

# Estimates of current capacity for diagnosing and implementation of new treatment Alzheimer's disease in Slovenia

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## Abstract

**Background:** The limited efficacy of current symptomatic treatments for Alzheimer's disease (AD) leads many patients to forgo medical help. However, new disease-modifying treatments (DMTs), such as donanemab and lecanemab, show potential to change this.

**Objective:** To model the impact of these treatments on Slovenia's healthcare system by analyzing patient flow under both current and enhanced capacities, assuming DMT availability.

**Methods:** The study estimates 76,923 potential DMT candidates aged 65 years and older with mild cognitive impairment or mild AD. Using data from Slovenia's three specialized centers for cognitive disorders, a Markov model simulated five five-year scenarios: baseline, real-life, real-life with capacity enhancement, biomarker integration, and biomarker integration with capacity enhancement.

**Results:** Waiting times for specialist evaluation would increase from the current 3–12 months to 1.8 years. The primary bottleneck is lumbar puncture with cerebrospinal fluid (CSF) analysis, during which 64% of patients would become ineligible for DMT. The shortest waiting time to receive DMT occurs in the biomarker integration with capacity enhancement scenario, at 4 years, reducing ineligibility to 7%.

**Conclusions:** Current specialized outpatient facilities are limited, causing significant bottlenecks, especially in CSF analysis. Severe waiting times under current capacities mean many patients would progress to moderate or severe dementia or die before receiving treatment. Plasma biomarkers offer a promising triage approach to guide patients toward lumbar puncture or other confirmatory diagnostics, potentially easing this critical bottleneck. Substantial infrastructure and workforce improvements are essential to ensure timely and equitable access to DMTs in Slovenia.

## Keywords

Alzheimer's disease, dementia, disease-modifying treatment, healthcare organization, mild cognitive impairment

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## Introduction

Dementia poses a significant global health challenge, with over 46 million individuals worldwide affected with this condition as of 2015.<sup>1</sup> Despite the prevalence, the limited efficacy of existing symptomatic treatments has led to a considerable number of patients not seeking medical attention.

The advent of new disease-modifying treatments (DMTs) for Alzheimer's disease (AD) signals a potential paradigm shift. This change is anticipated to bring about a substantial transformation in the demands and expectations of individuals affected by dementia, consequently reshaping the approach taken by physicians. DMTs for AD are intravenous monoclonal antibodies that remove amyloid- $\beta$  plaques from the brain. Donanemab and lecanemab were approved by the US Food and Drug Administration and are closest to the widespread clinical implementations.<sup>2,3</sup> Lecanemab received a marketing authorization by the European Commission in April 2025<sup>4</sup> and donanemab in September 2025.<sup>5</sup> While these therapies offer new hope, their successful implementation depends not only on clinical efficacy but also on the capacity of healthcare systems to provide timely diagnosis and treatment.

Hlavka et al. highlighted that implementing DMTs for AD in European countries such as Germany, Sweden, the United Kingdom, France, Spain, and Italy face significant challenges, with waiting times for diagnostic evaluations ranging from months to several years. In Germany, the rate-limiting step is treatment, while in France, it is the specialist visit, underscoring the need for healthcare systems to address infrastructure and capacity gaps.<sup>6</sup>

Slovenia, a country of just over two million inhabitants, operates a highly centralized healthcare system. Diagnostic and treatment capacities for cognitive disorders are concentrated in two university medical centers—Ljubljana and Maribor—and the University Psychiatric Clinic Ljubljana. While centralization allows for standardized clinical protocols and efficient use of limited specialist resources, it also creates critical bottlenecks in access to care. Until recently, amyloid positron emission tomography (PET) imaging has been available exclusively for research purposes and not for routine clinical diagnostics; while its clinical introduction is anticipated in 2026, availability is expected to remain severely limited, further constraining diagnostic pathways. Limited specialist capacity and infrastructure for procedures such as cerebrospinal fluid (CSF) analysis may impede timely diagnosis and initiation of DMTs, highlighting the need for strategic planning and capacity expansion to ensure equitable and timely access to treatment.

This study aims to provide a model of patient flow in the current state of health system capacities in Slovenia, envisioning a scenario where DMTs are readily available. We explore the potential impact if patient interview and baseline cognitive testing were conducted at the primary level,

resulting in the referral of all potential candidates for DMT to specialists. Furthermore, we contemplate various scenarios involving an increase in diagnostic capacities and the feasibility of reliable screening utilizing blood-based biomarkers (BBBs).

## Methods

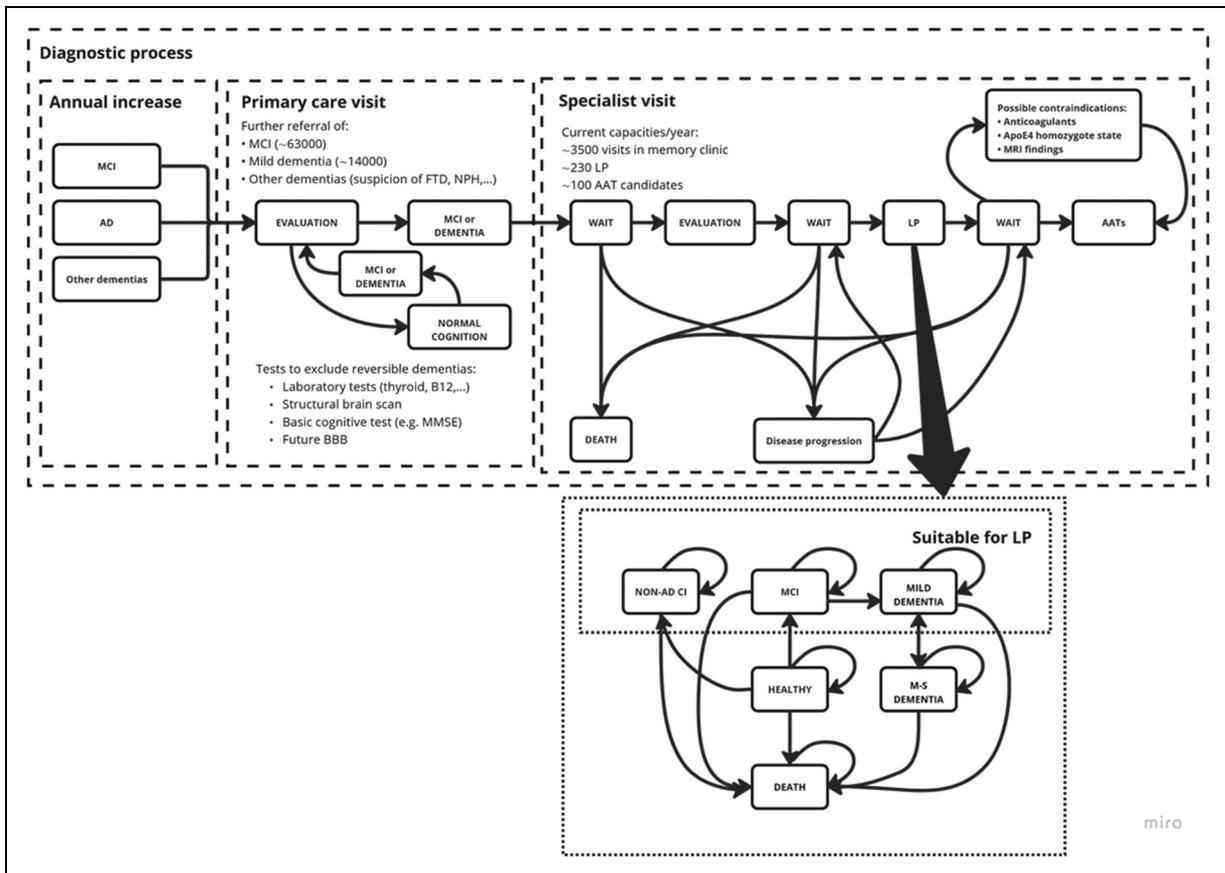
As potential candidates for treatment with DMTs for AD will comprise the population with mild cognitive impairment (MCI) or individuals at mild dementia stage aged 65 years or older,<sup>7</sup> we sought to estimate the number of potential candidates in Slovenia. Although a pTau217/ $\beta$ -amyloid plasma ratio test has recently received FDA clearance in the United States,<sup>8</sup> BBBs for AD are not yet authorized for clinical use in Europe. Hence, all patients at MCI or mild dementia stage should be referred to a specialist level for AD biomarker confirmation. Given the limited amyloid-PET imaging availability in Slovenia, lumbar puncture (LP) with CSF analyses is the only other option.

In Slovenia in 2022, the population aged 65 and above numbered 451,915 individuals, with 43.9% of them aged 75 or older.<sup>9</sup> Studies across Europe indicate that the prevalence of MCI varies; for instance, it ranges from 15.4% in individuals over 75 in Germany<sup>10</sup> to 6.6%-21.4% in those over 60 in Sweden.<sup>11</sup> Based on an estimated MCI prevalence of 14% among those aged 65 years and above in Slovenia, approximately 63,000 individuals ( $n = 63,268$ ) are affected. Of these, about 55% are attributable to AD,<sup>12</sup> corresponding to roughly 35,000 cases ( $n = 34,797$ ). Additionally, about 40% of all dementia cases are classified as mild.<sup>12</sup> Given 34,000 diagnosed cases ( $n = 34,137$ ) in Slovenia in 2018,<sup>13</sup> this equates to approximately 13,700 individuals ( $n = 13,655$ ) with mild dementia. Since about 70% of all dementias are due to AD,<sup>12</sup> this represents roughly 9600 mild AD patients ( $n = 9559$ ). Consequently, there are approximately 77,000 potential candidates ( $n = 76,923$ ), of whom around 44,000 ( $n = 44,356$ ) are expected to have underlying AD pathology.

Specialized outpatient facilities catering to patients with cognitive impairment are currently limited to the two University Medical Centers in Ljubljana and Maribor, as well as the University Psychiatric Clinic in Ljubljana. Information regarding the capacities of these centers for patient visits and procedures such as lumbar punctures were acquired through internal communication with the heads of memory clinics (Figure 1).

## Basic model design

The Markov model, featuring six transition states (healthy, MCI, mild AD, moderate to severe AD, non-AD cognitive impairment, and death), was employed to analyze a cohort comprising 76,923 potential candidates over a 5-year



**Figure 1.** Diagram of patient flow through the medical system and current capacities. Generated using Miro online whiteboarding software.

period. Our simulation aimed to replicate the natural progression of the disease, incorporating yearly transitions between states as outlined by Davis et al.,<sup>14</sup> with transition probabilities also factoring in age dependency (Supplemental Tables 1 and 2). The age distribution within the Slovenian population<sup>9</sup> was taken into account and the target cohort was categorized into two age subgroups: individuals aged 65–74 years and those aged 75 years and above.

To evaluate the potential impact of introducing DMTs for AD in Slovenia, five scenarios were developed to reflect different levels of healthcare system readiness, diagnostic strategies, and patient behavior. All scenarios were simulated using identical model parameters and capacity assumptions for a five-year horizon.

1. **Baseline Scenario:** this scenario reflects the current diagnostic and treatment capacities in Slovenia, assuming that all potential candidates with MCI or mild AD aged 65 years and above are referred from primary care to specialist evaluation within five years. Diagnostic confirmation of AD pathology relies solely on CSF biomarker analysis following LP. This scenario represents a theoretical upper

limit of referral demand under current conditions, illustrating existing systemic bottlenecks.

2. **Real-life scenario:** This scenario follows the assumptions used by Hlavka et al.,<sup>6</sup> reflecting realistic patient and physician behavior. It assumes that 80% of individuals with cognitive complaints present to their family physician. Of these, 50% wish to be referred to a cognitive specialist, and 90% of those referred proceed with LP for CSF biomarker confirmation. This model captures real-world dynamics and patient acceptance patterns, estimating system load after the introduction of DMTs such as lecanemab.
3. **Real-life with capacity enhancement scenario:** This scenario builds on the Real-life scenario but assumes a 50% increase in the annual capacity for both specialist visits and LP procedures. It models the impact of moderate system reinforcement—such as additional staff, extended clinic hours—on waiting times and patient eligibility for DMT. The scenario approximates short- to medium-term policy interventions aimed at improving diagnostic throughput without major restructuring.

4. **Biomarker integration scenario:** This forward-looking scenario assumes integration of validated BBBs into the diagnostic pathway, consistent with Schindler et al.<sup>15</sup> It is also based on real-life behavioral and referral patterns described in Scenario 2. In this model, BBBs are used at specialist triage level to determine likelihood of AD pathology. Only approximately 20% of cases with intermediate or inconclusive BBM results are referred for confirmatory CSF analysis. This approach markedly reduces the number of LPs required, alleviating the main diagnostic bottleneck while maintaining diagnostic accuracy and treatment eligibility.
5. **Biomarker integration and capacity enhancement scenario** combines plasma biomarker integration with expanded diagnostic and specialist capacities, as described in Scenarios 3 and 4. It represents an optimized system in which both triage efficiency and diagnostic throughput are improved. By simultaneously reducing the number of required LP procedures and increasing service capacity, this model is expected to yield the shortest waiting times and the highest proportion of patients eligible for timely DMT initiation.

The modeling was performed using MS Excel<sup>®</sup>. To visualize patient transitions over time, Figure 3 was generated using SankeyMATIC, an online tool that allows for custom flow visualization ([sankeymatic.com](http://sankeymatic.com)).

AATs: anti-amyloid therapies; AD: Alzheimer's disease; BBB: blood-based biomarkers; CI: cognitive impairment; FTD: frontotemporal dementia; LP: lumbar puncture; MCI: mild cognitive impairment; MMSE: Mini-Mental State Examination; M-S: moderate-severe; NPH: normal pressure hydrocephalus

## Results

If we assume that patients eventually diagnosed with MCI and mild AD would be initially assessed at the primary care level and only 20% of them would be referred to one of the three specialized centers in the first year, the waiting times become dependent on various scenarios.

1. Given the current capacities for initial visits at memory clinics, the waiting period for those referred in the first year would extend from the current range of 3–12 months (shortest at the University Psychiatric Clinic Ljubljana and the longest at the University Medical Centre Ljubljana) to an alarming 5 years. During the waiting period for specialist evaluation, out of the 15,385 patients referred in the initial year, approximately 2149 (14%) patients would either progress to a moderate or severe dementia state or face mortality, rendering them

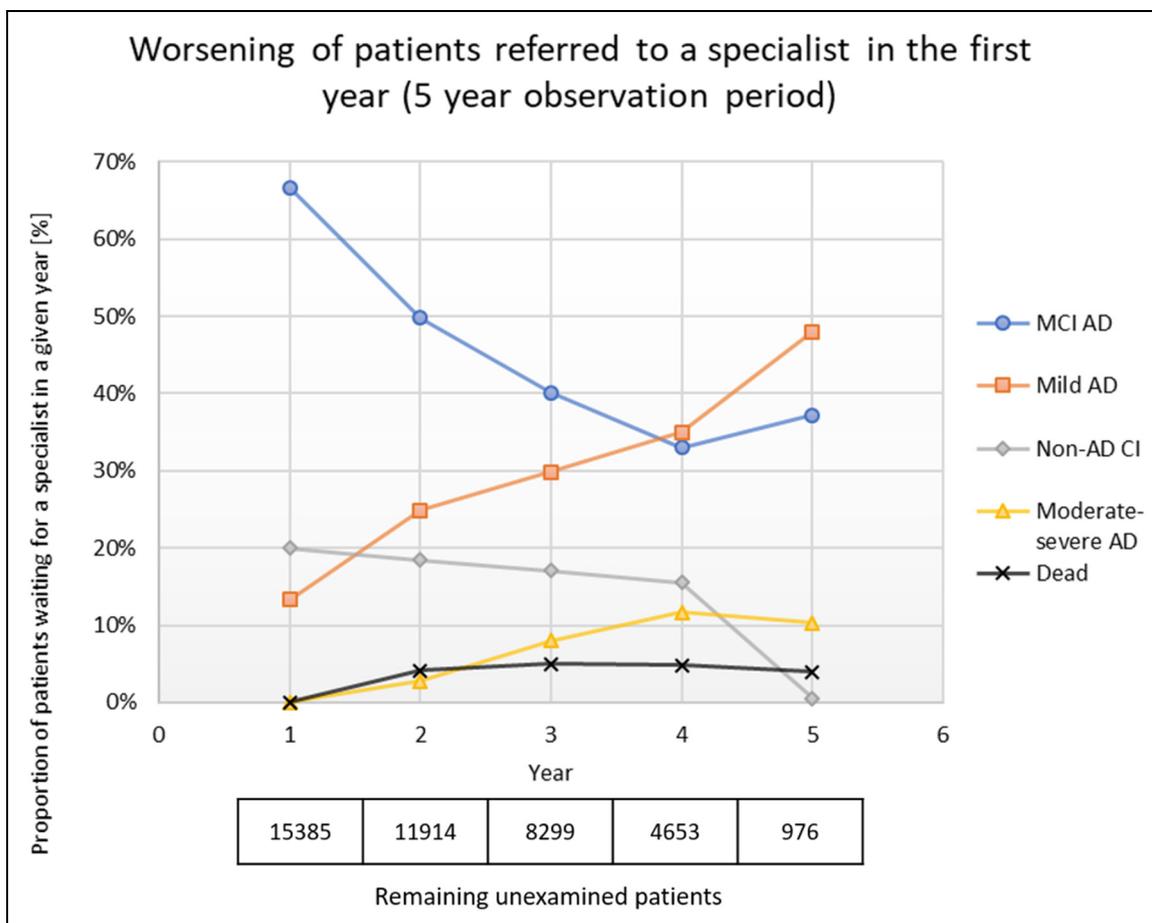
ineligible for DMT treatment (Table 1, Figure 2). However, a major bottleneck to receiving the DMT would be LP with CSF analysis, where the waiting times would increase to 25 years, effectively preventing timely treatment access under current diagnostic capacities. (Table 1).

2. In the Real-life scenario, waiting times for a specialist visit would be reduced to an approximately 1.8 years. Nevertheless, the waiting time for LP would still reach an unacceptably long 18 years. During this period, 57% (n = 3497) of patients would die and an additional 7% (n = 441) would experience disease progression to a moderate or severe dementia stage, making them ineligible for treatment (Table 1).
3. In the Real-life with capacity enhancement scenario, the waiting period for LP would decrease from 18 to 12 years, while the time to initial specialist assessment would shorten proportionally. Although this represents a moderate improvement, the diagnostic delay would still result in a substantial proportion of patients (48%) becoming ineligible for treatment before diagnostic completion.
4. In biomarker integration scenario, the waiting for LP would decrease to approximately 5 years. During this period, an estimated 278 patients (5%) would die and 194 (3%) would progress beyond the mild disease stage, reducing but not eliminating treatment ineligibility due to diagnostic delays.
5. Biomarker integration and capacity enhancement scenario combines plasma biomarker integration with expanded diagnostic and specialist capacities. It represents the optimal model, minimizing waiting times across the entire diagnostic pathway and ensuring the highest proportion of eligible patients reach timely DMT initiation.

These results represent data for patients referred during the first year of the model. Because waiting times for specialist consultations already exceed one year—and are even longer for LP—patients would progressively accumulate in the diagnostic pipeline. Consequently, overall waiting times would continue to increase over subsequent years, while an increasing proportion of patients would either die or experience cognitive decline beyond the treatment-eligible stage. Accumulation of potential candidates and changes of their (cognitive) states during the 5-year period are displayed in Figure 3.

## Discussion

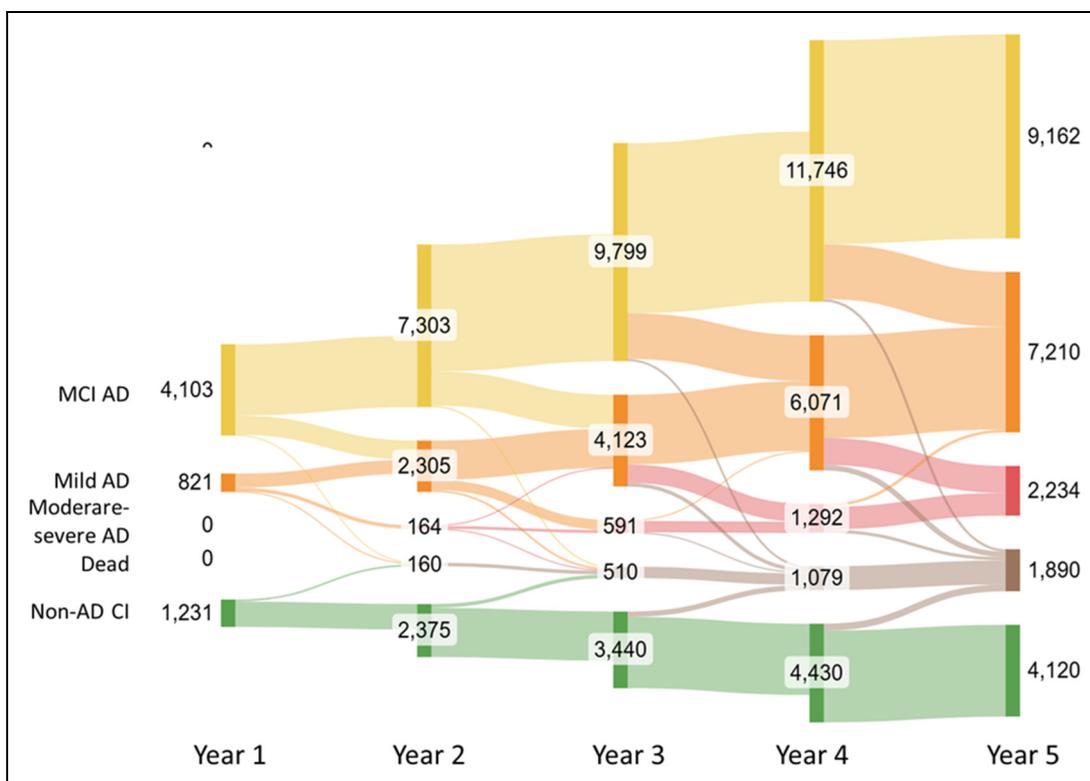
In the present study, we focused on modeling the diagnostic process in the context of the anticipated introduction of DMTs for AD in Slovenia. The principal findings of this study are: (1) under current real-life conditions,



**Figure 2.** Worsening of the patients referred to a specialist in the first year according to Baseline scenario (5-year observation period). AD: Alzheimer's disease; CI: cognitive impairment; MCI: mild cognitive impairment.

CSF-based confirmation represents the major bottleneck; waiting times for specialist visits and LP reach 1.8 and 18 years, respectively, leading to approximately 64% of patients becoming ineligible for treatment due to disease progression before diagnostic confirmation. Although not all diagnostically eligible patients will ultimately initiate DMTs, variation in treatment uptake is unlikely to substantially affect system-level bottlenecks as long as diagnostic confirmation remains rate-limiting. (2) Increasing specialist and LP capacities by 50% reduces waiting times to about 1.2 years for visits and 12 years for LP, lowering ineligibility to around 56%, but delays remain substantial, and (3) integration of BBBs, in combination with capacity enhancement, provides the most sustainable pathway, decreasing LP waiting times to about 4 years and treatment ineligibility to approximately 7%, thereby streamlining the diagnostic process and improving timely access to therapy. These findings are particularly concerning in light of quantitative evidence demonstrating a limited therapeutic time window for DMT in early AD, during which delays in treatment initiation may result in patients progressing beyond eligibility and reduced potential benefit.<sup>16</sup>

The Slovenian healthcare system operates on the principle of solidarity, with mandatory health insurance provided by a single public insurer and a gatekeeping mechanism requiring patients to obtain referrals from their primary physicians to access specialized treatments.<sup>17</sup> Regardless of critical understaffing issues, the healthcare system is perceived as relatively good.<sup>18</sup> However, primary care practices face significant challenges: physicians have an average of only 6.9 min per patient encounter (ranging from 1–16 min), with a large portion of visits consumed by administrative tasks.<sup>19</sup> In 2011, model practices were introduced to redistribute workload by empowering diploma graduate nurses to conduct comprehensive preventive screenings, manage chronic illnesses, and establish patient registers.<sup>20</sup> The model practices are designed to invite individuals aged 30 and above for screening of chronic conditions every five years, with annual follow-ups for identified chronic illnesses.<sup>20</sup> While these model practices cover conditions such as hypertension, diabetes, depression, and coronary disease, dementia and cognitive impairment screening or monitoring remain absent from their protocols.



**Figure 3.** Patient flow through the healthcare system over five years according to Scenario 5 (Biomarker Integration with Capacity Enhancement). This figure shows both the state transitions within the cohort and the effect of primary care referral limitations on patient flow through the diagnostic pathway. Since we assumed that primary care can only refer 20% of the initial cohort for further diagnostics each year, the number of patients progressing through the system gradually increases over time. Created using SankeyMATIC (sankeymatic.com). AD: Alzheimer's disease; CI: cognitive impairment; MCI: mild cognitive impairment.

**Table 1.** Waiting times in different scenarios.

	Baseline scenario	Real life scenario	Real life with capacity enhancement scenario	Biomarker integration scenario	Biomarker integration with capacity enhancement
Number of patients/year	15,385	6154	6154	6154	6154
Specialist visit capacity/year	3471	3471	5207	3471	5207
LP capacity/year	230	230	345	230	345
<u>Specialist visit</u>					
Waiting times (year)	5	1.8	1.2	1.8	1.2
Progression of dementia, n (%)	1 095 (7%)	75 (1%)	27 (0.4%)	75 (1%)	27 (0.4%)
Death, n (%)	1 054 (7%)	111(2%)	39 (0.6%)	111 (2%)	39 (0.6%)
Ineligible candidates, n (%)	2 149 (14%)	186 (3%)	66 (1.1%)	186 (3%)	66 (1.1%)
<u>Lumbar puncture</u>					
Waiting times (year)	25	18	12	5	4
Progression of dementia, n (%)	553 (4%)	441 (7%)	463 (8%)	194 (3%)	101 (2%)
Death, n (%)	9 506 (61%)	3 497 (57%)	2 983 (48%)	279 (5%)	252 (4%)
Ineligible candidates, n (%)	10 059 (65%)	3 938 (64%)	3 446 (56%)	473 (8%)	353 (6%)

Currently, there are fewer than 3500 yearly specialist visits for cognitive issues (neurologist or psychiatrist), with less than 230 referrals for AD CSF analyses. With the potential introduction of DMTs, confirming AD

pathology via LP becomes crucial, necessitating an increase in these capacities. However, 3% of patients become ineligible for treatment during the first year of waiting for a specialist, and this rises to 64% while awaiting LP

confirmation. Even under the capacity enhancement scenario (Scenario 3), waiting times for biological confirmation of the disease via LP would remain unreasonably long—approximately 12 years—in the first year following DMT introduction. The healthcare system would be most sustainable under the final scenario, in which current capacities are enhanced by 50%, BBBs are implemented and only a subset of patients requires confirmatory CSF analysis for definitive disease pathology.

Therefore, only through a substantial increase in the capacity for specialist visits and LP procedures could memory clinics accommodate all potential treatment candidates. However, systemic improvements—such as increasing the number of primary care physicians, implementing standardized management protocols for cognitive disorders within model practices, and establishing a national cognitive disorders registry—are imperative. Importantly, recent evidence suggests that only 8–15% of individuals with MCI or mild AD will ultimately meet eligibility criteria for new DMTs,<sup>21</sup> underscoring the need for efficient pre-selection and triage. Additional limiting factors, including frailty, complex comorbidities, concurrent use of contraindicated medications, lack of a caregiver, or other DMT-related contraindications could be identified early at the primary care level to reduce unnecessary referrals. Furthermore, with the approval of DMTs for AD, demand and pressure on primary care physicians from individuals not suitable for treatment—such as those with subjective cognitive impairment or advanced dementia—are expected to increase. In this context, well-structured model practices could help streamline patient flow and partially alleviate the burden on primary physicians.

In our previous study, in years 2021–2022 we retrospectively identified 114 potential candidates.<sup>22</sup> Due to current limitations in LP capacity, the process could only yield approximately 100 DMT candidates annually. This could be manageable with significant changes in logistics, personnel, and infrastructure, especially if treatment were to be administered across more than one center. However, the introduction of, e.g., lecanemab treatment adds further complexity. While most patients currently undergo an MRI scan as part of the diagnostic process, lecanemab treatment necessitates a minimum of three additional scans.<sup>23</sup> This would significantly increase the demand for MRIs and raise concerns about additional potential bottlenecks in the system.

Emerging BBBs have the potential to transform the diagnostic pathway for AD by reducing reliance on invasive LP. Plasma p-tau217, in particular, demonstrates high diagnostic accuracy, effectively identifying individuals with amyloid-positive pathology,<sup>24</sup> while p-tau181 is promising for detecting AD in older adults.<sup>25</sup> Currently, the Lumipulse G pTau217/ $\beta$ -Amyloid 1–42 Plasma Ratio assay has received full FDA clearance for clinical use in the United States.<sup>8</sup> In addition, several assays—including Quanterix

Simoa p-tau181 and p-tau217 and Roche Elecsys p-tau217—have been granted FDA Breakthrough Device designation,<sup>26–28</sup> reflecting their potential for near-future integration into clinical practice. While further validation and regulatory clearance are needed for these assays, their use could allow a subset of patients to bypass LP, alleviating current diagnostic bottlenecks and improving access to disease-modifying therapies. Furthermore, this could shift the determination of AD pathology to a primary level, potentially serving as a gatekeeping mechanism. However, implementing this approach would require additional resources and capacities at the primary level, which is already facing critical understaffing challenges. At present, the use of amyloid PET imaging in Slovenia remains highly limited. Broader availability of this modality would enable monitoring of amyloid clearance and provide objective criteria for DMT discontinuation, thereby improving resource allocation and expanding treatment access to a larger number of eligible patients.

The introduction of specialized therapies poses a significant ethical dilemma, as many patients with AD may not have sufficient time to receive treatment before death.<sup>29</sup> The annual conversion rate from AD-MCI to AD ranges from 5.4% to 16.5%, with community-based observations typically showing lower rates than clinic-based ones.<sup>30</sup> Not all patients with MCI progress to dementia within a 5-year timeframe, highlighting the necessity for prognostication to identify those with incipient dementia for more precise and timely candidate selection. Our findings highlight the urgent need to adapt organization and capacity across the Slovenian healthcare system to ensure timely, efficient care for a rapidly aging population. This aligns with Slovenia's Strategy for the Management of Dementia by 2030, emphasizing improved diagnostic access and professional competencies.<sup>31</sup> Implementing new anti-amyloid treatments will require education of general practitioners, adaptation of laboratory workflows, integration of MRI examinations, strengthening interdisciplinary teams, and reorganization of day hospital facilities. While broad access to specialist care will likely remain limited due to monitoring requirements and other constraints, the introduction of DMTs represents a pivotal step. It may also mark the beginning of a future in which treatments are more effective, easier to administer, and simpler to monitor, offering hope for wider and more practical therapeutic options.

### Limitations

In our model, we accounted for state changes during the waiting periods for memory clinic visits and lumbar punctures, following the natural progression of AD as described by Davis et al.<sup>14</sup> However, we did not factor in the aging of the population, which could cause individuals in the 65–75 age group to move into the 75+ group, where disease

progression and mortality are higher. This shift could result in more patients progressing beyond the point of eligibility for treatment. The assumptions regarding patient flow through the diagnostic pathway under the status quo were based on expert consultations and current clinical practices in Slovenia. While precise data are unavailable, these assumptions reflect the best-available information from memory clinic specialists and general practitioners, but we acknowledge that more detailed data and formal documentation would improve the transparency of these assumptions. Additionally, we assumed constant healthcare capacities throughout the simulation, not considering potential changes in staffing, resources, or infrastructure that could affect waiting times and treatment availability. Furthermore, while we modeled scenarios with enhanced capacities, the impact of these changes is based on hypothetical scenarios and may not fully reflect real-world challenges in adapting to the introduction of DMTs. Finally, while our model captures general disease progression, it does not account for individual differences in cognitive decline, such as the impact of comorbidities or genetic factors, which could influence eligibility for DMTs. Although our model is based on the Slovenian healthcare context, similar structural and capacity constraints are present in other Central and Eastern European countries. Therefore, this analysis may also serve as a projection framework for healthcare system adaptation in comparable settings.

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### Consent to participate

Not applicable

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### Author contribution(s)

**Eva Zupanic:** Conceptualization; Data curation; Formal analysis; Investigation; Visualization; Writing – original draft.

**Gašper Stegnar:** Data curation; Investigation; Methodology; Visualization; Writing – review & editing.

**Martin Rakuša:** Data curation; Investigation; Supervision; Writing – review & editing.

**Polona Rus Prelog:** Data curation; Investigation; Supervision; Writing – review & editing.

**Igor Švab:** Data curation; Investigation; Supervision; Writing – review & editing.

**Milica Gregoric Kramberger:** Conceptualization; Data curation; Investigation; Methodology; Supervision; Writing – review & editing.

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### Data availability statement

Datasets were generated or analyzed during the current study.

### Supplemental material

Supplemental material for this article is available online.

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