

Please cite this paper as:

OECD (2014-01-24), "Workshop on Integrating Omics and Policy for Healthy Ageing: Synthesis Report", *OECD Science, Technology and Industry Policy Papers*, No. 12, OECD Publishing, Paris.
<http://dx.doi.org/10.1787/5jzb0z52dc5c-en>



OECD Science, Technology and Industry
Policy Papers No. 12

Workshop on Integrating Omics and Policy for Healthy Ageing

SYNTHESIS REPORT

OECD

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FOREWORD

The increase in the human life span is a testament to the economic, social and medical progress made over the course of the last century. However, an ageing population brings some new challenges both to healthcare systems and to medicine in terms of the increased manifestation of specific diseases primarily seen in the elderly. Biomedical innovation, and in particular research into “omics technologies”, offers the promise of new means of detection, prevention and treatment of age-related disabilities and diseases. But the development of these new technologies will not be without challenges, in particular with respect to the difficulty of translating technological advances into innovation in the clinical setting.

To discuss these issues, the Organisation for Economic Co-operation and Development (OECD) Working Party on Biotechnology (WPB), together with the Human Genome Organisation (HUGO), organised a workshop on “*Integrating Omics and Policy for Grand Challenges: Healthy Ageing*” in Singapore on 13 April 2013. This event took place in the context of the Joint Conference of the Human Genome Meeting 2013 and the 21st International Congress of Genetics. The workshop focused on the latest advances in “omics” technologies for healthy ageing and the policies and practices needed to facilitate the safe development, approval and use of innovative diagnostics and therapies.

HUGO and the OECD have been closely collaborating since 2010 to advance discussion on critical issues linked to genomics and the bioeconomy. The OECD is very grateful to the Human Genome Organisation for this continuing and fruitful collaboration, which has allowed for a joint workshop on topics of high policy relevance to be organised every year since 2010 on the occasion of the annual Human Genome Meeting. We are very grateful, in particular, to the outgoing Chairman of the WPB, Dr. Gerardo Jiménez-Sánchez, who was instrumental in establishing this partnership between the two organisations.

The OECD and HUGO are grateful to those who gave their time to review this report, in particular speakers at the workshop and WPB delegates.

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EXECUTIVE SUMMARY

The Organisation for Economic Co-operation and Development (OECD), together with the Human Genome Organisation (HUGO), organised a workshop on “*Integrating Omics and Policy for Grand Challenges: Healthy Ageing*” in Singapore on 13 April 2013. The event was a 2.5 hours session and took place in the context of the Joint Conference of the Human Genome Meeting 2013 and the 21st International Congress of Genetics. The workshop focused on latest advances in omics technologies for healthy ageing and the policies and practices needed to facilitate their responsible development and integration in medical research and in innovation and health policy.

Human life span continues to increase, leading policy makers to be concerned about the social and economic implications of the future demand for health care. The ageing population is putting unprecedented pressure on social and economic policies, notably because of the rapid increase in the prevalence of age-related conditions. Ageing, and ensuring that ageing is healthy, has become a priority for reasons that include economic productivity, financial stability and sustainability, social engagement, human rights and ethics. Presentations and discussions at the workshop highlighted that biomedicine has an important role to play in enabling people to live longer and healthier lives. In particular, omics technologies are very strongly supporting medical innovation in the field of ageing.

Omics technologies – technologies supporting the study of groups of biological molecules, such as the genome, or proteome¹ – are used in the discovery and development of new solutions for the prevention, diagnosis, monitoring and treatment of age-related diseases, notably through the discovery of new biomarkers. However, an improved environment for innovation and for the integration of omics technologies in medical research is needed, in particular for facilitating the transfer of technology-associated discoveries from the laboratory to the point of care. The workshop concluded that reinforced models for stakeholder collaboration at national and global levels are the cornerstones of facilitating: *i*) medical discoveries; *ii*) the transfer of innovation from the lab bench to the patient; and *iii*) most specifically, the decision-making processes for policy makers and regulators in validating interventions for age-related conditions.

Some of the most frequent age-related diseases that are significantly impacting societies and economies are complex multifactorial diseases, such as Alzheimer’s disease, which have only very few, and only partially effective, treatments. Despite the significant progress that has been made in the past decade to elucidate the risk factors and biological mechanisms leading to these diseases, a deeper understanding will be required to enable the discovery of biomarkers and the development of effective, targeted treatments to delay or alter the disease’s progression. Omics technologies have already significantly contributed to discoveries in the field of ageing. Omics are most notably used as profiling tools in epidemiological studies of ageing (for example, in Genome Wide Association Studies [GWAS]). However, translating scientific and technological advances into innovation in the clinical setting presents a number of governance challenges some of which were highlighted in the workshop.

Governance challenges include:

- **Reinforcing strategic collaboration:** the strengthening of stakeholder collaboration is needed to overcome the challenges associated with the development and validation of new interventions for age-related conditions. Reinforcement of collaboration can include creating innovative partnerships between governments and public entities and the private sector in order to bring together the resources needed for an efficient research and for risk sharing among the different actors. The need to support collaboration via new models of financing and investment for research, development and implementation of innovation was also discussed. For example, the workshop highlighted the importance of developing new schemes of public-private research funding and pre-competitive consortia for shared risk management. As part of these collaborative mechanisms, issues surrounding data access and sharing were highlighted. Patients are becoming central actors within these collaborations.
- **Supporting innovation:** addressing the biological complexity of certain age-related diseases will require not only an exceptional level of collaboration but also an environment that stimulates innovation. Innovation can be stimulated through supportive policies but also by the way that regulatory pathways are organised.
- **Modernising regulatory science:** many of the innovative solutions to address the challenges presented by the complexity of age-related conditions will be technology-driven, and will be dependent on rapid advances in emerging fields such as omics technologies, but also on regenerative medicine, nanosciences and synthetic biology. The workshop specifically pointed out the importance of adapting regulatory pathways in order that regulators are better able to navigate through an environment of uncertainty *vis-à-vis* emerging technology-driven solutions for ageing, in particular that regulation can support the responsible transfer of biomedical innovation to the point of care. This includes, for example, an early and continuous dialogue between the regulators and the innovators engaged in the development of technology-driven solutions for ageing. This should be supported by regulatory systems that are dynamic and forward-looking in order to facilitate innovation in emerging fields.

Introduction to the workshop

The increase in the human life span is a testament to the economic, social and medical progress made in OECD countries over the course of the last century. However, an ageing population brings some new social and economic challenges in terms of the increased manifestation of specific conditions primarily seen in the elderly. Age-related diseases, in particular those affecting the brain, represent a particular and very significant challenge to the health of the population, national prosperity, productivity and economic growth. A number of complementary actions will be needed to help to tackle challenges associated with an ageing population, for example measures to support innovation in technological domains such as omics² technologies. Innovation in biomedicine through omics techniques offers the promise of new solutions for prevention, detection and treatment of age-related conditions, notably through research into new biomarkers. But this will not be without challenges, in particular with respect to the difficulty of translating scientific and technological advances into innovation in the clinical setting and throughout the entire health innovation cycle: from research and development to regulation, delivery and diffusion.

The Organisation for Economic Co-operation and Development (OECD), together with the Human Genome Organisation (HUGO), organised a workshop on “*Integrating Omics and Policy for Grand Challenges: Healthy Ageing*” in Singapore on 13 April 2013. The event was a 2.5 hours session and took place in the context of the Joint Conference of the Human Genome Meeting 2013 and the 21st International Congress of Genetics (see www.hgm2013-icg.org/scientific_programme.html). The objective of the workshop was to:

“discuss the latest policy developments, challenges and obstacles in omics technologies for healthy ageing, and most specifically for dementia and Alzheimer’s disease [...] focussing on the latest advances in omics technologies for healthy ageing and the policies and practices needed to facilitate their responsible development and integration into medical research and into innovation and health policy.”

The workshop was organised around expert talks and discussions on issues such as: the underlying molecular mechanisms and genetics of healthy ageing, the role of new omics tools (such as Genome Wide Association Studies [GWAS]) and their application in epidemiological studies of ageing, in particular of brain ageing (e.g. twin studies). The workshop also addressed governance and policy issues linked to new developments in omics technologies for ageing, focusing on the regulatory challenges and the mechanisms to support effective translational research through, for example, new collaborative models of investment and risk-sharing initiatives. The workshop also examined the underlying principles of challenge-driven innovation policy for healthy ageing, notably putting the emphasis on the central role of patient empowerment and user-driven innovation.

This report summarises the discussions and key messages from the workshop. It does not necessarily represent the views of HUGO or the OECD or a consensus among participants.

The workshop agenda can be found in the Annex to this report. Affiliations of participants in the report are as of April 2013. The event included one session on *Omics technologies for healthy ageing* and one on *Governance of omics for healthy ageing*.

Omics technologies for healthy ageing

The first workshop session discussed the role of genetics when looking at ageing mechanisms, and the tools and methods available to further investigate the underlying molecular pathways of ageing (e.g. animal models, omics-based tools, epidemiological studies).

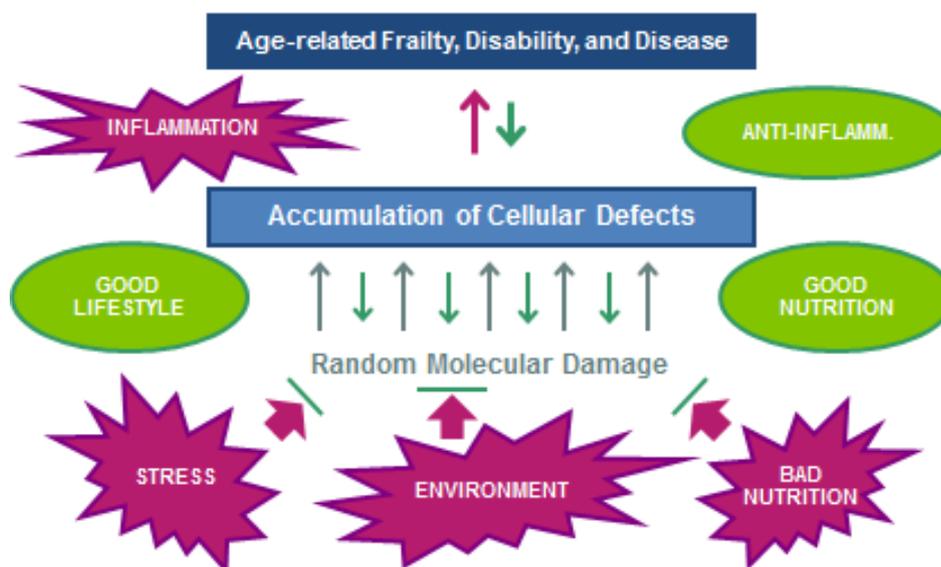
Presentations and discussions highlighted that, despite advances in understanding the mechanisms of ageing, there is still much to be learned about the underlying molecular basis of certain age-related disabilities and diseases, in particular those of neural systems failure, which manifest as brain-behaviour dysfunction, including dementia. The gap in finding new biomarkers of brain diseases was, for example, pointed out as a critical challenge. A deeper understanding of these biological mechanisms, in particular of the influence of genetics, will be required for the development of effective prevention, diagnosis, and targeted treatments that might delay or alter the progression of a pathologic condition. The session presented some of the tools and methods that are used to investigate the molecular mechanisms of ageing and of potential biomarkers. In particular, the session presented progress made in epidemiological studies (e.g. twin studies) with the use of “omics” screening techniques such as GWAS. The importance of accurate animal models of ageing was also raised, together with the limitations of those models.

The critical importance of environmental factors on the mechanisms of ageing was also brought to the forefront during the session.

The genetics of healthy ageing

Mr. Tom Kirkwood (Director, Institute for Ageing and Health, Newcastle University, United Kingdom) presented one of the hypotheses being used to examine the mechanisms by which ageing occurs. In particular, he discussed the role of genetic factors in the ageing process. In this model, ageing is not genetically programmed but results from an accumulation of damage made to the cells over time. Longevity is regulated by the efficiency of somatic maintenance and involves factors, including genes, influencing cell maintenance and repair.

Research is continuing, trying to increase our understanding of the genetic control of longevity. Epidemiological studies have shown that both genetics and environmental factors are involved in the ageing process and in the development of age-related diseases. Twin studies have revealed that genes account for about 25% of what determines longevity. The rest involves a combination of external factors modulating the biological pathways leading to ‘healthy’ or ‘unhealthy’ ageing. Over time, environmental factors, such as stress and bad nutrition, lead to an accumulation of molecular damage and cellular defects, creating an inflammatory ground supporting the development of age-related frailty, disability and disease (see Figure 1).

Figure 1. Ageing process and its malleability

Source: OECD based on OECD/HUGO Workshop on “Integrating Omics and Policy for Grand Challenges: Healthy Ageing”, 13 April 2013, Singapore, presentation from Prof. Tom Kirkwood, Director, Institute for Ageing and Health, Newcastle, United Kingdom.

Genetics intervene in the capacity and efficacy of the body to repair damage to the cells. There has been significant progress made in identifying the genes that are involved in the ageing process. A very large number of alleles³ are likely to be involved in ageing/longevity. Mr. Kirkwood highlighted that genes were essentially linked to functions of repair, but also to responses to damage and metabolic regulation (e.g. polymorphisms of the apolipoprotein E, notably in the development of late-onset Alzheimer’s disease). Both genetic and environmental factors are thus involved in the ageing process and in the pathways that lead to the development of age-related conditions, with environmental factors playing a particularly important role in the way the body will age.

Tools and methods for an ‘omics’ investigation of ageing

Progress in genomics and functional genomics in the past decades have significantly supported our understanding of the molecular mechanisms associated with ageing. Most specifically, advances in the genetics of ageing have been made possible thanks to a number of tools and investigative methods. Some of these were highlighted in the speakers’ presentations, notably:

- **Transgenic animal models of ageing:** animal models of ageing play a critical role in recent findings about the role of genetics in longevity and healthy ageing. For example, mouse models have been developed for premature ageing, thereby enabling the analysis of the ageing effect caused by a deficiency in DNA repair. However, questions remain about the accuracy of the models used and the extent to which they also cover lesions similar to those happening in normal ageing. This leads to doubts around their absolute value in giving an appropriate picture of the biological mechanisms of ageing.
- **Epidemiological studies using ‘omics’ tools such as genome wide association and linkage studies:** advances in genomic and sequencing technologies now make it possible to conduct large-scale genome-wide association and sequencing studies (Beekman et. al 2010). Comparison of data across genetically-diverse cohorts can provide insights into the underlying pathogenic

mechanisms of disease and help to identify potential therapeutic targets. Such information is essential for the discovery of possible biomarkers. It is also relevant to achieving more accurate risk assessment leading to more timely and accurate prediction for those at risk of developing the disease, including the potential to identify environmental modifiers of disease risk. Similar types of investigation are made for establishing a broader omics profile, including proteomics,⁴ lipidomics⁵ and transcriptomics,⁶ for example.

The speakers’ presentations indicated that a significant number of epidemiological studies have been conducted to date aiming to reach a full picture of the factors leading to healthy versus unhealthy ageing. These studies include research on the influence of environmental factors on ageing, as well as “omics” profiling, in particular genetic profiling through GWAS. Examples of this research were presented at the workshop, notably through the Older Australian Twins Study.

Example of ‘omics’ and environmental studies of brain ageing: The Older Australian Twins Study

Ms. Margaret Wright (Senior Research Fellow, Group Leader of Neuroimaging Genetics, Queensland Institute of Medical Research, Australia) presented the Older Australian Twins Study (OATS) that was launched in January 2007 with comprehensive assessments at baseline, and follow-ups at both two and four years (see Figure 2). By establishing a well-characterised cohort of elderly monozygotic (identical) and dizygotic (non-identical) twins for longitudinal study, the OATS aimed to:

- Examine the extent to which genetic and environmental factors promote ‘healthy brain ageing’;
- Establish which genetic and environmental factors trigger, modify or protect against neurodegenerative disease (cognitive and motor) in the elderly;
- Identify which factors influence burden of disease and health-seeking behaviour in the elderly;
- Search for genetic loci related to healthy brain ageing and neurodegenerative disorders; and
- In the longer-term, link into an existing brain donor programme for definitive tissue diagnosis and molecular studies to consolidate the findings and provide new insights into pathophysiology.

Figure 2. Current status of OATS



Source: OECD based on OECD/HUGO Workshop on “Integrating Omics and Policy for Grand Challenges: Healthy Ageing”, 13 April 2013, Singapore, presentation by Margaret Wright (Senior Research Fellow, Group Leader of Neuroimaging Genetics, Queensland Institute of Medical Research, Australia).

The study was developed in order to identify genes for successful ageing rather than those for absolute longevity. Different markers were used to monitor outcomes in the cohort: clinical and cognitive, neuroimaging, health and lifestyle, cardiovascular, blood (e.g. genotyping, inflammatory and metabolic markers) and brain donation. The study revealed that most cognitive functions in older individuals show significant heritability, with the exception of some aspects of processing speed. The heritability of a neurocognitive disorder is lower than for other features, possibly due to the complexity of the manner of determination of the disorder, which takes account of both the severity of cognitive deficit and its functional impact. The study concluded that more detailed exploration of environmental and genetic factors on cognition in older people should be carried out in future studies.

Identifying the genes responsible for successful ageing is important for a number of reasons:

- It gives an insight into the biological mechanisms involved in ageing successfully. Discovering the genes that matter for general brain health will help identify critical molecular pathways contributing to brain deterioration or health throughout life;
- It helps to decrease unexplained variability in the phenotype, facilitating the identification of non-genetic factors important for general brain health (e.g. adjusting for genetic risk profiles should empower clinical trials assessing the brain);
- Prediction of individuals at risk of pathological ageing (e.g. for early prevention, people with a genetic vulnerability to brain disease could receive early interventions to protect the brain and delay the onset or prevent disease).

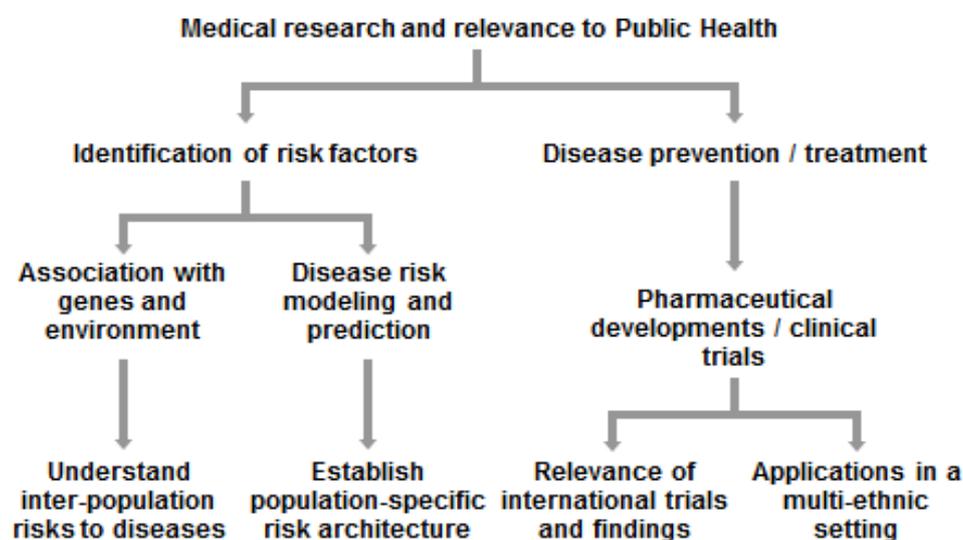
Epidemiological studies such as twin studies, by investigating the patterns, causes, and effects of health and disease conditions in defined populations of the elderly, are creating a foundation for the formulation of public health policy. The studies can inform policy decisions and evidence-based medicine by identifying risks factors for disease and targets for preventive medicine. They can also inform pharmaceutical developments.

With progress made in omics screening techniques and the establishment of omics profiles of defined populations, omics is becoming a fully integrated tool for supporting public health policy decisions.

Public health and integrative ‘omics’

An ageing population is a burden on health care systems, economies and society as a whole. Assuring a high standard of quality of life for the elderly is becoming a priority in many OECD member and non-member countries. Investigation of the risk factors of diseases of ageing is being combined with risk modelling and prediction to inform public health policies.

Mr. Teo Yik Ying (Associate Professor, Saw Swee Hock School of Public Health and Department of Statistics & Applied Probability, National University, Singapore) highlighted that medical research, aided by epidemiological studies, omics techniques, basic science and etiologic discoveries, is supporting the identification of risk factors (association of genetic and environmental factors) in order to establish models for the population at risk of developing age-related diseases. Omics screening techniques, in particular, are helping in the discovery of biomarkers to make possible disease prevention, diagnosis and treatment (see Figure 3). Mr. Teo mentioned the Singapore Natural Variation Project which aims to establish the omics profile (genomics, transcriptomics, lipidomics) of 120 individuals from three major ethnic groups and combine those with data on lifestyle, nutrition and clinical markers.

Figure 3. Medical research and public health

Source: OECD based on OECD/HUGO Workshop on “Integrating Omics and Policy for Grand Challenges: Healthy Ageing”, 13 April 2013, Singapore, presentation from Mr. Teo Yik Ying (Associate Professor, Saw Swee Hock School of Public Health and Department of Statistics & Applied Probability, National University, Singapore).

Research into genetic risk prediction, notably using GWAS, aims to collect evidence supporting the investigation of the delay or prevention of the onset of age-related diseases dependent on the genetic profile. The link between the genetic profile and pharmacologic interventions (pharmacogenomic) has already proved its relevance for a number of treatments (with drugs such as Warfarin and Abacavir) and has been integrated into public health policies (e.g. the United States Food and Drug Administration recommended genetic screening to identify the optimal starting dose of Warfarin). However, for complex multifactorial and multigenic age-related diseases such as dementia and Alzheimer’s disease, establishing genetic risk profiles appears to be a very challenging task.

Mr. Teo highlighted that more data are needed to get a full picture of the factors (genetic and environmental) that are leading to healthy/unhealthy ageing. Models of ageing are necessary to support the formulation of health care policies of ageing and the development of education and health promotion strategies. Mr. Teo also highlighted the importance of “big data” analytical tools in establishing such models.

Concluding remarks

The first workshop session concluded that ‘omics’ technologies are supporting medical innovation in the field of ageing. They are the cornerstone of the discovery and development of new solutions for the prevention, diagnosis, monitoring and treatment of age-related diseases, notably by enabling the discovery of new biomarkers. However, translating scientific and technological advances into innovation in the clinical setting will not be without challenges. Participants in the workshop highlighted that a number of complementary governance actions will be needed to tackle challenges associated with the scientific complexity of certain age-related diseases, making medical advances difficult and presenting obstacles in moving innovation from the lab bench to the bedside. A particular emphasis was made on: 1) the need to look at current regulatory frameworks, on a global scale, which could impede new technology-driven solutions reaching the patient, notably the conditions of access of new technological solutions in clinical research; and 2) the importance of integrating research for age-related diseases in science, technology and

innovation policy roadmaps, with greater, reinforced collaboration between public and private entities. These elements are further described in the next sections.

Governance of ‘omics’ for healthy ageing

The second workshop session discussed some of the main governance issues associated with the development of ‘omics’ for healthy ageing and related policy needs.

Presentations and discussions highlighted that the efforts needed to validate alternative models and develop therapeutic strategies for age-related diseases such as Alzheimer’s will require an unprecedented level of collaboration as well as investment in research, most specifically in translational research. National and international collaborations can help to focus disparate actors on the single strategic goal of the development (and validation) of interventions to reduce the prevalence and impact of dementia, for example. The workshop session strongly emphasised the fact that patients are primary actors in achieving this goal. Success, however, will not be easy to achieve. Numerous scientific, governance, regulatory, infrastructure and financial obstacles will need to be overcome.

Taking the example of Alzheimer’s disease, the workshop session pointed out the urgent need to address the lack of efficient treatment for the disease. This has triggered a response from governments aiming to facilitate and accelerate the transfer of science and technology from the laboratory to point of care. These efforts include fostering innovative partnerships between governments and public entities and the private sector in order to bring together the resources needed for efficient research. For example, the workshop session highlighted that new models of risk sharing and new models of investments are being explored that aim to share both the ‘risks’ and ‘benefits’ of the entire enterprise equally between all partners. Indeed, companies are still hesitant to engage fully in research on Alzheimer’s disease. This reluctance derives from a number of factors including regulatory uncertainty; the particular complexity of developing new drugs for brain diseases, in particular the passage from pre-clinical to clinical studies; and the risks of investing in emerging breakthrough technologies which could bring real value added solutions for Alzheimer’s disease, but which come with significant development and regulatory challenges.

The workshop highlighted the importance of developing new schemes for public-private research funding and pre-competitive consortia for shared risk management. At the research, development and early commercialisation stages, more innovative approaches to sharing risk and knowledge could be developed based on large consortia comprising companies, public laboratories and institutions. Such consortia would allow for risk sharing between public and private entities, but also risk sharing between companies themselves. Such consortia may also help to manage the uncertainty of bringing new technology-driven solutions to the market when no similar technologies have previously been commercialised. Together, these initiatives should provide a foundation for developing and validating interventions to reduce the prevalence of Alzheimer’s and other brain disorders.

Generally the workshop session emphasised the importance of reinforced communication between all the stakeholders involved - from public entities and the private sector, to policy makers, economists and regulators and including patients at the central focal point. The workshop specifically pointed out that regulatory innovation and flexibility is required to address issues in validating emerging technology-driven solutions for ageing. Current regulatory frameworks could be impeding or complicating the development of innovative areas of research for age-related diseases, in particular complex ones such as Alzheimer’s disease.

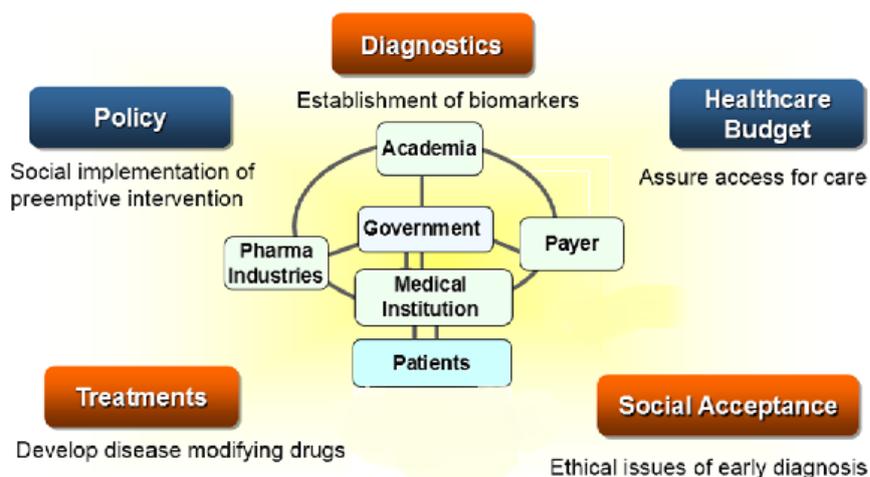
Linking omics with an integrated policy roadmap: The example of Alzheimer's disease

The economic and social impact of age-related disease such as dementia is becoming a major global challenge requiring a global response. Mr. Richard Johnson (CEO, Global Helix LLC; National Academy of Sciences Board on Life Sciences; Advisory Council, Global Coalition on Ageing, member of BIAC) emphasised that Alzheimer's disease, the most common form of dementia, affects over 36 million people worldwide and this number is expected to triple by 2050. The disease has become a fiscal burden and thus a barrier to sustainable economic growth. This does not only touch on health care policy but also on fiscal, political and social policies. OECD countries are increasingly facing the urgent need to develop solutions for the most efficient prevention, diagnosis and treatment of the disease. This has been translated into action in terms of the financing of research, the development of a number of programmes and initiatives at the national and global level, and associated policies.

Mr. Johnson emphasised the importance of genomics in these policies. For example, genomics plays a critical role in recent United States and European Union initiatives for Alzheimer's, in particular in searching for solutions for early detection and early intervention. Omics technologies are at the centre of the discovery of new biomarkers of the disease. However there are a number of governance challenges that are linked to the successful application of omics technologies. Mr. Johnson highlighted the main elements that need to be considered in any global, co-ordinated policy approach for Alzheimer's:

- Innovative regulatory science and governance for the discovery and validation of new biomarkers and for the design of smarter clinical trials;
- Addressing data-intensive research challenges for Alzheimer's by dealing with issues including ownership, data access and sharing, privacy, informed consent, patient choice, and patient engagement around Alzheimer's data sets;
- Developing a basic and translational research agenda, including collaborative models for translational research (e.g. new forms of public-private interactions in an era of fiscal austerity), and pre-competitive consortia and risk-sharing management practices;
- Recognising Alzheimer's disease as an economic growth and skills challenge.

Mr. Johnson re-emphasised the need for an integrated action involving stakeholders at all steps in the innovation cycle (see Figure 4).

Figure 4. Stakeholder involvement in addressing Alzheimer’s disease

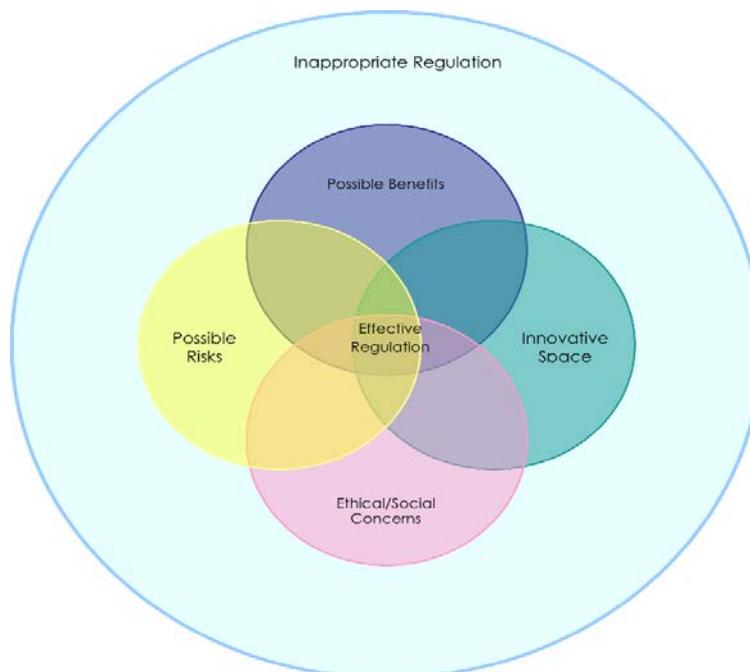
Source: OECD based on OECD/HUGO Workshop on “Integrating Omics and Policy for Grand Challenges: Healthy Ageing”, 13 April 2013, Singapore, presentation from Richard Johnson (CEO, Global Helix LLC; National Academy of Sciences Board on Life Sciences; Advisory Council, Global Coalition on Ageing, BIAC).

Models of co-operation need to evolve, for example, through policies to promote and enable innovative public-private partnerships for Alzheimer’s research and new collaborative translational research models to leverage public-private funding and enable risk sharing among multiple stakeholders. Mr. Johnson emphasised the importance of regulatory innovation and flexibility for realising the potential of omics technologies for Alzheimer’s disease and other age-related conditions.

Navigating the regulatory challenges

The evolution of new technologies and the introduction of technology-enabled products into the market can present a myriad of regulatory challenges, many of which were highlighted by Ms. Diana Bowman (Assistant Professor, Risk Science Centre, Department of Health Management and Policy, University of Michigan, United States). Innovative solutions are required to address the diversity of challenges presented by an ageing population. Many of these will be technology-driven, and dependent on rapid advances in emerging fields such as nanosciences, genomics, synthetic biology and regenerative medicine. Modernising regulatory pathways for biomedicine for ageing is a multidisciplinary challenge, requiring a multidisciplinary response. In addition, the distinctions between different forms of medical products, such as drugs, diagnostics and devices, are becoming blurred. Combination products fall between regulatory regimes (e.g. regulation of medical devices, of drugs and of food) and thus require novel regulatory approaches.

Ms. Bowman pointed out the different factors that need to be taken into account for assuring an effective regulation of emerging technological fields and technology-enabled products: their possible benefits, their possible risks, their associated ethical and social concerns and the space for blue-sky research and innovation (see Figure 5).

Figure 5. Competing dimensions for appropriate regulation

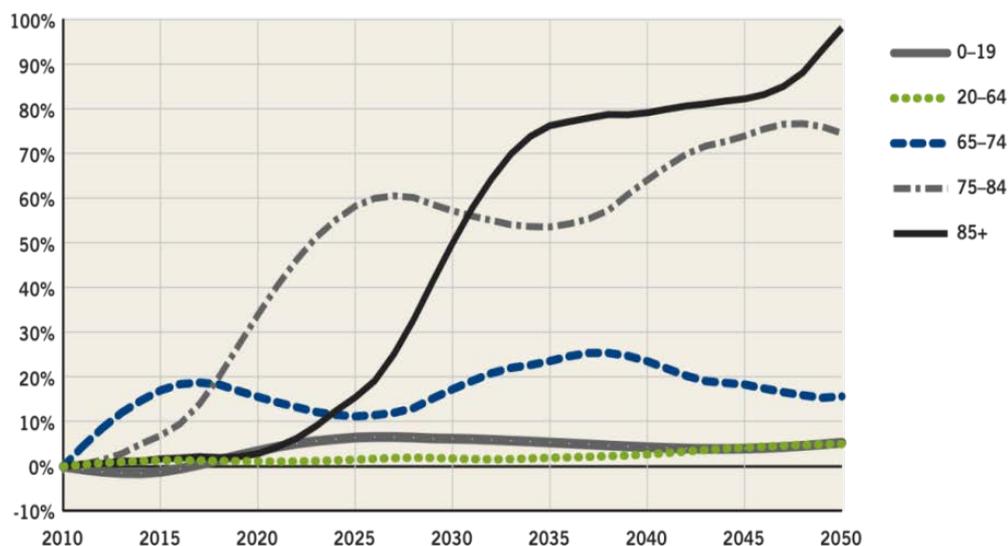
Source: OECD based on OECD/HUGO Workshop on “Integrating Omics and Policy for Grand Challenges: Healthy Ageing”, 13 April 2013, Singapore, presentation from Mrs. Diana Bowman (Assistant Professor, Risk Science Centre, Department of Health Management and Policy, University of Michigan, United States).

Integrating these four components requires the strengthening of communication between the stakeholders involved in order to successfully navigate all the potential roadblocks. In particular, communication is key to balancing risk and benefit within a context of limited knowledge and uncertainty, as at the core of biomedical innovation management. Ms. Bowman highlighted the need for innovative models and tools able to integrate the different parameters that will make regulation more effective, in particular, tools and methods that support the management of uncertainty (e.g. technology forecasts, new models of co-operation).

Finally, it was noted that, as ageing is a global challenge, communication and coordination should happen at the national but also at the international level and be supported by global efforts. Integrated discussion on risk, benefit, potential applications and social needs is important for effective regulation.

Challenge-driven innovation policy for healthy ageing: the example of Sweden

A number of policy measures are necessary to support innovation for healthy ageing, measures within health policy, within science, technology and innovation policy, and more widely. Sweden, for example, has adopted a challenge-driven innovation policy approach, promoting technology to respond to economic and societal challenges. The ageing population is a major societal and economic challenge for Sweden. Its population is ageing rapidly with the percentage of people aged 85 and over predicted to almost double by 2050 (see Figure 6), leading to increasing costs of consumption of health and elderly care.

Figure 6. Sweden: Percentage change in number of people per age group 2010–2050

Source: OECD based on Statistics Sweden, 2010. OECD/HUGO Workshop on “Integrating Omics and Policy for Grand Challenges: Healthy Ageing”, 13 April 2013, Singapore, presentation from Jenni Nordborg (Department Head, Bioentrepreneurship, VINNOVA, Sweden).

The Swedish healthcare system and life science policies have some specific characteristics which will help support innovation in biomedicine for healthy ageing. Mrs. Jenni Nordborg (Department Head, Bioentrepreneurship, VINNOVA, Sweden) highlighted some of these:

- A long tradition of strong clinical research and excellence in several important research areas;
- Access to nation-wide data sources (registries) including all citizens and over the long-term;
- Strong links between academia and health care and a dominant public health care sector;
- An industry with international focus and a very large number of SME companies.

Swedish health care policy and health innovation policy are orientated towards delivery of clear added-value and measurable benefits. This policy there aims to stimulate broad deployment and user-driven innovation in health. Patients are at the centre of policy with the promotion of inclusion and participation. Patient commitment and patient empowerment are key terms used in Swedish health care policy, in particular in relation to healthy ageing.

Ms. Nordborg emphasised the importance of policy support at different steps in the development of new solutions for healthy ageing, notably in:

- Supporting innovation (e.g. promote creativity, use driven innovation);
- Supporting ways of measuring the value of innovation (e.g. through test-beds: pilot projects that aim to validate and demonstrate value and help to create generic implementation models);
- Supporting innovative procurement by, for example, identifying innovation needs and creating new markets.

Concluding remarks

The second workshop session highlighted that, to move forward in developing solutions for healthy ageing and specific age-related diseases such as Alzheimer's, an improved environment for innovation is important, including research infrastructures and networks; collaborative mechanisms, in particular new consortia for risk and investment sharing between public and private actors; modernised governance and regulatory science to allow for innovation in breakthrough technologies to emerge and reach the patient; education; and public engagement. This environment should be fully integrated in health innovation schemes and policy, and be supported by the wider policy environment.

ANNEX: WORKSHOP AGENDA

“Integrating Omics and Policy for Grand Challenges: Healthy Ageing”

OECD/HUGO Session at the Joint Conference of the Human Genome Meeting 2013 and the
21st International Congress of Genetics

Saturday 13 April 2013 from 10h00 to 12h30

- 10.00 –10.05 **Welcome**
Jacqueline Allan, Head of the Secretariat, Working Parties on Biotechnology and Nanotechnology, OECD
- 10.05-10.15 **Introductory Remarks from the Session Chair**
Gerardo Jimenez-Sanchez, Chair, OECD Working Party on Biotechnology
- Session 1: Omics Technologies for Ageing**
- 10.15 -10.30 **Genetics of Healthy Ageing**
Tom Kirkwood, Director, Institute for Ageing and Health, Newcastle University, United Kingdom
- 10.30 -10.45 **Big Data and Integrative Omics in tackling Public Health issues for Ageing**
Teo Yik Ying, Associate Professor, Saw Swee Hock School of Public Health and Department of Statistics & Applied Probability, National University, Singapore
- 10.45- 11.00 **Older Australian Twins Study (OATS) & other research**
Margaret Wright, Senior Research Fellow, Group Leader of Neuroimaging Genetics, Queensland Institute of Medical Research, Australia
- 11.00 -11.15 **Question and Answer Session**
- Session 2: Governance of Omics for Healthy Ageing**
- 11.15 – 11.30 **The Need for Global Action on Ageing**
Richard Johnson, CEO, Global Helix LLC; National Academy of Sciences Board on Life Sciences; Advisory Council, Global Coalition on Aging
- 11.30-11.45 **A Regulatory Perspective**
Diana Bowman, Assistant Professor, Risk Science Centre, Department of Health Management and Policy, University of Michigan, United States
- 11.45-12.00 **Challenge Driven Innovation Policy for Healthy Ageing**
Jenni Nordborg, Department Head, Bioentrepreneurship, VINNOVA, Sweden
- 12.00-12.20 **Question and Answer Session**
- 12.20-12.30 **Concluding Remarks by the Session Chair**

NOTES

- ¹ “The term ‘proteome’ refers to the entire complement of proteins, including the modifications made to a particular set of proteins, produced by an organism or a cellular system”, description from the National Cancer Institute, see <http://proteomics.cancer.gov/whatisproteomics>
- ² For example, genomics, proteomics, lipidomics and transcriptomics.
- ³ Alternative forms of the same [gene](#) or same [genetic locus](#) (generally a group of genes).
- ⁴ “The term ‘proteomics’ is a large-scale comprehensive study of a specific proteome, including information on protein abundances, their variations and modifications, along with their interacting partners and networks, in order to understand cellular processes”, description from the National Cancer Institute, see <http://proteomics.cancer.gov/whatisproteomics>.
- ⁵ “Lipidomics is a systems-based study of all lipids, the molecules with which they interact, and their function within the cell”(Watson, 2006).
- ⁶ Transcriptomics is the study of the complete set of RNAs (transcriptome) encoded by the genome of a specific cell or organism at a specific time or under a specific set of conditions.

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