

Sustainability of Health Systems



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WORKSHOP
Sustainability of Health Systems

European Parliament, Brussels

15 May 2018

PROCEEDINGS

Abstract

This report summarises the presentations and discussions of a workshop on sustainability of health systems, held at the European Parliament in Brussels on Tuesday 15 May 2018. The aim of the workshop was to provide background to facilitate information exchange between health system experts and members of the ENVI Committee on the challenges and opportunities related to the sustainability of European health systems.

The first part of the workshop focused on challenges to health system sustainability. Presentations looked at the sociodemographic challenges such as the aging of the population and the social determinants of health, at the impact of new technologies and access to medicines, and at the emergence of genetic and precision medicine.

The second part of the workshop brought together different experiences of health system sustainability, looking at how the health systems of Japan, the Netherlands and Andalusia have adapted and are adapting to challenges to their sustainability.

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LIST OF ABBREVIATIONS

ATMPs Advanced Therapy Medicinal Products

DG SANTE Directorate General for Health and Food Safety

EC European Commission

EEA European Economic Area

EP European Parliament

EU European Union

GP General Practitioner

FRA Fundamental Rights Agency

MS Member States

PM Precision Medicine

WHO World Health Organisation

EXECUTIVE SUMMARY

This report summarises the presentations and discussions at the “Sustainability of Health Systems” workshop held on 15 May 2018 and co-hosted by Ms Soledad CABEZÓN RUIZ (MEP) and Mr Alojz PETERLE (MEP), co-chairs of the Health Working Group within the ENVI Committee. The aim of the workshop was to exchange views about the challenges and experiences on the sustainability of health systems between members of the ENVI Committee and experts from academia, international and national health organisations.

Co-chair Ms Cabezón Ruiz welcomed the speakers and participants and opened the discussion by highlighting the importance of EU health in the face of challenges ranging from the economic crisis to the impact of sociodemographic changes, and the implications of new technologies for the sustainability of health systems. Next, co-chair Mr. Peterle also welcomed the audience and highlighted the role of the EU and Member States in ensuring the sustainability of health systems, while also emphasising the need to identify good practices and policy frameworks that can help EU systems adapt to challenges ahead.

The first part of the workshop focused on the main challenges to the sustainability of health systems. Dr Clare BAMBRA, Professor of Public Health at the Institute of Public Health of Newcastle University, gave her presentation on the sociodemographic challenges facing European health systems via a pre-recorded video due to the cancellation of her flight. In her presentation, Dr Bambra highlighted the pervasiveness of inequalities in health and ageing both within and between Member States. She also argued that, while these inequalities are influenced by social determinants of health, they can also be influenced and reverted by health policies.

Co-Chair Ms CABEZÓN RUIZ (MEP) presented an overview of the challenges surrounding access to new medical technologies. She highlighted the importance of the principle of universal healthcare while acknowledging the challenges of growing public spending and considering the socio-economic costs of limiting access to health. Next, Ms Cabezón Ruiz discussed the rising costs of pharmaceutical products within the EU and the need for striking a balance between providing incentives for innovation and ensuring access to medicines. Ms Cabezón Ruiz closed her presentation by illustrating several measures at EU and Member State level aimed at addressing this delicate balance and promoting sustainable health systems.

The first panel finished with a presentation on genetics and precision medicine from Dr Barbara PRAINSACK, Professor at the Department of Political Science at the University of Vienna, and at the Department of Social Science, Health and Medicine at King’s College London. After briefly tracing the evolution and meaning of personalised and Precision Medicine, she argued for the need to rethink PM to make it work for, rather than against, more sustainable health systems. Dr Prainsack identified three key areas where PM could influence the sustainability of health systems: improving data governance; integrating health into all policy areas; and reducing harm and waste by limiting low-value interventions.

The second panel brought together different experiences of reforms aimed at addressing the sustainability of health systems in Japan, the Netherlands and Andalusia. Dr Akiko MAEDA, senior health economist at the OECD, opened the panel with a presentation on Japan. After listing some of Japan’s successes, such as low obesity levels and high life expectancy, she stressed Japan’s difficulties in keeping spending on health to a sustainable

level. Dr Maeda explained the vision for Japan's health system in 2035, which includes a horizontal transformation of healthcare by engaging all sectors, not just health, and the promotion of innovation and key health technologies to drive Japan's growth.

Dr Thomas PLOCHG, Director of The Netherlands Public Health Federation and Professor at the Department of Health at the University of Amsterdam's Academic Medical Centre, spoke about the experience of The Netherlands. He began by calling for a person-led health system based on a heal-deal model. Using multi-morbidity as an example, he pointed out the unsustainability of a system organised around health specialisations, and proposed an alternative model, which emphasises prevention and encourages patients to be active participants in their health.

The final speaker of the workshop, Dr Natividad CUENDE, Executive Director of the Andalusian Initiative for Advanced Therapies, presented the situation in Andalusia, which is the biggest region in Spain yet has one of the lowest GDPs per capita in the country. Dr Cuende explained how Andalusia has put forward a policy on the rational use of medicines, based on the recommendations of the World Health Organisation. She explained how the active use of a hospital exemption for non-industrial manufacturing of Advanced Therapy Medicinal Products (ATMPs) –including cell and therapies, and tissue engineering— has helped the region strike a balance between making its health system sustainable and promoting innovation.

Ms Cabezón Ruiz wrapped up the session by thanking the speakers and audience for participating in a very interesting debate. She reiterated the range of challenges that European health systems face, and the need to consider user experience, the adaptability of business models, and indicators that account for happiness and life satisfaction in debates about the sustainability of national EU health systems. Ms Cabezón Ruiz closed by underlining the need to continue the debate on this topic on behalf of EU citizens.

EU POLICY CONTEXT

Health systems are essential to ensure the wellbeing of EU citizens and can potentially improve labour market participation and productivity. Healthcare is also a key economic sector and a major employer, accounting for 8% of the total European workforce. The EU has recognised the need to build sustainable health systems offering universal access, which are able to harness the sector's potential to catalyse economic growth.

The OECD 'Health at a glance: Europe 2016' report estimated that the EU spends 9.9% of its GDP on healthcare. Health expenditure is projected to continue to increase, mainly due to sociodemographic changes – the ageing population and the subsequent increase in chronic diseases and long-term care needs — as well as the impact of new technologies¹. In addition to the above-mentioned challenges, during the recent years, EU health systems have also been under significant pressure due to the economic crisis².

The EU has recognized the need to reform health systems, while at the same time ensuring universal access to high quality healthcare including medicines³. In 2014, the European Commission set out actions to strengthen the effectiveness and resilience of health systems⁴. In 2015, the Council highlighted the importance of reforming healthcare and long-term systems in order to manage the impact of demographic changes in health systems⁵. More recently, the European Pillar of Social Rights recognized that “everyone has the right to timely access to affordable, preventive and curative health care of good quality”⁶.

New technologies such as genetics and Precision Medicine, 3D printing, robotics and artificial intelligence promise to bring significant solutions to current problems related to the ageing population, the prevalence and incidence of multi-morbidities and chronic conditions requiring long-term care. Precision Medicine aims at increasing the effectiveness of healthcare by tailoring diagnostic, therapeutic or preventive interventions to the needs of individuals or sub-populations of individuals that share common characteristics – such as susceptibility to a particular disease, treatment, or preventive interventions⁷. While the uptake of new technologies has the potential to bring solutions to current and projected problems of health systems, new medicines and technologies also raise multiple questions about financial sustainability and equal access to healthcare⁸.

Health system performance and responses to sociodemographic trends and technological advancements vary significantly across countries⁹. Thus, different countries' experiences

¹ OECD, *Health at a Glance: Europe 2016, State of Health in the EU Cycle* (2016).

² European Commission, *Joint Report on Health Care and Long-Term Care Systems & Fiscal Sustainability* (2016)

³ Council of the European Union, *Council conclusions on the economic crisis and healthcare*, (2014/C 217/02), para. 33

⁴ European Commission, *Communication from the Commission on effective, accessible and resilient health systems*, COM (2014) 215 final.

⁵ Council of the European Union, *Council conclusions on the sustainability of public finances in light of ageing populations*, 12 May 2015.

⁶ Conti, R., Veenstra, D. L., Armstrong, K., Lesko, L. J., & Grosse, S. D. (2010). Personalized medicine and genomics: challenges and opportunities in assessing effectiveness, cost-effectiveness, and future research priorities. *Medical Decision Making*, 30(3), 328-340.

⁷ Gyorffi, Miklos Laszlo (2017) Personalised Medicine – Current Status, EPRS-European Parliament Think Tank, Policy Department A: Economic and Scientific Policy, Briefing, November 2017.

⁸ McClellan, K.A., Avard, D., Simard, J. and Knoppers, B.M., 2013. Personalized medicine and access to health care: potential for inequitable access?. *European Journal of Human Genetics*, 21(2), p.143.

⁹ See Eurohealth, providing performance assessments of health systems for Member States of the WHO European Region. available at: www.euro.who.int/en/about-us/partners/observatory/publications/eurohealth. See also Braithwaite, J., Hibbert, P., Blakely, B., Plumb, J., Hannaford, N., Long, J.C. and Marks, D., 2017. Health system frameworks and performance indicators in eight countries: A comparative international analysis. *SAGE open medicine*, 5, p.2050312116686516.

can provide a basis for identifying good practices that can be used to formulate appropriate recommendations for Member States and promote sustainable health systems.

For example, Japan's remarkable improvement in population health following World War II has been attributed, in large part, to its health system, which promoted preventive public health measures and access to advanced medical technologies through the framework of a universal health insurance system¹⁰. The Dutch health system has been ranked very highly both internationally and amongst European health systems, based on several indicators provided by consumers (e.g. patients' rights, information, accessibility, prevention and outcomes) and current policy discussions have focused on the results of two major reforms since 2006 concerning long-term care and the introduction of a universal health insurance scheme¹¹. In the region of Andalusia in Spain, the health system is being redesigned to place greater focus on primary care and to better meet the needs of patients with multi-morbidities, an increasingly common phenomenon linked to the ageing of the population¹², and the region is also putting emphasis on the rational use of medicines to contain health expenses, including in the area of advanced therapies¹³.

¹⁰ The Lancet published a series on universal health care in Japan in 2011. One of the key papers is as follows: Ikeda, N., Saito, E., Kondo, N., Inoue, M., Ikeda, S., Satoh, T., Wada, K., Stickley, A., Katanoda, K., Mizoue, T. and Noda, M., 2011. What has made the population of Japan healthy?. *The Lancet*, 378(9796), pp.1094-1105.

¹¹ Kroneman, M., Boerma, W., Van den Berg, M., Groenewegen, P., De Jong, J. and Van Ginneken, E., 2016. Netherlands: health system review. *Health systems in transition*, 18(2), pp.1-240.

¹² Román, P., and A. Ruiz-Cantero. "Polypathology, an emerging phenomenon and a challenge for healthcare systems." *Revista Clínica Española (English Edition)* 217, no. 4 (2017): 229-237.

¹³ Cuende, Natividad. "Andalusian Initiative for Advanced Therapies: Fostering Synergies." *Stem cells translational medicine* 2.4 (2013): 243-245.

PROCEEDINGS OF THE WORKSHOP

1.1. Introduction

1.1.1. Welcome and opening

MEP Ms Soledad CABEZÓN RUIZ and MEP Mr Alojz PETERLE, Co-Chairs of the ENVI Health Working Group

Ms Soledad CABEZÓN RUIZ, MEP, opened the event by reminding the audience that health is one of the most important values for European citizens. She mentioned that whilst the economic crisis has presented challenges to European health systems, perhaps new technologies and innovations such as Precision Medicine, could provide new solutions. In announcing the first speaker of the day, Ms Cabezon Ruiz informed the audience that due to a flight cancellation, Professor Clare BAMBRA was unable to attend the workshop, but had provided a recorded version of her presentation.

Mr Alojz PETERLE, MEP, commented that health systems contribute to maintaining and restoring the good health of Europeans, as well as to economic prosperity. Despite the differences between national systems, European health systems share objectives such as the need to focus on patients, the importance of harnessing the benefits of technological innovation, and the critical need to achieve financial sustainability. This diversity across Europe provides an opportunity to identify good practices that can be transferred. Mr. Peterle mentioned that our health systems are becoming more and more difficult to finance, and that with growing resources needed, Member States are also faced with growing fiscal pressures. Mr Peterle announced that the objective of this workshop would be to look at ways to make health systems more sustainable without compromising access and quality.

1.2. Panel I: Main challenges of the sustainability of health systems

1.2.1. Sociodemographic challenges: Aging of the population and Determinants of Health

Professor Clare BAMBRA, Professor of Public Health at the Institute of Public Health at Newcastle University

Professor Claire BAMBRA began her presentation by stating that health inequalities are pervasive within the EU, and exist within countries, regions and even neighbourhoods. To illustrate this point, she pointed to the gap between countries of Europe's East and West, and countries of the North and South of Europe, which can differ significantly in measurements such as death rate and life expectancy.

Prof. Bambra described the differences between European countries in the aging of the population by providing data showing, for instance, how there was a larger proportion of older people in northern Spain and Scotland than in other European regions. She continued by illustrating the difference in the aging of population within regions using examples from England and Germany. In England, people from the rural areas in the North are on average older than people living in the core of England, closer to London; in Germany, the population in the East is older than that of the West. Moving to the local level, Prof. Bambra explained that differences are also identifiable between neighbouring areas in the same

city, pointing to examples from Berlin, London and Paris. These health inequalities across countries, and within countries and neighbourhoods have increased over time since the 1980s.

After presenting the geographical inequalities in health and in the aging of population in Europe, Prof. Bambra moved to addressing the causes of those differences, identifying several factors: unemployment, healthcare services and housing, education, work, environment and health behavioural factors such as smoking or drinking alcohol.

Prof. Bambra explained that while the social determinants of health can explain inequalities, politics and public policy also play a role in causing and addressing them. She highlighted the role of health decision-makers on public health policies and health systems and recalled that healthy public policy has been a focus for the European Commission, with reports produced on health inequalities in the EU, and for the WHO Europe Region. Prof. Bambra stressed the role that the European Social Charter can have in helping to address health inequalities and issues related to the aging of the population.

Prof. Bambra continued her presentation by showing examples of how key policy changes have been able to reduce health inequalities. The first example concerned regional health inequalities within a country, focusing on the situation in Germany before and after reunification. Data shows that the gap in life expectancy for women living in the East and women living in the West was four years just before reunification; by 2010 it had completely closed. This improvement was largely due to health system changes, the introduction of good pension provisions for older women, and better nutrition. She said that the example shows that it is possible to reduce regional health inequalities thanks to sustained governmental action.

The second example focused on the English health inequality strategy (1997-2010) and showed how neighbourhood health inequalities can be tackled through policy actions both in the healthcare sector and in other connected social sectors. Data shows that the gap in life expectancy between men and women living in the poorest 20 % of neighbourhoods and the average of the rest of the population closed over time. Professor Bambra explained that this was due to several different changes within the health system, but also to investments in housing services within multi-tier neighbourhoods, the introduction of the minimum wage, and the allocation of additional benefits available for people in poverty.

Widening her scope, Prof. Bambra explained that Europe is affected by significant inequalities in health and in the aging of the population within and between countries, within regions, and between neighbouring areas in cities.

She underlined that health inequalities have a significant cost for the EU, estimated at EUR 980 billion per year, which is the equivalent of 9.4% of GDP. Moreover, unequal aging also poses challenges to health systems and welfare systems, particularly when thinking about pension age in relation to life expectancy.

Prof. Bambra concluded her presentation by reminding the audience that while these health inequalities are influenced by social determinants, they can also be influenced by public policies and can therefore be reduced. Such a reduction requires policy cohesion across different sectors, which touch the wider social policy issues such as those enshrined within the European Social Charter.

At the end of Prof. Bambra's presentation, Mr. Peterle addressed the audience to mention how "inequalities has become a key word repeated in the European Parliament". He explained that while there have been health inequalities in all times and places, "in a Community or Union that aims at improving the situation, the increase in inequalities should raise an alarm". Mr. Peterle said he was pleased to hear that inequalities can be reduced, and that whereas the language used by a professional is that "inequalities can be reduced", for a politician this means that 'inequalities should be reduced'. Next, Mr. Peterle announced the next speaker, co-chair Ms Cabezón Ruiz, who would give a presentation about how new technologies and the issue of access to medicine can affect the sustainability of health systems.

1.2.2. New Technologies and Access to Medicines

Ms Soledad CABEZÓN RUIZ, MEP, co-chair of the Health Working Group

Ms CABEZÓN RUIZ began her presentation by explaining that while it was unusual for a co-chair to also be a speaker, she would be sharing her experience as Rapporteur of the EP Report on EU options for improving access to medicines in the EU, and also her current work on the European Health Technology Assessment proposal.

Ms Cabezón Ruiz opened her presentation by highlighting the increasing trend in health expenditure, which amounts to 15% of total public expenditure in OECD countries, and has followed an increasing pattern of more than 70% since 1990. She mentioned that while in 2014 health expenditure represented 6% of GDP, it is projected that by 2030 it could represent 9% and by 2060 14%. Ms Cabezón Ruiz explained that an ageing population and innovation are the main drivers of this increasing trend and are currently challenging the sustainability of health systems.

Next, Ms Cabezón Ruiz presented a figure showing how this projected increasing trend in expenditure in health and long-term care will affect EU countries. More than asking why we need to reform health systems, she suggested that we need to ask why we need to maintain the health systems of European member states.

To answer this question, Ms Cabezón Ruiz, firstly highlighted the quality and efficiency of European health systems, which have made significant contributions to improvements in life expectancy (about 1 year since 1990), the reductions of inequalities, and to increasing productivity and growth. She mentioned that a return of about EUR 4.30 is estimated for each euro invested in health.

Secondly, she mentioned the importance of principles such as universality, equity and quality of health systems, which are key for EU health systems. Ms Cabezón Ruiz explained how the economic crisis has contributed to focusing the political debate only on controlling health expenditures and warned against this narrow approach. To illustrate the point, she used the example of a 2015 study by FRA, which estimated that the costs of breaking the principle of universality of healthcare for migrants was higher than those of maintaining the core principles of European health systems.

Ms Cabezón Ruiz explained how the need for reform stems out of the inadequacy of current health systems for addressing these challenges. While the contribution of health systems to health is important, other health determinants, including education and socio-economic status, also contribute to health outcomes. Furthermore, she highlighted the importance of challenges such as an ageing population, the increasing need for long-term care and the increasing burden of chronic diseases. Lifestyle factors including tobacco and alcohol consumption, and other health determinants such as air pollution, are increasing the

burden of chronic diseases, and health systems need to address these challenges. She noted that while investing in health prevention and promotion could help to address these challenges, only 3% of current health expenditure is currently being invested in health prevention and promotion in Europe.

Ms Cabezón Ruiz continued by illustrating how this increasing burden of chronic diseases – around 86% of deaths in the EU are caused by chronic diseases, including cardiovascular diseases, cancer and chronic respiratory diseases – imposes important new challenges for health systems. She also mentioned how chronic diseases disproportionately affect low income people, further exacerbating health inequalities, and are increasing the need for long-term care: it is estimated that around 30% of the population in OECD countries currently require long-term care.

Next, Ms Cabezón Ruiz explained that another important challenge for the sustainability of health systems is access to medicines and new medical technologies. She mentioned that around 17% of health expenditure, corresponding to approximately 1.41% of GDP, are due to pharmaceuticals, and that in the EU, pharmaceutical expenditure is expected to grow by up to 7% in the next five years.

In parallel with this trend, Ms Cabezón Ruiz noted that most of the new medicines being authorised are high-priced but incremental innovations rather than breakthrough ones. Along with high prices, she also mentioned the problem of increasingly unmet needs. For instance, the absence of new antibiotics poses a major public health problem due to the emergence of antibiotic resistance. She mentioned that it is calculated that antibiotic resistance could cause at least 25000 deaths per year. In other areas, such as rare diseases, special incentives built into regulation help overcome the problem of low investments from the private sector. While this has led to an increasing number of medicines being developed, the high prices of these medicines (around 150000 EUR per patient) are also contributing to growing expenditure. Lastly, she mentioned that with Precision Medicine, many new cancer medicines have been developed. Most of these new medicines are also expensive yet show a limited impact on the life expectancy of patients. All these trends signify further challenges for health systems.

Ms Cabezón Ruiz concluded her presentation by reflecting on the different measures that could be enacted both at EU and national levels to increase the sustainability of health systems. Nationally, there are fiscal and budgetary-control measures. Beyond these, she mentioned how the next panel will discuss Japan and other successful examples of health reform. Ms Cabezón Ruiz explained that one key aspect of health reform in Japan was to emphasise health prevention and promotion, a more patient centred system, and a further emphasis on primary care which would address the important increase expected in the ageing population of Japan.

Ms Cabezón Ruiz continued by referring to the 2016 European Commission Report of the Expert Panel on Effective Ways of Investing in Health, and the necessity to address the unmet needs of the population in different European countries. At national level, fiscal measures can be taken to contain costs, although they will not necessarily address health inequalities. As was said in the previous presentation, inequalities between and within countries must be tackled.

At the EU level, Ms Cabezón Ruiz mentioned clinical trials, health prevention and promotion, intellectual property policy, research and innovation, and the concept of one-health as key areas where the EU has wide competences to support the sustainability of health systems. She mentioned how the EU could further contribute to improving the sustainability of health systems and how a Parliament report suggested that the EU could adopt further legislation with a view to ensuring a more consistent approach.

Ms Cabezón Ruiz explained that the EU could further contribute through the Health Technology Assessment (HTA) proposal, to ensure that value of new medical interventions improves the quality of innovation while contributing to health system sustainability by incentivizing real innovations over incremental innovation.

Ms Cabezón Ruiz closed her presentation by mentioning that the EU can also contribute in the area of research and development. With Europe having one of the biggest publicly-funded programs for research and innovation, it must ensure that investments are addressing the most important needs and contributing to reducing inequalities and increasing access to medicines and new technologies. Finally, she mentioned how big data also shows the need for the EU to consider the interface between the public and the private, with emphasis on the public use of data needed to ensure the sustainability of research and health systems.

Mr. Peterle closed the session by sharing his recent visit in Japan, in which it was decided that health would be included as one of the key areas for cooperation between Japan and the EU.

1.2.3. Genetics and Precision Medicine

Professor Barbara PRAINSACK, Professor at the Department of Political Science, University of Vienna and Professor of Sociology at King's College, London

Professor Barbara PRAINSACK began her presentation by defining Precision Medicine (PM). PM has been mainly seen as a cost driving and technology driven practice that would increase health inequalities. Professor Prainsack explained that PM could be a key for sustainability, but if it is to be used to this end we need to rethink the very term of personalization and precision medicine.

Before entering further into the question, Professor Prainsack made some clarifications about the terminology. Firstly, the way in which we are currently using the term PM, does not merely mean that a person is at the centre of the care provided by doctors or clinics. PM has been used in the current sense after the Human Genome Project sequenced the human genome at the beginning of the 2000s, Personalized medicine was defined by the fact that for the first time, there was the possibility to personalize drug treatments and create drugs that would better cure individuals sharing the same genetic markers.

Professor Prainsack explained that nowadays, PM has evolved from the previous concept of "Personalized Medicine" to encompass the collection and use of and all the individual patient information (e.g. genome, microbiome, and information related to lifestyles) and integrate them to create a map that gives the possibility of predicting when people will have a health problem. The reason why we talk about a shift from Personalized Medicine to Precision Medicine is that although the genome is still a component, it is now part of a bigger orchestra which also includes the consideration of individual characteristics in health prevention, diagnostics, treatment and monitoring.

Professor Prainsack continued her presentation by showing the key promises of PM. Firstly, PM uses a systematic and multi-omic approach, meaning that the focus is not on one specific organ or on the DNA, but on the whole person; secondly, PM is aimed at closing the actionability gap between evidence-based medicine and individual patients, meaning that it helps decide which treatment will work for a specific patient; thirdly, PM promotes a departure from symptomatic and "episodic" medicine to continuous and pre-symptomatic

medicine, through the longitudinal comparison of patients at the point of health, but also at the point of disease.

The second part of Professor Prainsack's presentation focused on proposing some conditions that could facilitate the use of PM to increase the sustainability of health systems. The first measure would be to improve data governance. Currently we are missing data on certain population groups and on individuals. As to population groups, Professor Prainsack stressed that human genome data available is mostly linked to a narrow ethnic group that has been over-studied over the years while entire populations are missing from genomic studies. At the individual we are also limited to data recorded by doctors while many aspects of individual's lifestyles (so called "social biomarkers") are not collected despite having huge impacts on health outcomes. Professor Prainsack underlined that in connection with this need of data there is a strong need of data protection, which must be accompanied by a new system of data governance, a legal framework for data accountability and a better harm mitigation system.

The second measure would be to insert health in all policies: our healthcare systems in the narrow sense account only for some proportion of the health outcomes. We need to think about housing policies, welfare, future of work and the reduction of inequalities as health policies.

The third measure is reducing harm and waste. The traditional idea that PM makes everything to be more expensive is not true. There are already mechanisms to reduce waste: important initiatives promoting low-cost interventions such as the "preventing over-diagnoses" movement, or the realistic medicine initiative. These show that by rewarding healthcare practitioners and by focusing on listening to people we would be able to reduce unwanted low-value interventions and reduce waste and cost. In this perspective we should also systematically explore low-tech and high-touch practices and their effects, which is currently not a big enough part of the conversation on PM.

1.3. Panel II: Experiences of reforms of health systems for the sake of sustainability

1.3.1. Healthcare System Model of Japan

Dr Akiko MAEDA, Senior Health Economist at the Organization of Economic Co-operation and Development (OECD)

Dr MAEDA began by comparing Japanese performance in healthcare to other countries in the OECD. Japan continues to lead in achieving good health outcomes, she noted. In 2015, Japan had the longest life-expectancy amongst OECD countries, at an average of 83.9 years, and the lowest obesity rate, just 3.7% compared to an OECD average of 19.4%. Heart condition is also very good with a low Ischemic Mortality rate (34.1 for 100,000 people in 2015), and while smoking rates were still near the average, they are decreasing. Japan has also good access to healthcare, low out-of-pocket payments, relatively high cancer survival rates and, a good quality primary care.

Nevertheless, Dr Maeda noted that although health outcomes are improving, challenges remain. In a society known for its ageing population, dementia prevalence is high, with 2.3% of the population afflicted in 2017. Suicide rates are also significantly above OECD

average, although they have decreased from a historic high in 1998. She said that this has been linked to stress at work, and that the issue has been taken up by the Japanese Parliament as a serious problem.

Moving on to what Dr Maeda called the 'big items', she highlighted the high per capita spending on health, high capital investment in the health sector, and a lack of efficiency in the use of hospitals. This is demonstrated by the high number of hospital beds: long-term care is often done in hospitals, accounting for a much higher average of total hospital spending (11% in Japan vs. 4% in OECD countries)

Moving into more detail on Japan's very high capital investment rates, Dr Maeda observed that whilst some investment goes to valuable areas such as stem-cell or cancer research, an important part is spent in less productive areas. She used the example of the high density of Computed Tomography (CT) scans, which, whilst being useful for diagnostics, do not often add value in terms of treatment. Dr Maeda said that she hoped that discussion between the EU and Japan could help to find solutions for business plans that direct investments into the right places.

Dr Maeda continued by noting that Japanese spending per capita is above average in the OECD but by no means the highest, especially considering the large number of elderly people in the population. She said that the key problem for Japan is that it is paying for its healthcare through debt, and that this has gone on for two decades with the result of a government debt of over 200% of GDP. She noted as problematic that discussions about funding healthcare through debt mostly focus on cutting back benefits and increasing co-payments.

Having assembled this tableau of the current state of the Japanese health system, Dr Maeda asked how Japan's Vision 2035 could meet current challenges. As she had already indicated, tackling fiscal deficits and ensuring economic stability are priorities. Growing healthcare needs, changing social environments, increasing inequities, globalization --and the effects that this brings, such as health tourism—are problematic. She explained that Japan also wishes to consolidate its position as an authority on healthy longevity and is reaching out to the EU and others with a view to sharing Japan's successes, although this initiative is still in its early stages.

Dr Maeda explained that the Japanese government wants to do this by investing in multi-sectoral projects. This would entail creating an urban infrastructure that is conducive to multi-generational living, enhancing social connectivity and making medical care services, social services and long-term care more coordinated. She said that the government also wants to use investments in care services as a way to create quality employment and breathe new life into local communities.

Continuing on this same theme, Dr Maeda described the five types of investment at community level that the government would like to introduce to promote integrated care. These include healthcare, long term care and social services, but also housing and preventative care, meaning infrastructure and design of a system to promote wellbeing.

Bringing her presentation to a conclusion, Dr Maeda stated that Japan wants to transform healthcare into a horizontal system that engages all sectors through shared vision and values, rather than maintaining the current system through increased cost-sharing and cutting benefits. She said that while this is what most governments are doing, Japan would

like to change the paradigm. Complementing this, Japan wishes to invest in innovation, in order to maintain excellence in health in fields including stem cell research, cancer research, internet of things and robotics. Some of this research, for instance, making robotics useful for healthcare, would require an intense discussion on ethics. Dr Maeda closed her presentation by saying that she hopes that Japan and the EU will have the opportunity to talk about these values, as well as technology and economic growth.

1.3.2. Health System in the Netherlands

Dr Thomas PLOCHG, Director of the Netherlands Public Health Federation

Dr Plochg started his presentation by saying that he wanted to talk about the transformative change that is emerging in the Netherlands. The two messages that he wanted to impart to his audience were that a sustainable healthcare system required thinking outside of the box, and that this would lead to a person-led heal-deal health support system that complements the professional-led cure-care system.

Dr Plochg noted that the Netherlands performs very well in international rankings on health. This is due to competition between healthcare insurers and healthcare providers, good access to healthcare, good quality of care and consumer choice, amongst other things. But he said that with growing costs and fiscal pressures, the current system is not sustainable. He noticed that while this debate is happening now, and it is improving performance 'in the box', we also see that transformative change is needed 'outside the box'.

Using multi-morbidity as an example, Dr Plochg explained what was wrong with the organisation of the Dutch healthcare system. The current system is very successful at treating acute, single diseases, which creates a vacuum where multi-morbidity comes in. He explained that this style of healthcare system is unsustainable by design because 10-20 specialists are organised around one patient, while 70% of costs are related to staff. He said that we make the error of thinking that all of this different expertise will add up to coherent diagnosis and treatment, but this is clearly not the case.

Instead, according to Dr Plochg, the Dutch health system must be aligned with the values of the Dutch population. While the current attitude of the system is very reactive --waiting for people to be sick before doing something-- he said that it must be more proactive by using tools such as health prevention, health promotion and PM as described by Dr Prainsack. Along with this, he explained that a 'zoom out' vision of the system is needed, in order to have a more holistic, integrative view of health. Finally, he explained that health systems have made patients passive, whereas they should be more active and have a role in coproducing their health. Implanting this change is difficult, he said, but it is on the agenda in the Netherlands, and Dr Plochg in his role as Director of the Netherlands Public Health Federation is pushing it. We are seeing the early signs of change through appearances in policy reports.

To demonstrate the change that is happening in the Netherlands, Dr Plochg pointed to two areas: the concept of 'positive health', and the development of business models for health. He cited the article 'How should we define health?' by Machteld Huber which defines positive health as 'the ability to adapt and self-manage in the face of social, physical and

emotional challenges'¹⁴. He paraphrased this as saying that at the moment with 'cure and care', life is extended to be as long as possible, when in fact health systems should target a different type of value, where joy is prioritised, and death is embraced in the end. He said that this idea is resonating with the Dutch population and health professionals, where implementation experiments with GPs and in hospitals have resulted in significant decreases in referrals for treatment.

Moving onto the second area, the development of business models, Dr Plochg said that currently healthcare business models are based on disease, and that instead, they should be more focussed on health. He used Spotify as an example for a healthcare business model, in that it sells a long-term relationship, selling access to the value of music. It could be possible to use a similar subscription-style service for health. Having said that, he acknowledged that this business to consumer health relationship already exists. The major technology companies are already building business models to help people stay healthy. He had two major observations about this: that their users are essentially the product, and that this approach with health data is very dangerous; and that if there are losses, the burden of payment is placed on society rather than the private company, so public interest needs to be safeguarded.

Dr Plochg concluded by referring back to his vision for a person-led heal-deal system that will not disrupt the current system but complement it. He said that his hypothesis is that a similar change is happening in other countries, and that in other countries with less developed systems it may be easier to implement the change. He finished by saying that the European Union must safeguard the public interest in health from private and commercial interests.

1.3.3. The Andalusian Health System

Dr Natividad CUENDE, Executive Director of the Andalusian Initiative for Advanced Therapies

Dr CUENDE began her presentation by comparing the size of the area and population of Andalusia in to those of other countries of the European Union, noting that it has roughly the same number of people as Austria. She said that she would focus her presentation on a particular area of the Andalusian health system, their drug policy, and how this is making the system sustainable and facilitating access to innovation.

Giving some statistical context for the region, she noted that Andalusia is among the European regions with the lowest GDP per inhabitant and with the lowest number of hospital beds, but, with a very high life expectancy. Regional governments in Spain are almost solely responsible for public expenditure on health, with competences on legislation, planning, delivery and funding whilst also being the owner of most hospitals. Comparing Andalusia to other regions of Spain, she explained that Andalusia spent a higher than average percentage of GDP on healthcare, but with the lowest healthcare expenditure per capita.

Dr Cuende then began talking about the policy background to Andalusia's attempts to maintain the sustainability of its system, mentioning a law that is currently being finalised: the 'Law on Guarantees and Sustainability of the Andalusian healthcare system'. Article 14

¹⁴ Huber, M., Knottnerus, J. A., Green, L., van der Horst, H., Jadad, A. R., Kromhout, D., ... & Schnabel, P. (2011). How should we define health? *BMJ: British Medical Journal (Online)*, 343.

of this law, on the rational use of medicines, reinforces a policy implemented in Andalusia since 1992. This policy is based on two measures: promoting appropriate medicine prescription and encouraging competitiveness among pharmaceutical companies. The latter is achieved through prescribing by active substance (rather than brand), the use of more efficient therapeutic alternatives, and public bids for the selection of the brand of medicines that pharmacists will use when dispensing by active substance.

Pointing to a graph, Dr Cuende explained that this policy had led to 93.4% of medicines being prescribed by active substance in 2017, which in turn had led to Andalusia's hospital pharmaceutical spending per capital being the lowest in Spain, far below the Spanish average. Zooming out to a global level, she described how the OECD also recognised the importance of access to innovation for ensuring health system sustainability. She mentioned the use of a monopoly for a drug treating Hepatitis C by drug company Gilead to recoup 25 times its initial investment in R&D in less than two years, which she called immoral.

Dr Cuende then shifted the focus of her presentation to Advanced Therapy Medicinal Products (ATMPs), which include cell therapy, gene therapy and tissue engineering. She noted that ten ATMPs have been granted market authorisation in Europe, and that average price is 500,000 EUR. This very high price is partly due to the complexity of the technology and partly due to the need to comply with an intricate web of legislation to which ATMPs are subject. As most ATMPs share several characteristics with transplants, they need to comply both with the specific ATMPs regulation as well as with the human tissues and cells legislation. She said she believed that this is the justification for a hospital exemption clause, which allows Member States to regulate non-industrially manufactured ATMPs. Spain has become a leader in the ATMP sector through the public sector, with hospitals regulated as an alternative to marketing authorisation, but only with ATMPs meeting the same standard as commercial medicines.

Dr Cuende introduced her organisation as being publicly funded by the regional government of Andalusia, promoting R&D and coordinating the provision of regenerative medicine treatments in the public health system. It supports researchers and small enterprises in clinical development and has a network of laboratories producing ATMPs. Dr Cuende said that a key element of its work is coordinating a network that includes hospitals, the Spanish Medicines Agency, the Transplant Coordination and other institutions to provide patients with ATMPs through clinical trials under compassionate use or through the hospital exemption. She noted that Spain is the leader in Europe of clinical trials in ATMP, and the Andalusia health system is the only one in Europe acting as ATMP manufacturer, clinical trial sponsor, healthcare provider and funding entity.

In her conclusion, Dr Cuende underlined the potential for improving health system sustainability through a policy of rational use of medicines and finding mechanisms that make innovation and financial sustainability compatible. She said that commercialised ATMPs are some of the most expensive medicines and therefore very challenging for sustainable health systems. But ATMP manufacturing requires several procedures that are identical to those of cell and tissue donation and transplantation, in which health systems have experience.

The 'hospital exemption' for non-industrially manufactured ATMPs in the EU legal framework represents an opportunity to make industrial interests compatible with the interests of health systems and lead ATMP manufacture from the public sector, as in

Andalusia, therefore improving patient access to ATMPs. Dr Cuende finished by saying that the pharmaceutical and biotechnological sector should not be defended at the expense of health system sustainability. She said that a balance between both interests must be found, which protects health systems from the costs arising from monopolies on certain innovative drugs.

1.3.4. Questions and Answers

Ms Cabezon Ruiz opened the floor to discussion.

Professor Prainsack asked Dr Plochg to clarify his example comparing healthcare systems and Spotify. Professor Prainsack argued that Europeans should be proud that their healthcare systems are not things that need to be sold, whereas Spotify uses our data and wants to sell something to us. Dr Plochg replied that he used the Spotify example because Spotify does not sell a product or a service, but a long-term relationship. Of course, health cannot be bought; the only customer of public health is government, but new technologies are facilitating a market where health can be sold. In this context, he argued, we must ensure that these new business models are inclusive and support the public interest.

Next, Dr Akiko asked Professor Prainsack how Precision Medicine (PM) and the high-touch and face-to-face approach can work together. She said that she shared the view that high-touch can be highly sophisticated and can go hand-in-hand with high-tech. Professor Prainsack agreed with this assumption and reaffirmed that high-tech is not necessarily incompatible with high-touch. High-touch elements should be used in a systematic way and should be brought into decision making. PM creates systems within healthcare systems where different professionals learn from each other through the combination of the two approaches.

Ms Simone MOHRS from the European Hospital and Healthcare Employers' Association asked Professor Prainsack how and where she can see PM taking place and how she sees the actual transition to PM in the healthcare setting. She also asked how feasible and affordable this transition would be. Finally, Ms Mohrs asked what changes are needed at local level and in the education of healthcare professionals. Professor Prainsack replied that this depends on the way we understand PM: if there is a narrow understanding of PM, the change can easily take place inside hospitals; if there was to be a broader understanding of PM – meaning integration of care and of different types of care – PM needs to start outside the hospitals, with prevention, social policies and then a political decision would be needed to invest resources. Moreover, we would probably need a new specific profession that creates a bridge between the collectors of data and healthcare professionals.

Ms Mohrs asked if this role can be played by health informatics and Professor Prainsack reaffirmed that what we would need is somebody who can really do the interface by translating aggregated data into individual treatments. Dr Plochg added that the professionalization of health workers has become a synonym of specialization, which is against the vision for the future of health systems in the Netherlands, which he explained during his presentation. He further argued that this trend should be reversed.

Finally, Mr Peterle said that he considered that discussions had been conceptually rich and that he liked the accent on thinking out of the box. He noted that, as explained by the speakers, equality is certainly a political keyword, but he remarked that prevention is also.

Particularly, he noted that when thinking about prevention with an “in the box” approach, prevention is not seen as an economic category, while when thinking “out of the box” we can identify what it means to invest in prevention. With this view, he asked the speakers how prevention can be sold.

Dr Akiko replied that we need to move away from the negative perception that the concept of “prevention” has; politicians should talk about creating joy, about social connections and on how to create policies for a better life and not a longer life in misery. He argued that this is the real core of human beings and could help in promoting prevention as a positive thing. Dr Plochg also noted that there is a high demand of health as a value and people want to invest in this, but he is unsure how it can be targeted in such a way that it is possible to make a business out of it; perhaps through a public-private collaboration. Professor Prainsack affirmed that from a practical point of view we can foster the idea of life lived-well by changing incentives in healthcare systems, maybe through value-based reimbursement.

1.3.5. Closing remarks by the Chair

Ms Cabezon Ruiz thanked the speakers for their contributions and closed the workshop underlining the new challenges of using new technologies and of developing new business models in order to ensure that the focus would be on health prevention and on the reform of national healthcare systems.

ANNEX 1: PROGRAMME

Workshop

Sustainability of Health Systems

**Tuesday 15 May 2018 from 10.00 to 12.00
European Parliament, Brussels**

AGENDA

Co-Chairs: Ms Soledad CABEZÓN RUIZ (MEP) and Mr Alojz PETERLE (MEP)

10:00 – 10:05 Opening and welcome by the co-chairs Ms Soledad CABEZÓN RUIZ (MEP) and Mr Alojz PETERLE (MEP)

Panel 1- Main challenges of the sustainability of health systems

10.05 – 10.15 Sociodemographic Challenges: Aging of the Population and Determinants of Health
Prof. Clare Bambra, Professor of Public Health at the Institute of Public Health at Newcastle University

10:15 - 10:25 New Technologies and Access to Medicines
Ms Cabezon Ruiz, MEP, co-chair of the Health Working Group

10:25 – 10:35 Genetics and Precision Medicine
Prof. Barbara Prainsack, Professor at the Department of Political Science, University of Vienna, Austria, and Professor of Sociology at King's College London

10:35 – 10.50 Questions & Answers

Panel 2 – Experiences of reforms of health systems for the sake of sustainability

10:50 – 11:00 Introduction to Panel 2 by the co-chairs Ms Soledad CABEZÓN RUIZ (MEP) and Mr Alojz PETERLE (MEP)

11:00 – 11:10 Healthcare System Model of Japan
Dr Akiko Maeda, Senior Health Economist at the Organisation for Economic Co-operation and Development (OECD)

11:10 – 11:20 **Health system in the Netherlands**
Dr Thomas Plochg, Director of the Netherlands Public Health Federation (NPHF)

11:20 – 11:30 **The Andalusian Health System**
Dr Natividad Cuende, Executive Director of the Andalusian Initiative for Advanced Therapies

11:30 – 11:40 **Questions & Answers**

Closing Session

11:40 – 12:00 **Conclusions and closing by the co-chairs Ms Soledad CABEZÓN RUIZ (MEP) and Mr Alojz PETERLE (MEP)**

ANNEX 2: SHORT BIOGRAPHIES OF EXPERTS

Professor Clare BAMBRA

Clare BAMBRA PhD is Professor of Public Health in the Newcastle University Medical School and Associate director of Fuse: the Centre for Translational Research in Public Health. She also leads the EU-Norface funded project HiNEWS – Health Inequalities in European Welfare States. Her research focuses on understanding and reducing health inequalities within and between countries with particular regard to the effects of social and healthcare policies. She has published extensively including *Health Divides: Where you live can kill you* (Policy Press, 2016).

Soledad CABEZÓN RUIZ, MEP

Soledad CABEZÓN has been a socialist member of the European Parliament since 2014, is member of the Committee on Environment, Public Health and Food Security, member of the Petitions Committee, and substitute member of the Committee on Industry, Research and Energy. She has a degree in medicine, a Master's degree in Health Law and has worked as a cardiologist at the Virgen del Rocío University Hospital in Seville, where she served until her election as deputy in the 2008 elections. Between 2003 and 2011, she was the mayor of Albaida del Aljarafe and Federal Secretary of Equality between 2008 and 2012. She is one of the most active and enthusiastic MEPs in health files. Since the beginning of her mandate in the EP she has been very committed with patients affected by the Hepatitis C virus and their treatment, pushing for an EP Own-initiative report on improving Access to Medicines, of which she was the rapporteur. This work has been determinant on compelling European Commission on a Health Technology Assessment (HTA) proposal and on the review of health R&D incentives. She is a currently the rapporteur of the HTA proposal.

As a politician and as a cardiologist, she is also very committed to Thalidomide victims. More than 50 years after the biggest health disaster in Europe, her efforts to encourage the EU to recognise more Thalidomide victims are well known. She is also a fierce defender of the European health systems as one of the values most appreciated by European citizens and as the most important basis of the EU social pillar. Working on R&D is also her priority, asking for reinforcing health research not only to fight against current threats but also to allow all citizens to access R&D results. She has also been involved in the opinion on Antimicrobial Resistance (AMR), putting all her commitment and efforts into a global strategy to combat AMR. Currently she co-chairs the Health Intergroup.

Professor Barbara PRAINSACK

Barbara PRAINSACK is a Professor at the Department of Political Science at the University of Vienna, and at the Department of Social Science, Health & Medicine at King's College London. Her work explores the social, regulatory and ethical dimensions of biomedicine and bioscience. Her current research projects focus on personalised and "precision" medicine, on citizen participation in science and medicine, and the role of solidarity in medicine and healthcare. Her latest books include: *Personalized Medicine: Empowered Patients in the 21st Century?* (NYU University Press, 2017); *Solidarity in Biomedicine and Beyond* (with Alena Buyx, Cambridge University Press, 2017), and *Genetics as Social Practice* (ed. with Silke Schicktanz and Gabriele Werner-Felmayer, Routledge, 2014).

Barbara is a member of the Austrian National Bioethics Committee advising the federal government in Vienna, the European Group on Ethics in Science and New Technologies advising the European Commission, and she chaired the European Science Foundation's (ESF) Forward Look on Personalised Medicine for the European Citizen (2011-2012, with Stephen Holgate and Aarno Palotie). She is also a member of the British Royal Society of Arts, and an elected foreign member of the Danish Royal Academy of Sciences and Letters.

Dr Akiko MAEDA

Akiko MAEDA is a senior health economist at the OECD, where she currently leads projects on health workforce policies for the OECD member states. She has over 25 years of experience in international development with various UN agencies and development finance institutions. Dr Maeda has managed investment projects and advised governments on health policy reforms and health sector investment strategies in over 30 countries in the Middle East & North Africa Region, Asia and Europe. Before joining OECD, Dr. Maeda held positions as lead health economist and manager at the World Bank. She also served in various field positions with the Asian Development Bank, UNICEF and UNDP. Dr. Maeda has a Ph.D. in Health Economics from Johns Hopkins University; and MA in Biochemistry and Molecular Biology and a second MA on Political Economy of the Middle East from Harvard University.

Dr Thomas PLOCHG

Thomas PLOCHG combines policy and academic work. He holds positions both as the director of the Netherlands Public Health Federation (NPHF) and as an assistant professor at the department of Public Health at the University of Amsterdam's Academic Medical Centre. As director of the NPHF he governs a health network of approximately 70 public and private organisations whose mission is to shift the healthcare systems' focus to the upstream of health problems. Currently, key focal points are the National prevention agreement, and the development of business models for health (rather than disease). As an academic, he gives classes in medical and public health curricula as well as participating in various research projects. His main expertise and interest is in the sustainability of healthcare systems. Within this broad topic, his research focus is on the reconfiguring of the health profession to obtain health professionals that are fit for purpose in the 21st century.

Dr Natividad CUENDE

Dr Natividad CUENDE has been the Executive Director of the Andalusian Initiative for Advanced Therapies (AIAT) promoted by the Regional Government of Andalusia, Spain, since its creation in 2008. (AIAT is a publicly-funded organisation fostering both cell and gene technologies and therapies, and which coordinates the provision of regenerative medicine treatments within the Andalusian Public Healthcare System. AIAT is playing a major role in Spain's European leadership in the clinical development of cell-based therapies). She is the Director of the International Master's Degree in Manufacturing of Advanced Therapy Medicinal Products and has published more than 150 scientific and technical publications. She has been the Chair of the European Legal and Regulatory Affairs Committee of the International Society for Cellular Therapy since 2014 and she also participates in several scientific committees and in multiple expert working groups. She has also been the Deputy Director of the Andalusian Transplant Coordination since 2005 and previously worked at the National Transplant Organization for over seven years. After six years as a resident physician at different hospitals, she qualified as a specialist in Family and Community Medicine as well as in Preventive Medicine and Public Health.

This report summarises the presentations and discussions of a workshop on sustainability of health systems, held at the European Parliament in Brussels on Tuesday 15 May 2018. The aim of the workshop was to provide background to facilitate information exchange between health system experts and members of the ENVI Committee on the challenges and opportunities related to the sustainability of European health systems.

The first part of the workshop focused on challenges to health system sustainability. Presentations looked at the sociodemographic challenges such as the aging of the population and the social determinants of health, at the impact of new technologies and access to medicines, and at the emergence of genetic and precision medicine.

The second part of the workshop brought together different experiences of health system sustainability, looking at how the health systems of Japan, the Netherlands and Andalusia have adapted and are adapting to challenges to their sustainability.

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