

# Models Of Patient Engagement for Alzheimer's Disease

## Moving towards earlier diagnosis of Alzheimer's disease

### RECOMMENDATIONS FOR POLICY MAKERS AND REGULATORS



**Tackling dementia and Alzheimer's disease (AD) is an imperative that calls for robust policy action in the context of societal and economic challenges faced by the EU** (ageing of the population, increase in the number of persons likely to be impacted by AD and the consequent increase in healthcare and social costs putting in danger the sustainability of the healthcare services).

Evidence shows that the disease pathological process starts many years before clinical symptoms appear. This calls for the importance of identifying a disease-modifying therapy targeted at early AD (mild cognitive impairment (MCI) due to AD and mild AD dementia). Research has also brought evidence about risk factors and prevention strategies that could potentially delay the onset of the disease.

Some studies have evidenced the economic and social value of early detection of AD. However, an important proportion of people with mild dementia due to AD symptoms in need of care and treatment still miss a timely diagnosis.

The early detection strategies tested and evaluated by MOPEAD have shown that it is possible to identify AD at-risk cohorts. **Based on MOPEAD's and research learnings, policy makers and governments should start implementing risk-modifying strategies on a broad scale and be ready if disease-modifying therapies reach the market.**

MOPEAD has been innovative in the sense that it has tested patient engagement models that have until now received little attention. Cost-effective early detection measures have been identified that can help shift the paradigm to earlier diagnosis of AD, tackle societal challenges and remove barriers to innovation. The models tested were also instrumental in raising awareness of AD, memory complaints and cognitive decline risks in the general population.

Dementia and AD have been recognised as a public health priority at national, European and international levels. The international community's work towards the 2025 dementia goals is articulated around four key areas: finding a disease-modifying therapy, living well with dementia, better care, and reducing the impact of dementia. Despite many efforts having been made, research funding still needs to be significantly increased to meet these four goals.

## Overall policy recommendations

The overarching policy recommendation is to improve the early diagnosis of people with MCI or early AD. Not only will this improve the quality of life of people with AD and their carers, it will also prepare an environment that will readily benefit from modifying therapies for early stage AD if they reach the market. This calls for a concerted approach involving civil society, patients, health professionals, industries, policy makers and governments, regulatory bodies.

**Raising awareness** about the disease, its symptoms, diagnosis, treatment, risk factors and prevention is the cornerstone to better care and quality of life for patients and carers and a powerful means to reduce the stigma associated with the disease. Without thorough knowledge and understanding about AD among society, governments and policy makers, scientists, health care professionals, there is no impetus to take action.

**Developing early diagnosis of AD** : governments need to adapt their health systems to facilitate the early identification of people with early AD, before the symptoms are too advanced. This will help respond to the urgency to lessen the toll the disease currently has on society and citizens. It will also help prepare the environment to be ready if a disease modifying therapy for early AD eventually reaches the market. Early diagnosis also benefits society, providing access to available treatment options and support for patients and families.

**Engaging patients to participate in clinical trials** : the misconception that dementia is a normal part of aging is a barrier to individuals getting a diagnosis, getting the health and care support they are entitled to and living in communities that support them. Involving patients with dementia, carers and professionals in national, European and global policy work as experts can contribute to eliminate stigma around the disease and create strategies tailored to their needs.

**Ensure rapid access to new therapies** : finding effective ways to match patients' need to get access to therapies as soon as they have been approved and national regulators' increased pressure on their healthcare budgets require enlightened discussions. Patients are experts with their disease and can bring valuable insight into therapies development and health technology assessment (HTA). They need to be considered as full partners in decisions made about their health.

**Health literacy** : empowering citizens to take care of their brain health includes being aware about risk factors and disease prevention. The growing evidence showing great progress in understanding ways in which individuals may be able to reduce their risk of dementia must be fully grasped.

Therefore, the following recommendations should be embraced by national and European policy makers, the international community and regulators. They are geared towards MOPEAD's goal to shift the paradigm to early diagnosis of AD, engaging patients and carers at early stages of the disease and improving patients participation in clinical trials.

MOPEAD has tested and evaluated four patient engagement strategies in five EU countries (Germany, the Netherlands, Slovenia, Spain and Sweden): two whereby citizens actively performed a cognitive test: **Citizen Science** (online pre-screening tool), **Open House** (pre-screening tests performed in a memory clinic without a physician's referral) and two strategies for patients at risk, in which their cognition was tested in two settings: **Primary Care setting** (patients were identified and tested by their General Practitioner [GP]) ; **Tertiary Care setting** (the identification and tests were performed by endocrinologists specialised in treating Type 2 diabetes, a risk factor for AD). The persons considered of being at risk were then offered a full diagnostic assessment in a memory clinic that they were free to accept or refuse.

#### Some facts and figures

- ◆ Alzheimer disease is the most common form of dementia and may contribute to 60–70% of cases
- ◆ Around 9 million people are estimated to have dementia in Europe
- ◆ Women are at the epicentre of the Alzheimer's crisis (close to 6 million women have dementia)
- ◆ The number of people with dementia is estimated to continue rising in Europe to 13.4 million in 2030 and 18.7 million in 2050
- ◆ Dementia leads to deterioration in memory, thinking, behaviour and the ability to perform everyday activities
- ◆ Dementia is the second largest cause of disability and dependency among older people worldwide
- ◆ Although dementia mainly affects older people (the estimated proportion of the general population aged 60 and over with dementia at a given time is between 5-8%), it is not a normal part of ageing
- ◆ Dementia has a physical, psychological, social, and economic impact, not only on people with dementia, but also on their carers, families and society at large
- ◆ Dementia is a costly disease (€ 22,000 per year)
- ◆ No treatment has reached the market for over 20 years



The **MOPEAD** (Models Of Patient Engagement in Alzheimer's Disease) project is based on the fact that in clinical practice, the diagnosis of AD is still occurring late in the disease process. This creates a barrier to access available treatments and support services, as well as the opportunity to enrol in clinical trials at early stages of the disease.

The project responds to the cultural shift towards early diagnosis of AD, at the initial symptomatic stages of the illness, as detection of early AD is the first step toward providing patients with optimal opportunity for intervention and involvement in clinical trials.

MOPEAD will also positively influence public education about AD, memory complaints and cognitive decline.

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## European Commission

The European Commission has helped tackle the dementia challenge: from its Communication on a European initiative on Alzheimer's disease (2009) and its implementation report (2014) to exchange of best practices through EU Joint Actions on dementia (ALCOVE and Act On Dementia), support to tackle societal challenges and unmet needs by increasing dementia research through its Research Framework Programmes (Horizon 2020 and Horizon Europe), the EU Joint Programme - Neurodegenerative Diseases Research (JPND), to Innovative Medicines Initiative projects like MOPEAD. The new European Commission needs to take stock of the achievements made to-date and carry the torch over the next 5 years.

<p>Transform the future of dementia in Europe: develop a holistic and coordinated European Dementia Strategy to tackle the dementia challenge with a focus on: access to diagnosis (in particular early diagnosis), treatment and care, research (including non-biomedical research and encouraging patient participation in clinical trials), prevention, participation in society, respect of human rights, gender mainstreaming</p>	<p>In the context of MOPEAD, the development of a European Dementia Strategy must take stock of the evidence that the pathological process of AD starts many years before clinical symptoms appear. Hence the importance of shifting the paradigm to early diagnosis of AD and prepare the environment should a disease-modifying therapy targeted at the early stages of the disease come to the market.</p>
<p>Integrate dementia into the EU 'Economy of Well-being' policy orientations and the European Semester taking into account the benefits resulting from health promotion, measures to prevent AD, early diagnosis of AD and inclusion of people with AD and their carers in society and the work-place</p>	<p>The 'Economy of Well-being' as a policy orientation and governance approach which aims to put people and their well-being at the centre of policy and decision-making can help mitigate the impacts of AD by raising awareness about the disease, its risk factors, prevention and value of early diagnosis.</p> <p>The European Semester is another EU mechanism that can further propel AD on the national agenda and encourage Member States to implement measures that will respond to the human, economic and societal challenge of AD. People with dementia and their carers must be fully included and contribute to society for as long as possible.</p>
<p>Allocate significantly increased EU funding to medical and social research for AD, including systematic sex, gender and age disaggregation and, in particular, dedicate a mission on the brain in the next EU research programme (Horizon Europe)</p>	<p>Dementia is still an underfunded area of research at EU level compared to other disease areas despite the growing economic and social impact of the disease on society at large. All research must include women as they are at the epicentre of the disease. The European Commission must consider a specific brain mission within Horizon Europe: it would give a clear signal that the EU is taking stock of the AD challenges and is keen to contribute to the global research efforts to find a therapy and support people with dementia and their carers.</p>
<p>Increase research to maximise the potential of modern technologies and Artificial Intelligence to significantly improve care, support and quality of life of people with AD and their families, better understand the biology of dementia and its development</p>	<p>Artificial Intelligence (AI) is central to society changes and offers major opportunities to improve people's lives. AI helps solve challenges like chronic diseases and AI-supported medical diagnostics are areas of application that will soon be common place. AI must benefit people with AD and their carers notwithstanding ethical considerations.</p>
<p>Improve cross-national data collection and sharing to accelerate progress to treatments and cure of dementia</p>	<p>The opportunity of data sharing is widely recognised but the challenges are substantial: differing national laws on research have been compounded by the confusion that exists surrounding the interpretation of the European General Data Protection Regulation (GDPR). The GDPR may unintentionally create obstacles to the sharing of health data.</p>

## European Parliament

The European Parliament has proved to be a key ally over the past years in raising awareness about the urgency to tackle dementia at EU level and influencing the EU and national agenda. Some resolutions on dementia, research or ageing and a Written Declaration on dementia (2008) have significantly contributed to raising awareness and policy actions. Members of the European Parliament (MEPs) who are members of the European Alzheimer's Alliance give further credit to the necessity to address the dementia challenges. At national levels, some MEPs have been active dementia ambassadors.

<p>Advocate that dementia is a public health priority with huge human and economic challenges and lead policy advocacy to create a European Dementia Strategy</p>	<p>The European Parliament is a driving force to motivate and activate EU action on AD. MEPs have the power to lead the advocacy activities on AD at EU level and must be considered as full partners.</p>
<p>Work hand in hand with organisations dealing with brain and neurodegenerative diseases, improving women's health, supporting patients and carers, and the disability community</p>	<p>There is value in large collaborations and learning from experience. The MEPs must harness the work and findings of other disciplines (like cancer) and reach out to all stakeholders to lead AD policy advocacy campaigns (through, inter alia, EP Interest Groups and Intergroups) and at national level (linking-up with their national Alzheimer associations).</p>
<p>Be dementia ambassadors at national and international level</p>	<p>As directly elected by their national citizens, the MEPs can make a bridge between EU and national action.</p>

## National governments

The national governments have responsibility over their healthcare systems or education systems. They are on the front line to directly offer answers to people with AD, their carers, professionals, researchers and businesses at national level. As such, they have a role in promoting awareness campaigns on AD including key elements such as symptoms, diagnosis, treatment, support, risk factors and prevention, for the sake of their citizens and the sustainability of their systems. Health professionals must operate in a supportive environment too: MOPEAD's General Practitioners survey showed a lack of confidence in diagnostic procedures. On a more global side, they have a key role to play in the international drive to tackle dementia by getting involved in research projects or sharing best practices.

<p>Transform the future of AD at national level: develop and support holistic and coordinated national AD strategies to tackle the dementia challenge: access to diagnosis (in particular early diagnosis), treatment and care, research, prevention, participation in society, respect of human rights and gender mainstreaming</p>	<p>The development of a national AD plan must take stock of the evidence that the pathological process of AD starts many years before clinical symptoms become apparent, that there is value in early diagnosis. Hence the importance of shifting the paradigm to early diagnosis of dementia and prepare the environment (including the diagnostic structures and reimbursement system) should a disease-modifying therapy targeted at the early stages of the disease come to the market. All sections of society should be involved in the production of a national AD plan.</p>
<p>Implement regular awareness campaigns on AD, especially on risk factors and prevention to engage citizens to take care of their memory and health</p>	<p>In the absence of a disease modifying therapy for AD and keeping in mind that there is evidence for early diagnosis of AD being cost-effective in the long term, the national governments should organise regular awareness campaigns on AD. This will help break the misconceptions and taboos about AD, raise awareness about the risk factors and how to prevent them. The population should be stimulated to take care of their brain. Such campaigns must be an intrinsic part of a national AD plan.</p>
<p>Significantly increase funding in basic research on dementia</p>	<p>Dementia research funding must significantly be increased at national level: in some EU countries, there is still a lack of government investment in basic science on dementia and many pharmaceutical companies are dropping further efforts in developing AD therapies.</p>
<p>Adapt healthcare professionals curriculum to improve confidence and competence in cognitive disorders and promote health professionals team-work as an innovative step to promote early diagnosis of AD</p>	<p>The medical curriculum must be adapted and include dementia and AD in order to meet the new societal trend: because of the ageing of the population, more and more people will be presenting with MCI or early AD. Medical professionals must be empowered to detect these people at an early stage. Diabetes being one identified risk factors, diabetologists, endocrinologists, internal medicine physicians must be trained to identify such patients. Nurses can also be trained to join multi-disciplinary teams.</p>

## International community

A number of converging recommendations have been made over the years by a number of international stakeholders (World Health Organisation (WHO), the Organisation for Economic Co-operation and Development (OECD), the United Nations (UN Sustainable Development Goals), the World Dementia Council (WDC), the CEO initiative (CEOi) or Alzheimer's Disease International). While some progress has been made, still too little progress has been made considering the burden and impact of AD on the community at large. The recommendations remain valid. Lately, the OECD has recommended to step-up efforts to better identify and diagnose patients with dementia and raise standards of care. A recent article in The Lancet ('The scale and profile of global dementia research funding') states that despite significant progress, dementia research is still hugely underfunded, this being especially apparent in non-biomedical research.

<p>Develop a global and holistic action plan on dementia, building on the findings of European collaborations on dementia</p>	<p>The development of a global action plan on dementia is an opportunity to promote innovative patient engagement in the early diagnosis of dementia. The four patient engagement strategies tested and evaluated by MOPEAD could serve as a base, be replicated and assessed in other parts of the world.</p>
<p>Facilitate global collaboration of research efforts to reduce fragmentation, promote good practices, exchange, optimize resource utilisation and open access data</p>	<p>International organisations such as the WHO should continue to facilitate global coordination of research efforts to reduce fragmentation, promote good practice exchange, optimise resource utilisation and open access to data.</p>
<p>Support EU Member States in implementing dementia plans</p>	<p>The WHO Global Dementia Observatory (GDO) is a data and knowledge exchange platform that offers easy access to key dementia data (policies, service delivery, information and research) from countries around the world. It assists the countries in strengthening dementia policies, service planning, and health and social care systems.</p>

## National and EU regulators

National and EU regulators provide recommendations on medicines and other health technologies that can be financed or reimbursed by their healthcare systems. National regulators face increased pressure on their healthcare budgets and consequently need to take prudent decisions. Patients are experts with their disease and can bring valuable insight into therapies development and assessment. They need to be considered as full partners in decisions made about their health.

**Accelerate the pace of clinical trial recruitment that is, after low research funding levels, the largest impediment to finding dementia therapies**

The importance of developing therapies that prevent, slow, or stop the progression of AD makes it incumbent on nations to take concrete steps to ensure people with AD are encouraged to enrol in clinical trials. A significant benefit of data sharing and open science can help ensure the most appropriate individuals are recruited into clinical trials (examples: Join Dementia Research in the UK (a service that allows people to register their interest in taking part in dementia research), the European Prevention of Alzheimer's Disease (EPAD) Consortium).

**Increase patient participation in Health Technology Assessments (HTA) and include a sex and gender perspective in decision-making**

Patients need to get access to therapies as soon as they have been approved. As experts with their disease, they can have a constructive role in formulating health policies that are safe, effective and patient-focused and in HTA. The European Patients Forum and EUPATI (the European Patients Academy) propose capacity-building programmes to empower patients in HTA.

## Involving patients

The misconception that dementia is a normal part of aging is a barrier to individuals getting a diagnosis, getting the health and care support they are entitled to and living in communities that support them. It is imperative to involve patients with dementia alongside carers and professionals in national, European and global policy work as experts who can contribute to eliminate stigma around the disease and create strategies tailored to the patients' needs.

**Promote patient engagement in clinical trials**

The development of therapies that will target early AD means that patients will be in a better position to decide to engage in a clinical trial or not. Patients can find information on clinical trials on various websites (Alzheimer Europe, ClinicalTrials.gov, the EU Clinical register) or training. EUPATI focuses on education and training to increase the capacity and capability of patients to understand and contribute to medicines research and development (including the design and conduct of clinical trials). The on-going EU-funded MultiAct project will create and implement a new model allowing for the effective cooperation of all relevant stakeholders.

**Engage patients to contribute to the development of innovative therapeutic solutions to deliver better health outcomes**

Involving patients in research can hugely benefit the medicines development process. By bringing in their priorities and perspectives, patients can contribute to developing better treatments for them and others. Greater patient involvement in R&D will boost the efficacy and safety of new treatments and increase public support for medical research.

*After receiving my diagnosis, I could understand the problems I had been experiencing and could take actions (like taking part in research projects) that I firmly believe are slowing the progression of the disease.'*  
Hilary Doxford, England

*When I was given the diagnosis confirming the beginning of dementia, my life changed a lot. For the better! I became more attentive, with improved self-discipline. And my quality of life is better. I am really more committed because I know what is ahead of me. My present is still OK. Let it last!*  
Tomaz, Slovenia

*Early diagnosis gave me time to understand the disease, discuss it and draw my care plans with my doctor and my family for now and for the future. It enabled me to choose how to live the rest of my life and engage in peer support.*  
Agnes Houston, Scotland

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