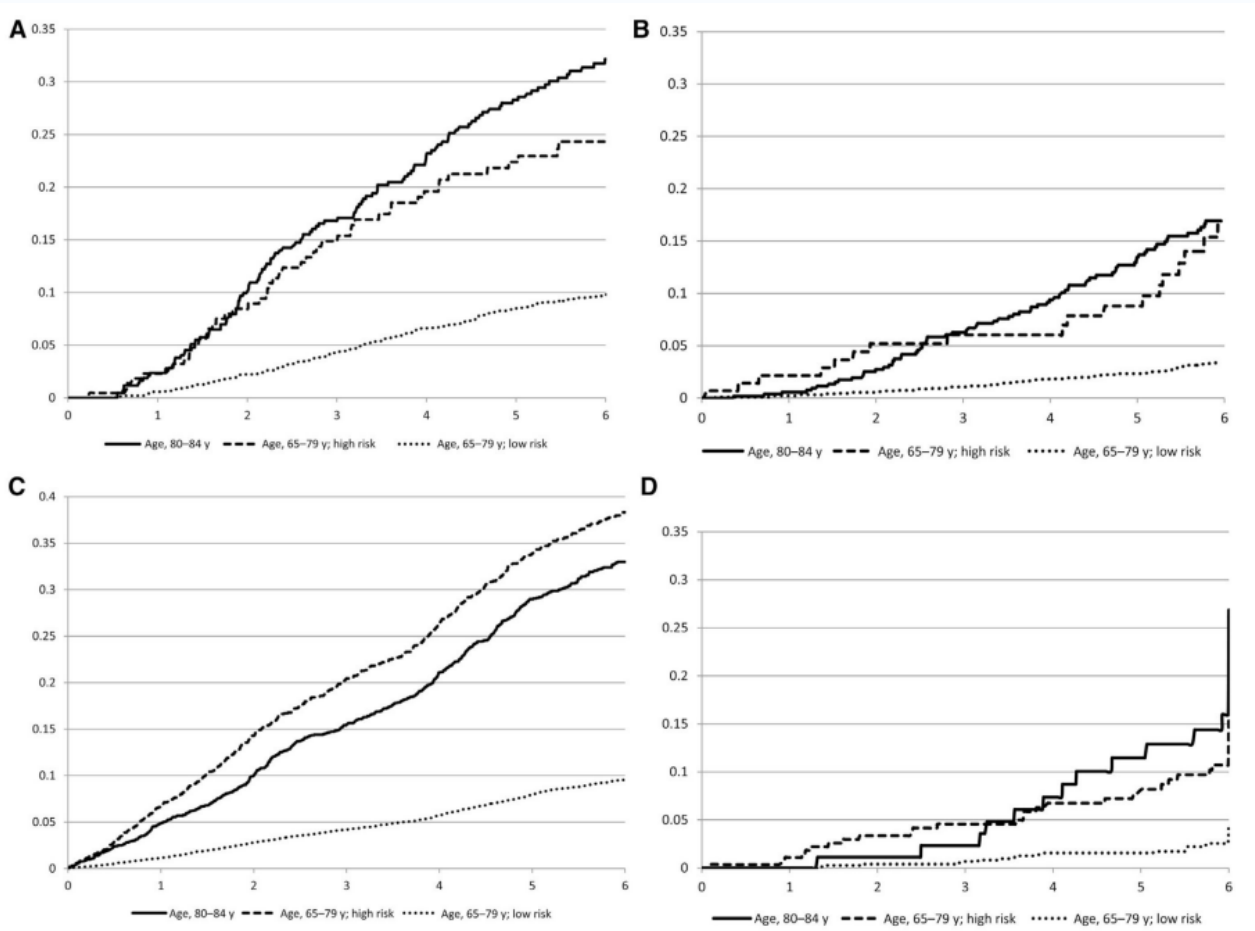
If yes to any: Your patient should be screened for cognitive impairment.

Is your patient age 80 years or older? ☐ yes ☐ no

If yes: Your patient should be screened for cognitive impairment.

If no: Administer Dementia Screening Indicator.

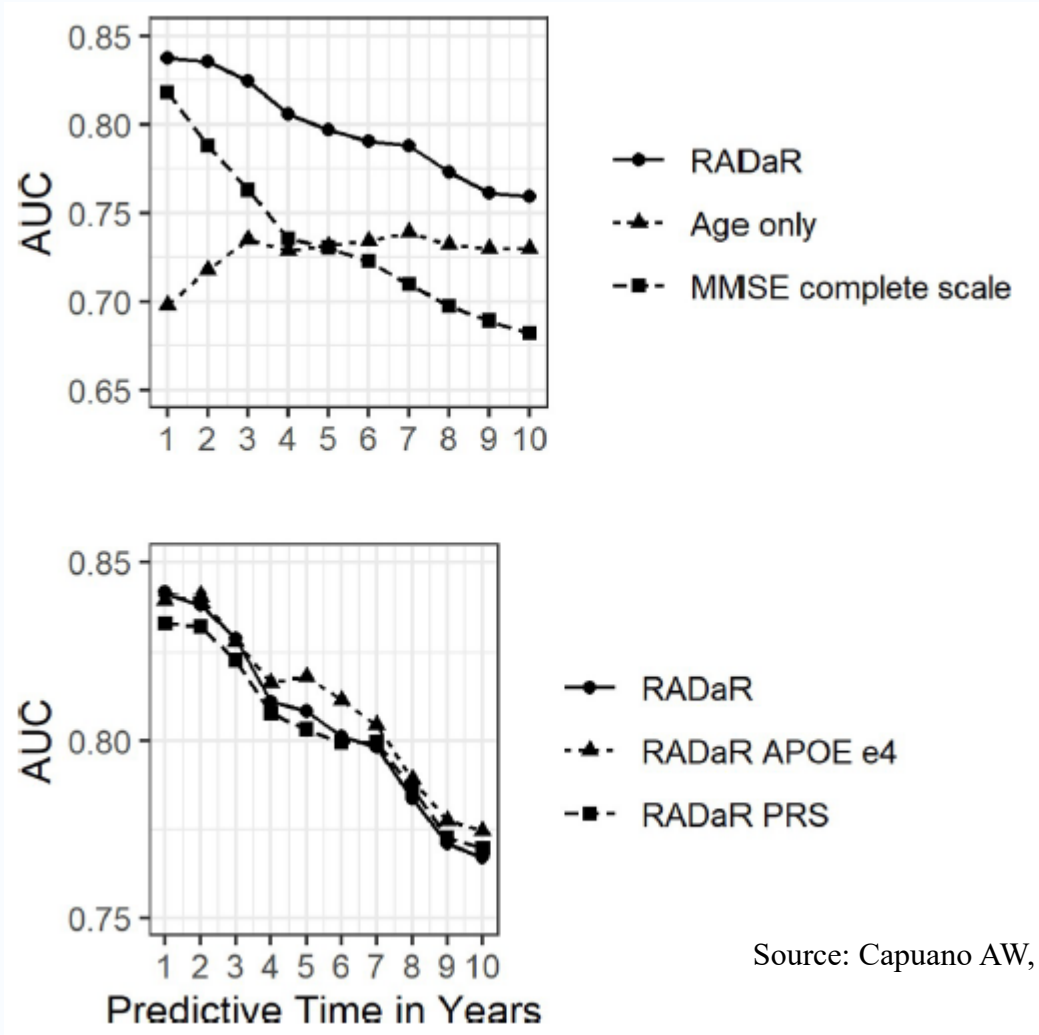
Dementia Screening Indicator			Points
1. How old is your patient? _____ years *If 65-79 years, assign 1 point per year above age 65. Example: age 65 years receives 0 points; age 72 years receives 7 points.*			
2. Does your patient have < 12 years of education? [1]	No (0)	Yes (9)	
3. Is your patient's BMI < 18.5 kg/m^2? [2]	No (0)	Yes (8)	
4. Does your patient have a history of type 2 diabetes?	No (0)	Yes (3)	
5. Has your patient ever had a stroke?	No (0)	Yes (6)	
6. Does your patient need help from others to manage money or medications? [3]	No (0)	Yes (10)	
7. Does your patient currently take anti-depressant medications OR report that "everything was an effort" ≥3 days per week over the past week? [4]	No (0)	Yes (6)	
Total point score: *If ≥ 22, your patient should be screened for cognitive in*			



26 Barnes DE, Beiser AS, Lee A, *et al*. Development and validation of a brief dementia screening indicator for primary care. *Alzheimers Dement* 2014;10:656–65.

RADaR – Value Add of Biomarkers with Clinical Tools

Rapid Assessment of Dementia Risk (RADaR)	Date:__/__/__ Room:_____	
		Score
From medical records		
Age of the patient:____ years ***Add 5 point for every year above 65 (e.g. for 75-year-old, subtract 65 from 75 equal 10, 10 times 5 is 50 point)***		
Assessment		
Delayed recall – words provided**	Instructions: "To start our assessment I am going to name 3 objects. After I have said them, I want you to repeat them. Remember what they are, because I am going to ask you to name them again in a few minutes. The objects are:..." *Say the name of three common objects* (i.e. apple, table, and penny): _____, _____, _____ Instructions: "Good, now please repeat the objects". *Allow to repeat until able to say all three words.*	
Functional status	"Are you able to take care of your own finances - including paying bills, writing checks, keeping track of income (but not necessarily preparing your own taxes) completely by yourself or does someone else help you?" o no help ***add 0 points*** o needs some help ***add 70 points*** o unable to do ***add 70 points***	
Memory complaint***	"People find that they sometimes have more trouble remembering things as they get older. About how often do you have trouble remembering things?" o Very often ***add 30 points*** o Often ***add 30 points*** o Sometimes ***add 0 points*** o Rarely ***add 0 points*** o Never ***add 0 points***	
Orientation**	"What is the month?" _____ o patient report correct month ***add 0 points*** o patient does not report correct month ***add 120 points***	
	"What is the room you are in?" _____ o patient knows the room ***add 0 points*** o patient does not report know the room ***add 60 points***	
Delayed recall **	"What were the three objects I asked you to remember?" _____, _____, _____ ***Add 50 for each word that the patient did not remember***	
		TOTAL



Source: Capuano AW, et al. PloS One. 2022

71/journal.pone.0265379.g001

Use of Electronic Health Record Data

External Validation of the eRADAR Risk Score for Detecting Undiagnosed Dementia in Two Real-World Healthcare Systems

R. Yates Coley, PhD[1,2], Julia J. Smith, MS[1], Leah Karliner, MD MAS[3,4], Abisola E. Idu, MS MPH[1], Sei J. Lee, MD MAS[5,6], Sharon Fuller, BA[1], Rosemary Lam, BA[4], Deborah E. Barnes, PhD MPH[5,7,8,9], and Sascha Dublin, MD PhD[1,10]

Source: J Gen Int Med 2022
DOI: 10.1007/s11606-022-07736-6

Limitations of Current Dementia Risk Prediction Models

- Currently, very few models (and tools developed) for primary care late-life risk assessment with validation (esp. in public domain)
- Model area under the curve metrics still need to get above 0.75
- Mixed reporting of model analytic validation properties makes it difficult to do “apples to apples” comparisons of models
- Need “gold standard” cohort dataset for model validation
- Need to conceptualize outcomes research clinical trials to test models in diverse primary care settings.
- Need to compare investment in clinical data-based dementia risk prediction models with biofluid-based (e.g. blood) markers which may make universal screening possible.

Regulatory

Pathway to Alzheimer biomarker development

	Primary and secondary aims	Adaptations from oncology to AD
Phase 1: preclinical exploratory studies	Primary aims: (1) identify leads for potentially useful biomarkers; (2) prioritise identified leads	No substantial change
Phase 2: clinical assay development for Alzheimer's disease pathology	Primary aims: (1) estimate the frequency of true-positive and false-positive results or ROC, and assess ability to distinguish individuals with and without Alzheimer's dementia Secondary aims: (1) optimise procedures for assays and their reproducibility within and between laboratories; (2) determine the relation between phase 1 biomarker measurements made in tissues and those made in phase 2 studies in non-invasively collected clinical specimens; (3) assess variables (eg, sex and age) associated with biomarker status or concentration in controls (eg, healthy individuals);* (4) assess variables, especially disease characteristics, associated with biomarker status or level	Established disease in cancer is believed to correspond to overt dementia in AD; the preferable standard of reference in AD is pathology, although AD dementia is acceptable if there is reason to believe that most individuals being assessed have AD pathology (eg, NINCDS-ADRDA probable AD dementia)[3]
Phase 3: retrospective studies using longitudinal data available in repositories	Primary aims: (1) assess the capacity of the biomarker to detect early disease†; (2) define criteria for a positive screening test in preparation for phase 4 Secondary aims: (1) explore the effects of covariates on the discriminatory abilities of the biomarker before clinical diagnosis; (2) compare biomarkers to select the most promising; (3) develop algorithms for likelihood of positive results based on combinations of biomarkers; (4) determine required interval between biomarker testing if repeated testing is of interest in phase 4	In contrast to phase 3 studies in oncology, which are retrospective, nested, case-control studies, AD requires prospective longitudinal repository studies, in which the biomarker is measured at baseline in individuals with MCI and AD status ascertained at follow-up, preferably by AD pathology, but also by incident AD dementia or cognitive progression; as in cancer, AD biomarker results would not be used for diagnosis or treatment
Phase 4: prospective diagnostic accuracy studies	Primary aims: (1) determine the accuracy of core biomarkers in the clinical setting by calculating frequencies of positive and false-positive detection Secondary aims: (1) describe the characteristics of disease detected by the biomarker test, particularly with regard to potential benefits incurred by early detection; (2) assess the feasibility of implementing case-finding programmes and likely adherence of individuals with positive test results to work-up schedules and treatment recommendations; (3) make preliminary assessments of the effects of biomarker testing on disease-associated costs and mortality; (4) monitor disease diagnosed clinically but not detected by biomarker testing	The major difference with phase 4 in oncology is that studies will not involve clinically asymptomatic individuals; AD studies would include symptomatic but non-demented (MCI) patients and, therefore, would need to be done in highly specialised clinics that have guidelines for the collection, measurement, and interpretation of biomarkers; as in oncology, AD biomarker results would be used for diagnosis and treatment
Phase 5: disease burden reduction studies	Primary aims: (1) estimate reductions in mortality, morbidity, and disability associated with biomarker testing Secondary aims: (1) obtain information about costs of biomarker testing and treatment and per life saved or quality-adjusted life year gained; (2) assess adherence to testing and work-up in various settings; (3) compare different biomarker testing protocols, approaches to treating test-positive individuals in regards to effects on mortality, costs, or both	No adaptation needed, although the achievement of phase 5 outcomes is unlikely until treatments able to delay progression are available

AD=Alzheimer's disease. ROC=receiver operating curve. NINCDS-ADRDA=National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association. MCI=mild cognitive impairment. *Thresholds might need to be defined separately for different target subpopulations. †MCI or prodromal AD.

Table 3: **Five-phase framework to develop biomarkers for early diagnosis of Alzheimer's disease**

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Conclusion

Conclusion

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Questions