

LAUSANNE V: TAKING TRANSFORMATIVE ACTION TO CHANGE THE COURSE OF ALZHEIMER'S DISEASE

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The current worldwide healthcare system is poorly equipped to handle the wave of aging baby boomers or the anticipated introduction of innovative treatments and advanced diagnostics for Alzheimer's disease. Global Alzheimer's stakeholders met at the 2018 Lausanne Workshop, for the fifth year in a row, to discuss this challenge and ways drug and diagnostic advancements will fundamentally change the disease landscape.

Following two days of presentations, discussions, and deliberations, stakeholders called for urgent attention in seven critical areas. Spotlighted opportunities for collaboration and action to deliver innovations to patients globally are listed below:

1. **Build a comprehensive and cohesive global response to Alzheimer's disease.**
2. **Shift treatment efforts to earlier in the disease stage.**
3. **Pave the way for precision medicine approaches to Alzheimer's disease through novel biomarker development.**
4. **Advance the development and integration of digital technologies in Alzheimer's disease to improve detection and diagnosis and provide tools that can scale globally.**
5. **Integrate patient and carer perspectives in drug development and future value-based payment decisions.**
6. **Prepare the healthcare system to deliver innovation to patients and carers.**
7. **Ensure value for payers and healthcare providers is defined, aligned, and well-understood.**

Lausanne V was organized under the auspices of the Organisation for Economic Co-Operation and Development (OECD) and supported by the Swiss Federal Office of Public Health (FOPH), The Global CEO Initiative on Alzheimer's Disease (CEOi) and Alzheimer's Disease International (ADI). This Workshop is the world's leading stage for global dialogue on Alzheimer's-related efforts and a platform for Alzheimer's stakeholders to report on progress, hold each other accountable, align on opportunities for collaboration, and drive change. The effort launched in 2014 as a response to the challenge articulated at the UK G8 Dementia Summit to stop Alzheimer's by 2025.

I. BUILD A COHERENT AND COHESIVE GLOBAL RESPONSE TO ALZHEIMER'S DISEASE.

Five years since the G7 meeting in Paris, where a global commitment was made to address the Alzheimer's crisis, only 29 national plans exist. This number accounts for approximately 15 percent of the WHO Member States with plans varying in quality and funding. There are approximately 30 in development with two thirds of these plans situated in lower- and middle-income countries (LMIC). Ensuring a global and comprehensive response will require pressuring governments to create national plans that address the unique needs of their citizens, including lowering barriers to the delivery of new and effective treatments in LMIC. These plans can be most effective if they engage non-traditional partners such as the banking and insurance industry and promote worldwide dialogue among regulators, payers, and health technology assessment organizations.

OPPORTUNITIES FOR COLLABORATION AND ACTION:

- The World Health Organization (WHO) will support implementation of national plans by initiating policy dialogues and providing tools that enable governments to conduct situational analyses and needs assessments. As part of the Global Dementia Observatory, WHO will provide a knowledge exchange platform that will facilitate sharing of experiences and expertise whereby accelerating mutual learning.
- ADI, through high-level governmental meetings with national members, continues to advocate for and promote the importance of national plans. ADI tracks national plan development, hosts national plans on its website, and produces reports and information geared to progress plan development. Reports include the annual '[From Plan to Impact](#)' report presented each year at the World Health Assembly.
- The Japanese government plans to promote scientific innovation within the Sustainable Development Goals at the 2019 G20 meeting in Osaka. This will provide an opportunity to embed Alzheimer's in the discussion and further national leadership, which could serve as a potential model for other countries.

2. SHIFT TREATMENT EFFORTS TO EARLIER IN THE DISEASE STAGE.

Developing and delivering effective treatments that delay disease onset or slow progression will require intervening at an early stage of disease, including before symptoms appear. This work can only be accomplished with the following achievements:

- Development of improved methods for early detection, monitoring, and diagnosis;
- Raising understanding in the healthcare community and public about the importance of early identification; and
- Creating the infrastructure needed to conduct large global clinical trials and provide care across the continuum of the disease.

OPPORTUNITIES FOR COLLABORATION AND ACTION:

- Regulators and health authorities worldwide are working to align regulations that are more flexible regarding the approval of treatments for early stages of dementia.
- Switzerland is developing and expanding regional and networked centers of competence for diagnostics to improve the early and accurate diagnosis of dementia.
- ADI is developing an educational program demystifying clinical trials for the professional and lay audiences, identifying barriers and enablers, and educating primary care physicians to encourage them to recommend clinical trials for their patients.
- The Global Alzheimer's Platform Foundation has requested increased funding to build the infrastructure needed to identify, recruit, and process the estimated 25,000 participants that will be needed for a range of oncoming Phase 2 and 3 trials anticipated over the next few years.

3. PAVE THE WAY FOR PRECISION MEDICINE APPROACHES TO ALZHEIMER'S DISEASE THROUGH NOVEL BIOMARKER DEVELOPMENT.

Precision medicine will enable the delivery of treatments optimized for each individual to target the molecular drivers, precise pathologies, and co-morbidities associated with their disease. To achieve this specificity, a broad array of novel biomarkers are needed for more precise diagnosis, prognosis, stratification, progression, and treatment monitoring.

OPPORTUNITIES FOR COLLABORATION AND ACTION:

- Bill Gates and the Alzheimer's Drug Discovery Foundation launched the Diagnostics Accelerator to promote the discovery and development of novel biomarkers and diagnostic technologies.
- The Biomarkers Consortium Initiative is developing a platform to enable the sharing of clinical trials data as a prelude to the regulatory qualification of biomarkers and the development and commercialization of novel biomarker assays.
- The Italian Medicines Agency launched the Interceptor Project to establish a biorepository and identify the best combination of biomarkers to predict conversion from mild cognitive impairment to Alzheimer's disease with high accuracy, low invasiveness, and best financial sustainability.
- To better understand the natural history of cognitive aging and dementia there is need and opportunity for advocacy organizations to pressure the National Heart, Lung, and Blood Institute of the National Institutes of Health. Advocacy efforts would propose to lower barriers of access and use of large epidemiologic longitudinal databases and biorepositories that include brain aging data such as the Framingham Heart Study and the Atherosclerosis Risk in Communities Study.
- ETH Zurich and the Ruhr-University Bochum are developing innovative diagnostic technologies, including plasma and cerebrospinal fluid biomarker approaches, and advanced imaging diagnostics with improved sensitivity, specificity, and accessibility.

4. ADVANCE THE DEVELOPMENT AND INTEGRATION OF DIGITAL TECHNOLOGIES IN ALZHEIMER'S DISEASE TO IMPROVE DETECTION AND DIAGNOSIS AND PROVIDE TOOLS THAT CAN SCALE GLOBALLY.

Digital technologies and big data applications offer opportunities to conduct large-scale longitudinal assessment of cognition and function in naturalistic settings and to incorporate complex multifactorial data into predictive algorithms for drug development and clinical decision making.

OPPORTUNITIES FOR COLLABORATION AND ACTION:

- Project INSIGHT, a collaboration of The Global CEO Initiative on Alzheimer's Disease, Optum Labs, and three pharmaceutical companies, is applying artificial intelligence, advanced analytics, natural language processing-derived concepts, and machine learning technologies to predict dementia quickly and accurately by analyzing complex multifactorial data (clinical, imaging, biomarkers, neuropsychological tests) from claims and electronic records data.
- Altoida, a diagnostics company, is developing and validating a platform called Neuro Motor Index that uses smartphones to detect micro errors during the performance of cognitively demanding tasks, which enables identification of cognitive decline six-eight years prior to the onset of Alzheimer's disease.
- The Framingham Heart Study has over 8,800 voice recordings including those from a subset of individuals who progressed to dementia; and are open to exploring ways to deidentify and share these data with researchers.
- The WHO now has a mandate to work in the digital health space, including the development of a mobile health for ageing (mAgeing) program to support clinicians, patients, and carers.
- The US Food and Drug Administration (FDA) has launched a Digital Health Innovation Action Plan to accelerate development and application of digital technologies for health related utility.

5. INTEGRATE PATIENT AND CARER PERSPECTIVES IN DRUG DEVELOPMENT AND FUTURE VALUE-BASED PAYMENT DECISIONS.

A new science of patient input has emerged to incorporate patient and carer voices and preferences in a rigorous and systematic manner across the drug development continuum. Both the US FDA and the European Medicines Agency (EMA) have emphasized the importance of the patient voice in developing meaningful outcome measures, as well as the need to map clinical meaningfulness to changes in cognition.

OPPORTUNITIES FOR COLLABORATION AND ACTION:

- In Europe, IMI PREFER has brought together a consortium of stakeholders to conduct patient preference studies in both academic and industry settings with the goal of recommending guidelines for industry, regulatory authorities, and health technology assessment agencies.
- Alzheimer's Research UK and UsAgainstAlzheimer's (AD PACE), separately, have launched projects to collect qualitative and quantitative evidence about what matters most to patients and carers across the Alzheimer's lived experience. They plan to consolidate data to develop understandings across demographic and geographic subpopulations about changes in preferences and risk tolerances over the continuum of Alzheimer's disease.
- The Center for Medical Technology Policy and its Green Park Collaborative are using a multi-stakeholder structured consensus process that includes patients and advocates, payers, regulators, drug developers, and others to agree on a minimum set of outcomes recommended to be measured in all clinical trials for a given condition (i.e., a “core outcome set,” or COS). By building consensus in this way, patient-vetted, stakeholder-important information is consistently accessible for assessments of effectiveness and value across a range of products. The group is currently exploring development of a COS for studies of early AD.

6. PREPARE THE HEALTHCARE SYSTEM TO DELIVER INNOVATION TO PATIENTS AND CARERS.

As treatment for Alzheimer's moves increasingly to earlier stages of disease, healthcare systems in many countries remain inadequately prepared to screen, monitor, diagnose, deliver new treatments, and care for the millions of people at risk of or living with dementia. In addition to attracting and training many more healthcare professionals to the field, new practice models need to be evaluated and implemented that enable service and care delivery to broader and more diverse populations.

OPPORTUNITIES FOR COLLABORATION AND ACTION:

- A promising model out of Canada comes from the federally-funded Canadian Foundation for Healthcare Improvement (CFHI). It is promoting the spread of Sinai Health System's Acute Care for Elders (ACE) strategy to provide a continuum of care that incorporates evidence-based community, home-based, telemedicine, outpatient, inpatient care programs as well as support, and training for caregivers. One important component is a program to train emergency department and in-patient staff to screen older persons for delirium and dementia to better manage their care.
- The RAND Corporation has released US and EU readiness analyses and is currently looking at the infrastructure to deliver a potential disease-modifying treatment in Australia, Canada, and Japan.
- The Nigerian government has developed a strategy targeting the workplace to enable people with dementia to continue working as long as possible. The strategy includes creating dementia-friendly work environments, educating workers about dementia-prevention strategies, and reducing workplace discrimination and stigmatization.
- UsAgainstAlzheimer's and The Global CEO Initiative on Alzheimer's Disease launched the Brain Health Partnership to bring families, communities, payers, providers, and policymakers together to develop and implement policies that can realize cost savings through the promotion of better management, planning, and care.
- Alzheimer's Research UK has established a Dementia Access Taskforce with an initial three-year plan to develop solutions to overcome access barriers and ensure that people with dementia will benefit from anticipated new and effective treatments.

7. ENSURE VALUE FOR PAYERS AND HEALTHCARE PROVIDERS IS DEFINED, ALIGNED, AND WELL-UNDERSTOOD.

Health economists are working with the payer and care communities to build new value-based models that assess the potential of early diagnosis and early treatment to reduce the economic burden for health systems, characterize uncertainty in downstream outcomes and costs, and prioritize research and data collection efforts to reduce uncertainty.

OPPORTUNITIES FOR COLLABORATION AND ACTION:

- Duke University and The Global CEO Initiative on Alzheimer's Disease are collaborating to identify value-based payment approaches to address access and coverage issues across multiple populations and treatments including early-stage AD drugs.
- Pathways for the Introduction of AD treatments (PIAdT) is laying the groundwork for introduction of a new disease-modifying treatment by developing and testing value and funding approaches across the lifecycle of a new drug. The effort brings together a host of key stakeholders to develop a shared analytical framework that will help them work the problem together and build actionable pilot programs.
- The International Pharmaco-Economic Conference on Alzheimer's Disease (IPECAD) Modelling Collaboration is developing an open-access model to incorporate multidimensional data on disease progression and treatment effectiveness in order to estimate cost-effectiveness of existing and anticipated treatments and diagnostic strategies.

If you would like to learn more about these opportunities and join the efforts underway, please contact Yasmin Dias Guichot at ydiasguichot@highlanterngroup.com for further information.

