

Understanding The Barriers To Recruiting Patients With Cognitive Impairment For A Pragmatic Blood-based Biomarker Study

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Introduction

- The implementation of blood-based biomarkers (BBM) in the diagnostic pathway for Alzheimer’s Disease and Related Dementias (ADRD) is critical for early and accurate detection of Alzheimer’s Disease in primary care.
- Cleveland Clinic is engaging in a pragmatic randomized controlled trial related to the implementation of BBMs in the diagnostic pathway.
- At this time, BBMs are recommended only for patients with suspected or documented cognitive impairment (CI).
- To recruit these patients for our prospective randomized control study, a chart review was conducted to identify suspected CI.
- In this analysis of screening data, we identified barriers to recruiting appropriate patients for the BBM study.

Methods

Candidates

- 657 participants were screened for eligibility using a chart review to identify documentation of cognitive impairment or cognitive concerns from September- December 2025.

Inclusion Criteria
• Aged 55 or older • Suspected cognitive impairment indicated in the medical record by the Mini-Cog screening test, history, or other cognitive screen
• Scheduled for geriatric medicine consult • Hearing and vision sufficient for cognitive testing
Exclusion Criteria
• Prior diagnosis of Alzheimer’s disease or related dementias whether coded or in the medical record • Prior completion of a Brain Health visit including BBM, CSF, or PET diagnostics.

Table 1: Inclusion & Exclusion Criteria

Methods

Screening Methods

- Pre-screening lists were extracted from the electronic medical record using age and ICD-10 diagnosis codes related to cognition as criteria.
- Research coordinators performed chart reviews and identified suspected cognitive impairment/cognitive concerns using recent notes, reasons for visits, cognitive assessments, and symptom codes.
- Research coordinators contacted the candidate patient to obtain consent prior to the scheduled standard of care geriatrics visit.

Results

Sample Characteristics	
Age	
Mean (SD)	77.3 (8.0)
Age range	56-101
Sex (%)	
Female	427 (65)
Male	230 (35)
Race (%)	
White	469 (71.4)
Black	132 (20.1)
Unknown	29 (4.4)
Multiracial/Multicultural	11 (1.7)
Asian	10 (1.5)
Other	6 (0.9)
Ethnicity (%)	
Hispanic	18 (2.7)
Not Hispanic	616 (93.8)
Unknown	23 (3.5)

Table 2: Sample Characteristics

Barriers to Enrollment	Candidates
Ineligible - No documented cognitive impairment	220 (33.5%)
Eligible - No Response	185 (28.2%)
Declined	97 (14.8%)
Other	90 (13.7%)
Enrolled	45 (6.8%)
Ineligible - Prior ADRD Diagnosis	20 (3%)
Total	657

Table 3: Barriers to Enrolling Primary Care Patients for Blood-Based Biomarker Study

Conclusions

- Trials validating novel BBMs in less-differentiated primary care patient cohorts to detect early ADRD are essential.
- Currently, BBMs are only indicated for patients with symptomatic or suspected cognitive impairment.
- Our data indicate that enrolling these patients can be challenging because of inadequate documentation of prior cognitive problems or missing diagnosis codes related to of cognitive concerns, which hampers identification by research teams for recruitment for the study.
- The high non-response rate highlights the need for alternative methods to reach these patients for trials.

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Scan to learn more about the Alzheimer’s Disease Accurate Diagnosis Project.

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