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# The Journal of Prevention of Alzheimer's Disease

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## Low number of patients qualifying for amyloid targeting immunotherapy

In a recent paper in this journal, Rosenberg et al. reported first data on patient selection for treatment with lecanemab and donanemab from one of the most prominent European memory clinics at the Karolinska Institute in Stockholm [1]. The same group reported earlier an estimate of the number of patients potentially eligible for treatment in their memory clinic [2].

In the present publication, 410 consecutive patients are described. The mean age of the sample was 59 years, which is younger than the population of the clinical trials of both compounds. This is because the Karolinska memory clinic serves as a national center for patients under the age of 70 years. Of the 410 subjects only 69 (17%) had evidence for amyloid pathology in the cerebrospinal fluid (CSF) according to the center specific biomarker cut-off. Of note, the authors applied the criterion of amyloid positivity only, without the requirement for tau positivity, which agrees with the European Union (EU) label. The low number of amyloid positive cases may result from the fact that 52% of the sample had the diagnosis of subjective cognitive impairment (SCI), which is not associated with Alzheimer pathology in most cases.

The authors applied both, the EU label inclusion and exclusion criteria as well as those from the United States (US) appropriate use recommendation (AUR) for the respective antibodies [3,4]. Without considering the Apolipoprotein E-genotype (APOE), only 26 patients met the inclusion criteria for lecanemab and 25 for donanemab with a partial overlap of 20 patients. Of these, 12 would be excluded from treatment due to an APOE4/4 carrier status. After applying all criteria, 14 remained eligible for lecanemab (3% of the full cohort, 5% of all MCI and 9% of all dementia cases) and 13 for donanemab (3% of the full cohort, 4% of all MCI and 9% of all dementia cases).

In a second analysis, the authors applied a more liberal data-driven CSF A $\beta$  cut-off, which resulted in a slightly larger group of eligible patients.

These data align with the previously estimated numbers by the same group [1]. In their current paper, the authors also cite several other reports, which all have shown that the proportion of eligible patients for treatment with either lecanemab or donanemab is only a small fraction of all patients attending memory clinics. The number observed in the present study seem particularly low, which is most likely due to a high proportion of patients with SCI and the strict application of the AUR. This paper also shows that different ways of defining the cut-off of A $\beta$  in the CSF leads to different groups of patients, who qualify for the treatment. Given the major impact, this treatment can have on patients and families in terms of clinical benefit, but also in terms of risk and costs, the amyloid-positivity threshold must be well defined in each treatment providing center.

There are intense discussions in many countries on the healthcare

cost related to these treatments with the fear of overwhelming expenses, which has facilitated several national decisions against reimbursement. This report and others show that the actual number of patients qualifying for these medications is much lower than generally expected, and only comprises a very small fraction of all individuals with early AD. In addition, these numbers do not consider those patients, who qualify for treatment, but decide against it for various reasons. Overall, there is no evidence at present that the number of treated AD patients will reach a level with threatening impact on national healthcare budgets.

These data also show that the diagnostic effort is high given the high number of workups needed to distinguish those, who qualify for treatment from those, who do not. Since the number of referrals to memory clinics is substantially increasing in those places, where new therapies are provided, memory centers need to adopt to higher patient numbers by adjusting processes and optimizing referral pathways with the aim of providing a diagnosis that leads to a decision for or against a disease modifying treatment in a reasonable timeframe.

In conclusion, the report by Rosenberg et al. demonstrates that the concern of overwhelming numbers of patients causing major impact on national health care resources is not justified at present and that investments in diagnostic capacities with optimized patient pathways and workflows are urgently needed.

### Declaration of the use of generative AI and AI-assisted technologies in scientific writing and in figures, images and artwork

No AI or AI-assisted technologies were used for the writing of the manuscript.

### CRediT authorship contribution statement

**Frank Jessen:** Writing – original draft.

### Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Frank Jessen reports no competing interest regarding the manuscript. Frank Jessen is the Chairman of the European Alzheimer's Disease Consortium (EADC), the association of European academic memory clinics.

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