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European Health Forum Gastein 2016



➤ Demographics and Diversity in Europe: New Solutions for Health

- Inter-culturally competent health care
- Health literacy
- EU policies to aid innovation
- Dementia challenges
- Life-course approach and intersectoral action
- Life-course vaccination
- Innovation and patient benefit
- Hearing loss
- Health priorities of Slovak EU Presidency
- Refugees and German hospital care
- Big data for health services research

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DEMOGRAPHY, DIVERSITY, DEMOCRACY, SOLIDARITY, SECURITY ... AND HEALTH

Once again the theme of this year's European Health Forum Gastein touches upon the very core of current European policy debates. Many of the events that are now dominating the news relate in one way or another to demographic change and increasing cultural and socio-economic diversity in our societies. Our steadily ageing population is combined with growing migration flows. This, together with the aftermath of a financial crisis that not only hit our economies hard but also severely shook trust in our political and financial institutions, is creating dangerous waves of insecurity and fear on which several populist politicians are surfing and which may even threaten our fundamental values of solidarity and democracy.

For some time now many pundits have begun to spell the doomsday of European welfare states, arguing that demographic ageing would make them unsustainable. Now, with increasing pressure coming from the economic downturn and global migration, the political argument even risks moving from the feasibility to the desirability of solidarity. Often spurred on by vested political interests who are keen to demonstrate – and overstate – the failures of the welfare state, the abuses by beneficiaries, as well as the high tax burden that goes with it, several countries have started to cut down on their “overly generous” social benefits amidst fears that they may attract more refugees or migrants.

Even though there is good evidence to show that high levels of social protection actually strengthen the ability of our society to face the challenges ahead,

and that mobility and inflow of young people from the East and South will be necessary to rejuvenate our labour force and sustain our economies, we seem to have had only limited success in persuading policy makers, let alone in swaying public opinion. This has not only to do with perceptions and preconceived beliefs, often inflated by some media, it also relates to the conception of society and the way its underlying values and policy goals are implemented. It reveals a lack of unity and identification with other groups, primarily stemming from a feeling of “disenfranchisement”. This is where diversity becomes division. When the so-called middle-class reads about Panama papers, fiscal paradises and tax evasion by the rich and the large corporations, they fear they will be left with paying an ever-increasing bill for social welfare. At the same time the more deprived groups who were already badly hit by the

recession and who have not felt much of the benefits of Europeanisation or globalisation, see migrants and refugees arriving and fear losing their jobs or social support. In both cases they feel abandoned by the political, professionals and business 'elites' (and by extension the 'Eurocrats') who have failed to deliver on economic improvement and equal distribution of the benefits and the burdens.

This also seemed to be at play in the recent UK referendum on *Brexit*. The consensus view is that the 'leave' vote had little to do with the perceived *ills* of the EU but rather reflected a protest against the 'establishment'. This growing disenchantment with the 'establishment', both nationally and internationally, is not a phenomenon unique to the UK but seems to occur in other EU countries as well. A recent survey, which was conducted before the Brexit referendum, shows large divisions in views and values within and between Member States, as well as a mounting disaffection with the EU across the board.* In seven out of ten countries surveyed, half or more of the public said their country should let others fend for themselves. In five countries more than half of the population felt that refugees constitute a threat. Similarly, the survey showed new declines in favourable opinions of the EU in France, Spain and Germany in comparison to the same time last year, although we have seen signs of rising EU sympathy after the Brexit vote and the turmoil it created. Brexit has shown that there is also a demographic divide with much of the younger generation in the UK standing in the 'remain' camp.

The questions we want to pose to Eurohealth readers and EHFG participants are how the demographic transformation and increasing societal diversity as well, as the changing political climate of mounting Euroscepticism and anti-globalisation, will influence future health policy development at European and national level? And, more importantly, how can we respond both as individual health professionals and as members of the 'European health community'? The forum sessions, summarily introduced in the pages of this journal, will offer participants some of the armamentarium of evidence, arguments and politics to better comprehend these phenomena as well as a range of best practices to address them.

The Opening Plenary, for instance, will focus on the increasing diversity in Europe, raising its health policy implications and seeking reactions from a range of high level stakeholders. The Thursday Plenary led by Nobel prize-winner Paul Krugman, will centre on the economics of healthy ageing. Several forum sessions will delve into related areas such as the issues faced in delivering health care to multi-cultural populations; the importance of, and approaches to, strengthening health literacy to make citizen empowerment more meaningful; addressing the health implications of diversity; or the implementation of life course based health interventions which are tailored to the needs of specific demographic groups.

As we plunge ourselves into the policy debates, in sharing, learning and networking in the Forum, our plea from these pages is that we must continuously ask ourselves whether and how these policies benefit our populations, how we best communicate those benefits and ensure a buy-in from both populations and decision-makers, and ultimately, how we make a real difference through advocacy and implementation. Some may say that the EHFG's constituents are part of this reviled 'establishment' of professionals and intellectuals that have become more remote to the health realities of the common folk. That is certainly far from the aims and values underpinning the EHFG. This is why we should prove them wrong with our deeds and actions again and again.

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RECONCILING DEMOGRAPHICS AND DIVERSITY – A COMMON EUROPEAN CHALLENGE

By: Tobias Vogt and Helmut Brand

Summary: The trias of ageing of European societies – fertility decline, increased life expectancy and migration – is often overshadowed by current crises that need immediate attention. Because European states will get older, smaller and more diverse, all branches of our welfare systems will be affected with, health care being in a key position to shape the demographic development. Investing in health and maintaining high-quality living into older ages will allow us to make the most of our longer lives. Diversity in demographic developments will put additional pressure on European unity, thus we should perceive population ageing as a common challenge.

Keywords: *Life Expectancy, Fertility, Migration, Population Ageing*

Population ageing – a common European experience

Among the many crises that Europe faces today, population ageing is perceived, almost with relief, as a challenge that we will face only in a distant future. It is certainly right that population processes are slow and demographic realities do not change overnight, but the seed to address future challenges must be planted today. Low fertility and rising life expectancy among many European countries during the last decades has led to a situation where nine out of the top ten oldest countries worldwide are European.¹ This development will continue in the future and put European economies and the financial sustainability of social security systems under pressure.

However, the fact that we are getting older and older may be also seen as an extraordinary European success. Most

babies born in this decade have very good chances to live to very old ages: in some countries every second girl born today will celebrate her 100th birthday.² Living long and healthy lives is what most of us want and should therefore not be seen as a catastrophe but as a desirable societal achievement. Nevertheless, older and smaller populations need adjustments. Decision makers across Europe still have time to react to the changing demographic conditions, as demography is not destiny. A central aim should be to maintain good health and to finance the availability of good health care for all European citizens to make most of our gained years of life.

Long live Europe – diversity across the continent

Europeans across the continent born today will enjoy longer lives than their parents do. However, there are still substantial

► #EHFG2016 Opening and Closing Plenaries

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differences in the expected length of life between individual countries. The Swiss, as the European champions, have a life expectancy at birth of 83 years and live on average around thirteen years longer than Moldovans or Russians.⁸

At the same time, we spend most of our lives in good health, and despite longer phases with disabilities and chronic conditions at the end of our life, current research suggests that the additional years of life gained in wealthier societies are mainly healthy years.⁹ Again, there are larger disparities between European countries but as with life expectancy we observe forerunners predominantly in high income western countries and followers that witness health improvements later.¹⁰ A catch up of central and eastern European countries depends to a large extent on the availability of modern health care and a rise in living standards, a success story that we have observed in several countries since the fall of the iron curtain.

Meanwhile the leaders in life expectancy will face the challenge of degenerative diseases and questions as to what extent we can and want to afford further improvements in health and life expectancy. This applies not only to the question of rising treatment costs for certain diseases or the intensification of long term care needs, but also to services and devices that maintain our quality of life.

Working with older populations

A large concern when it comes to ageing populations is that health and long term care expenditures are consuming increasing shares of national gross domestic products and are projected to soar as populations get older during the next decades. Population ageing alone will not have a significant impact on health care expenditure.¹¹ Living long and healthy is certainly not cheap and there is room for efficiency gains in health care delivery but a curtailing or rationing of health care could be demographically problematic in the long run.

A certain change of perspective on health care costs seems necessary. Preserving good health in an ageing society is not

only a cost that we have to bear because we are getting old,¹² it is an investment in our human capital that Europeans need to face the demographic challenges of diminishing labour market potentials and productivity losses. Investments in our health stock enable us to make longer use of improving average education levels and prolong phases at older ages where we are self-sufficient and not dependent on financial transfers.¹³

Finding adjustments to population imbalances

The affordability of successful ageing in most European welfare states is heavily dependent on younger generations and their ability and willingness to pay for the needs of older people. The number of Europeans in the age groups who are also tax payers or contributors to the social security system is decreasing. Since the 1970s, fertility in many European countries has started to fall below replacement level and every cohort born since then is smaller than the previous one. With the exception of northern European countries and France, there is no marked recovery in sight that would mitigate population imbalances in the near future.¹⁴

Nonetheless, there are approaches to reduce the imbalance between working contributors and dependents at older ages. An intuitive way is to make use of workforce reserves that are already there. Female labour force participation in European economies is still below that for men and we may have the chance to further engage women in the workforce if we allow them to decrease the time they spend on informal care for children and older parents.¹⁵

Another approach is to prolong the phase of life in work, when we are giving transfers to the social security system. Currently, Europeans live for around 30 years on their labour income and finance parts of the remaining years of life by transfers and assets.¹⁶ The ongoing improvements in life expectancy and health provide the chance to work longer and still have the same number of years in retirement as earlier cohorts did. Therefore, we should consider abandoning static measures of old age, like a fixed

retirement age – around 65 years old – that has existed for several decades.¹⁷ Instead, we could peg retirement age to life expectancy and retire when our remaining life expectancy is 15 or 20 years.

On the latter point, it might also help to redistribute work more equally over the individual life course to keep older people in the labour market for longer. In the rush hour of life between age 25 and 45, Europeans work hard to get their education, build a career, start a family and take care of their children and older parents, while the number of hours worked decreases markedly already before retirement age.¹⁸ A reshuffling of workloads may alleviate the time and priority constraints for younger age groups and make it easier to consolidate families and jobs.

A final approach is to attract people from other populations and countries to fill perceived shortages.

New Europeans – migration and fertility

Migration is a central determinant of population change and currently, in the course of the refugee crisis, very present in the public discussion. A predominant focus of European policy makers with regard to migrants, independent of their length of stay, should be investments in their human capital, especially in education and health literacy. These measures are beneficial either for a prospective successful integration into European societies or it will help refugees to rebuild their home countries if there is a chance for return. A far larger reason for concern than the current inflow of refugees is the distribution and direction of general migration flows between European countries. Migrants with EU citizenship or from outside the EU increasingly decide where they find promising perspectives or better wages which results in more population diversity and economic growth of prosperous cities and regions. At the same time, less developed regions lose a fraction of their population in the age groups that are needed in the current and future labour force. Unfortunately, the movement of industry and enterprises to less developed regions in search for lower

costs is not as lively. Thus, European countries will be affected very differently by population ageing.

Richer western European states may compensate for their low fertility and older populations and alleviate their projected shortages in workforce and tax payers by immigration from Europe or elsewhere. This has severe consequences for the EU member states, mainly in central and eastern Europe, that struggle to catch up to western levels. Their populations will age faster and welfare states will face unsustainable financial pressure. To prevent increasing demographic pressure on the EU's integrity we should avoid one-sided solutions in which the already poorer European states have to shoulder the demographic costs of losing larger parts of their younger population to the wealthier states. A viable way, worth discussing, would be to include demographic parameters into the distribution of EU funds. As it is already possible to use the structural funds for health this could be accompanied by demographics. This would help to reimburse southern and eastern EU countries for their educational investments and contribute to covering the needs of older populations.

Another adjustment to intra-EU imbalances is the intensification of cross-border delivery of social security, including health care. As we will not be able to provide the highest level of health care in less populated regions, new ideas for delivering services like e- and m-health are explored and sharing the services of highly specialised treatment centres between (especially small) countries will be the norm. This would not only help to share the burden of demographic change, but may increase the chance for poorer countries to catch up in terms of health and life expectancy.

When we speak about the general chances of migration, we should keep in mind that it is a limited resource that can only partially solve the problems created by population ageing. European cohorts are getting smaller and migration may replace current shortages, but fertility has been below replacement levels for decades. This would require large numbers of migrants mainly from

outside Europe. Despite the chances that successful integration brings for individual immigrants, the societal costs of countries that suffer from an outflow of mainly educated population subgroups are sizeable.

While migration is certainly necessary, we should not forget that we have to provide the right environment and support for young Europeans to increase their fertility. This is especially true as migrant fertility over time converges to the lower level of the host countries.¹³ We should learn from successful countries, like France, how European societies can become more family friendly in order to raise the size of our future generations.

Slow changes but need for action

Even though population ageing is often described with alarmism, we have the chance to make our future less bleak or grey than predicted. Demographic change is not a tornado or a natural disaster that will hit us by surprise, but rather a slowly rising tide. Because we are not yet in deep water, we have the time to find the right adjustments for the long process of population ageing.

Stay moderate: The increasing population pressure over the next few decades is particularly a result of the ageing baby boomer cohorts that were born after World War II. The cohorts that follow are smaller and will lead to a stabilisation of the ratio between old and young on a high level.¹⁴ At the same time, we should look for alternative measures of age: being 65 or 70 years old today, in terms of health and cognitive functioning, is very different from what it was in the past. Despite the need for political action, we should keep the right measures.

Stay balanced: Migration certainly matters but equally important are changes in European fertility levels and improvements in health.

Stay positive: Population ageing may even provide some chances for younger generations.¹⁵

Stay united: Europe should face demographic pressures together and not as

individual national states. Deeper social integration could be a step towards this aim and act as a new narrative for Europe.

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CULTURE MATTERS – DELIVERING INTERCULTURALLY COMPETENT HEALTH CARE

By: Dorli Kahr-Gottlieb and Martin McKee

Summary: The growing diversity of Europe demands that both incoming and host populations understand each other’s cultural origins and values. This is particularly the case for the health care workforce, whose members are asked increasingly to deliver culturally sensitive care to patient groups with diverse backgrounds. This requires an open discussion about the cultural impact on health and a deliberate addressing of their own cultural imprints by both groups. These issues will be addressed throughout the European Health Forum Gastein 2016 programme, with topics such as values, diversity, migration and refugee health and the responses of health systems being discussed in the Opening Plenary and in parallel sessions such as “Desperate migration and health”, organised by the International Peace Institute and “Refugee health” organised by DG SANTE.

Keywords: Migration, Culture, Cultural Diversity, Language, Intercultural Awareness

► **#EHFG2016** Parallel Forum 4:
Desperate migration and health

► **#EHFG2016** Workshop 7:
Refugee health

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People on the move

Not for the first time, the population of Europe is changing. Throughout history, people have been moving to, through and from Europe and have been bringing their genes, their customs, and their ideas to Europe. Movement within Europe has been on a similarly large scale, most often in the aftermath of conflict. However, today, the actual migration numbers are greater than ever, reflecting the urgent need for non-European populations to flee their war-ridden territories, the growth in the world’s population and the relative ease of transportation.

It is not, however, only contemporary migration that has shaped the complex cultural landscape of Europe. Ethnic and

religious minorities have lived among the majority populations for centuries. Some of these groups, such as Roma and certain religious minorities, have, to varying degrees, retained distinctive cultures. Events in the 20th century, especially during one of the darkest periods of Europe’s history, but also in the post-war period, have powerfully influenced the distribution of different groups across the continent. Movement on this scale and over so many years has had profound implications for the composition of European populations.

Implications for health care

As health facilities reflect the populations they serve, health systems increasingly

provide care for patients from many different ethnic and religious groups and cultures. The growing diversity of European populations, bringing with them an array of cultural values, challenges health care providers to adapt their services to more culturally sensitive care and communication. Anand and Lahiri point out the importance of health care choices and outcomes being understandable not only regarding language but also in terms of other cultural frameworks and experiences.¹ On the other hand, the health workforce also derives from many different cultural backgrounds as Europe has underinvested in training health professionals for decades. This has caused many national health services to depend on migrants, in all aspects of the delivery of care. In the United Kingdom, for example, about 11% of health workers are migrants.² In some areas, such as mental health and care of older people, the figures are much higher. Indeed, contrary to what has been alleged by some of Europe's populist politicians, migrants in hospitals are much more likely to be providing treatment than receiving it.

“adapt their services to more culturally sensitive care and communication”

Both aspects are important. The way that both patient and carer understand many of the things that happen in health care facilities is shaped by their culture. Amongst other cultural dimensions, Hofstede distinguishes collectivistic and individualistic approaches to health. Individualism dominates in societies in which the ties between individuals are loose, who mainly take care of themselves and their immediate family (which tends to be seen in many European countries); while collectivism is seen in societies in which a person is integrated into strong and cohesive groups from birth onward,

which continue to protect them with unquestioning loyalty.³ An understanding of these and other cultural dimensions, like masculinity versus femininity or cultural differences in power-distance/hierarchy, could overcome problems that can arise in many everyday health care situations.

Nowhere are cultural values more important than at the extremes of life, in birth and death. How do we welcome a new life into the world and how do we ensure the best possible departure from this earth? Who should be present at these events? Patients from a collectivistic society will expect a large extended family to be present, with implications for the functioning of the facility. Even after death there may be strongly held beliefs about who can touch the body and what can be done with it. But there is much more. Is it deemed acceptable for someone of the opposite sex to see us naked? Does our understanding of the world include the concept of asymptomatic illness, such as hypertension, requiring long-term treatment, especially when that treatment may be causing side effects? Different cultural groups may fail to respond to treatment, simply because they are not taking it for varying reasons. These examples affect the relationship between the individual patient and the health worker, but there are times when belief systems also impact on others, as when fundamentalist Christians prevent their children from being immunised or Jehovah's Witnesses refuse a life-saving blood transfusion.

Language and cultural barriers

The situation is complicated further by differences in language. Recent migrants, and especially the extended family of those who move first, may have limited ability to communicate in the working language of the country concerned. Sometimes this can be overcome but in many cases there will be a need for interpretation. This, itself, creates many challenges. Are there sufficient adequately trained interpreters, are their costs covered by the health care system, especially when the language involved is spoken by few people in the country concerned? Also, how well do the concepts of modern medicine translate into such languages? Frequently family

members are requested to help, but this raises issues of confidentiality and also, in some cases, control, especially where women depend on male relatives. The challenges are even greater in some areas, such as mental health, where additional barriers and questions of stigmas and taboos may influence the care process.

It is well recognised that language barriers matter; where health professionals and patients do not share a common language there is greater use of diagnostic investigations, poorer uptake of preventive services, worse adherence to self-monitoring, and lower patient satisfaction.⁴ In contrast, training health professionals to work with qualified interpreters improves quality of care and patient satisfaction.^{5 6}

Language and culture come together in communication. Hall coined the terms high-context and low-context cultures. A patient from a low-context culture tends to communicate directly and explicitly with the goal of receiving and giving information. High-context communication is generally more context-oriented, less explicit, with those involved tending to “beat around the bush”, with gestures and tone of voice supporting the message.⁷ A failure to appreciate these differences can have important consequences for diagnosis and the success or failure of treatment.⁸ Nor should we forget that the relationship between the health worker and the patient is bi-directional. Given the dependence of health systems on migrant workers, there may also be cultural misunderstandings when a health worker with a different cultural background is treating a native patient.

Finally, we cannot ignore the uncomfortable fact that, on rare occasions, health workers not only fail to act in the best interests of their patients but even abuse them.⁹ This is most likely to occur when patients are disempowered and vulnerable, as is often the case with migrants and other minorities. Such abuse can take many forms, starting from an active disregard for the cultural needs of the patient concerned.

Language is, however, one area where much has been achieved, with the Netherlands and Sweden developing

systems of “community interpreting” since the 1980s,⁹ while in several countries a right to have an interpreter is recognised in law. However, in others, such services are simply unavailable. This is an area where technological advances offer considerable potential, whether through the involvement of interpreters located remotely, using applications such as Skype, or if no interpreting is available even automated translation, such as Google Translate, though not optimal, can offer support in an acute care situation.

“essential that health systems recognise the importance of cultural awareness

Intercultural awareness and competence

For all these reasons, it is essential that health systems recognise the importance of cultural awareness and competence among all their staff that come into contact with patients. This requires intercultural awareness training, not only for health professionals, but for all staff in health care facilities.

Fortunately, there are many good examples from across Europe of how health services can respond appropriately to the cultures of those for whom they care.^{10 11} In 2004, the European project “Migrant-friendly Hospitals” published the Amsterdam Declaration, describing the then available hospital services for migrants and ethnic minorities in Europe, noting many examples of poor quality services. It emphasised the importance of improving quality for migrants and ethnic minorities as a means of achieving better care for all. It concluded with recommendations on the specific contributions that can be made by hospital management and health

workers, health policy-makers, patient organisations, and researchers. It has since been endorsed by many European and international organisations.

There is also a much greater awareness among those designing curricula for health professionals of the need to include cross-cultural competence, something that begins with becoming aware of and understanding one’s own culture.¹² This includes the importance of eliciting a patient’s language, culture and ethnic group, being aware of cultural stereotypes, caution in using family members as interpreters, understanding of culturally specific expressions of distress, religious and social taboos, attitudes to health workers of a different sex, and culturally specific rituals, especially at death.¹³

It is for these reasons that the focus of the European Health Forum Gastein 2016 will be on diversity, offering once again an unparalleled opportunity for sharing ideas and experiences.

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VOICES FROM EUROPE



Vytenis Andriukaitis: EU Commissioner for Health and Food Safety



Zsuzsanna Jakab: Regional Director, World Health Organization Regional Office for Europe (WHO/Europe)



Sabine Oberhauser: Federal Minister of Health, Austria



Tomáš Drucker: Minister of Health, Slovakia



Natasha Azzopardi Muscat: President-elect, European Public Health Association (EUPHA)



Richard Bergström: Director General of the European Federation of Pharmaceutical Industries and Associations (EFPIA)



Nina Renshaw: Secretary-General of the European Public Health Alliance (EPHA)

As in previous years we have asked some prominent ‘voices’ in Europe to reflect upon the topics to be discussed at the European Health Forum Gastein 2016.* They represent the various key stakeholders attending the EHF: international and national policy makers, academic researchers, industry and civil society.

***EH:** European health systems need to adapt to the demographic challenge as well as to the increasing diversity in citizens’ health profiles and needs. How well-prepared are we to face this challenge?*

Oberhauser: Looking at the various challenges that we’re currently facing, we need a strong public health system, now more than ever. We need to develop a new way of thinking about healthy ageing, not only to focus on the economic burden of ageing populations. This will allow older people to remain in the labour force, to volunteer, to provide (informal) care and to maintain their consumption patterns. The ultimate goal of the Austrian government’s program is to “empower people to live and work longer in good health”. This requires interventions across the life-cycle. Following the Austrian Interdisciplinary Study on the Oldest Old (ÖIHS), the health of individuals aged 80 and older in Austria is much better than assumed. However, we will continue pursuing this approach in order to gain more healthy life years.

***EH:** WHO/Europe will organise a session in Gastein on implementing the life-course approach in health. What does this mean in practice and how will it require policy makers to change their policies accordingly?*

Jakab: The life-course approach looks at health through the lifecycle and acts on the physical and social factors affecting health at critical times and transitions – such as during pregnancy, childhood, adolescence, young adulthood and later adult life. It seeks to build health advantages that can last a lifetime and reach across generations. This approach is one of the principles underpinning Health 2020, the WHO policy framework for health and well-being in Europe. It is also emphasised in the Sustainable Development Agenda where goal 3 seeks to “Ensure healthy lives and promote well-being for all at all ages.” A life-course approach calls for coherent, cross-sectoral policy-making where different sectors cooperate to improve health. For example, evidence shows that when reproductive-age women enjoy good nutrition this helps prevent their children from developing obesity later in life and reduces their risk of non-communicable diseases. The health, agricultural, social and economic sectors must therefore all play their part in ensuring that pregnant women have access to healthy and nutritious food.

***EH:** With the European Innovation Partnership on Active and Healthy Ageing the Commission set out an ambitious agenda for meeting the societal challenge of demographic change. What lessons can be drawn from the experience so far? Have other pressing topics and crises diminished political attention for this challenge?*

* The statements were selected from written contributions received from the various panel members to questions submitted to them, and re-organised by the Eurohealth editors.

Andriukaitis: It is true that the EU has been beset by crises in recent years. However, while events such as the economic crisis and the influx of refugees have dominated the headlines, Member States have continued to work together and to exchange best practices and expertise on innovative ways to ensure active and healthy ageing. Indeed, health is an area where the added value of EU level cooperation is clearly demonstrated. Five years since the launch of the European Innovation Partnership (EIP) on Active and Healthy Ageing, innovative programmes on adherence to medication, prevention of frailty, chronic disease management and integrated care, for example, are being rolled out, scaled up and replicated across the EU. This wide deployment of innovative practices is a prime example of how combining our efforts can improve health and quality of life of citizens aged 65+ across the EU.

EH: *One of the EHFG sessions will deal with ‘healthy innovation’, i.e., how to ensure that innovation will indeed lead to better health by focusing on the real priorities and ensuring that the entire population can benefit. Can the current market-driven model of pharmaceutical innovation deliver on these conditions?*

Bergström: It can absolutely do that, with over 7000 medicines in development, the pipelines of the industry are filled with innovation that will help address currently unmet health needs, in everything from cancer over Alzheimer’s to rare diseases. But we need to strengthen collaboration with policy makers, payers, patients and other stakeholders to set priorities and we need to get the incentives right. The threat of anti-microbial resistance is a clear example of what can happen if the incentives to innovate are not there, and if there is a lack of frank discussion about this for many years. We are now making a lot of progress in that area to make up for lost time, but we must get better at having these conversations across all areas.

EH: *EPHA chose antimicrobial resistance (AMR) as the focus for its next annual conference? Do you think that there is not enough awareness of the public health threat that AMR represents? What needs to be done to improve national and international preparedness to fight AMR?*

Renshaw: AMR is a symptom of severe, long-term political neglect of public health and failure to invest to head off an unprecedented humanitarian crisis. But we still have an opportunity to act and put in place health-coherent policies across sectors and at all levels, from international to local. European researchers and governments have taken a leading role in identifying the causes and costs of AMR, but must now put in place effective and urgent measures to stop its spread. Europe should also lead the coordination of international responses – as we did for climate change – that will be needed to avert a global disaster. The European discussion has so far neglected the important role of environmental pollution in pharmaceutical supply chains. Much still needs to be done to make sure everyone understands the scale and severity of the threat. We need to emphasise that ‘superbugs’ can dismantle modern medicine,

with truly frightening consequences. We require strong political commitment and action that addresses all facets, including human medicine, agriculture/food production and drugs manufacturing. We need better data and surveillance, rapid diagnostic testing, and ambitious targets. There is an essential role for Europe acting in solidarity and investing in everyone’s interest, with close coordination and control – none of us can afford a weak link in one country that will rapidly undo progress in others.

EH: *How can a common approach at international level help to better achieve our goals? In which way do the health priorities chosen by the Slovakian government for its current EU Presidency match with the EHFG’s focus on demographics and diversity and the issues addressed in the various sessions?*

Drucker: International cooperation is key towards sustainable problem solving in the EU. We are no longer running our health care systems in silos. We need to pool our resources, best minds and practices in order to jointly create a better future. Slovakia chose its health priorities for the EU Presidency based on two factors. Firstly, we aimed to create a continuum between the Dutch and Slovak Presidencies, to ensure that unfinished projects are completed and value generated. Secondly, we aimed to choose topics that will benefit the population across the EU. In other words, we looked into topics that present a challenge, or a threat for a majority of the EU population. Therefore, the Slovak topics for the Presidency (access to medicines, MDR-TB and reformulation of food ingredients) reflect the international-level interests and try to be equitable, solving problems that an entire population of the EU is facing†.

EH: *How can international collaboration also help to address the challenges of healthy ageing? The Austrian government identified quality of life of older people as a priority topic, with the development of an integrated national strategy for dementia as one of the concrete outcomes. What can we learn from the Austrian experience?*

Oberhauser: Non-communicable diseases (NCDs) are increasingly putting a burden on all health systems. Dementia is a silent NCD pandemic affecting all countries. We should jointly seek solutions addressing these challenges, by exchanging best-practice and putting an emphasis on a gender-sensitive and human-rights based approach. Our dementia strategy provides an integrated and inter-sectoral framework of objectives and recommendations for improving the lives of people living with dementia, including their families and caregivers. It promotes a better understanding of dementia, raises public awareness and engagement, including respect for human rights, reducing stigma and discrimination, and promoting early diagnosis and care. Key aspects are a better coordination between the health and social sector, as well as specific measures to tailor health promotion, health literacy, prevention and care to people living with dementia.

† A more detailed article on the Slovak EU Presidency health priorities can be found later in this issue.

EH: *So how should we tackle these NCD challenges together? In your view, what is the most pressing issue in this context that needs to be addressed by policy makers both nationally and internationally?*

Jakab: Reducing inequities is the challenge of our time. Although people living in the WHO European Region are living longer than ever before, there is an eleven year inequity gap between countries with the highest (82 years) and lowest (71 years) life expectancy. Similarly, there is a 10.5% inequity gap in primary school enrolment rates, and a 30.5% inequity gap in unemployment rates. If we are to respond to population ageing, the chronic disease burden and migration, we must ensure that the building blocks for a secure, rewarding, life of good health and well-being – education, employment, housing, active participation in civic society and control over life – are available to all. The Sustainable Development Agenda mandates and sets out a framework for individuals, civil society, governments and the private sector to contribute to a fairer, safer and healthier world. We must recognise and seize this opportunity.

EH: *The theme 'All for Health – Health for All' at the upcoming European Public Health Conference aims to highlight persisting inequalities in health. Why aren't we managing better to close the gaps in healthy life expectancy?*

Azzopardi Muscat: Health inequalities are a key sentinel indicator for general inequality. Growing inequalities have profound political, social and economic consequences. A breakdown in intergenerational solidarity and inter-racial tensions are key political issues for Europe. Fostering better health, particularly for children, adolescents and young families in socially deprived communities is necessary to address these ominous trends. Investment in education, health systems and public infrastructure is necessary to address persisting inequalities. Older populations and minorities compel us to prioritise such investments. The future of the European project must be built around health and social well-being for all. Strong markets can be an important vehicle to achieve these goals, if managed well. European public health researchers and practitioners have an onus and responsibility to contribute towards shaping a better future for all European citizens. EUPHA, through the organisation of conferences such as the one being held in Vienna in November 2016, provides an opportunity and a platform to rethink our approach in striving to achieve Health for All in the 21st Century.

Renshaw: EPHA also advocates inclusive health systems that are accessible to all, including people living in vulnerable situations. There has been much talk about healthy ageing in Europe, but this can only be accomplished if people have the opportunities and the best conditions to be healthy and access employment throughout their lives. We must also better value the experiences of older people in the job market and foster increased intergenerational contact.

EH: *Clearly, ageing and diversity force us to rethink our approaches to public health, prevention and health care provision? In what way is this also offering a positive outcome or opportunity?*

Andriukaitis: The most pressing issue is also the greatest opportunity. We need to improve the health systems in all Member States to make sure they are fit for purpose. This includes strengthening their effectiveness, increasing their accessibility, and improving their resilience[‡]. However, if we want to improve the performance of our health systems, we have to assess them first. This is why I have recently announced a Commission initiative called “State of health in the EU”[§] which will bring together internationally renowned expertise to strengthen country-specific and EU-wide knowledge on health in a concise, digestible and coherent package. The aim of this two-year exercise is to boost analytical capacity and support EU countries with their evidence-based policy making, so they can make the best decisions for them. The first results of this overview should be available in November 2017.

Bergström: I think the good news is indeed that we more or less know what we need to do. Now we just have to do it. We need to create more effective and responsive health care systems focused on improving patient outcomes. They have to deliver better value for money, and for this we need to focus more on patients with chronic diseases and multi-morbidity, since these are driving the costs of health care and will do so even more in the future.

Azzopardi Muscat: We have to make health care professionals better understand how their roles need to change and evolve in order to meet these new challenges. Health systems are increasingly about being able to deliver chronic care in the community adapted to the local contexts and needs, in partnership with social care organisations, as traditional family structures have been replaced.

EH: *In what should health systems invest to improve their performance and better meet the needs of an ageing and more diverse population?*

Drucker: The more diverse needs of a population, the greater the cost, the less flexible the system and the greater the likelihood of medical malpractice. Taking into consideration rising expenditure on health care and a growing number of reform activities across the EU, it is clear that current socio-demographical changes across Europe have become the key challenge of the Union. And most EU countries have only just started to address them. Diversity in the needs of the population has to be addressed by a flexible system that can respond to varying needs in a fast and effective manner. This will require a broadening of competencies, more expandable capacities of providers, better support of home and self-care as well as mobile and telecare solutions. But the key to creating a more flexible

‡ See the Communication from the Commission on effective, accessible and resilient health systems. Available at: http://ec.europa.eu/health/systems_performance_assessment/docs/com2014_215_final_en.pdf

§ See http://ec.europa.eu/health/state/summary/index_en.htm

health care system is integration. Vertical integration – by sharing information between different levels of providers and ensuring a smooth flow of patients according to their needs, facilitating self and preventive care. Horizontal integration – by creating financing mechanisms that support cooperation and are based on outcomes rather than on inputs or service provision. The most important type of integration is integration at an international level.

Bergström: A key enabler for transforming health care in this direction is data management. We must dig out and connect all the data that today are scattered across the health system, but also data from outside the system, such as data generated by social media and health apps. Through a better use of data we can analyse what interventions actually give the best outcome for specific patients for available resources. This will require some investments in the short term to build the necessary health information infrastructure, including through electronic health records and disease registries. But if we make that investment now we will be in a much better place to meet the future.

Azzopardi Muscat: Ageing and diversity provide an opportunity for new recruits to the health system and this has so far been mostly overlooked.

Renshaw: Europe urgently needs more health workers and carers, at the same time our economies are restructuring further away from heavy industry due to technological change. We must better recognise the value of caring roles in our societies and economies. Many carers today are undervalued and underpaid, or unpaid in caring for relatives.

***EH:** Can migration help in that respect?*

Renshaw: Migration can represent a huge opportunity for Europe in this context. It is simply not true that health services are at breaking point because of immigration; lack of investment in health services is a political decision. In fact, health workers from all over the world make an invaluable contribution. Their much needed skills can be an asset for sustainable, resilient health systems today and in future. While the current migration situation is problematic due to lack of solidarity in Europe, complicated asylum procedures and few opportunities for legal migration, Europe will continue to become more diverse and health systems will need to adapt. Opening up to new cultural perspectives will make us richer and more resilient in the long run.

Oberhauser: Social and health systems in countries with an ageing society will benefit from increasing mobility mainly of younger migrants who leave their home countries searching for new opportunities. However, for countries from where these young people depart this migration represents a major challenge for the health sector. Being both, a transit and a destination country for refugees, we do see the importance of a responsive public health system and intersectoral action for health. While there is high demand for basic medical examinations and treatment for refugees when arriving in Austria, we do not

experience an increase in the incidence of infectious diseases. However, we are currently facing increasing demand for psychosocial support of refugees and aid workers. Therefore, the Austrian Federal Ministry of Health has commissioned the establishment of a national coordination platform. Much more concerted action will be needed at a European level to effectively manage the current refugee influx and to identify best practices and innovations.

***EH:** Thank you for this interesting exchange!*

HEALTH LITERACY IN EUROPE: GETTING TO THE NEXT LEVEL

By: Matthias Wismar, Helmut Brand and Ljubiša Stojanović

Summary: Health literacy is the ability to access, understand, appraise and use information relevant to health. This may apply to joint decision making in clinical settings but it is equally important in disease prevention, health promotion and health policy making. This article reviews the definitions and concepts of health literacy, presents an overview on how health literate Europeans are and provides some perspectives on how to get from science and surveys to the next level, including the implementation of national programmes and action plans.

Keywords: Health Literacy, Joint Decision Making, Healthy Behaviours, European Health Literacy Consortium

Introduction

Why should we address health literacy? According to a *Eurobarometer* survey a large number of Europeans are unaware that antibiotics are ineffective against viruses (57%), colds and flus (44%).¹ This lack of appropriate and actionable knowledge, or in other words, the lack of health literacy, may affect the interaction between doctor and patient, joint clinical decision making, the effectiveness of treatment and the patient experience. In the worst case scenario this lack of health literacy may result in unrealistic expectations, incorrect decisions, ineffective therapies, poor outcomes and patient dissatisfaction. Moreover, an insufficient level of health literacy, for example through the continued inappropriate use of antibiotics, may undermine policy responses which aim to tackle the challenge of antimicrobial resistance. Health literacy is not only important in the clinical setting. Healthy behaviours, including diet and physical activity, or the under- and overuse of health systems' resources or the

understanding of new health technologies are all influenced by the level of health literacy.

Typically, people who have higher levels of health literacy are healthier and use health care resources more appropriately under similar conditions. Strengthening health literacy is possible. However, we need to be aware that it is a *specific* competency people need to acquire and develop. Simply increasing the flow of public health information is not enough: according to the same survey,¹ only a third (34%) of those Europeans who have received information said that the information they received – from any source – led them to reconsider their use of antibiotics. In contrast, people with better knowledge of antibiotics use them less often. A recent wave of health literacy surveys in Europe has shown deficiencies in existing health competencies in the population, but also the potential of this tool to increase awareness of the benefits stemming from strengthening health literacy. The time has come to act upon it and get to next level!

► #EHFG2016 Lunch workshop 4:
Health literacy

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Table 1: What the health literacy survey measured: matrix of sub-dimensions

Health literacy	Access/obtain information relevant to health	Understand information relevant to health	Appraise/judge/evaluate information relevant to health	Apply/use information relevant to health
Health care	1) Ability to access information on medical or clinical issues	2) Ability to understand medical information and derive meaning	3) Ability to interpret and evaluate medical information	4) Ability to make informed decisions on medical issues
Disease prevention	5) Ability to access information on risk factors	6) Ability to understand information on risk factors and derive meaning	7) Ability to interpret and evaluate information on risk factors	8) Ability to judge the relevance of information on risk factors
Health promotion	9) Ability to update oneself on health issues	10) Ability to understand health related information and derive meaning	11) Ability to interpret and evaluate information on health related issues	12) Ability to form a reflective opinion on health issues

Source: Ref. ³

Defining health literacy

Clearly, health literacy is an important ability for patients and citizens. But what is it exactly? Initially, the concept of health literacy emerged from the clinical context when health workers realised that patients with limited reading skills had particular difficulties in understanding and complying with medical advice. Plenty of research has reproduced this causality. Much of the subsequent research has contributed to broadening the scope of the definition of health literacy.² Today, health literacy comprises the ability to find, understand and assess health related information helping with co-decision making in clinical settings, helping to make healthy choices, and decision making on public health and health system issues.

There are plenty of definitions of health literacy and many of them only differ in nuances. For this article, an important one is the definition used by the European Health Literacy Consortium (HLS-EU Consortium) because it is the foundation of the main health literacy survey in Europe (see Box 1).

Health literacy beyond clinical settings

Health literacy goes well beyond the clinical setting. It is relevant for all areas of daily decision making. Checking the ingredients of different foods, including salt, sugar, fats, calories, etc. can be quite cumbersome. It has actually been argued

that the availability of highly processed, pre-packaged massively commercially pushed foods and drinks make the healthy choice sound naïve.⁴ Alcohol adverts were seen almost once-per-minute during telecasts of the Euro 2016 games, where a brewer replaced its brand name on pitch-side digital boards with one of its well-known slogans.⁵ This calls not only for better information systems for consumers, but also for a more level playing field in which the commercial determinants of health have less opportunity to promote unhealthy choices.

“people who have higher levels of health literacy are healthier”

Health literacy has also to do with wider health system decisions. Would the NHS be better off inside or outside the European Union (EU)? This was one moot point in the discussion on the so-called “Brexit” vote on whether the UK should leave the EU. It was important because it included questions of migration and financing. Key issues were staffing, accessing treatment in the UK and abroad, regulation, cross-border cooperation and funding and finance.⁶

Box 1: Definition of health literacy according the HLS-EU Consortium

‘Health literacy is linked to literacy and entails people’s knowledge, motivation and competences to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course’.

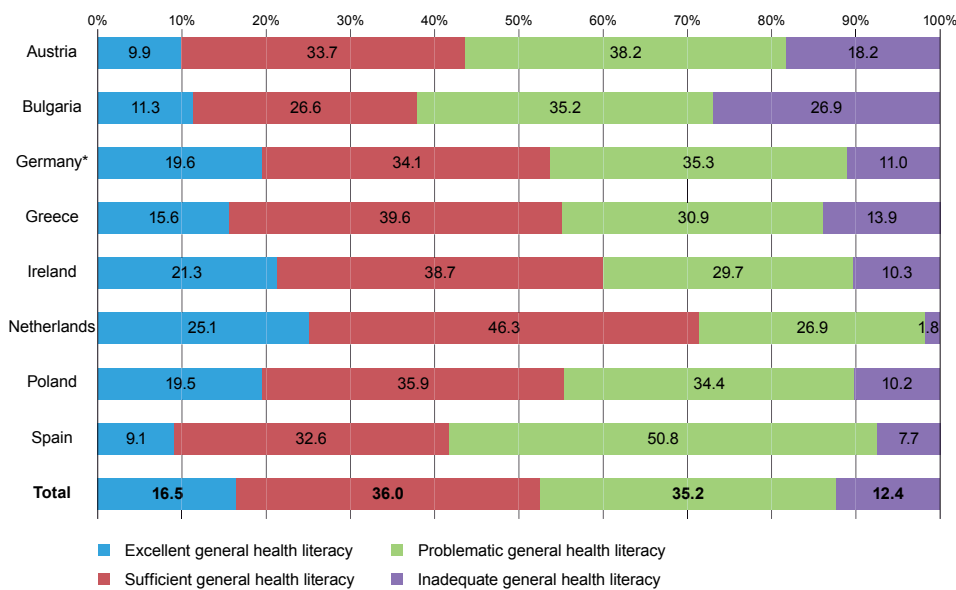
Source: Ref. ³

In order to make informed choices, patients and citizens need interaction, independent information, easily accessible points of information covering different languages for different parts of the population. A great example is the “*Health with Migrants for Migrants*” in Europe project run by the ethno-medical centre in Hannover Germany, which won last year’s prestigious EHPG Health Award.⁷

How health literate are we?

The European Health Literacy Survey (HLS-EU)⁸ was conducted during the summer of 2011 across eight European countries including Austria, Bulgaria, Germany (North Rhine-Westphalia), Greece, Ireland, Netherlands, Poland, and Spain. The researchers in each country sampled a random selection of approximately 1000 EU citizens who, at

Figure 1: Levels of general health literacy, % of those surveyed in European Health Literacy Survey



Source: Ref. 8

Note: * North Rhine-Westphalia

the time of the survey, were aged fifteen years or over. Overall, they interviewed approximately 8000 people. The researchers developed a questionnaire featuring 47 items. As presented in **Table 1**, they were based on twelve sub-dimensions derived from crossing three areas (health care, disease prevention and health promotion) and four information-processing stages (access, understand, appraise, apply), following the definition presented in **Box 1**.

Overall, the survey provided, for the first time, a detailed though somewhat unflattering insight into health literacy in Europe. The value of the results must not be underestimated, especially since the survey was conducted in several countries, allowing for comparison.

Looking at the general health literacy level for the eight countries included in the survey, it has to be said that more than one tenth (12.4%) of respondents had inadequate general health literacy and more than a third (35.2%) had problematic general health literacy. This means that for the eight countries included nearly every second (47.6%) respondent's general health literacy was limited. There are some variations between countries: 62% of respondents from Bulgaria had limited

health literacy while this was the case for only 37.7% of respondents from the Netherlands. If general health literacy is disaggregated into the three areas it shows that limits in health prevention health literacy are higher (with 50.9%) than in health care literacy (40.9%), with disease prevention literacy in the middle (42.8%).

The publication of **Figure 1** attracted a lot of attention, particularly in German speaking countries. Some countries did not participate in the initial HLS-EU survey but used the same tool for their own surveys. For example, in Germany the initial survey conducted in North-Rhine Westphalia was extended to the whole country with an additional focus on health literacy in migrant populations. The results confirmed the data from the initial HLS-EU survey. General health literacy in Germany was inadequate for 14.5% of respondents, problematic for 45.0%, sufficient for 33.7% and excellent for 7.0%.

More recently, in 2015, Switzerland used the HLS-EU questionnaire to conduct a survey on health literacy.⁹ In general, the results confirmed the findings of the earlier surveys in other countries. Although in Switzerland the proportion of people with an inadequate level of health literacy (9%) is somewhat lower

than the average level in the eight original countries, the proportion of people with "problematic" health literacy was rather higher (45%). A clear link appears between the levels of health literacy and physical activity: among people with the lowest level of health literacy, 78% said that within the last month they had not once practiced a sports activity for at least 30 minutes. This proportion drops linearly to 10% for the group of people with the highest level of health literacy. Furthermore, a lower level of health literacy was also associated with more frequent hospital stays and/or emergency ward consultations.

Health Literacy: from surveys to health(y) outcomes?

The levels of limited health literacy in Europe are an issue of concern and may limit the effectiveness of health promotion, disease prevention, health care and health policy. However, policy responses addressing this issue are shaping up. Austria might be the country where health literacy has attracted the highest interest from political decision makers in recent times. In 2011/12, a set of ten general health targets was defined,¹⁰ one of them being the strengthening of health literacy. Implementation was commissioned to *Fonds Gesundes Österreich*, the national competence centre and central funding office for health promotion. But the results from the HLS-EU have also mobilised policy makers, health professionals and stakeholders in other countries. Many realised that the awareness generated by the survey should be used as a window of opportunity for action. Hence, for example, in the German speaking countries national platforms have been created to support projects aimed at strengthening health literacy.¹¹ Key stakeholders in these countries also used the momentum to produce a German translation of a WHO-publication on health literacy facts¹² and to instigate a three-country dialogue to build a joint basis for domestic discussions.*

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This is a beginning, but further action is needed. First, there is an abundance of health literacy interventions for individuals in different settings. And there are plenty of good practices sponsored by sickness-funds, health administrations and civil society organisations. The robustness of health literacy interventions may vary and transferability needs to be taken into account but there is no excuse for abstaining from action.

Second, we need health literate organisations. You can operate your smartphone without knowing or understanding the highly complex technology working inside it. It is about the “user-interface” which makes people able to deal with complex issues. This is also true for health. Trying to increase health literacy on an individual level has its merits but also limits. It has to be accompanied by re-thinking the organisations and structures in which health and care is provided from a health literacy perspective to reduce complexity for the citizen and patient to have lasting effects.

Third, we are getting a handle on intersectorality, including the framing of the issue. Health literacy has some direct contacts in the health sector where general practitioners, nurses and other health workers, ministries, competent authorities and sickness funds may also play a role in commissioning or providing patient information. However, many fields where health literacy may be strengthened will be outside the health sector. Therefore, ministries of health need to reach out to other sectors for dialogue and collaboration. And here are where the ‘co-benefits’ come into the picture. Co-benefits are those which materialise in another sector. Instead of telling the story of how good health literacy interventions in educational settings are for improving health, which no one will deny (but few will get started on) we can now produce a narrative on how good health literacy is with regard to the goals of the other sector: improving educational attainment, reducing bullying, lowering rates of burnout of teachers are just a few examples that can make a big change in the storyline.¹³

Fourth, there are now talks of repeating the HLS periodically to monitor the development of health literacy in Europe. Through this we will be able to monitor developments in the different dimensions of health literacy over time and place. It will be possible to keep the same methodological comparisons between countries and regions and we will be able to identify good practice examples. Moreover, a general evaluation of the different interventions will tell us if we are on the right track.

In the field of education, the PISA-Surveys have harmonised expectations in Europe and other OECD countries regarding the mathematical, verbal and science skills that students are expected to acquire during their school years. When the results first came out many countries were alerted to the mediocre performance of their youth. This awareness resulted in political action. School reforms were initiated, best practices from high-achieving countries were examined and adapted to local needs. This action has brought about many positive results during the last decade and student PISA-performance levels have improved in many countries. This is something we should also aim at with respect to health literacy in Europe: the window of opportunity is open.

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DEMOGRAPHICS AND DIVERSITY IN EUROPE – INNOVATIVE SOLUTIONS FOR HEALTH

By: Isabel De La Mata Barranco, Dominik Schnichels, Tapani Piha and Arila Pochet

Summary: Whilst still recovering from the economic crisis, Europe's health care systems are facing the growing challenges of an ageing population and a rise in chronic diseases. A new phenomenon is the migrant challenge. This article outlines various issues related to demography and diversity which affect health systems. It summarises the ways in which the Commission tries to support Member States both through tried and tested methods and through EU cooperation on innovative solutions for health – in particular, eHealth and Health Technology Assessment.

Keywords: Health Systems, Ageing, Chronic Diseases, eHealth, HTA, Migrants, Health Workforce

► **#EHFG2016** Forum 9:
Reality meets Reality

► **#EHFG2016** Workshop 3:
New frontiers in HTA

► **#EHFG2016** Forum 4:
Desperate migration and health

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Introduction

Europe's health systems are facing an ageing population and rise in rates of chronic disease, threatening universal access to health care and the sustainability of health systems. The migration of health care professionals within the European Union (EU), and the consequent shortages in medical personnel in the countries they leave behind, is another predicament. A new phenomenon is the influx of migrants and refugees, which poses challenges for countries on the frontline, particularly Greece, as well as final destination countries such as Germany and Sweden. These challenges are taking place against a backdrop of the continuing effects of the economic crisis and the strain it has placed on health budgets.

Whereas the organisation and delivery of health care is in the hands of Member States, this article focuses on the many

ways that working together at EU-level can help address challenges related to demography and diversity. Much can be achieved through sharing expertise and best practice and working together in collaborative projects and joint actions. However, we also need new solutions for health, and here we focus on two areas in particular – eHealth and Health Technology Assessment (HTA).

The ageing demographic and rise in chronic diseases

The ageing trend in Europe is set to continue in the decades to come. Life expectancy has increased for both sexes in all EU countries. The average lifespan has risen from 74 years in 1990 to 80 in 2015, and by 2060 life expectancy will have risen by seven more years for men and six for women.¹

However, healthy life years are not increasing accordingly. Longevity and healthy life years are strongly affected by the cumulative effect of health behaviours and inequities across the life cycle. Large health inequalities persist both between and within EU countries. For example, in 2012 the gap in life expectancy between the Member States at the lowest and highest end of the spectrum was 18.7 years for men and 19.3 years for women.²

“ageing population and rise in rates of chronic disease

In parallel, the burden of chronic diseases in the EU is growing, causing drawn out suffering for patients and placing a huge burden on health care budgets: an estimated 70% to 80% of health care costs, representing some €700 billion in the EU,³ are spent treating chronic diseases. In 2012, EU countries devoted an average of 8.7% of GDP to health spending, up significantly from 7.3% in 2000.⁴

The European Commission takes a multi-faceted approach to supporting EU countries' efforts to deal with an ageing population and prevent, reduce and treat chronic diseases – supporting partnerships, providing fora for exchanging good practice on risk factors, various sources of funding, advice, and more. Three examples include the following:

1. The European Innovation Partnership on Active and Healthy Ageing has, to date, brought together over 3000 partners, 1000 regions and municipalities, and 300 organisations to examine new ways of addressing the challenge of an ageing population. This has led to innovative programmes being rolled out – for example, on adherence to medication, prevention of frailty, chronic disease management and integrated care, and a strategy to scale-up successful practices.

2. In the context of the European Semester, the Commission provides recommendations and advice to a number of EU countries to help them design resilient health systems that can withstand current and future pressures and to continue to provide patients with the best possible care.
3. The CHRODIS Joint Action⁵ of 25 countries is among the many projects and joint actions co-financed by the Commission's Health Programme aimed at preventing chronic diseases and promoting healthy ageing across the lifecycle.

Furthermore, there is a growing pace of technological advancement and innovation that has the potential for improving health in Europe. The challenge is to ensure the availability, affordability, cost-effectiveness and safety for products and technologies for patients, whilst preserving an innovation-friendly environment. We would like to highlight two particular areas of innovation that can offer new solutions for Europe's health systems in terms of providing more care with less expense: **eHealth and Health Technology Assessment (HTA)**.

eHealth

eHealth and mHealth products and services have already become firmly established within the public health and health care sectors. More and more people use smart-phones and other electronic devices for prevention and monitoring of diseases. And more countries are integrating telemedicine into their health systems, such as consultations over the internet.

This promising field is gaining momentum and acceptance across Europe; and the Commission is seizing the opportunities offered by the emerging European Digital Market to create an environment in which practical, innovative, and cost-effective eHealth solutions can thrive.

The key to maximising the potential of these various technologies is for EU countries to ensure that their respective eHealth systems can communicate with each other. To this end, the Commission is working closely with Member States

to overcome interoperability challenges between EU health systems so that patients can fully benefit from a digital single market in health – for example, through cross-border e-prescriptions or electronic patient summaries.

The EU also provides various tools to finance eHealth; for example, the Connecting Europe Facility (CEF) is financing, amongst other things, the building of an EU digital infrastructure for health. To date, 20 Member States have applied for funding under this project in order to build up concrete capacity to exchange health data, e-prescriptions and patient summaries.

Such EU collaboration and connectivity in the area of eHealth aims to bring about four big wins:

- 1) Empowered patients who are able to manage their own health thanks to a better flow of information and interaction with health professionals.
- 2) Increased sustainability and efficiency for health systems.
- 3) Greater access to personal health data for patients and health professionals, enabling faster diagnosis, improved monitoring, more effective treatment and better health outcomes.
- 4) Support for patients' access to health care services across Europe.

HTA

In a climate where the challenge for all countries in the EU is to do more with less, cooperation on HTA at EU-level can help decision makers in all 28 Member States formulate safe, effective and cost-effective health policies.

HTA answers questions like: Is the technology effective? For whom does it work? What costs are entailed? How well does it work compared to alternative technologies? Such questions are vital for health policy makers and administrators to face the increasing burden on Europe's health systems.

The benefits of a sustainable EU cooperation on HTA are numerous. It can ensure better use of resources in HTA production, contribute to the functioning

of the internal market for health products, ensure that patients have timely access to innovative health technologies and treatments, and improve the sustainability of health care systems.

The Commission has supported voluntary cooperation in this area for more than 20 years. In 2013, the voluntary EU-wide network on HTA composed of national HTA bodies or agencies was set up. This work, complemented by three Joint Actions* on HTA, has enabled us to build a solid knowledge base on methodologies and information exchange.

Now we are embarking on the next step. Preparatory work on HTA is included in the 2016 Commission's annual Work Programme. This is a crucial milestone, enabling us to build on our achievements and bring fresh impetus to the efficient use of HTA resources in Europe. We are now working on an inception impact assessment to carefully assess various options linked to continuing the cooperation on a permanent and sustainable basis.

The migrant challenge

As of the end of February 2016, over 1.1 million people – refugees, displaced persons and other migrants – have made their way to the EU, either escaping conflict in their country or in search of better economic prospects.[†]

Migrants entering Europe are, in general, healthy and do not bring diseases with them. However, most have travelled in dreadful conditions to arrive at overcrowded ‘hotspots’ in a state of mental and physical exhaustion. It is a desperate situation for these individuals, and an enormous strain for the countries on the frontline, particularly Greece which is already facing severe economic hardship.

The Commission's immediate concern is providing these countries with the support they so desperately need – e.g., with piecing together migrants' health records and vaccination history, training staff and volunteers, and, in the longer

term, ensuring migrants' integration into primary health care systems, and protecting against stigma and health inequalities. Concrete actions include:

- Producing a Personal Health Record to reconstruct the medical history of incoming migrants and refugees[†] jointly with the International Organisation for Migration (IOM) and the European Centre for Disease Prevention and Control (ECDC), and an accompanying Handbook for health professionals.[‡]
- Mobilising the EU budget to help countries on the ground with activities such as health care models for vulnerable migrants, integration of migrants in primary health care systems, and training of health professionals.
- Coordinating activities within the Health Security Committee, e.g.
 - gathering requests for vaccines and other health supplies from the countries most affected, so that other Member States can provide support;
 - reinforcing surveillance of communicable diseases via the Early Warning and Response System; and
 - connecting national contact points for health with those in charge of civil protection and asylum, migration and integration funds.
- Participating in discussions on the integration of third country nationals, particularly as there are health workforce shortages in the EU, and many incoming refugees and migrants are health care professionals.

Migration within the EU

This last example leads us to look further at the migration challenge within Europe. The “brain drain” affecting some countries, as doctors relocate to countries with better conditions and remuneration, has led to critical shortages and concerns for access to health care for the patients in the countries they leave behind.

While the mobility of health professionals is a fundamental right under the Treaty, facilitated by the Directive on the mutual recognition of professional qualifications, an EU Action Plan to address challenges to the EU's health workforce[§] focuses on issues such as recruitment and retention of health professionals. Last year, the Commission published a study on innovative and effective recruitment and retention strategies[¶] to assist EU countries with developing policy responses to recruit and retain staff. In addition, a Joint Action on health workforce forecasting and planning, co-financed by the Health Programme and bringing together 28 European countries and 16 stakeholder organisations, has just ended, delivering results such as:

- A handbook of good practices and methodologies;
- A study looking at the main drivers of changes through to 2035, and implications for the health workforce in Europe;
- Data analysis to support improved data quality, availability and comparability, for the benefit of EU countries.

There is commitment to continue this work. Indeed, support for cooperation at EU level to address health workforce shortages remains a key priority of the Commission's Health Programme.

Conclusion

There are many ways in which the EU can help Member States with the challenges to their health systems – both in emergency situations such as the refugee crisis where the EU principle of solidarity is put to the test, and in serious long-term issues such as increasing rates of chronic diseases and shortages of medical personnel. These include methods with a proven track record, and vitally, ramping up EU collaboration on new innovative solutions such as eHealth and HTA. With the commitment and solidarity of EU countries and stakeholders we can accelerate progress in these areas, which is expected to bring direct benefits to health systems and patients in Europe.

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► #EHFG2016 Forum 10:

The challenges of Alzheimer's and other dementias

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DEMENTIA: PRESSING POLICY CHALLENGES

By: Martin Knapp

Summary: Dementia is one of the biggest clinical, social, economic and policy challenges for European health and care systems today. I argue that a collective (policy) response to these challenges must be multi-dimensional. Societal responses to dementia in many countries are already better today than they were ten years ago, but much more needs to be done. There must be earlier and more effective prevention, better care and treatment (although no 'cures' have yet been discovered), more support for family and other unpaid carers, and continued investment in basic science to find disease-modifying treatments.

Keywords: Dementia, Long-term Care, Prevention, Unpaid care

Introduction

Dementia is a major clinical, social, economic and policy challenge across the whole of Europe. It is a devastating, distressing collection of illnesses, the most prevalent of which is Alzheimer's disease. Recently, I have heard a number of people describe dementia as the 'new cancer': a collection of different diseases, some of them highly prevalent, none with a known cure, all of them life-shortening, and all widely feared.

Dementia is already very costly, and the costs – both to the public purse and to individuals and families – will get considerably greater over coming decades. Since dementia prevalence has a steep age gradient – fewer than 1% of people aged under 70 have dementia, but 30% of those aged above 90 – one could almost suggest that the policy challenge is actually growing faster than the population is ageing.

Recent studies suggest that age-specific incidence rates may be falling in some countries (e.g. England), probably due to better health behaviours earlier in life.¹ However, in reporting similar overall findings from the well-known Framingham Heart Study in the US,² Satizabal and colleagues point out that this improvement is only found among the better educated members of the cohort. The otherwise welcome reduction in dementia incidence is therefore far from equally enjoyed across all sections of society.

Challenges of the near-future

Despite these important (if small and unequal) changes in incidence rates, the total prevalent number of people with dementia will continue to grow considerably over the next few decades. Growth will be especially rapid in low- and middle-income countries. According to Alzheimer's Disease International³

there are currently 47 million people with dementia worldwide, with the number likely almost to double every twenty years, reaching 75 million by 2030 and 132 million by 2050.

“a collective response to dementia needs to be multi-dimensional”

Taking a broader view, we need to remember that healthy life expectancy (HLE) *at age 65* is not growing as fast as life expectancy (LE), even though HLE is the same as LE *at birth*.⁹ In other words, population ageing today is associated with more years of poor health in many European countries. One particularly important feature of this changing demographic profile is multi-morbidity: a growing number of older people have more than one long-term condition (often including dementia). Given that most health systems are still dominated by the ‘single morbidity paradigm’, this multi-morbidity considerably complicates treatment and care.

Unless a cure or disease-modifying treatment is found very soon, and then quickly made available at an affordable price, the attendant costs of dementia care will grow considerably for a few decades. Projections of this kind are not new¹⁰ but they seem only recently to have begun to focus the minds of many governments on how they might contain expenditure whilst ensuring a good quality of life for people living with dementia and their carers.

What then should policy-makers be doing? It is clear that policy needs to be multi-dimensional, organised around four core aims: better prevention, better care, better support for family and other unpaid carers, and better support for basic research to find a cure. And, if cost containment is required – i.e. if pursuit of these aims does

not bring down the costs of dementia – then policy-makers may also start to think about how to change health and social care financing arrangements.

Better prevention

Reducing the number of people who develop dementia, or delaying the age at which these diseases begin to interfere significantly with their lives, must surely be a priority aim. There are a number of known *mid-life* risk factors for the development of Alzheimer’s disease and other dementias: physical inactivity, smoking, diabetes, hypertension, obesity, depression, and lower educational attainment.¹¹ Alcohol consumption, social isolation and air pollution are among other factors suggested as associated with a higher risk of dementia, but the evidence is not yet conclusive. These risk factors are clearly interconnected; after adjusting for correlations, Norton et al¹² reckoned that almost a third of Alzheimer’s disease cases might be ‘attributable’ to risk factors that are potentially modifiable.

A couple of years ago, my colleagues and I were asked to examine the economic consequences of a range of future scenarios for dementia.¹³ Some scenarios looked at the wider availability and use of evidence-based interventions (see below), while others looked at the consequences of either better prevention or of a disease-modifying treatment (as yet undiscovered, of course) with the aim of either slowing disease progression or delaying its onset. We estimated that if such a strategy could delay onset by a year or longer, aggregate costs would come down substantially. Slowing the progression of the disease without changing the age of onset would also potentially reduce costs, because it would delay the need for people to go into care homes or hospital. There would also be important gains in health and quality of life for the individuals at risk of developing dementia and their families.

The big challenge, of course, is to get people to engage in preventive strategies – giving up smoking, taking more physical exercise, ensuring a better diet and so on – early enough in life to make a difference, and to make sure that the costs of prevention are not disproportionate

when compared with later savings. It is often said that ‘what is good for your heart is good for your brain’, and certainly public health campaigns that target cardiovascular health will have spill-over benefits for dementia. Lifelong learning and other efforts are also needed to build or protect cognitive capital in a broader sense (i.e. not just in relation to dementia).¹⁴

‘Better prevention’ is undoubtedly a sensible long-term policy aim for dementia, just as it is for many other conditions, but at the moment there is very little evidence on how to operationalise it in ways that ensure effectiveness and fairness, nor do we know anything about the cost-effectiveness of such strategies.

Better care

Timely identification of dementia through better screening (both faster responses to early signs of cognitive decline as well as better diagnostic accuracy) should help to improve the lives of individuals who are developing dementia and of their close family members. Timely diagnosis helps them to plan ahead and, if health and social care systems are adequately prepared, it should also enable them to get treatment and support, which in turn could avoid some later crisis-related costs (such as emergency inpatient admissions).

Post-diagnostic support encompasses a range of community and other health and care services, as well as the unpaid (‘informal’) care of family members and other carers. It includes specialist settings such as dementia cafes and memory clinics, as well as specialist housing and nursing homes for people whose cognitive impairment has reached such a level of severity that they can no longer live in their homes. Robust evidence is accumulating rapidly on what works in post-diagnostic support.¹⁵ There are symptomatic medications and psychosocial therapies that can slow cognitive decline or treat other symptoms such as agitation, and there is some evidence that better home-based care, care co-ordination and targeted support for family carers can improve wellbeing.

There is now also a body of *economic* evidence to guide commissioning and delivery decisions.¹¹

The ‘scenario exercise’ described earlier included examination of what might happen if evidence-based interventions were more widely available, given that they are not currently rolled out to everyone who could potentially benefit from them.¹² We focused on four: anticholinesterase inhibitors (the most commonly used anti-dementia medications), cognitive stimulation therapy, case management and carer support. The overall economic impact was actually rather modest: there were important health and wellbeing improvements, but little change in cost. So, more widely implementing what we know today to be effective and cost-effective would definitely improve people’s lives but it would not bring down the total economic impact of dementia. (We are continuing to explore this area in greater depth in the MODEM study; see www.modem-dementia.org.uk.)

Clearly, much more needs to be done to develop ‘better care’. One emphasis should be responses to need that are *person-centred*, better attuned to individuals’ preferences and that protect their dignity. The tremendous potential of *assistive and other technologies* has not yet been realised in any clinical area, and certainly not in relation to dementia where there are anyway particular complications.¹³ There is also a need to think through how to invest in *housing* that adapts to needs as people age. The design of *communities* to make them age-friendly and dementia-friendly should be another aspiration. *End-of-life care* is generally poor across all European countries, and especially poor for people with dementia. Managing multi-morbidities better is also likely to improve health and wellbeing, and could potentially be cost-effective.

Better support for carers

The demographic challenge of dementia is perhaps exacerbated because projected trends are not only rapidly increasing the number of older people with long-term conditions, but also reducing the potential supply of unpaid family carers. Falling

fertility rates and greater geographical mobility will be major influences on this supply. But because most carers have traditionally been women (and this is still very much the case), rising rates of female labour force participation over recent decades are also highly pertinent. Indeed, many women are today juggling paid employment with unpaid care not only for ageing parents but also for grandchildren.

“much more needs to be done to develop better care”

Good family care for someone with dementia can certainly greatly improve that person’s wellbeing, whilst also delaying nursing home and hospital inpatient admissions.¹⁴ Yet being a carer – especially of someone with moderate or severe dementia – can be enormously stressful, with a high risk of anxiety or depression,¹⁴ as well as the well-known potential ‘burdens’ of out-of-pocket costs and lost opportunities for paid employment or social activities.

Although the pivotal roles played by family and other carers in dementia care have been recognised for a long time, there has not been a great deal of research into what can be done to support them. One successful approach that *has* been evaluated is START (STrategies for RelaTives). This is an intervention to help family carers to develop better coping strategies, delivered by psychology graduates over eight one-to-one sessions. An evaluation of START over 24 months found very positive outcomes for carers (in terms of health-related quality of life and mental health), no effects on people with dementia (either negative or positive), and clear evidence of cost-effectiveness.¹⁵

Finding a cure

It has often been said that perhaps 99 out of 100 attempts to find a disease-

modifying treatment for dementia have failed. Billions of Euros have been spent on dementia medications that never made it to market. The pharmaceutical industry has therefore become somewhat pessimistic about what can be achieved in this therapeutic area, and hence increasingly cautious about making big speculative investments. Of course, the flipside is that the prize for the winner would be very lucrative indeed.

International bodies such as the World Dementia Council are trying to find ways to generate a collective pool of resources to keep the science going, and some national governments and research charities are committing additional funds, as illustrated by the establishment of the UK’s Dementia Research Institute.¹⁶ There are also discussions about how to harmonise regulatory pathways to accelerate drug development, efforts to share knowledge, and the beginnings of investment in ‘big data’.

Even if there were to be a major scientific breakthrough in the next few months, it would probably be more than a decade before a new medication was widely enough available to make any noticeable difference to people living with dementia across Europe. This obviously does not mean that efforts should not be made in basic science, but it *does* mean that – today and for the immediate future – we also need to make major efforts to improve care and support within the present therapeutic environment.

Funding reforms

Many European countries have already embarked on reforms that change how health and long-term care are financed. Rapid population ageing means that the previously assumed ‘balance’ between years spent in education, employment and retirement – on which post-Second World War pension, health care and other systems were constructed – no longer holds. Financing reforms are generally shifting the balance of responsibility from the collective to the personal. The burgeoning cost of dementia care is obviously not the only pressure on health systems, but it does reflect very well the growing fiscal challenge.

Multiple policy aims

I have argued that a collective response to dementia needs to be multi-dimensional: earlier and more effective prevention, better care, more support for families and greater investment in science to find a cure. But if dementia really is the ‘new cancer’ then perhaps we should be heartened by how scientific endeavour in that field, allied to (some) public health successes, better therapeutic alliances and altered societal attitudes have changed things for the better.

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The Netherlands: Health system review

By: M Kroneman, W Boerma, M van den Berg, P Groenewegen, J de Jong, E van Ginneken

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The Dutch population enjoys access to essential health care services that are within easy reach and with reasonable and decreasing waiting times. The basic health insurance and compensation package for citizens on lower incomes protects against catastrophic spending. Out-of-pocket payments are low from an international perspective. The Dutch rate the quality of the health system and their health as good. International comparisons show that the Netherlands has low antibiotic use, a small number of avoidable hospitalisations and a relatively low avoidable mortality. National studies show that healthcare has made major contributions to the health of the Dutch population as reflected in increasing life expectancy. Furthermore, some indicators such as the prescription of generics and length of stay reveal improvements in efficiency over the past years.

The fact that the Netherlands has one of the highest per capita health expenditures in Europe remains an important concern



although growth has slowed considerably after reverting to more traditional sector agreements on spending. However, the most transformational change has been the impact of the two major reforms implemented since the mid-2000s. These ongoing reforms are changing the way the Dutch health system operates today. The 2006 reform replaced the division between public and private insurance with

one universal social health insurance and introduced managed competition in the health care system. Although the reform was initiated almost a decade ago, its gradual implementation continues to alter the health care system in general and the role of actors in particular. The newly implemented long term care reform aims to achieve a transition from publicly provided care to more self-reliance on the part of citizens and a broader role for municipalities. Whilst these reforms are ongoing, a particular point of interest is how effectively the new governance arrangements and responsibilities in long term care will work together.

IMPLEMENTATION OF THE LIFE-COURSE APPROACH THROUGH STRENGTHENED INTERSECTORAL ACTION

By: Manfred Huber, Gauden Galea, Gunta Lazdane and Monika Kosinska

Summary: Reliance on policies that address narrowly defined stages of life is not enough to improve health and reduce inequalities. A strong case exists for coherent policies that consider the influence of early or timely action on health throughout life and across generations. Important points in people's lives – particularly transitions during changes in role and status – offer opportunities to act that improve health outcomes later. Adoption of a life-course approach that mobilises a range of actors across government and society presents policy-makers with unique opportunities to improve health and well-being, promote social justice and contribute to sustainable development and inclusive growth.

Keywords: Life-Course, Public Health, Non-Communicable Diseases, Intersectoral Action, Health-in-all-Policies

► #EHFG2016 Forum 1:
Life course and intersectoral approaches to public health

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Overview

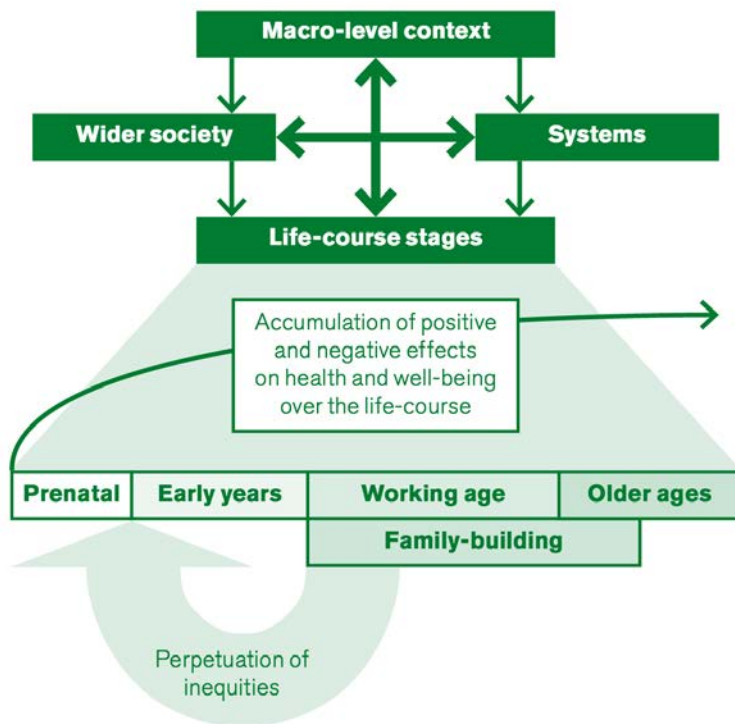
Adopting a life-course approach is one of four strategic principles of Health 2020, the WHO policy framework for health and well-being in Europe.¹ This approach builds on growing evidence on the pathways by which health advantages and disadvantages accumulate throughout life. New and remarkably consistent findings are available from a range of scientific disciplines – including genetics, epidemiology, psychology, neuroscience, economics and environmental sciences – adding to the knowledge on factors that influence health throughout the life-course and across generations.

At the 2015 WHO European Ministerial Conference on the Life-course Approach in Minsk, Belarus, Member States agreed on the importance of the life-course approach for the successful implementation of Health 2020 and the goals and targets of the United Nations 2030 Agenda for Sustainable Development.

The Minsk Declaration² includes a commitment to an agenda for acting:

- early
- appropriately during life's transitions
- together.

Figure 1: A life-course approach to action areas across stages and transitions in life



Source: Ref. ⁷

This article reflects on the implications of evidence on life-course trajectories for policies that fit this agenda and illustrates key policy interventions.

“importance of action in the earliest days of life”

The three principles for action involve many different actors across a range of sectors. A life-course approach thus aims at solutions that encompass a wide array of possible areas (see Figure 1). These often focus on early years or target important life transitions, supporting people during family-building, the working career and in transition to retirement, including interventions that facilitate active and healthy ageing.

Acting early: the importance of investing early on

The importance of action in the earliest days of life is a strong message within the life-course approach, supported by new evidence in recent years.⁸ For example, if a woman is malnourished before she becomes pregnant and during pregnancy, it may increase the risk that her offspring will develop obesity and diabetes during middle age.

Moreover, good nutrition during the first two years of a child's life is particularly important to combat morbidity and mortality and to reduce the risk of chronic disease in later life. Early initiation of breastfeeding is recommended to protect the newborn from acquiring infections. Exclusive breastfeeding for the first six months of life has many additional benefits and can have important protective effects throughout life – for example, by reducing the risk of overweight and obesity in later life. Despite this evidence, breastfeeding rates in many countries in the WHO European Region are low, and in some cases mothers with low socioeconomic status are much less likely to begin breastfeeding.⁴

Other important early interventions are programmes that prevent adverse childhood experiences, which have been associated with health-harming behaviours such as smoking, substance misuse, physical inactivity, attempted suicide and being a victim or perpetrator of violence, among other risks.

Among the most important early interventions with lifelong benefits is protection against vaccine-preventable diseases and their consequences. While vaccination coverage across the European Region remains high, with first-dose measles-containing vaccination coverage at around 94%,⁹ significant recent measles outbreaks in a number of countries show the dangers of remaining gaps.

Acting during life's transitions and preventing inequalities

Several distinct transition life phases present both risks and opportunities for dealing with inequities. Negative experiences from previous phases can have an important compounding effect, with the risk that an individual may fall to a lower level on the social ladder. This has special relevance for transitions during mid-life, such as becoming parents, entering and staying in the workforce and preparing for active and healthy ageing. These transitions offer opportunities to stop the intergenerational transmission of inequities and to rise to a higher level on the social ladder.

Reaching adolescents before they start to adopt unhealthy behaviour can have a sizeable impact on later health. Health promotion initiatives in schools can play an important role, linking health to the core task of schools – education. The fact that most adults who smoke acquired the habit in adolescence demonstrates the need for early intervention; peer pressure, role models and societal norms all contribute to this outcome. Conversely, adolescents who reach early adulthood without smoking almost never take up the habit. The emphasis must therefore be on actions that ensure environments free from harmful substances such as tobacco, alcohol and recreational drugs.

A major upsurge has been seen in the availability and affordability of energy-

dense foods that are high in saturated fats, trans fats, free sugars and salt, and in sugar-sweetened beverages. Schools have been identified as a high-priority setting for policies that address unhealthy food environments for all ages: implementation of comprehensive standards that apply to all foods available on school premises can have an important impact.⁶

Progress has also been made in promoting sexual and reproductive health and well-being in the WHO European Region, but important opportunities for improvement are often missed. Comprehensive health education includes education about people's sexuality and sexual health. This calls for close collaboration between the health and education sectors, but because of its sensitive nature, such education is often complicated and sometimes neglected. Moreover, Europe is rich in examples of programmes ensuring that schools are free from bullying and other forms of violence, but successful interventions can still be further scaled up.

On leaving school, many young people face important barriers that prevent them from gaining work experience and further qualifications in today's labour markets, which are still affected by the financial and economic crisis. The association between education level and health over the life-course is well established, but there are also immediate risks: periods of unemployment of two years or more in early adulthood, for example, have been correlated with higher rates of risk-taking behaviour, such as heavier drinking and smoking in mid-life and higher prevalence of mental health issues. Ultimately, the danger is that the combined effects of poorer health and lower employment and income security in early adulthood create a vicious cycle.⁷

Supporting families to build parenting capacities can be crucial for the health of parents and the next generation. This includes access to evidence-based information and services that address the medical, psychological and social impacts of pregnancy, supported by the use of public information portals and other – preferably interactive – dissemination methods.

Acting together: mobilising all sections of society

Awareness is growing that actions proposed in a life-course perspective should target all segments of society, tackling the different underlying mechanisms that lead to health inequity in each group. This includes giving special care and attention to disadvantaged and minority groups, and addressing mental health and occupational health issues. These initiatives are often more effective if they bring together a broad coalition of sectors of government, academia, civil society, private sector, media and communities, making full use of available policies, tools and resources.

Stakeholder coalitions for better health are in fact at the heart of many communities within the movement for healthy cities. Local knowledge, leadership and resources can make a difference in public health for the two thirds of the population of the WHO European Region living in towns and cities.

There is room to improve intersectoral cooperation for mental health, in particular. Mental health and well-being and mental disorders are associated with socioeconomic and material determinants from birth onwards. For example, low income and low social status both predict postpartum depression*, which negatively affects long-term mother-child bonding.

About 50% of mental disorders have their onset before the age of fifteen; some last a lifetime, causing suffering to individuals and families and a burden to society. Early intervention, particularly in the most prevalent problems such as anxiety disorders and depression, is possible, as demonstrated by effective partnerships between mental health services and schools.

Depression and anxiety are major causes of long-term sick leave and early retirement and are associated with noncommunicable – particularly cardiovascular – diseases. Prevention of sick leave or measures to encourage early return are important, since any

lengthening of the absence period is strongly associated with reduced chances of return to work. Partnerships between employers and the health service have been shown to be effective.

Preventing or postponing health-related retirement – not only that caused by mental health issues – remains a challenge for all countries in Europe. Early retirement and permanent living on disability benefits in early old age puts people at higher risk of social exclusion and faster health decline. Health systems can contribute by improving their capacity to prevent and treat common causes of early retirement, such as chronic back pain and common mental disorders.

Another important area of policy innovation in cross-sectoral cooperation is the development of age-friendly cities, communities and environments. Age-friendly supportive environments can help older people stay active, engage socially and live independently as long as possible, even when living with functional limitations or dementia (see Figure 2).

Safe and attractive environments for active transport and physical activity in daily life, for example, can be one of the most powerful ways to reach all people and ages. These investments in the urban physical and social environment also combat the rise in obesity and noncommunicable diseases.

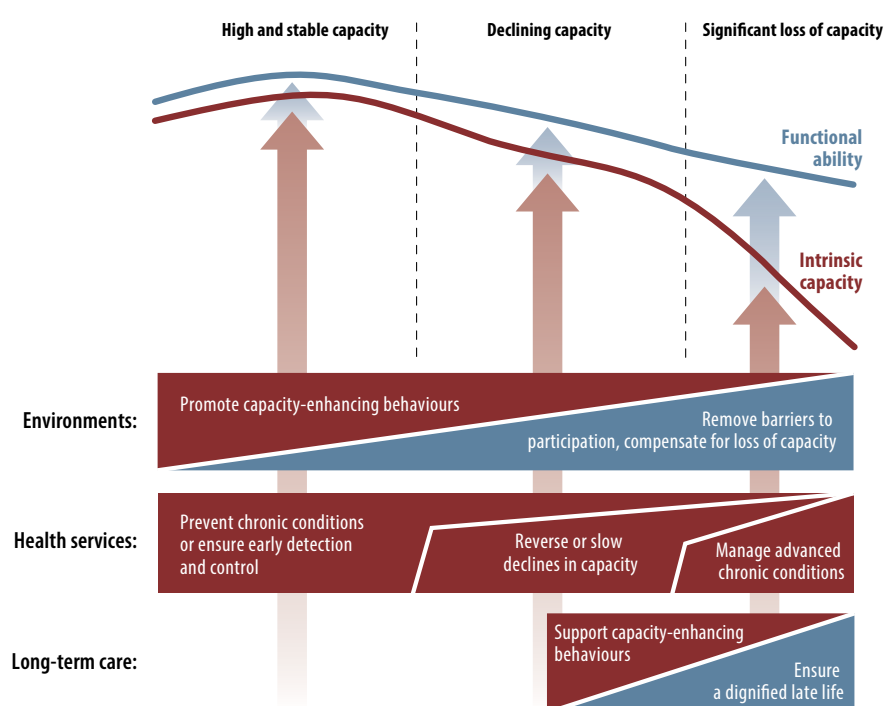
Policies for healthy ageing include raising health literacy and awareness of the health changes in older age and creating understanding about how to cope with them better, including for those living with dementia. A life-course approach for healthy ageing also includes training and counselling, as well as respite care and income support for family carers – important measures to protect carers' health, many of whom are themselves 50 years or older.

Strengthened intersectoral governance for health and well-being

Strengthening partnerships across government and society as part of the life-course approach means also investing

* Postpartum depression is a moderate to severe form of depression in a woman after she has given birth. It may occur soon after delivery or up to one year later.

Figure 2: A public health framework for healthy ageing: opportunities for action across the life-course



Source: Ref. ⁸

in the instruments, mechanisms and capacities that facilitate working across sectors. The diversity of the European Region has given rise to a rich experience of building partnerships between sectors, with a number of commonalities emerging as pre-conditions and challenges to intersectoral working.

Successful whole-of-government approaches means strengthening the policy coherence between sectors, including through various concrete measures such as impact assessment, common targets and shared budgets. This sustained and systematic action takes commitment, political will and leadership to implement and sustain.

Where there is an absence of political will, the experience of the European Region shows that progress is still possible: successful partnership and work across sectors needs time, buy-in from others, and institutional and human capacity to take work forward. Bringing the right stakeholders to the table, developing shared goals and accountability requires

preparation and relationship building—which can then be leveraged when political windows arise.

Finally, collective whole-of-society approaches and stakeholder coalitions mean the involvement of communities and populations into the design, implementation and evaluation of policies and services impacting on their health and well-being. Community involvement can improve the quality, relevance and ownership of the policies and services, as well as contribute to empowerment through an increased ability to influence and control decisions that affect them.

Conclusions

The policies outlined in this article illustrate important opportunities to improve health and well-being using a life-course approach. The more general implications are that public policies and services should be designed to promote the health of each generation and to prevent, as far as possible, disadvantage passing from one generation to the next.

Poor health is both a cause and consequence of deprivation. Policies need to recognise this reality and seek to address it. Solutions should be sought beyond the health sector: society as a whole needs to work together. A life-course approach involving early, timely and collective action offers the chance to ensure that no opportunity is missed – from pre-conception to the last years of old age – to maximise health and well-being and to meet the ambitious goals of Health 2020 and the 2030 Agenda for Sustainable Development.

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FINDING THE BALANCE IN LIFE-COURSE VACCINATION

By: Karam Adel Ali and Lucia Pastore Celentano

Summary: Progressive changes to the EU's demographic structure have given impetus to renewed research on more effective and sustainable ways of investing in health and healthy ageing. The role of prevention is paramount in this regard, and it has been suggested that expanding vaccination programmes to embrace the entire life-course could be instrumental in helping to meet disease elimination goals, as well as to maximise opportunities for reducing disease burden in later years of life. There are nonetheless a number of challenges that will require careful consideration in prioritising vaccinations across all age groups, and to develop the necessary evidence that can drive a radical shift.

Keywords: Vaccination, Life-course, Prevention, Healthy Ageing

Progressive changes to the EU's demographic structure have given impetus to renewed policy interest and research on innovative and more effective ways of investing in health. Life expectancy, migratory flows, and dynamics in fertility are expected to significantly change the age structure of the EU's population over the coming decades. By 2060, those aged 65 and over will become a much larger proportion of the population (from 18% to 28%), and those aged 80 and over will be almost as numerous as the young population (0 to 14 years old).¹ Long-standing concerns around the viability of sustaining increasing health care costs as a consequence of demographic change, together with the observed rise in the burden of chronic diseases, and demands for improved quality and patient-centred care have been further exacerbated by the most recent financial and sovereign debt crisis.

In the face of such challenges, attention has been given to the identification of more effective, sustainable and efficient ways of delivering health care underpinned by a strong evidence-base for resource allocation. The role of prevention is paramount in this regard. According to the OECD, overall spending on prevention generally stands at less than 3% of the general government health expenditure (GGHE); since 2009 spending on preventative care has continued to bear the 'brunt of cuts' with an estimated contraction of 0.6% on an annual basis.² This has encouraged calls for re-balancing spending on care and cure versus opportunities to maximise health promotion and protection, and disease prevention programmes.

Vaccination is a mainstay of prevention programmes in Europe and worldwide, and remains one of the most cost-effective ways to prevent disease. Traditionally,

► #EHFG2016 Lunch workshop 1:
Life-course vaccination

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however, it has been looked at as a primarily childhood-focused public health intervention. In recent years, it has been argued that expanding vaccination programmes to include adults and embrace the entire life-course could be instrumental to meeting disease elimination goals, as well as to maximise opportunities for reducing disease burden in later years of life.

One reason for this suggested approach has been the fact that over the last few decades there has been a shift in the burden of diseases that were traditionally those of childhood towards older age groups, and new vaccines are being licensed as indicated for adults. Adult vaccination, immune-senescence and vaccine immunology will progressively constitute central topics of interest in recognising the ageing demographic and the EU's commitment to healthy ageing. At the same time, more diseases will become preventable as new vaccines are developed, with the potential of accruing fundamental public health and economic gains.

In the light of such factors, the *2014 EU EPSCO* Council Conclusions on Vaccinations as an Effective Tool in Public Health* invite the Member States and the European Commission to consider vaccination beyond infancy and early childhood by creating programmes with a life-course approach.

This article describes and discusses the rationale for life-course vaccination, the current status and challenges of its introduction, and the already ongoing initiatives at the EU level.

The whats and whys of life-course vaccination

There are a number of fundamental reasons for considering immunisation strategies with a life-course approach as a public health imperative.

First, adults may not have received all of the necessary vaccinations during

childhood years as a consequence of a variety of factors. This could leave them unprotected against some of the most common vaccine-preventable diseases (VPDs) associated with an age-related increase in severity and complications, such as measles, rubella, and pertussis. These diseases become of particular concern in settings where childhood immunisation rates are sub-optimal, or where coverage is not uniform across sub-national geographic areas. The accumulation over time of non-immune people and social and geographical clustering of under-vaccinated people will continue to be a significant challenge for measles and rubella elimination in the EU. In October 2015, the European Regional Verification Commission for Measles and Rubella Elimination (RVC) reported immunisation gaps in adolescent and young adult sub-sets of the population in several countries. It was concluded that closing immunity gaps may require targeted supplemental immunisation activities.

Closing immunisation gaps is also relevant in the light of the most recent migratory influx into the EU. Migrants arriving from countries where certain diseases are endemic, or where vaccination programmes have been interrupted due to political circumstances are vulnerable to VPDs and should be prioritised for vaccination. For those whose vaccination status is unknown or undocumented, EU Member States might consider immunisation activities for children, but also adolescents and adults, particularly against the priority diseases targeted for elimination and eradication (measles, rubella, and polio). Additional vaccinations should be considered based on risks arising from living conditions, season, and the epidemiological situation.⁵

Acquired immunity through earlier vaccination or infection can also wane over time, requiring the administration of periodical boosters in adulthood. For certain VPDs, adult vaccination can confer indirect protection to susceptible populations unable to fully benefit from immunisation. For example, in the case of pertussis, the vaccination of pregnant

women has been implemented by some countries to protect new born babies still too young to be vaccinated.

At the same time, new generation vaccines are being licensed and promoted as being indicated to meet health needs in populations other than children. Examples include those aimed to prevent human papilloma virus-caused cancers, and other vaccines that can respond to age-related specific needs.

Older age groups represent a heterogeneous population, with different needs and whose health status is impacted by multi-faceted determinants beyond biological and medical factors alone. Nonetheless immune-senescence and declining immune response to antigen challenges with advancing age can result in the elderly being more susceptible to infectious diseases than younger adults. In such populations, infectious diseases of high incidence such as influenza, pneumococcal disease, or herpes zoster can have debilitating consequences, severely affecting quality of life, or be a significant cause of death.

Vaccination is also critical for individuals with underlying chronic conditions to reduce the burden of co-morbidities and risks and challenges of poly-medication, including the potential for interactions between antimicrobial treatments and chronic disease treatments and the risks of some antimicrobial treatments in patients with impaired renal or hepatic function. Though multimorbidity is not just a problem for older adults, the prevalence is significantly higher in older age groups, with 65% of people aged 65–84 and 82% of people aged at least 85 years being affected.⁶ Patients affected by heart disease, stroke, chronic obstructive pulmonary disease, and diabetes – among the most burdensome disorders according to the WHO Global Burden of Disease – or disorders affecting the immune system are at higher risk of experiencing complications and a worsening of their pre-existing condition if they contract infections such as influenza or pneumococcal disease. This can result in higher hospitalisations and fatality cases. There is thus a fundamental link between chronic and infectious diseases,

* EPSCO is the Employment, Social Policy, Health and Consumer Affairs Council which brings together ministers responsible for employment, social affairs, health and consumer policy from all EU Member States.

which must be recognised, and for which comprehensive preventative approaches are key.

Finally, other adult vaccinations might be needed or tailored to meet variations in risk determined by occupation, e.g. in the case of health care workers to protect themselves and their patients, or for travelling needs.

State of play in Europe

Currently, vaccination policies for adults vary significantly across Europe. Data extracted from the *ECDC Vaccine Schedule Platform*⁵ on three selected vaccinations targeting the elderly are reported below to illustrate the heterogeneity of the situation.

In the EU/EEA 31, nineteen EU/EEA countries currently recommend vaccination against pneumococcal disease for older individuals above 60 or 65 years, mostly as a general recommendation (in 17 out of 19 countries). In more than half of these countries, the vaccine is not funded as part of the national vaccine programme. Five EU/EEA countries offer/recommend the vaccination for adults below the age threshold for universal pneumococcal vaccination if they are considered to be at increased risk of pneumococcal infection; however, the age range that is vaccinated on this basis can vary significantly depending on the country. In the case of the herpes zoster vaccine, only four EU/EEA countries currently recommend it for their older populations. All four have a general recommendation in place, with two recommending it without public funding. The latter two countries recommend it for individuals over 50, and in the two others, one country recommends its administration between 65 and 80 years, while the other for those aged above 70 years. Seasonal influenza is the only disease for which a recommendation on vaccination for older age groups is in place across all EU/EEA countries. In fifteen countries the vaccine is not funded by the national health system. Seasonal influenza vaccination for the elderly is also the only case where specific EU vaccination coverage targets exist and have been agreed upon by the EU Council.⁶

These examples show not only that policies on indications for use are different, but that funding mechanisms for implementing recommendations differ. This is an important element, as the way a vaccine is funded can have an impact on the overall levels of vaccination coverage that can be achieved. The magnitude of such policy effects is difficult to assess, since routine adult vaccination coverage data are often lacking or poorly available, making it challenging to evaluate the performance of existing adult and elderly vaccination programmes.⁷ The challenge of measuring vaccine coverage is greatest in countries where recommendations mainly target at-risk categories, as the size of the denominator population may not be known.

The decision-making challenge

Decisions concerning the introduction, financing, organisation, and delivery of vaccination programmes, including adult vaccination, are the preserve of individual EU Member States. The decision-making process can be guided by several weighting factors that are inevitably context-specific, such as disease epidemiology and burden, groups at higher risk, cost-benefit and cost-effectiveness analyses vis-à-vis resources available and acceptable thresholds, where these are applied. Countries may also have different priorities and so set for themselves different immunisation or prevention policy goals. While, for some, closing immunisation gaps and achieving high vaccination coverage levels with current vaccines could be of highest priority, for others, particularly those with higher rates of childhood immunisation coverage, the goal might be to expand the existing schedule through the introduction of newly available vaccines. And such choices might often be constrained by budgetary availability and considerations.

While the argument for the public health and economic value of implementing a life-course approach to immunisation, is compelling and should continue to be explored, its actual implementation can be challenging. The integration of new vaccines or vaccination strategies brings about a number of challenging questions. For example, what criteria can or should

be used to prioritise among vaccines available for different age groups and populations, particularly in a context of limited economic resources and competing priorities; and what are the best vaccination strategies considering direct and indirect effects of a given approach.

With an ever-increasing number of vaccines on the market, making the right choices, both in terms of vaccine effectiveness and budget planning, has become increasingly important. In order to find the ideal balance between cost and quality (i.e. providing the best possible protection to those who benefit the most in a given population), it is essential to first assess all of the relevant evidence in a transparent and standardised manner before introducing a new vaccine to a national immunisation programme. More so at a time of tighter overall fiscal space in EU Member States.

The decision to introduce a new vaccine, or to offer a vaccine to a new population group, is not the end of the process of assessing the impact of such decisions. Post-implementation monitoring of the effectiveness of vaccination programmes, including the assessment of the frequency of rare or very rare adverse reactions, the assessment of whether strain-specific vaccines give rise to the phenomenon of strain-replacement, and the impact not only on the incidence of targeted VPDs, but also on longer term consequences of infection, such as liver cirrhosis or cancer development, are an essential component of modern vaccine programme management.

On a political level, the feasibility of driving a radical shift towards a life-course approach to vaccination will require leadership and commitment to drive change and expand the fiscal space for immunisation programmes as part of the GGHE. On an operational level, such a shift will also require putting in place new, or expanding existing, components of immunisation programmes in order to meet the needs of adult segments of the population. The introduction and recommendation of new vaccines will not *per se* be sufficient, but should be accompanied by:

- systems capable of comprehensive and reliable monitoring of coverage and uptake rates across all age groups;
- organisation and establishment of appropriate channels or infrastructures necessary to identify, reach out, and deliver the vaccination to the targeted population;
- integration of appropriate surveillance systems;
- monitoring activities that can generate evidence on vaccine effectiveness and vaccination impact so as to inform strategies over time;
- training of health care workers on adult and elderly recommendations and vaccination needs;
- design and roll-out of effective communications and educational activities that are adapted to the needs of an adult population in an era of increasing ‘vaccine hesitancy’ and complacency towards disease risks.

EU added value and ECDC strategic actions

As set out in its *Strategic Multi-Annual Programme 2014–2020*,¹ and in line with the afore-mentioned *EPSCO Council Conclusions on Vaccination as an Effective Tool in Public Health*, within the ECDC, one of the strategic aims of the VPD Programme is to assist the EU Member States and the European Commission in the needs and impact assessment for, and the implementation of, life-course vaccination at EU level, by providing tools and evidence for national decision-making.

A set of strategic initiatives are already ongoing with a view to contributing to this goal. In the area of surveillance, a number of key hospital sentinel-based EU-wide surveillance networks are being funded at EU level with the aim of driving excellence in the collection of data on VPDs, complementing routine surveillance activities. In particular, the ongoing ECDC-funded PERTINENT, SpIDNet, and Horizon2020-funded IMOVE+ projects focusing on pertussis and invasive pneumococcal disease are expected to generate fundamental

evidence on effectiveness and impact of vaccination strategies in the paediatric and older populations.

In the area of scientific advice, the ECDC’s VPD Programme will continue to develop up-to-date evidence-based guidance on priority disease and vaccinations across all age groups as identified by the Member States. Such guidance will help in providing elements for use in national decision-making concerning the introduction of new vaccines and vaccination strategies, including evidence derived from relevant experience available at EU and global levels. Also, the recently launched *ECDC Burden of Communicable Disease in Europe toolkit*² aims at helping Member States to generate evidence on the burden of VPDs in the adult and older person populations, thus supporting the formulation of most appropriate policy responses, including vaccination.

Furthermore, following up on one of the recommendations of the Second External Evaluation of ECDC,³ the Centre will increase focus on facilitating the use of its scientific outputs by bodies involved in the national immunisation policy-making process. Frameworks for the decision-making process on vaccination programmes can vary between countries, but in general the core evidence base for decision-making is common for any given vaccine and target population. To avoid unnecessary duplication of effort in developing this evidence base, a potential key added value offered by ECDC is to improve the qualitative and quantitative efficiency of the analysis required to inform the decision-making process at the national level, with assessment of options for implementation, including their cost-benefit analysis, while also encouraging peer-learning and experience-sharing.

Ongoing work in the area of scientific and technical advice on electronic immunisation registries is also critical, and should in the long term help to strengthen capacity and expertise to implement functional systems to effectively monitor and evaluate the performance of vaccination programmes across all ages. Finally, sustained efforts to generate evidence on drivers and barriers

to vaccination uptake on the part of both general public and health care workers will be continued, including based on specific vaccinations.

As new vaccines will continue to become available to meet today’s demographic and health care needs, a life-long vaccination calendar is likely to become the norm in the EU.

Now is the time to discuss the opportunities and value of life-course immunisation, but also to understand the challenges and information needs faced at decision-making level to promote such a shift. And while the quest for increased and sustainable resource allocation to health services is easy to postulate, it will be key to also agree and define the right evidence that would help in prioritising vaccinations across age groups, as well as the relevance and scope of EU level action to support country efforts in this regard.

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“HEALTHY” INNOVATION: PRIORITISING PATIENT BENEFIT OVER ECONOMIC INTERESTS

By: **Els Torreere** and **Yannis Natsis**

POLICY ADVOCACY

Summary: Unaffordable medicines prices, restrictions on access, and unmet patient needs are a new reality and a new debate for Europe. There is growing consensus among experts around the need to adopt alternative models for conducting and financing pharmaceutical research and development (R&D) – in particular for essential and life-saving health technologies. This article examines the deficiencies and challenges of the current system and some of the forces that are working against effective and patient-focused medical innovation. It suggests shifting the paradigm from a focus on the economic interests of pharmaceutical companies to health needs-driven innovation as a public good.

Keywords: *New Medicines, Access to Medicines, Innovation, Therapeutic Value, Pharmaceutical Pricing*

► **#EHFG2016** Parallel Forum 3:
“Healthy” Innovation

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Introduction

Over the past two to three years there has been an unprecedented debate around the pricing and financing of new medicines in Europe, and how to ensure patients can benefit from the exciting progress in medical sciences in a timely way. Notwithstanding major public investments in biomedical science and technology, public health systems face growing challenges to cope with the increasingly

high prices of the new medicines that come out of the medical innovation pipeline. Faced with unapologetic high pricing strategies of pharmaceutical companies, there are polarising debates, even in the wealthiest of European Union (EU) Member States, about the reimbursement of certain new medicines, as well as rationing of some treatments, whereby patients at the early stage of their disease are excluded until their condition

worsens.¹¹ Meanwhile, medical innovation is lacking for important health concerns, such as antimicrobial resistance,¹² while the large majority of new medicines developed have no or little added therapeutic value to what already exists.¹³ These debates often pit financial and economic concerns against patient needs, and are a clear indication that the current private, market-driven model of medical innovation, which relies on patent-based monopolies and profit-maximising pricing, is not fit for purpose.

Affordability and curbing patent monopolies

Unaffordable prices for medicines, restrictions on access, and unmet patient needs are a new reality and present a new debate for Europe, including in the Council of EU Health Ministers. During the first half of 2016, and spearheaded by the Dutch Presidency, some of the major flaws of the current model of medical innovation were brought centre-stage in the political arena, in particular the unsustainability of ever rising prices. At both national and international level, fierce debates are unfolding about: the need for healthy and robust generic competition; the importance of health technology assessment (HTA); the pricing strategies adopted by pharmaceutical companies; the need for pricing regulation and transparency; the misuse of orphan drug incentives in combination with the trend of “orphanisation” of the drug development pipeline*¹⁴; the need to balance intellectual property rules as innovation incentives in ways that also ensure accessibility and affordability; the structure of the pharmaceutical sector and its financialisation; the proper implementation of competition rules; the way in which priority setting in medical innovation is misaligned with public health

needs, leaving important health needs unmet; and questions around the real added therapeutic value of new medicines.

These issues increasingly appear on the agenda at the highest political level in the EU,¹⁵ despite opposing pressure.¹⁶ Moreover, echoing the global character and growing importance of the problem, the United Nation’s Secretary General has called for the misalignment between the rights of inventors, international human rights law, trade rules and public health where it impedes the innovation of and access to health technologies to be addressed. It has established a High Level Panel to propose a way forward.¹⁷ Healthy innovation and access to affordable medicines are no longer challenges for low and middle income countries alone, but topical issues in high-income countries too. This political momentum offers an unprecedented window of opportunity to look at the real problems and develop creative ways forward.

“we
need new
medicines that
offer real
therapeutic
advance

A broken innovation model

There is growing consensus among experts about the need to adopt alternative models for conducting and financing research and development (R&D) – in particular for essential medicines (e.g., antibiotics, hepatitis C drugs, certain cancer medicines).¹⁸ In this new model, critical health needs are prioritised, medicines are considered public or social goods and the cost and risks of R&D are not commercialised in the market place and recouped via high prices.¹⁹ Given the significant public investments in medical R&D, there is a strong case for the price of the end product to reflect this investment and be affordable. In order

to transform the current pharmaceutical innovation model into one that is more health and public interest-oriented, there is a need to contest the prevailing narrative and underlying economic rationale that maintains that the current monopoly-based incentive model not only works, but is also the only option we have.

The pharmaceutical industry has been effective at promoting its innovation model and justifying high medicine prices, but this narrative is increasingly being challenged.²⁰ The myth of ever-increasing R&D costs that must be recouped to finance further innovation (now into the €1–3 billion range for a new drug) does not hold up to data scrutiny (real expenditures are more in the range of €50–200 million, as documented for instance by DNDi),²¹ much of which is paid for through public funding.²²

The public at large as well as policy makers, however, are not sufficiently aware that the current model is inadequate by being overly expensive while delivering little health value, and excluding the majority of people from accessing products of innovation. Thanks to well-financed marketing and lobbying campaigns, the pharmaceutical industry remains highly influential with opinion leaders (e.g., the medical establishment) and at multiple policy levels, and dominant in shaping public discourse. Their business model relies on a strong legal framework of intellectual property and market exclusivity protections that industry lobbyists have been effective in expanding globally through various policies that extend the life of patents, including free trade agreements.

This presents a major challenge in promoting a counter-narrative despite growing evidence on the failures and harms of the current system. At a fundamental level, this will require re-examining what is meant by innovation in the field of medicine (if there is no therapeutic benefit, does that constitute true innovation?); how should pharmaceutical innovation be measured, incentivised and rewarded, and what are the roles and responsibilities of public and private sectors?²³ and what constitutes a fair price for such innovation? While

* There is a well-documented increase in marketing authorisations for new medicines for niche indications under various “orphan drug” incentive schemes on both sides of the Atlantic, including authorisations of a single product for segmented patient groups within a disease area and repeat authorisations of the same product for several rare diseases or niche populations. Companies typically seek, and obtain, very high prices for these products. In fact, seven of the top 10 best-selling drugs in the United States for 2014 came on the market with an “orphan” designation.

patents and the associated monopoly pricing are currently used to reward innovation, pharmaceutical patents are ill-suited to incentivise therapeutically useful innovation as there is no correlation between patentability and medical benefit (i.e., a patent rewards chemical novelty, not medical innovation and therapeutic advance). In fact, evidence shows that in the field of pharmaceuticals, patents incentivise firms to reshuffle old combinations of compounds or argue for second uses of existing ones, instead of searching for breakthrough drugs. This explains, in part, why the current pharmaceutical pipeline delivers ‘me-too’ drugs that offer little or no added therapeutic value. Another important issue to consider is the extent to which the pharmaceutical sector is increasingly “financialised” and focused on maximising shareholder value and its “bottom-line”, resulting in more spending on marketing and share buybacks (to boost stock prices) than on productive R&D.¹³

Deregulation by stealth?

While the pressing issue of high drug prices and inadequate medical innovation in Europe demands a comprehensive policy solution along the principles outlined above, there are systematic efforts to: (a) shift attention away from the core problem (i.e., that the current pharmaceutical business model thrives on ever higher monopoly prices for even mediocre medical advances); and (b) reframe the debate by focusing on “earlier and faster access to medicines and innovation” in ways that misdiagnose the real problems with our current innovation model, including pricing.

The long-term strategic goal of the proponents of this approach, including the pharmaceutical industry, is to restructure the EU medicines regulatory framework, such that more products can be sold in the market faster, even if their medical value is not (yet) established. They argue that the current regulation is too complex and stands in the way of patients having timely access to medical innovation, while proposing a new frame of reference to deal with the risks around potential benefits and harms of experimental medicines. Practically, what is sought after is to save

companies’ time and money by changing the way we develop and approve new drugs, and shifting the responsibility and burden of demonstrating an acceptable benefit/harm ratio to after the drug is approved in the market, de facto lowering evidentiary requirements, mostly via prioritising medicines’ efficacy over safety. This is the spirit of a range of policy proposals such as the Adaptive Pathways pilot project and the Priority Medicines (PRIME) scheme, both run by the European Medicines Agency (EMA) and initiatives within the Innovative Medicines Initiative (IMI), all supported by drug-makers. Importantly, while these discussions also aim at regulating reimbursement conditions, the notion of affordability is notably absent. In addition, it is difficult to see how lowering the burden of proof about efficacy and safety, including a focus on niche populations, will address the current innovation deficit that results in a large majority of the new drugs having no added therapeutic benefit compared to what we already have.

While much of these discussions are held behind closed doors, it should be understood that these are not minor technical issues but constitute a paradigm shift with far-reaching economic, political and public health consequences.

The way forward: prioritising therapeutic advance for patients

A growing movement of patients groups, consumer organisations, health practitioners, researchers, clinicians, and health advocates is calling upon policy makers at national and international levels to start addressing this pressing issue.¹⁴ First and foremost, we need new medicines that offer real therapeutic advance. Independent reviews from organisations, including the Cochrane Collaboration, Prescrire and several national HTA bodies, point to the fact that most new drugs offer no or only marginal therapeutic benefits in comparison to the best alternatives already on the market. It is therefore critical to re-think current incentives to move the industry away from its focus on developing ‘me-too’ drugs and increasing their market share to focus on “healthy” innovation that addresses priority health needs, delivers safe, effective and

affordable products that benefit society as a whole. Regulators should send a strong message to manufacturers about the quality of the innovation they want to see, in particular – added therapeutic value – rather than lowering standards for marketing authorisation. Secondly, Europeans pay for medicines twice, as a large portion of medical R&D is publicly funded—from support to early research to various forms of subsidies throughout the pipeline. Hence, it is essential to have full transparency on actual R&D costs and contributions from both public and private sectors, and on how prices are set and take the respective contributions into account. Public financing to R&D should comprise criteria that safeguard the public interest and guarantee a return on public investment (in the form of accessibility and affordability). Thirdly, public health needs should dictate research priorities and public funding should be allocated accordingly whilst promoting open access to research data. Fourthly, a level-playing field, transparency and balanced involvement of all stakeholders in decision-making are critical in order to avoid regulatory capture.

The Council of the EU’s recently released conclusions on medicines is a first step in the right direction.¹⁵ The time has come for the EU to review the impact of the current incentives on real medical innovation, and the availability, accessibility and affordability of the resulting products—and for it to consider possible solutions away from exclusivities and patent-based monopolies. A recent joint initiative of the Belgian and Dutch health authorities already made a noteworthy effort to come up with four creative scenarios about drug development and pricing that would provide patients sustained and affordable access to the safe and effective drugs they need.¹⁶ Last, but not least, it should be emphasised that access to medicines is a human right as well as a matter of social justice for millions of Europeans, and from their perspective, an unaffordable treatment is as good as a non-existent one.

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Slovenia: Health system review

By: T Albreht, R Pribaković Brinovec, D Jošar, M Poldrugovac, T Kostnapfel, M Zaletel, D Panteli, A Maresso

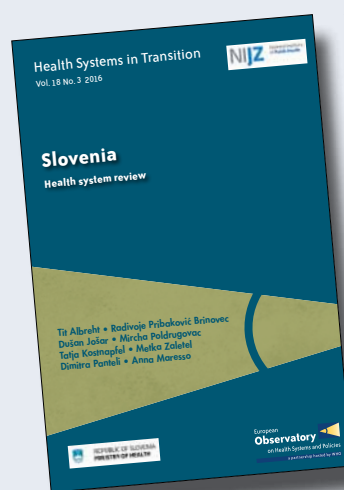
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Slovenia has a well-developed health system with good population health outcomes. Access to health care is also generally good. Despite this, there are persistent disparities in morbidity and mortality between regions and population groups and waiting times for some outpatient specialist services have increased in recent years. These present challenges, as do relatively high cancer rates and increasing multi-morbidity linked to population ageing, requiring a strengthening of prevention activities and co-ordination of care. There is also a need to address the funding and provision of long-term care as service users incur large out-of-pocket expenditures and consolidation of eligibility criteria, funding and benefits is overdue.

Another important challenge is how to ensure the future financial stability and sustainability of the health care system



through diversifying its funding base. Currently, Slovenia's compulsory health insurance system relies almost exclusively on payroll contributions, making it very susceptible to economic and labour market fluctuations. Overall, the share of out-of-pocket payments, including co-payments, is high. While the latter are buffered by complementary health insurance (CHI) there is

some concern that CHI flat-rate premiums are regressive and may become unaffordable for lower income groups. Finally, more efficient use of health care resources needs to be addressed through reform of the purchasing system and provider payment mechanisms, both of which are out-dated and lack incentives for rational reimbursement levels and quality services.

HOW CAN INNOVATIVE TECHNOLOGIES IMPROVE THE QUALITY OF LIFE FOR PEOPLE SUFFERING FROM HEARING LOSS?

By: Patrick D'Haese

POLICY ADVOCACY

► #EHFG2016 Workshop 5:
Hear today, here tomorrow

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Summary: In Europe, around 20% of women and 30% of men have a degree of hearing loss by age 70. Untreated hearing loss puts pressure on Europe's already struggling health and social care systems, partly because it risks the onset of other diseases. Innovative technologies such as the Cochlear Implant offer a real solution for the individual with a hearing loss too high to benefit from a hearing aid. Action from European policy-makers is called for to help raise awareness of the condition, facilitate access to these technologies where appropriate, and share best practice amongst Member States.

Keywords: Sustainability, Active ageing, Hearing Loss, Health Economics

Introduction

Europe's population is ageing fast. By 2025, it is predicted that 20% of the population of the 28 EU member states will be over 65 years old. Whilst there are obvious benefits to living longer, such as opportunities to pursue a lengthier career, discover new hobbies, explore further education and spend quality time with family, there are also associated risks. Perhaps when one considers the risks of growing old they think of increased frailty, or maybe cognitive decline—but what about the impact of hearing loss and its associated morbidities on quality of life?

There are currently an estimated 300 million people in the world with age-related hearing loss and it is predicted that this statistic will triple by 2050.¹ In Europe, around 20% of women and 30%

of men suffer from a degree of hearing loss by the age of 70.² The inevitable act of ageing is the most common cause of hearing loss in adults. In Germany, for example, 1% of 14 to 19 years old experience hearing loss, and that statistic rises to 54% for those over 70 years old.³ The statistics are similar across Member States. Couple this with an ageing demographic, it is evident that the burden of untreated hearing loss will increase.

Age-related hearing loss is caused by the degeneration of sensory cells and cannot be reversed. Studies show that hearing loss has a negative impact on overall health; it increases the risk of the onset of other diseases in older adults (see below) and is associated with an increased use of health and social care systems.⁴ Given the current risks to the

sustainability of health systems, in part due to Europe's ageing demographics but also due to a rise in chronic diseases, it makes sense for European policy-makers to take action to ease this burden where possible. Understanding the impact of hearing loss on older people, and subsequently its impact on the European economy and society is therefore crucial. European policy-makers could seek to take appropriate measures and invest in innovative technologies to tackle this burden.

Helping keep Europe's older generation socially active

Currently in Europe, we see an older generation that is more engaged in their community and society than ever before. For European citizens to benefit the most from their later years, they need to be able to communicate independently, remain active and maintain their autonomy. For this reason, even early signs of hearing loss could be tested. Untreated hearing loss very quickly leads to social isolation and depression. Patients speak of the impact of fragmented communication, the inability to participate in conversation and therefore diminishing circles of friends.

Hearing loss also has the potential to restrict a person's independence. It can become difficult for an older person to take care of themselves and hearing loss sufferers are likely to depend on their friends and family for support. This leads to the risk that it will accelerate their progression into facilitated living or social care. It is also important to remember that a lot of older people act as carers to their partners. That role can be restricted by the onset of hearing loss, accelerating the chances of their partner's progression into facilitated living. Therefore, hearing loss has a huge impact on an individual's quality of life.

The economic impacts of hearing loss

Public spending on ageing in the EU accounts for 50% of general government expenditure.⁸ This is a significantly high proportion and the EU needs to look for ways to minimise such spending. Research shows that people living with hearing loss are more likely to experience the onset

of other costly and debilitating diseases; this includes blindness, cognitive decline, dementia⁹ and diabetes.⁸ There is also the risk of more frequent falls.⁸

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Untreated hearing loss puts unnecessary pressure on Europe's health and social care systems

Diabetes is considered a serious threat to the sustainability of European health care systems. According to the International Diabetes Federation, estimates indicate that diabetes was responsible for 9% of total health expenditure in the Europe Region for 2015.⁸ Untreated hearing loss makes the onset of diabetes more likely; this is, in part, related to the fact that those living with hearing loss are less likely to be active or feel comfortable participating in sport.

Looking at cognitive decline and the risk of the onset of dementia, there is a growing body of evidence to suggest that they are strongly associated with hearing loss. Hearing loss has been linked to amplifying cognitive decline in the ageing process.⁷ This is because communication, which is facilitated by hearing, leads to cognitively stimulating abilities such as social interactions and improved mood. People with mild hearing loss have nearly twice the chance of going on to develop dementia as people without any hearing loss.⁸ Furthermore, the EU is estimated to have invested €400 million on research on neurodegenerative diseases.⁹ Understanding these diseases better will facilitate work to prevent and treat them. By treating hearing loss we can hope to remove a contributing factor.

The World Health Organization (WHO) estimates that the total cost of untreated hearing impairment in the EU amounts to a startling €213 billion each year.¹⁰ People who suffer from hearing loss are less likely to be employed and therefore are less likely to be able to actively contribute to the economy. Unemployment also increases the likelihood of the need to receive state benefits. For the older generation, this means that hearing loss has the potential to cut the working life span of an adult, weakening the potential of Europe's silver economy.

The benefits of an integrated and innovative approach

First, national screening programmes play a significant role in the treatment and care of hearing loss sufferers. They allow hearing loss to be treated early, and the patient to be referred to the correct specialist care. The National Screening Programme for the over 65s in the United Kingdom is estimated to produce £2 billion (€2.34 billion) worth of national savings in ten years.¹¹ Moreover, economic modelling has shown that £28 million (€32.7 million) in national savings could be made in total in the United Kingdom alone, by properly managing hearing loss in people with severe dementia and delaying admissions into residential care.⁹

Clearly, early intervention can help our health care systems remain sustainable by relieving costs, related to the prevention of other diseases, the risk of more frequent falls and necessary social care as a result of these conditions. There should be a push from policy-makers to see more of these types of screening programmes across Europe. Furthermore, there needs to be increased education of health care workers and general practitioners to better understand the severity of hearing loss, and encourage older patients towards screening and appropriate treatment.

Despite the severity of consequences of hearing loss, treatment is more advanced than ever before. Hearing implants have been used successfully for over 30 years. For example, Cochlear Implants are used to treat those who experience hearing loss too severe to benefit from a hearing aid. The surgery required for a

Cochlear Implant is largely considered routine with a low complication rate: after implantation, transient dizziness is the most common side effect, which is usually treatable and temporary.¹ Furthermore, the benefits to older adults of the Cochlear Implants are almost the same as the benefit to the younger person. A small difference in the benefits felt by an older and younger person is found in the ability to differentiate speech from background noise. This is because later in life, human hearing is less able to distinguish speech in complex hearing situations.

Thus, innovative medical technologies, targeted at the appropriate patient group, can play a part in reversing the impact of hearing loss on the health and wellbeing of the individual and also reduce the impact on the economy and society. For example, in a study that looked at 93 Cochlear Implant users, six years after they had been implanted, statistics demonstrated that the unemployment rate had dropped from 60% to 49%. The same study also demonstrated the impact of hearing loss on personal income – 31% of respondents had increased income enough to move income brackets.² It is also important to note that the economic positive impact of treating hearing loss in a child continues up until old age. Children who live with untreated hearing loss are less likely to attend mainstream education and this has an overall impact on their employment opportunities and earnings potential. Later on in life this can lead to reduced pensions and smaller savings, thus hindering financial security. Treating hearing loss saves society money over a patient's lifetime.

Cochlear Implants are largely funded by Europe's national health care systems, yet at present, evidence suggests that more work needs to be done to ensure patients have access to this technology. It is estimated, for example, that only one in twenty people who could benefit from a Cochlear Implant have access to the technology in the United Kingdom.³

Conclusion

To support its older population, EU initiatives on active-ageing could pay particular attention to the impact of

hearing loss and the necessity of screening programmes and treatment. WHO defines 'active ageing' as the process of optimising opportunities for health, participation and security to enhance the quality of life as people age. From an EU perspective, there are a variety of schemes, policies and organisations which exist to facilitate this, including active ageing guidelines, an 'Active Ageing Index' and the work being done by the European Innovation Partnership for Active and Health Ageing. However, minimal attention is being paid to the impact of hearing loss on a person's quality of life as they enter their 'silver years'. In its guiding principles on Active Ageing, the European Council outlines three key priorities. These are: *employment, participation in society and independent living*. Treating severe hearing loss can facilitate all three.

In addition, can an ageing Europe afford not to address hearing loss? A key focus of the health agenda of the EU and of many Member States at the moment is on how to help keep our health care systems sustainable. It is clear to see that the impact of untreated hearing loss puts unnecessary pressure on Europe's health and social care systems, especially as treatment by innovative technologies can be so effective. Furthermore, there are further implications of untreated hearing loss for the economy, society and the quality of life of an individual.

There are appropriate circumstances where people could be fitted with a Cochlear Implant if their degree of hearing loss warrants this treatment, especially as implantation is largely complication free. Furthermore, screening programmes could be introduced in Member States and play an increasingly integrated part of the routine care of Europe's ageing citizens. Early intervention plays a significant role in the prevention of the onset of other costly diseases.

The ask of policy-makers is straightforward: support awareness-raising of the impact of age-related disability on quality of life and hearing impairment in older adults, acknowledge access to hearing impairment care as a right and facilitate best practice sharing amongst governments. Through these measures,

we can hope to improve hearing care across Europe, contributing to the active ageing of our society and helping to keep Europe's health care systems sustainable.

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THE HEALTH PRIORITIES OF THE SLOVAK REPUBLIC'S EU PRESIDENCY

By: Dominika Greisigerova, Olga Zajicova, Tomas Kuca and Eva Slovakova

Summary: The Slovak Republic, which will be at the helm of the Council of the European Union until the end of the year, has embraced some key health priorities, building on previous Presidency agendas. These priorities include: tuberculosis, antimicrobial resistance and vaccination, medicines shortages and access to innovative medicines, as well as, combating chronic non-communicable diseases and putting greater emphasis on food reformulation. The legislative agenda will focus on making progress on regulatory proposals for medical devices and the authorisation and supervision of medicinal products. The Presidency will promote the health agenda through engaging experts and civil society representatives in mutual dialogue.

Keywords: *Slovak Presidency Health Priorities, AMR, Food Reformulation, Tuberculosis, Medicine Shortages*

Introduction

Due to the fact that the Slovak Republic has taken over the Presidency of the European Union (EU) in a time of vivid political challenges, the Presidency has had to approach its general goals in a flexible manner. The scope of general priorities is comprehensively cross-cutting based on four elements: an economically strong Europe, a modern single market, sustainable migration and asylum policies, and a globally engaged Europe. Against the backdrop of these priorities, which are closely interlinked with, for example, migration and potential health threats, the Presidency will strongly endeavour to make progress in these health domains.

Legislative agenda

As the complex negotiations under the previous Presidency resulted in a few legislative proposals not reaching a conclusion, these are being continued. Firstly, further work on the proposal for a 'Regulation on medical devices' aims to create a clearer, stricter and a more manageable framework for the medical devices sector, with significant benefits expected for patients, health professionals and other consumers. Secondly, in relation to the proposal for a 'Regulation on the authorisation and supervision of medicinal products for human and veterinary use', the Presidency will continue to examine this proposal further, with a view to making as much progress as possible.

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Presidency priorities

The Slovak Presidency has contextualised its health priorities to synchronise with the agenda of previous Presidencies – that is, within current political realities. The package of health priorities includes tuberculosis; antimicrobial resistance and vaccination; medicines shortages and access to innovative medicines; non-communicable diseases and food reformulation; and Alzheimer's disease.

Tuberculosis

Tuberculosis (TB) is considered a major public health challenge in many countries worldwide. Even though overall EU countries recorded a decline of 3.8% in the number of TB cases over the last five years,¹ eastern European countries recorded a corresponding increase of 6.2%. Bearing in mind the Riga Declaration from 2015 which reaffirmed partnership efforts between eastern European states' governments and the EU,² the Slovak Presidency will focus on the problem of TB and facilitate the discussion on next steps to enhance cooperation in this field, thus promoting an integrated EU policy framework on TB. The subsequent debate on TB will follow at the political level during the EU Informal Health Council in October 2016 in Bratislava.

Antimicrobial resistance and vaccination

Antimicrobial resistance represents a major threat to global, regional and national health security and is interconnected with TB, as evidenced by the WHO European Region showing the highest incidence rates of multidrug-resistant TB. Especially alarming is the fact that multidrug-resistant TB is also responsible for more antimicrobial resistance deaths than any other infectious agent.³ The Presidency also considers high population vaccination rates to be a major tool in combating over-consumption of antibiotics and expanding resistance to antibiotics. As a result, the topic of vaccination will be discussed during the Informal Council of Ministers in October 2016.

Medicine shortages and access to innovative medicines

On the one hand, the Presidency surmises that shortages of medicines are of utmost importance all over the Europe. These shortages are occurring across the supply chain and are caused by various factors such as non-compliance with Good Manufacturing Practices (GMP), parallel trade, labour disruptions, economic reasons or changing market situations. On the other hand, throughout Europe, there is no harmonised definition of 'drug shortages' or 'availability of medicines'. In most cases, non-availability or shortages of medicines are addressed at the national level, depending on the type of a medicine and on the type of shortage. The Slovak Presidency aims to encourage a common reflection process on the different ways to tackle this problem. With regard to innovative medicines, the Presidency will build upon the Netherlands's initiative to explore ways of accessing innovative treatments that might not qualify for registration or reimbursement within the current medicines authorisation and health insurance system.

Non-communicable diseases and food reformulation

The Slovak Presidency aims to strengthen the objectives and activities in combating chronic non-communicable diseases via raising awareness and bringing together experts to share their views and knowledge. Equally, food reformulation is one of the most effective ways to reduce health risk factors such as saturated fats or elevated quantities of sugar and salt in food products. Therefore, the Slovak Presidency will focus on the exchange of best practices among EU Member States in the area of food product improvement.

Alzheimer's disease

More than 600 disorders afflict the nervous system: they include a variety of dementia diseases (including Alzheimer's), brain cancer, encephalitis, epilepsy, stroke and multiple sclerosis. According to World Health Organization (WHO) data, up to 35% of the European Region's population live with brain disorders.⁴ The direct costs of brain disease are accompanied by indirect costs that are more difficult to enumerate,

including loss of productivity, the profound negative impacts on the quality of life of patients as well as their relatives or carers, and significant associated stigma (see also the article on *Dementia: pressing policy issues*, in this issue of *Eurohealth*). Therefore, the Presidency will organise a conference specifically on Alzheimer's disease to bring together people from various fields of expertise in order to address key scientific, medical and social aspects of dementia.

The way forward

The EU is constantly being challenged by very diverse points of view when it comes to searching for compromises and addressing health issues. The Slovak Presidency firmly believes that bringing about at least a partial solution to the issues outlined here will contribute to better health practice delivery across the Union.

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REFUGEES AND ASYLUM SEEKERS IN GERMANY'S HOSPITALS

By: Marc Schreiner

Summary: The influx of migrants to Germany is relevant to the health care and hospital systems and has developed strong dynamics since 2014. This article provides an overview on how German hospitals are incorporated into migrants' health care, the problems that occur at the organisational and financing levels for hospitals dealing with the special health care regime for migrants, and which measures have been taken to address evolving needs by politicians and responsible authorities. Additionally, the article explores the invention of the migrants' health card.

Keywords: *German Hospitals; Health Care for Migrants; Default Risk for Helping Hospitals; Migrants Health Insurance Card; Extra-budgetary Accounting of Migrants*

Introduction

The influx of refugees and asylum seekers (referred to herein as “migrants”) has been subject to extraordinary dynamics since 2014, but especially since the second half of 2015. Since Angela Merkel’s “Wir schaffen das”^{*} policy stance this fact is extremely relevant for Germany. In 2014 and 2015, there was a net influx of 1,715,000 refugees (see Table 1) – a population comparable to the size of Hamburg. Asylum applications are also on the increase (see Table 1); however, these figures are incomplete. According to Federal police assumptions approximately 500,000 additional refugees are actually living in Germany in recent years, without being registered by the responsible authorities.

First health check

In principal, people arriving in Germany need to get registered, which for logistical reasons is often organised by the first admission centres. Migrants are obliged to have their health status checked within the first few days after they arrive at their final destination. Therefore, they have to present themselves to a doctor who reviews their general health status and their vaccination coverage. Additionally, a chest x-ray to detect infectious tuberculosis has to be performed as long as the migrant is neither pregnant nor a minor.

The Federal States (*Bundesländer*) are responsible for these “first health checks”. In general, the federal state governments (regional governments) use the capacities of their public health services. However, due to cost cuts over recent years, capacities have not been sufficient in most of the Federal States to cope with the large number of migrants in 2015 and 2016. In order to have access to an

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^{*} Chancellor Angela Merkel coined the expression “We'll manage this!” during the annual summer press conference on 31 August 2015. This expression became a synonym for the so called “welcome culture” in Germany which represents an open door policy with respect to the European migration crises. See also: <http://www.faz.net/aktuell/politik/angela-merkels-sommerpressekonferenz-13778484.html>

Table 1: Refugees and asylum applications in Germany, 2014–2016

	2014	2015	2016 (Jan–June)
Registered refugees	1,342,529	1,997,000	
Departed refugees	765,605	859,000	
Net influx	576,924	1,138,000	
Asylum applications	202,834	476,649	396,947

Source: Ref. [1–3]

adequate number of doctors and medical equipment for the first health checks, the governments of the Federal States are contracting with third parties, e.g. hospitals or doctors in hospitals, using a number of different arrangements. In some Federal States, refugees are brought to hospitals and get checked there, whereas in other Federal States hospital doctors are asked to conduct the first health checks in premises belonging to public health services or in first health check centres that are in or near first admission centres where migrants are housed during the first weeks of their stay. In yet other Federal States, first health checks are organised at first admission centres and are conducted by hospital doctors. As in 2015 and at the beginning of 2016, the number of arriving migrants became overwhelmingly large and rose faster than the official structures available. This meant that a lot of hospitals and hospital doctors worked in a honorary capacity as a personal contribution, often without receiving pay for their services.

Reports from hospitals and the Robert-Koch-Institute showed that the vaccination status of arrivals was in many cases insufficient or non-existent, thus endangering themselves and other migrants at overcrowded first admission centres. At the same time, experts were concerned about a possible threat to the health of the resident population. Some cases of infectious tuberculosis were detected, as well as cases of some other diseases, e.g. scabies,⁵ which were non-existent in Germany.

The financing of these support services was also problematic, especially during the second half of 2015. Contracts with service providers were consequently negotiated by the responsible authorities, setting the somewhat spontaneous cooperation on a more reliable footing. Nonetheless, at least

in some of the Federal States authorities were lagging behind in paying hospitals for their support.

Hospitals' role in migrants' health care

Apart from their involvement in the first health check, hospitals also provide health care to migrants. As soon as migrants leave the first admission centres and are admitted by and housed in cities and municipalities, the provision of health care is organised by the latter. The legal basis for migrants' claims to treatment is the "code on services for asylum seekers" (*Asylbewerberleistungsgesetz*), along with the relevant rules in the Federal States. The cities and municipalities in which the newly arrived migrants have their "usual domicile" are also charged with paying for medical care.

Only limited access to care for migrants

The scope of the health care basket for migrants is defined by the "code on services for asylum seekers". For those who have been in Germany for at least fifteen months as official asylum seekers, no restrictions apply in comparison to the normal scope of the health care basket. For migrants who have not yet completed this waiting period and for foreigners who are officially bound to leave Germany, only a limited scope of health care services is made available, i.e., only acute care or pain relief as part of necessary medical care or dental care are provided for this group. Thus, treatments which cannot be delayed because of suddenly occurring cases of illness, as well as medicines necessary for healing and curing are covered. This is also valid for chronic diseases, e.g. hypertension or diabetes, if the omission of care were to lead to an acute status and would endanger the patient. Pregnant

women are entitled to the same care services as those insured under statutory health insurance (preventive medical examination, delivery and midwife-care), while minors have access to the full range of care.

In several Federal States, migrants who are only entitled to a limited scope of care have to present an authorisation from the responsible authority to the health care provider. This authorisation, which is issued by a civil servant of the authority, is subject to criticism as nonmedical staff are required to decide on the urgency of treatment. Additionally, this entails a bureaucratic burden and may cause longer waiting times for migrants. Despite this, it is considered to be an adequate means of control and cost containment for the responsible authorities.

The experience of hospitals in the Federal States where this system of prior authorisation applies has been mixed. In some of them the cooperation between health care providers and the responsible authorities works well as patients show up with the entitling document and hospitals get reimbursed shortly after invoicing for the treatment. However, in some other Federal States hospitals reported problems concerning the fulfilment of formal prerequisites as well as timely reimbursement. This applies particularly in the numerous cases when patients show up at the emergency department or without prior authorisation.

High risk of default for hospitals

Hospitals are legally bound to deliver health care and rejecting a patient may subject them to criminal prosecution. German hospitals completely fulfil their responsibility. At the same time, the default risk for assuming the treatment costs of migrants is borne by hospitals as securing reimbursement from the responsible authorities is difficult for practical and legal reasons. On the one hand, claims from the hospital for medical assistance provided at emergency departments to patients in urgent need, but without any entitling documents, are in the first instance transferred to the patients and can only be further settled with their cooperation. On the other

hand, linguistic and cultural barriers as well as time constraints in emergency departments can make it problematic for a hospital to fulfil the legally-imposed burden of proof. This problem becomes extremely relevant for migrants who are not registered as there is no responsible authority for them and thus, hospitals have only a very limited chance of obtaining reimbursement for their treatment.

An (unpublished) survey, conducted by the German Hospital Federation in late 2015/early 2016, found that at the end of 2015 a total of €50 million was owed to clinics/hospitals for health care to migrants and for required extra services, e.g. translation services. However, the figures are not completely reliable as it remains unclear whether the amounts were still pending payments or whether they were lost completely. The ratio of claims considered to be depreciated is 10% higher for ambulatory services (compared to inpatient services) and 20% higher for non-registered migrants (compared to registered migrants).

Migrants' health card does not solve the problems

As an alternative to the system of prior authorisation, migrants in some Federal States can present a "migrants' health card" that entitles them to the limited version of the health care basket during the first fifteen months. With the Asylum Process Accelerating Act passed in late 2015, regional governments were given the opportunity to contract with statutory health funds in their region in order to provide migrants with their own health insurance card. With this card, migrants can attend the health care provider directly without first having to obtain prior authorisation from the responsible authority. After treatment, the health care provider directly invoices the health insurance fund issuing the relevant card and gets reimbursed. Finally, the health insurance funds get the money back from the responsible authority, including an added service fee. This arrangement is called the "Bremer Modell" as this kind of cooperation was invented in the Federal State of Bremen and implemented since 2005, joined by the Free State of Hamburg since 2012.

After the Asylum Process Accelerating Act was passed, a further six Federal States made use of this new opportunity (Berlin, Brandenburg, Niedersachsen, Nordrhein-Westfalen, Schleswig-Holstein, Rheinland-Pfalz) and contracted with their regional statutory health insurance funds in late 2015 and early 2016. Their eight agreements differ with regard to claims for benefits and also with regard to the added service fee for the funds, which in the case of Nordrhein-Westfalen reached 8% of treatment costs without any ceiling. In the case of Nordrhein-Westfalen this was considered unacceptable by the responsible authorities and led to the health insurers refusing to opt-into the contract provided by the regional government. Finally, at least in the larger Federal States, the health insurance card for migrants is not used in a comprehensive manner, creating confusion for hospitals and problems in obtaining reimbursement.

Regardless of having a migrant health card, no progress has been made on clearly defining the limited services that new migrants (i.e., those who have been in the country for less than fifteen months) are entitled to. The Asylum Process Accelerating Act required the federal associations of cities and municipalities and the statutory health insurance funds to negotiate a framework agreement to define the scope of the health care basket for migrants, to harmonise invoicing and scrutiny procedures, as well as reimbursement for the expenses of the health insurance funds. The negotiations led to the signing of an agreement at the end of May 2016 but left open a number of questions on which the negotiators could not reach consensus. Thus, a catalogue of health care services that are guaranteed to migrants who have not been in the country for more than fifteen months still does not exist, either as a positive or as a negative list.[†]

Another problem has been that since it is not possible to visually mark the health insurance cards for migrants issued under this regime, hospitals needed certainty about the legal status of the patient showing the card when attending. Thus, a technical marker was agreed upon by the "Gematik" (the society for telematics applications), providing a special technical

code on the card for migrants, thus enabling the hospital to know that only the limited scope of the health care basket applies for this patient. This distinction has been possible from the beginning of 2016 and helps to prevent hospitals from having to pay back parts of invoices for the delivery of services for which a patient was not entitled to.

Extra-budgetary accounting of migrants

Knowing the residence permit status of patients is not the only relevant information that hospitals need when determining what health care basket applies in each case. They also have to prove that patients were treated under the special regime of the "code on services for asylum seekers" as special financing rules apply for these groups: hospitals are allowed, for accounting purposes, to count them as "extra-budgetary", even retroactively for the whole of 2015. This political opportunity was provided to hospitals in order to prevent them from losing out during price cuts based on the Hospital Structure Reform Act that came into force at the beginning of 2016 in response to the extraordinary rise of cases[†].

Conclusions

The enormous influx of migrants since late 2014 has created the need for several additional efforts in the German health care system. From early on, hospitals have taken their full responsibility, as evidenced by their pragmatic approach to the many organisational challenges, as well as by the personal commitment of hospital staff in a lot of cases, where many provide their services for free. Although problems regarding the provision of care do not occur nationwide, lack of financing and personal capacities are severe challenges in some regions.

Migration continues to increase due to global political, economic and climate developments. This has caused many

[†] Several mechanisms are in place to restrictively steer the development of the number of cases. Hospitals have to accept relevant price cuts for every case delivered beyond a ceiling in the budget negotiations. Additionally, fixed costs are deducted for a special group of cases.

people to search for shelter and a better life abroad. UNHCR estimates that 65 million people actually are displaced from their homes.¹ According to projections presented by the Federal Government, approximately 200 million migrants are estimated to reside in third countries, and a large part of them might come to Europe and to Germany.² Thus, migration most probably will become a permanent challenge for health systems. The special responsibility of hospitals requires a political and legal acknowledgement by politicians and systematic, adequate financing for delivering these services, which in general are the responsibility of the whole of society.

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Professorship in Global Health and Development

Job description

The University of Tampere (Finland) is seeking applicants for a new professorship in in **Global Health and Development**. By global health we mean a system-based and transdisciplinary approach to education, research, and practice. This field places priority on improving wellbeing, health and equity worldwide. It emphasises complex transnational issues and the search for sustainable solutions. It involves many disciplines and engages with a wide range of stakeholders.

The successful candidate is required to have broad experience in the field of researching Global Health, and especially expertise and promise in inter- or *transdisciplinary* study of the interaction between global phenomena, health and human wellbeing. Candidates from a diverse disciplinary background are considered and invited, but previous work and degrees must show both formal

competence and a strong track record in knowledge of the intersection of Health and Social Sciences. A higher education degree is required in Public Health or Medicine (licentiate, medical doctor) or Social Sciences, and formal studies or demonstrated strong knowledge in the other two fields. An appropriate doctoral degree is essential. The professorship will be filled on a permanent basis, starting as soon as possible (to be negotiated).

Background

University of Tampere will merge by 2018 with Tampere University of Technology and Tampere University of Applied Sciences. The profile of the new University will build on three major areas of focus: **Society, Technology and Health**. Within the focus, **Global Wellbeing** will play a major role. As a hub, including **Global Health and Development**, it is envisioned that it will enhance joint activities of disciplines in different faculties, such as Social and Health Sciences, Medicine and Life Sciences, Technical Sciences, Educational Sciences, Economics, and Management. The hub will facilitate innovative education and transdisciplinary research on global issues and on national

and local developments influenced by globalisation and regionalisation.

The appointed professor will participate in inter- and transdisciplinary education. In the area of research, s/he will be able to continue and expand her/his research field interests in so far as they contribute to Global Wellbeing. Examples of potential themes include:

- Global and Regional Policies; Socially Fit Health Technology
- Urbanisation and segregation; Forced Migration
- Global Environmental Health
- Impacts of Globalisation on Health and Health systems
- Human Rights and Bioethics; Global Governance.

The university is seeking a visionary person, who is able to utilise the potentials outlined, and shares the vision of *Global Wellbeing*.

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BIG DATA FOR HEALTH SERVICE RESEARCH: BALANCING POTENTIALS AND CHALLENGES

By: Anna-Theresa Renner, Julia Bobek and Herwig Ostermann

Summary: Big data, and digitised information in general, is of high importance and already widely used in most sectors and research fields, including health. Purposeful application of health data can contribute to better population health and more efficient health service provision. Nevertheless, precautions need to be taken, as individual health data is highly sensitive and misuse can have significant negative effects on the individual (e.g. on the labour market). This article explores the potentials and pitfalls of using big data in health service research. Furthermore, it highlights the necessity for governance of the interests of different stakeholders in accessing health data.

Keywords: *Big Data, Health Service Research, Health Data, Data Governance*

Introduction

Digitisation of everyday life and technological advancements in the storage of collected data (server sizes) have led to the increasing relevance of data for research and business. As the processing power of conventional computers has steadily increased and the public mind-set has turned towards data driven information over recent decades, the term “big data” is frequently used in scientific and non-scientific discussions. Even though there is no single definition of big data, the term usually refers to very large amounts of data that are routinely or automatically collected and stored. Data can be structured or unstructured (e.g. pictures) and can be mined for information, whereas the insights of conventional inductive statistical inquiries are fairly limited for big data.¹

Quite often big data is defined by three characteristics, known as the “3Vs”:

volume, velocity, and variety; it has been further suggested to add value and veracity as fourth and fifth “Vs”.^{2 3} Other authors have proposed to define big data with respect to the sample population which equals the whole basic population.⁴ Although there is currently no definition of big data in health, the importance of the topic has been recognised by the European Commission and its Directorate General for Health and Food Safety (DG SANTE), which is currently developing policy recommendations for big data in public health, telemedicine and health care*.

Potentials and pitfalls of big data

Health data are collected at different service levels of the health care sector (e.g. in hospitals, primary care or

* The full “Study on Big Data in Public Health, Telemedicine and Healthcare” written by the Gesundheit Österreich Forschungs- und Planungs GmbH and SOGETI will be published later in 2016.

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pharmacies), but also outside the health care sector (e.g. via mHealth-Apps or social media), and for different purposes, such as reimbursement and insurance claims, or for epidemiological reasons (e.g. registries). Other (secondary) uses of these data sources can be utilised for further applications such as health economic, health system or health service research, and of course clinical research (e.g. with genomic data). Data content ranges from genomic data to socioeconomic data, including, among others, data on pharmaceuticals, treatment processes, insurance claims, telemedicine, and on wellbeing and behaviours.

The possibilities of analysing these data are numerous, and possible research questions that can be answered increase even more when linking different datasets. Moreover, the costs of using big data for research are relatively low compared to data collected in clinical trials, but yield similar robust results due to the sheer volume.⁴ Utilising this potential of big data can benefit the single patient when used for research on effectiveness, quality, and safety of treatments and prevention, but also the whole population for example by using it for infectious disease monitoring. Furthermore, accessible big data facilitates comparative effectiveness research which will ultimately lead to cost-containment and more effective distribution of resources in the health care sector or the whole economy.

There are also some pitfalls related to big data in health that must not be neglected. These are mainly related to the fact that health data are not only individual-level data, but also highly sensitive, as misuse can negatively affect the individual, for example on the labour market or with regard to insurance payments. This is the reason why health data cannot be treated in the same way as data from other areas of life, but need special regulations. The European Parliament and the Council have recognised this fact in their recently ratified “General Data Protection Regulation” (GDPR), where health data are mentioned as one of the “special categories of personal data” [6, Article 9]. The GDPR allows for derogation from a prohibition on processing these special categories of personal data, only if its purpose is in the interest of the public, which includes to “ensure the quality and cost-effectiveness

of the procedures [...] in the health insurance system, or for [...] scientific or historical research purposes or statistical purposes”.⁵ This means that big data for health service research is in principle allowed, but only when its benefit for the public is substantiated.

Another pitfall that is related to data protection is the secondary use of data. Quite often data are collected for a specific purpose (e.g. a clinical study) to which the patient or any other data subject (e.g. a health care provider) has consented to. In some countries, use of these data for any other purposes, including research, needs further approval of the data subject.⁶ This presents a severe barrier for scientific research. In some other countries, access to health data is permitted for research if it is done in the public interest, and the individual-level data are anonymised or pseudonymised. Under the GDPR the processing of health data without consent of the data subject is possible under the condition that the rights and freedoms of natural persons are protected by suitable and specific measures. The GDPR is generally seen as a step in the right direction to align European national legislation, but critics have raised the concern that there is too much room for interpretation on how it should be implemented in the EU Member States. Even though some EU Member States already have stricter data and privacy protection laws in place, the implementation of the GDPR, especially the appointment of a Data Protection Officer in each country, is feared to increase administrative burden and to require a high level of human resources.

Another important issue that could mitigate the benefits of big data in health service research is the quality of the data and the data analysis. To derive valid conclusions from quantitative analyses, researchers need to be aware of the quality of their analysed data. Accuracy, completeness, consistency, reliability, timeliness, and validity are frequently named as indicators of data quality. Especially the quality of data from mHealth apps is often unclear, but highly relevant when linking these data with e.g. routinely collected health care records. To tackle this issue, the European Commission has set up a working

group that will develop guidelines for assessing the quality of data collected via health apps.

Other data sources and datasets comprise some intricacies as well. For example, diagnostic data that are collected in hospitals for reimbursement purposes, are generally regarded as high quality, but might be prone to up-coding, or a bias stemming from different coding routines in different hospitals. Being aware of these possible biases and using statistical methods to control for them is essential for health service research to produce robust results that eventually lead to more informed and evidence-based political decision-making.

Besides shortcomings in data quality, the quality of the data analysis is also key to the valuable utilisation of big data. In analysing big data, researchers should be aware that the probability of spurious correlations rise with the size of the available datasets. It is therefore imperative for the analysis of big data for health service research that analytical skills are paired with knowledge of the field. To exhaust the potentials of big data in health, researchers have to be able to identify, within the abundance of data, what information is crucial to answer a specific and relevant research question.

Using big data for research

Several projects in various EU Member States aim to facilitate health service research by linking relevant datasets. The Austrian project DEXHELPP (www.dexhelpp.at), which is co-funded by two ministries and the city of Vienna, uses existing health care data to develop methods, models and technologies for supporting decisions in health policy and planning. The project is coordinated by the Vienna University of Technology and carried out together with private and public partners, such as the Main Association of the Austrian Social Security Institutions (“Hauptverband der österreichischen Sozialversicherungsträger”) and the Austrian Public Health Institute (“Gesundheit Österreich GmbH”). By developing methods for linking different datasets, analyses of the current status but also models for forecasting and for comparative evaluations can be carried out.

One of the main achievements of this project so far has been the development of a secure research server for all project partners, where highly heterogeneous datasets can be safely stored and analysed. This server is the basis for other research areas of DEXHELPP, such as estimating the burden of disease with computer simulation models or the comparison of different health care interventions and payment systems. Many other European countries have implemented similar projects (e.g. UK Clinical Practice Research Datalink, Italian ARNO Observatory, Swedish ICT eHealth). Even though, the fields of application of these projects vary, the common objective is to make data available for research in the public interest.

The aforementioned research projects usually include data from electronic patient records or health records (EPR/EHR) and electronic prescription systems. The aim of such eHealth systems is to improve patient care pathways by enabling a secure exchange of the collected patient level data between health care providers. In Austria, the electronic health care record (“Elektronische Gesundheitsakte” – ELGA) (www.elga.gv.at), which includes an eMedication application, is currently being piloted in several regions. Other European countries are further ahead in the implementation of eHealth structures, such as the Netherlands (AORTA), Denmark (Shared Care Platform) and Estonia (E-Estonia national identity scheme).

There is currently no common understanding or guideline at the European level on which applications should be incorporated in a national eHealth structure or what the content of an EPR/EHR should be. However, efforts on this issue have been made by the European Union and its Member States, by co-funding the European Patient Smart Open Services (epSOS) project (www.epsos.eu), with the objective of improving the interoperability of eHealth systems to facilitate cross-border health care in Europe. epSOS focused on technical and semantic aspects, but also on legal and organisational frameworks, and developed recommendations for supporting further developments in cross-border interoperability. Making cross-border

EPR/EHR usable for research was not a primary goal of the epSOS. Nevertheless, aligning national eHealth structures, or at least defining a minimum level of technical and content-wise standardisation, will not only improve cross-border health care, but also enable cross-country comparisons for health service research.

Governance of stakeholder interests

Reservations against the widespread use of big data, especially of big health data, should be taken seriously, especially when coming from the data subjects (i.e. patients or health care providers). Communicating the potential benefits of big data to citizens and stakeholders will be crucial, and has to be done in a measured way. It will not be enough to highlight the benefits, but it must be made clear under which circumstances the analysis of big data sets has an advantage over other methods of evidence generation. Furthermore, the fears of the data subjects regarding privacy need to be addressed openly, which includes informing them about existing legal frameworks, as well as other data protection policies to reduce possible data breaches or data abuse to a minimum.

Big data not only offers potential opportunities for individuals and public health, but is also a big business opportunity for companies in the health care sector. European industrial stakeholders have raised concerns that the relatively high data protection standards in the EU compared to other parts of the world, might shift business opportunities to countries outside the EU. Contrary to this fear, the European Commission hopes to attract business by increasing the trust of its citizens, which in turn enables companies to establish sustainable relationships with their clients. Moreover, the EU rules on data protection and privacy apply to all companies, including those from non-EU countries, which operate in an EU Member State.⁶ Whether these efforts will yield the expected results, or whether business opportunities will accelerate elsewhere, remains to be seen. Independent of these developments, business considerations, unless they are in the interest of the general public, should not compromise the privacy rights of citizens.

For health service research it is crucial that the process of accessing data (and big data in particular) for research purposes is transparent, and equal for all researchers. Therefore, data governance is a key issue in utilising the full potential of big data analysis. Data governance includes clear guidelines on what data can be used, in what form (pseudonymised, level of aggregation etc.) and by whom. This not only encompasses (public) health researchers but also state institutions in their role of planning and organising (public) health service provision. This way, big data governance can substantially contribute to accountability, not only of individual health care providers, but also of the state as a regulator for the provision of health and social services, hence, shaping a more equal relationship between the state and its citizens. Therefore, the value of big data for health service research are not reflected in the sheer amount of available and accessible data, but in the sensible use of these data to generate high level evidence that can be used for (better) policy making targeted at the welfare of the population.

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NEW PUBLICATIONS

Voluntary health insurance in Europe: role and regulation

By: Anna Sagan and Sarah Thomson

Copenhagen: World Health Organization, 2016 Observatory Studies Series No. 43

Number of pages: xvii+ 122 pages; **ISBN:** 978 92 890 5038 8

Freely available for download at:

http://www.euro.who.int/__data/assets/pdf_file/0005/310838/Voluntary-health-insurance-Europe-role-regulation.pdf?ua=1

If public resources were unlimited, there would be no gaps in health coverage and no real need for voluntary health insurance (VHI). Most health systems face fiscal constraints, however, and VHI is often seen as a way to address these pressures. This study draws from the experiences of 34 countries to assess VHI's



contribution to health spending and to understand its role in Europe and in relation to publicly financed coverage. It looks at who sells VHI, who purchases it and why. It also reviews public policy on VHI at the national and EU levels and the related national policy debates.

The analysis shows that, while the markets for VHI vary considerably in size, operation and regulation, the vast majority are small. The study suggests that VHI is normally

a better way of meeting the population's health needs than out-of-pocket payments. VHI can contribute to financial protection, especially where it plays a substitutive and complementary role covering co-payments. Nevertheless, it is a complex, challenging and highly context-specific policy instrument that may undermine other health-system goals, including equitable access, efficiency, transparency and accountability, even where markets are well regulated.

Contents: Introduction; VHI at a glance; Why do people buy VHI?; Who buys VHI?; How do markets for VHI work? Public policy towards VHI.

Voluntary health insurance in Europe: country experience

By: Anna Sagan and Sarah Thomson

Copenhagen: World Health Organization, 2016 Observatory Studies Series No. 42

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Freely available for download at:

http://www.euro.who.int/__data/assets/pdf_file/0011/310799/Voluntary-health-insurance-Europe-country-experience.pdf?ua=1

No two markets for voluntary health insurance (VHI) are identical. All differ in some way because they are heavily shaped by the nature and performance of publicly financed health systems and by the contexts in which they have evolved.



This volume contains short, structured profiles of markets for VHI in 34 countries in the WHO European Region. These are drawn from European Union Member States plus Armenia, Iceland, Georgia, Norway, the Russian Federation, Switzerland and Ukraine. The book is aimed at policy-makers and researchers interested in knowing more about how VHI works in practice in a wide range of contexts.

Each profile, written by one or more local experts, identifies gaps in publicly financed health coverage, describes the role VHI plays, outlines how the market for VHI operates, summarises public policy towards VHI, including major developments over time, and highlights national debates and challenges.

Contents: Introduction; 34 country profiles.

NEWS

International

Conference on health and climate sets European priorities

The Second Global Conference on Health and Climate took place in Paris, France on 7–8 July. Hosted by the Government of France, holder of the Presidency of the 21st session of the Conference of the Parties (COP21) to the United Nations Framework Convention on Climate Change, the Conference was held to define an action agenda to implement the Paris Agreement on climate change. This action agenda will contribute to the 22nd session of the Conference of the Parties (COP22), to be held in November 2016 in Marrakesh, under the Presidency of the Government of Morocco.

The Paris Agreement, adopted on 12 December 2015 emphasised that “the right to health”, will be central to the actions to be taken. The Agreement not only sets ambitious aims to curb greenhouse gas emissions to keep global warming well below 2°C, it also commits countries to strengthen adaptation. This includes implementing plans that should protect human health from the worst impacts of climate change, such as air pollution, heat waves, floods and droughts, and the ongoing degradation of water resources and food security. It commits countries to finance clean and resilient futures in the most vulnerable countries. It is hoped that through monitoring and revision of national contributions every five years, the world will begin to see improvements not only in the environment, but also in health, including reductions in the more than seven million deaths worldwide that are attributed to air pollution every year.

The second Paris conference brought together more than 300 government ministers, health experts and practitioners, nongovernmental organisations and experts in climate change and sustainable development. Political will they noted needs to be mobilised to scale up action; they also highlighted the importance of the health sector providing strong leadership

in communicating with both policy-makers and the public about the urgent nature of climate change, with its severe and growing health risks.

Delegates also emphasised the importance of providing authoritative and evidence based guidance on health risks and benefits associated with different climate mitigation policies and about best buy options for climate and health. This, they noted, will require a more systematic analysis of the health effects of a range of actions from specific technology choices, such as for energy provision, to broader interventions such as carbon pricing. This should include estimates of the burden of disease and economic costs and benefits for health services and the wider economy, alongside estimates of effects on carbon emissions.

During the conference the World Health Organization (WHO) and the Climate and Clean Air Coalition launched the global Breathe Life campaign. It aims to raise awareness about the health risks of short-lived climate pollutants such as black carbon, ozone and methane, which contribute significantly to climate change and air pollution.

More on the Breathe Life campaign at: <http://www.who.int/sustainable-development/news-events/breathe-life/en/>

Detailed information on the conference is available at: <http://www.who.int/globalchange/mediacentre/events/climate-health-conference/en/>

European Commission publishes three-year report on implementation of pharmacovigilance legislation

On August 8 the European Commission published its three year review on the pharmacovigilance activities of the European medicines regulatory network. This is a closely-coordinated regulatory network of national competent authorities in the Member States of the European Economic Area (EEA) working together with the European Medicines Agency (EMA) and the European Commission. The EMA,

in addition to coordinating this network, provides technical, regulatory and scientific support.

The aim of EU rules on pharmacovigilance is to monitor the safety of medicines so that regulators can take action to reduce the risks and increase the benefits of medicines for human use. The role of individual EU countries is to monitor medicine safety data, assess signals of possible emerging side effects, and analyse the data when a safety issue is identified at European level.

The report describes the activities of the EU system for monitoring and managing the safety of human medicines from the time the new pharmacovigilance legislation came into effect in July 2012, until July 2015. It highlights that closer collaboration between the EMA, the European Commission and the EU Member States, enabled by the new European pharmacovigilance legislation, has enhanced the monitoring of the safety of human medicines throughout their life cycle for the benefit of patients.

In particular it notes that the creation of a dedicated scientific committee for the safety management of medicines, the Pharmacovigilance Risk Assessment Committee (PRAC), and the regulatory tools made available under the revised legislation, allow for a more proactive approach to ensuring medicine safety. For all medicines, pharmacovigilance activities are planned early on in the medicine development so that each medicine comes to the market with a comprehensive plan to gather more information on its benefits and risks. The analysis shows that the new system has been successful at detecting safety issues more quickly, thus enabling regulators to take rapid action when needed and provide advice and warnings to users of medicines. This system effectively engages patients and health care professionals, who report suspected side effects, contribute to the decision-making process in case of safety concerns and add the invaluable perspective of the people most affected by diseases and their treatment.

Some specific achievements noted in the review include:

- **Risk management plans**, which identify the studies and risk minimisation measures required to manage important known or potential risks, are an integral part of proactive safety management. The PRAC assesses around 600 risk management plans each year for centrally authorised medicines, while over the reporting period some 20,000 risk management plans have been submitted to the Member States for nationally authorised medicines.
- **Reporting of side-effects** has improved; in particular direct reports from patients have increased by 50%. Reporting of side effects by all stakeholders is an essential element for gathering more information on the benefits and risks of medicines in real life.
- Nearly 200 **safety signals** (information about new or changing safety issues potentially caused by a medicine) were investigated by the PRAC up to the end of 2014. Half of the confirmed signals led to updates of the product information, and a further quarter to other regulatory measures. Through rapid detection and management of safety signals, the EU pharmacovigilance system is delivering advice on the safe and effective use of medicines more quickly to patients and healthcare professionals.
- Regular re-assessment of the benefit-risk balance of marketed medicines is being carried out via submission of **periodic safety update reports** (PSURs) for assessment by regulators. Member States evaluated over 12,000 PSURs for purely nationally authorised medicines. In addition, PRAC reviewed and finalised over 900 assessments for centrally authorised medicines, or for active substances found in both centrally and nationally authorised medicines. Because PSURs can lead to directly-binding changes to product information this delivers faster safety warnings to patients.
- The PRAC led 31 safety-related **referrals**. This type of review procedure allows assessment of the safety or benefit-risk balance of a medicine or a class of medicines by the PRAC leading to a recommendation for a harmonised position across the EU.

- Around 200 pharmacovigilance **inspections** have been carried out every year.

A clearer focus was put on **medication errors** through the provision of new guidance. Side-effect reports related to medication errors increased from around 4,500 in 2012 to over 7,000 in 2014, in part because of increased awareness and a clearer legal basis for reporting.

Work is also underway on improving the system's infrastructure, and on simplifying and streamlining existing processes where possible, to minimise the administrative burden for all stakeholders. Ongoing research in regulatory science will also support future improvements.

The report is available at: http://ec.europa.eu/health/files/pharmacovigilance/pharmacovigilance-report-2012-2014_en.pdf

State of Health in the EU initiative

In June 2016 at the Employment, Social Policy, Health and Consumer Affairs (EPSCO) Health Council in Luxembourg, European Commissioner for Health and Food Safety, Vytenis Andriukaitis, announced the State of Health in the EU initiative for 2016–17. The initiative will bring together internationally recognised expertise to provide Member States with evidence on health that is relevant to their specific country context and that can help maximise the effectiveness, accessibility and resilience of their health systems.

The State of Health in the EU comprises four components with the following timeline:

1. November 2016: publication of the "Health at a Glance: Europe 2016" report prepared by the Organisation for Economic Co-operation and Development (OECD) in cooperation with the Commission. The structure of this report will be aligned to the objectives of the 2014 Communication on effectiveness, accessibility and resilience of health systems.
2. November 2017: a set of 28 individual country health profiles developed by the OECD and the European Observatory on Health Systems and Policies (Observatory) in cooperation with the

Commission. These expert-driven, analytical documents will provide complementary data and indicators, and emphasise the particular characteristics and challenges of each Member State.

3. November 2017: a Commission analysis accompanying the 28 country health profiles, giving Member States a succinct overview of the information provided in the first two products, linking them to the broader EU agenda and emphasising cross-cutting policy implications.
4. From December 2017: exchanges between individual EU countries and the Commission, the OECD and the Observatory, to discuss concrete implications of country findings and help Member States make the best use of gathered evidence.

Countries commit to keep Europe malaria-free

Countries in the WHO European Region at risk of malaria have reaffirmed their commitment to keep the Region malaria-free. The European Region is the first in the world to have interrupted indigenous malaria transmission. The number of cases dropped from 90,712 in 1995 to zero cases in 2015. On 21–22 July 2016, Armenia, Azerbaijan, Georgia, Kazakhstan, Kyrgyzstan, the Russian Federation, Tajikistan and Turkmenistan met in Ashgabat in Turkmenistan at the first high-level consultation on the prevention of malaria reintroduction.

The 50 participants unanimously:

- recognised the need to sustain their political commitment and vigilance and invest in strengthening health systems in order to control importation of malaria, prevent re-establishment of local transmission of the disease and rapidly contain any resurgence;
- stressed the need to continue collaborating across borders and mobilising resources to support countries in need; and
- called upon WHO/Europe to continue supporting countries in their efforts.

The consultation was convened by the WHO Regional Office for Europe in collaboration with the Government of Turkmenistan.

Country news

Ireland: rates of alcoholic liver disease treble

A report published in June by the Health Research Board (HRB) in Ireland examines national findings on the patterns and effects of alcohol consumption and how it is impacting Irish individuals and society. According to Dr Deirdre Mongan, lead author and Research Officer at the HRB, the report “highlights that the rate of alcoholic liver disease trebled between 1995 and 2013. The fact the highest rate of increase was found in 15–34 year olds is a real public health concern as alcoholic liver disease usually develops after a number of years of harmful drinking, and as a result it is normally seen in older people. However, these increases would reflect the high occurrence of harmful drinking patterns that have been observed in numerous Irish surveys over the past decade.”

The report noted that in 2013, alcohol-related discharges accounted for 160,211 bed days in public hospitals, that is 3.6% of all bed days that year; compared to 56,264 bed days or 1.7% of the total number of bed days in 1995. €1.5 billion is the cost to the tax-payer for alcohol-related discharges from hospital. That is equal to €1 for every €10 spent on public health in 2012. This excludes the cost of emergency cases, GP visits, psychiatric admissions and alcohol treatment services. Moreover, an estimated 5,315 people registered unemployed in November 2013 had lost their job due to alcohol use, while the cost of alcohol-related absenteeism was more than €41 million in 2013.

It is not just what Irish people drink, but the way they drink that causes harm. In 2013 the HRB Alcohol Diary survey showed that more than 50% of Irish drinkers consumed alcohol in a harmful manner – too much alcohol in one sitting and more than the recommended number of standard drinks in a week. In 2012 Ireland had the fourth highest alcohol consumption level among 36 OECD countries after Estonia, France and Lithuania. Current per capita consumption is 21% higher than the Department of Health alcohol steering group’s target which sets out to reduce per capita consumption, from 11.0 litres of pure alcohol per person to 9.1 litres.

The report is available at: <http://www.hrb.ie/publications/hrb-publication/publications//710/>

England: Government publishes plan for action on childhood obesity

On 18 August the UK government published a plan which it hopes will reduce England’s rate of childhood obesity within the next 10 years by encouraging industry to cut the amount of sugar in food and drinks and getting primary school children to eat more healthily and stay active. At a UK wide level a soft drinks levy will be introduced. In England, the revenue from the levy will be invested in programmes to reduce obesity and encourage physical activity and balanced diets for school age children. This includes doubling additional physical education and sport premium funding that primary schools receive and putting a further £10 million a year into school healthy breakfast clubs to give more children a healthier start to their day. Northern Ireland, Scotland and Wales will make their own decisions on how to spend their share of the levy.

Another key element of the plan is a voluntary structured sugar reduction programme to remove sugar from the products children eat most. All sectors of the food and drinks industry will be challenged to reduce overall sugar levels across a range of products that contribute to children’s sugar intakes by at least 20% by 2020, including a 5% reduction in year one. This can be achieved through reduction of sugar levels in products, reducing portion size or shifting purchasing towards lower sugar alternatives.

To ensure that the achievement matches expectations, progress will be reviewed by Public Health England who will publish interim reports on progress every six months. This will include reviewing reductions achieved through analysis of sales and food composition data, along with plans for further reductions. If insufficient progress is made then the government have said that they may take addition steps to achieve the same aims.

Other steps include a new voluntary healthy rating scheme for primary schools to recognise and encourage their contribution to preventing obesity by helping children

to eat better and move more. This scheme will be taken into account during official school inspections, while guidelines will be developed to provide more healthy meals in schools and nurseries.

The scheme has though been criticised by some public health organisations who would have liked to have seen a ban on price-cutting promotions of junk food in supermarkets, as well as the promotion of unhealthy food to children in restaurants, cafes and takeaways. There were also calls for advertising restrictions of unhealthy food high in salt, fat and sugar to children during prime time television schedules when children may be watching popular television programmes such as reality talent shows and soaps.

The plan can be viewed at: <https://www.gov.uk/government/publications/childhood-obesity-a-plan-for-action>

Germany: Cabinet approves draft law on mental health service reform

On 3 August the German Cabinet approved a new law intended to improve the quality of mental health services. The new measures abandon the previous intention to move to single set of national prices for mental health services. These prices will now be the subject of local negotiation. New requirements on minimum staffing quality are also being set out. The reimbursement system is also being reformed so that home treatments can, for reimbursement purposes, be considered as a hospital service so as to promote continuity of care and encourage the provision of more services outside of the hospital setting. The new law will take effect from 2017.

More on the new law (in German) at: <http://www.bmg.bund.de/ministerium/meldungen/2016/psychvvg-kabinett/faqs-psychvvg.html>

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