Project Alzheimer's Value Europe

PAVE

How Alzheimer's Disease Registries Can Facilitate Holistic Value Assessments

Lydia Lanman, Senior Global Access Policy Leader, F. Hoffmann-La Roche | Antonella Santuccione Chadha, Head of Stakeholder Engagement, Biogen International GmbH
Paola Barbarino, Chief Executive Officer, Alzheimer's Disease International

Project Alzheimer's Value Europe (PAVE) is a collaborative, multi-stakeholder forum focused on the value assessment of, and funding for, emerging therapeutic and diagnostic innovations in Alzheimer's disease in Europe.

Background

- Alzheimer's disease (AD) has been called the greatest health challenge of the 21st century—the disease is notoriously difficult to diagnose, gives rise to significant costs for individuals, families, communities, health systems, and has frustrated researchers looking for a disease modifying therapy (DMT).
- Adding urgency to an already critical situation, the incidence of AD is projected to quadruple by 2050 as populations age.
- Value assessment models that rely primarily on clinical trial data often cannot accurately quantify the full benefits and safety profile of AD DMTs.
- Future DMTs are likely optimally initiated when individuals are asymptomatic or exhibit mild cognitive impairment (MCI). Thus, registries can be used to inform epidemiological and lifestyle risk factors to enrich trials and patient selection.
- More robust real-world data that follow patients over the full course of disease would ensure proper patient selection, identification of appropriate therapeutic timing and duration, and minimise social and health system costs. Enrichment strategies could include the expanded use of biomarkers and neuroimaging.
- Fortunately, AD registries have already collected much of the data needed to better assess the value of these emerging therapies. In Europe, there are at least fifteen AD-specific registries. Nevertheless, experts and decision-makers recognize the importance of developing new strategies to realize the full potential of this registry data.
- Though important strides have been taken for delineating best practices for disease registries generally, optimizing the use of AD-specific registries remains an urgent next step for European stakeholders seeking to assess the value of and support access to advanced diagnostic tools and new Alzheimer's disease modifying therapies.

Methodology

- We conducted structured interviews with experts in academia, private industry, and the non-profit sector, investigating the following themes:
  - How can registry data be used to create drug value assessments that discern the full health and societal benefits of emerging therapies and treatments?
  - How can this information be leveraged to secure payer support that will result in patient access?
  - What are the current barriers to using Alzheimer's disease registry data?
  - How do you envision the use of digital biomarkers in registries?

Conclusions

- Registries are not currently maximized to support value assessment decisions. Registries could play an important role in facilitated holistic value assessments by:
  - Gathering more metrics to further understand and develop DMTs for AD such as blood based and imaging biomarkers;
  - Integrating digital biomarkers as these can improve the accuracy of symptom measurement as well as the amount of data gathered over the life course of patients;
  - Fully realizing the digitalization of the healthcare space as it would benefit the integration of new parameters;
  - Encouraging drug funds and managed access agreements to facilitate the collection and understanding of long term, real-world evidence;
  - Strengthening collaboration with technical legal structures that protect data privacy and incentivize data sharing by citizens;
  - Including low-to middle-income countries in the conversation as they need additional engagement and resources to build, maintain, and utilize registries; and
  - Engaging with payers with clear objectives of registries to ensure payers can see the economic and political benefits as there is considerable expertise, time, collaboration, and funding required to complete such registries.
- Our aim at PAVE is to use these foundational interviews to push forth advocacy efforts to secure payer support that will result in patient access.

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