

# EUROHEALTH

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## ➤ **Harnessing Big Data for Health**

- Putting big data to work for health systems
- Big data for better health outcomes
- Health priorities of the Maltese EU Presidency
- What does Brexit mean for health in the UK?
- Health policy in the United States under Trump
- Reforms to inpatient care in Slovakia
- Health care reform in Kosovo





## EUROHEALTH

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There is a growing awareness that harnessing 'big data', if done properly, could transform both the quality of health care for patients and how health systems perform. However, processes that can link the content of large and diverse health-related datasets from multiple sources in ways that achieve these goals without compromising privacy or other ethical concerns are only in their infancy.

In this Spring issue, the **Observer** section opens with an article that gives a panoramic view of the benefits of unlocking the potential of big data in health care – for patients, providers, policy-makers and researchers. Despite his optimistic view, the author does not shy away from the challenges, including technical hurdles to achieve compatibility, safeguarding personal data and the need for strong governance frameworks. Building on this overview, Szócska et al. share some initial results from the IMI2 BD4BO programme which explores the opportunities offered by big data in representative disease areas. In this article they discuss three disease-specific projects on Alzheimer's disease, haematological malignancies and cardiovascular diseases.

In our **International** section, Azzopardi-Muscat et al. discuss the health priorities of the 2017 Maltese Presidency of the EU, which endeavour to tackle childhood obesity and emphasise structured cooperation between health systems. They also identify many other important areas that will also be on the agenda.

This issue's **Systems and Policies** section features very divergent countries and some highly uncertain policy arenas. An article on Slovakia presents reforms to the acute inpatient sector since 2010. Spranger and colleagues analyse efforts which have targeted changes in payment mechanisms and strategic hospital planning as well as reducing bed capacity.

Moving to the US and Donald Trump's election pledge to dismantle 'Obamacare', Timothy Jost's article outlines the current attempts (in a fast-moving policy context) to repeal and replace the Affordable Care Act, which many see as the cornerstone of former

President Obama's legacy. As the author points out, the process will be far from straightforward, with significant hurdles already presenting themselves.

We are also very pleased to feature Kosovo in this issue. Discussing Kosovo's ambitious health care reform, divided into four pillars, Ademi et al. give a balanced and forthright appraisal of the progress achieved so far and the remaining challenges for successful implementation. Rounding off, Fahy and Hervey discuss the consequences of Brexit for health in the UK by focusing on the six areas identified in the Parliamentary inquiry.

Our **Monitor** section features two new Policy Briefs on structured cooperation related to workforce challenges in highly specialised health care and to voluntary cross-border collaboration in public procurement of health technologies, both written to inform discussions under the Maltese Presidency of the EU. We also have our usual roundup of health policy news from around Europe.

We hope you enjoy the Spring issue!

*Sherry Merkur, Editor*

*Anna Maresso, Editor*

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# CONNECTING THE DOTS: **PUTTING BIG DATA TO WORK FOR HEALTH SYSTEMS**

By: Maximilian Salcher

**Summary:** Linking existing databases is seen as key to unlocking the potential of big data to revolutionise health care. Shared electronic health records and provider benchmarking can improve the quality of care, while linked databases are deemed enablers to support the transformation towards value-based health care. The wealth of collected data allows researchers to answer questions that are of high relevance for policy-makers, patients and providers. However, data privacy concerns pose a challenge to the integration of data sources. Effective use of big data to transform health care systems requires substantial commitment from all stakeholders and a strong governance framework.

**Keywords:** *Big Data, Governance, Data Privacy, Data Linkage, Value-based Health Care*

**Acknowledgement:** This article partially builds on a mini-brief written by the author on behalf of the European Observatory on Health Systems and Policies. Independently of this, the author would also like to acknowledge that this work has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 116055. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

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## Introduction

Health care systems around the world routinely generate a wealth of data on every patient, providing a comprehensive picture of health care pathways and outcomes. Enhanced by data from non-health care system sources, such as geographic location, socio-economic status, lifestyle and social networks, a near-complete picture of the individual can be created. The increased supply of health-related data from multiple sources (“big data”) has the potential to change the face of health care and provide added value for all health care system stakeholders.<sup>1 2</sup> While no single definition for big data is universally accepted, all describe a similar concept: large, diverse, and rapidly increasing datasets that

contain information in various formats and which require novel methods to be processed.<sup>3</sup>

In theory, access to detailed data about individual patients supports patient-centred and outcomes-focused care through individualised treatment decisions, which take into account clinical, genetic, lifestyle and other information. However, most of the data are contained in silos, and even for health care-related data there is no or limited linkage between existing databases. Missing information about a patient’s background, history and outcomes poses a problem for a range of health care systems stakeholders, including care providers, who are interested in providing better quality care for their patients; policy-makers and regulators,

who aim to ensure effective and efficient services for the population; as well as researchers, who need comprehensive data to investigate risk factors and remedies in order to inform clinical practice and the development of new therapies. Linking existing databases is therefore seen as key to unlocking the potential of data-driven health care system change. Opportunities from using big data to improve quality of care, increase health care system efficiency, and conduct high-quality research are now presented, alongside considerations regarding the ethical and technical challenges associated with the use of large and linked databases.

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Meaningful use  
of big data could  
contribute to  
waste reduction

### Improving the quality of care

At the individual level, the integration of clinically relevant data can lead to significant improvements in clinical practice with tangible benefits for patients, including individualised treatment plans and fewer duplicate diagnostic tests. Increasingly, lack of linkage between existing databases is recognised as a barrier to coordinated provision of health care services and shared electronic health records (EHR) are introduced as a counter measure in many health care systems. Projects such as the Catalanian “HC3” shared EHR and the Danish sundhed.dk online portal act as information sharing platforms for all health care professionals involved in the care of an individual patient.

At the aggregate level, big data provides an opportunity to monitor provider performance and ensure high quality of care. In a survey of OECD countries, the measurement of various elements of the health care system was given as a key reason for enabling linkage between datasets, including measurement

of health care quality and system performance; coordination and outcomes of care pathways; quality of care through compliance rates with national guidelines; resource use and costs; disease prevalence; and the analysis of relationships between socio-economic status, health and health care.<sup>4</sup> However, many countries miss out on opportunities to improve clinical practice using linked data.<sup>5</sup> An example for putting data linkage to action is the National Board of Health and Welfare in Sweden, which monitors compliance of providers with national clinical guidelines in various disease areas using data from its patient registries network (the National Quality Registries) that are linked to mortality and prescriptions databases. Performance across providers can be compared and reasons for shortcomings investigated, which in turn informs action plans for clinical practice improvement.

### Improving the efficiency of health care systems

The existence of substantial waste in health care systems, stemming from underuse of effective treatments, overuse of ineffective treatments, failure to coordinate and execute care and other sources,<sup>6</sup> has given rise to the promotion of value-based health care as a priority for policy-makers: improving patient outcomes in a cost-effective way. Meaningful use of big data could contribute to waste reduction by identifying the most cost-effective treatments, enable care coordination (see shared EHR above), and accelerate the development of innovative and highly effective medicines. For example, linked data on long-term and real world outcomes can be used to assess the efficacy, (comparative) effectiveness and cost-effectiveness of new medicines, leading to more informed decisions about market access and availability of these drugs. However, the trade-off between rigorous evidence standards for market approval of new drugs and faster access to innovative medicines for patients needs to be carefully considered, and evidence on big data-induced efficiency gains in health care systems through value-based health care or other mechanisms is yet to emerge.

In the United States, the Centers for Medicare and Medicaid Services (CMS) aim to use big data to drive health care systems change and are planning to link two thirds of payments to value, including through initiatives such as Accountable Care Organizations and Coordinated Care Organizations. Data-driven health care system change is also on the agenda of the European Union (EU). The recently launched “Big Data for Better Outcomes” programme (Innovative Medicines Initiative) creates research platforms and big data networks for various disease areas (currently including Alzheimer’s disease, haematological malignancies, and cardiovascular diseases) with the aim of accelerating the transition towards value-based health care systems in Europe (see the article by Szócska et al. in this issue). In line with recommendations from a recent European Commission report on big data in health care,<sup>7</sup> this research programme leverages expertise from the public and private sectors in a public-private partnership to combine and expand existing data sources, build analytic capacities, and establish common standards.

Data linkage can also create efficiency gains in the collection and use of data. At the heart of the Belgian *healthdata.be* initiative is the recognition that the analysis of health care data can be improved significantly by linking and making better use of existing, rather than collecting additional, data. Integrating data from various sources is a particular challenge in decentralised health care systems and can require substantial investments in technical solutions and political will to overcome long-standing fragmentation. In the Belgian example, a new centre for the integration of existing databases was established as part of a national eHealth action plan that was agreed by a few hundred stakeholders.

### Research opportunities

For researchers, linked databases provide opportunities to analyse disease patterns, detect associations between exposures (such as behaviour or health care services received) and outcomes (e.g., acute events such as heart attacks or onset of chronic diseases such as Alzheimer’s), and



potentially identify causal relationships that can serve as starting points for the development of new therapies. As value-based health care gains traction, interest and investments in comparative effectiveness research have increased, with the wealth of collected data enabling researchers to answer questions that are of high relevance for policy-makers, patients and providers. Data linkage further widens the realm of possible research questions, adding outcome as well as prediction variables to the dataset at the researcher's disposal.

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Effective use  
of big data to  
transform health  
systems requires  
substantial  
commitment  
from all  
stakeholders

For example, the CALIBER project in the United Kingdom integrates data from different sources to depict the journey of patients with myocardial infarction through the health care system. Relevant data of events leading up to and after the infarct are collected in different electronic databases, including a database on primary care, hospitalisation with interventions and associated resource use, a disease registry, and the death certificate. Integration of the data contained in separate datasets provides researchers with a powerful tool to analyse the factors leading to heart attacks, as well as the relative effectiveness of different interventions to reduce the morbidity and mortality burden of these events.

Knowledge about prevalence of diseases and their patterns are important determinants of national and regional health care planning, yet gaps remain in

our understanding of chronic and multiple chronic diseases. Linkage of data from separate sources, such as administrative data from different payers, providers (in- and out-patient care, social care), diagnostic tests, laboratory results and prescriptions, can help to understand disease patterns. While public health monitoring is the most common use of EHRs in OECD countries,<sup>5</sup> fragmentation of the health care system with isolated points of care hinders records linkage. Research initiatives, such as the Austrian DEXHELPP project, which aims to combine data sources and develop methods to support decision-making at the population level, require substantial investments, technical expertise, and stakeholder buy-in to overcome these difficulties and play a role in informing health care planning.

#### Technical and ethical challenges: can data be linked?

Simultaneously with the formulation of the promises of big data, technical and ethical challenges for realising this potential have been identified.<sup>6,7</sup> Different standards in databases might prevent data from being used together or require significant resources to be made compatible.

Unique patient identifiers, which allow deterministic linkage of records, are not available in all countries. Projects addressing these challenges develop novel methods, such as statistical models and algorithms to match data from separate sources based on the probability of common features (probabilistic matching).

Data privacy concerns arguably pose an even greater challenge to the integration of data sources. Careful consideration needs to be given to the delicate trade-off between access to more personal information and associated potential individual and societal benefits in health care service provision, policy making and research on one side, and the need for data privacy on the other side. The English Department of Health is currently evaluating models to inform the public about usage of data in health and social care, including different options for opting out of information sharing between different service providers.<sup>8</sup> Some of the proposed opt-out models distinguish

between consent to using data for service provision (coordination and continuation of care) and for research purposes. While research plays an important role in improving quality of care, the benefits of using integrated data for research purposes are less tangible for the individual patient, requiring additional information to be made available to obtain consent.

The legal framework for allowing researchers to use existing data varies by country and disease area. The EU Data Protection Regulation allows the use of personal data for research of significant public interest. While data collection may be mandatory without an opt-out option in some areas (e.g. registries of infectious diseases), others require explicit consent from the patient. Either way, researchers and those managing the data have a responsibility to ensure trust in their handling of the data. Good practice measures make inappropriate use of sensitive data less likely, including establishing steering committees with patient representatives; using trusted third parties for data linkage; clear rules for requesting access to data and tracking data use; and safe data environments to conduct research.

#### Big data governance

While some countries lead the way in allowing data to be shared among government and health systems entities, as well as data to be made available for research (including the United Kingdom, Sweden and New Zealand), others remain much more restrictive and do not allow data custodians and researchers access to datasets they do not own. The different speeds at which countries are developing governance frameworks that maximise benefits while minimising risks showcase the complexity of integrating legal, ethical, technical, and political considerations into a common framework. Enabling governance mechanisms that reconcile data use with data protection include, among others, accessible and well-designed health information systems and a legal framework for processing sensitive information.<sup>9</sup>

As mentioned above, the European Data Protection Regulation provides for the

latter in the European context, although it leaves room for interpretation and requires countries to develop their own frameworks. The development of health information systems and investment in infrastructure is reflected in some national health strategies, including in France, where the recent health system reform foresees linkage of data from social health insurance with private insurance, social care and mortality records. Despite these developments, implementation of governance frameworks and associated investments can lag behind and delay the meaningful use of big data for quality of care improvement, efficiency gains, and research.

## Conclusion

Effective use of big data to transform health care systems requires substantial commitment from all stakeholders and a solid governance framework. Linkage of datasets is more than a technical exercise and requires reflection on data privacy and security, incorporation of data use into health system planning, and how

and by whom linked datasets will be used. Some of these questions cannot be answered globally, as fundamental differences exist in approaches to using data in health system planning and policy development, and in citizens' attitudes towards the trade-off between privacy and promised benefits from granting access to sensitive personal data. Trust, as an integral element of the patient-provider relationship, extends to using personal data for research, health system planning and monitoring and has to be won through open communication and the implementation of measures that demonstrate attention to citizens' concerns.

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## Malta: Health system review

**By:** Natasha Azzopardi-Muscat, Stefan Buttigieg, Neville Calleja, Sherry Merkur

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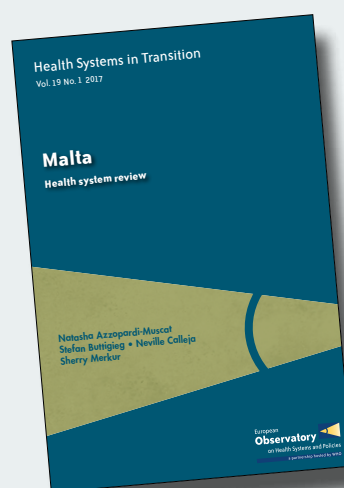
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The health care system in Malta offers universal coverage to a comprehensive set of services that are free at the point of use for people entitled to statutory provision although patients often choose to visit private primary care providers. The historical pattern of integrated financing and provision is shifting towards a more pluralist approach and in 2016 a new public-private partnership contract for three existing hospitals was agreed. Overall, the Maltese health system has been making remarkable progress, with improvements in avoidable mortality and low levels of unmet need. Maltese life expectancy continues to be high, and Maltese people spend on average close to 90% of their lifespan in good health. Malta has recently increased the proportion of Gross Domestic Product spent on health to above the EU average, though the private share of expenditure is still higher than in many EU countries.

The main outstanding challenges include: adapting the health system to an increasingly diverse population;

increasing capacity to cope with a growing population; redistributing resources and activity from hospitals to primary care and strengthening primary care; strengthening the mental health sector; building the health information system to support improved monitoring and evaluation; ensuring access to expensive new medicines whilst still making efficiency improvements; and addressing medium-term financial sustainability and ageing.

**Contents:** Preface, Acknowledgements, Abstract, Executive summary, Introduction, Organisation and governance, Financing, Physical and human resources, Provision of services, Principal health reforms, Assessment of the health system, Conclusions, Appendices.





# BIG DATA FOR BETTER OUTCOMES: SUPPORTING HEALTH CARE SYSTEM TRANSFORMATION IN EUROPE

By: Miklós Szócska, Sahan Jayawardana, Carin Smand, Tayyab Salimullah, Catherine Reed and Shahid Hanif

**Summary:** Large amounts of data from multiple sources have led to the opportunity of deriving health benefits through using sophisticated technologies. Regardless of the frequently cited revolution of data-driven health care, promises remain to be fulfilled. The IMI2 BD4BO programme recognises this in representative disease areas, providing a framework to guide research and invite stakeholders to discuss the future of health systems shaped by big data. The projects will impact the research environment through shared definitions and methods to avoid duplication of work, while transforming health care systems in terms of clinical operations, research and development, evidence-based personalised medicine and public health.

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**Keywords:** Innovative Medicines Initiative, Big Data, Health Outcomes, Knowledge Integration, Data Privacy

## Introduction

The computer age has brought about the rapid generation of large amounts of easily accessible data from variable, quickly developing, digital and non-digital sources, often referred to as “big data”. Big data has immense, yet so far hardly utilised potential to improve almost all areas of human life, including health. Whether this potential can be exploited depends on the sophistication of methods and technologies available to process and use (make sense of) big data. Regardless of the frequently cited revolution of data-driven health care decision-making, there are still promises to be fulfilled. This is also true for Europe, where the fragmented legal landscape, and inconsistent public opinion inhibits the

standardised collection of data, delaying or even diverting the implementation of data sharing agreements.

In the European Union (EU), the key health policy objectives are the strengthening of health system effectiveness, accessibility, resilience, quality and performance.<sup>[1]</sup> However, health care systems in Europe face significant challenges due to the high incidence of chronic diseases, ageing populations, rising cost of new drugs and widely varying health outcomes across the region.<sup>[2]</sup> Amid these challenges, the focused application of big data has the

potential to enable health care systems to effectively transform towards value-based health care.<sup>3</sup>

The Innovative Medicines Initiative 2 (IMI2), Europe's largest public-private initiative (a joint undertaking between the EU and the European Federation of Pharmaceutical Industries and Associations [EFPIA]), recognised this phenomenon through the recently launched Big Data for Better Outcomes (BD4BO) programme, which aims to catalyse and support the evolution towards outcomes-focused, sustainable health care systems in Europe. In order to reach its goal, it seeks to exploit the opportunities offered by big and deep data sources in a few representative disease areas, to put together a methodological framework to guide big data research and to invite a wide range of stakeholders to discuss the future of health systems shaped by big data.

The programme explicitly differentiates itself from previous initiatives through the high level of stakeholder engagement in leveraging existing databases and collaborations to reach its aim. It brings together the key stakeholders, including patients, payers, providers, regulators, academic researchers and health care policy makers that are required to create the synergies in big data policies needed to shift to value-based health care. The effective use of big data resulting from such synergies and the insights gained from projects launched under the BD4BO programme has the potential to transform health care systems in terms of clinical operations, research and development, evidence-based personalised medicine and public health. For example, better access to data may improve comparative effectiveness research, allowing providers to make more clinically relevant decisions and identify cost-effective ways to diagnose and treat patients.<sup>4</sup> Such improvements may enable health care systems to derive value by lowering expenditure and improving patient outcomes.

In more operative terms, the BD4BO programme provides a platform and resources for defining and developing enablers to enhance the transparency of

outcomes. The perception of health care stakeholders on outcomes are different, an issue that can only be tackled with a holistic approach by including as many perspectives as possible, continuously being adapted to the context of the disease, patient population or therapeutic field. The programme addresses the following key enablers: definition of outcome metrics; protocols, processes and tools to access high quality data; methodologies and analytics to drive improvements; digital and other solutions that increase patient engagement in the efforts for better outcomes. Each project launched under the BD4BO programme will make concentrated efforts to advance common outcomes definitions, use of more reliable data and related analytical methods with increased patient involvement.

With the BD4BO programme focusing on filling the gaps in availability of standard sets of outcomes, combining different data sources, identifying best practices, and increasing patients' engagement in their care, project deliverables will allow stakeholders to gain more powerful insights to improve health care. These features of the programme and the cooperation framework of IMI seek to promote an efficient dialogue between projects and with other similar non-IMI initiatives. Upon completion of the programme, the realisation of each disease project's aims will contribute to an organic transformation of research and clinical practice in health care systems.

### **Focusing on disease, population and therapeutic area**

Currently, three disease specific BD4BO projects have been launched within IMI2, focusing on Alzheimer's disease (AD), haematological malignancies and cardiovascular diseases. All of these projects attempt to use the toolbox of big data, but with a focus on somewhat different aspects of the selected diseases in relation to health outcomes.

#### **ROADMAP**

The first BD4BO disease specific topic is titled "Real World Outcomes Across the AD Spectrum (ROADS) to Better Care". The first phase of this topic provides an important initial step for identification

and integration of AD-relevant real world datasets that are suitable for answering questions about the natural history, cost-effectiveness, and clinical utility of new and innovative treatment interventions across the entire spectrum of the disease. The proposed pilot project under this topic (titled "ROADMAP") will align outcomes and methods to develop an approach within existing data systems to efficiently enable initiation, maintenance, and evaluation of the right treatment to the right patient at the right time in health care systems. Engagement with health technology assessment (HTA)/ national health care bodies, regulators, and patient advocacy groups will ensure that proposals for future prospective data collection efforts are relevant to access and reimbursement questions. The initial results produced by ROADMAP will be critical to ensure that the work proposed in the second phase of the project is realistic in scope, relevant to stakeholder needs, and complementary to ongoing IMI2 and other EU collaborations for better patient outcomes from pre-clinical/early stages of AD through all dementia stages.

#### **HARMONY**

The second BD4BO topic is titled "Development of an outcomes-focused data platform to empower policy makers and clinicians to optimise care for patients with haematological malignancies". The proposed project (titled "HARMONY") aims to deliver a series of benefits for patients, health care providers and manufacturers within this disease area. Due to the rarity of the conditions and the diverse health care practice across the EU, current health care systems are challenged with several issues. There is limited data on haematological malignancies that are comparable, making it difficult for policy makers to establish benchmarks such as risk/benefit ratios and payers to accurately make reimbursement decisions on life prolonging treatment options. In addition, the lack of data is forcing clinicians to make decisions based on short-term surrogate data that is often not comparable, which may result in patients not getting the right treatment at the right time. Further, there is a lack of definition and alignment on outcomes that is relevant to all stakeholders within this disease area.

HARMONY aims to use ‘big data’ to deliver information that will help to improve the care of patients with certain haematological malignancies. Specifically, the project will collect, integrate and analyse anonymous patient data from a number of high quality sources. This will help to define clinical endpoints and outcomes for these diseases that are recognised by all key stakeholders. Meanwhile the project’s data sharing platform will facilitate and improve decision-making for policy makers and clinicians alike to help them to give the right treatment to the right patient at the right time. Key to this is the collaboration and firm commitment of industry, HTA, payers and other stakeholder experts plus the input of patients. Harmonising data collection and subsequent data flows will rely on the collaboration between researchers, pharmaceutical companies, and academics, in order to advance structures that already exist and which include expert, pan-European groups. Sources certainly need to be of the highest quality throughout and thorough assessment to identify and utilise optimum data is key if the knowledge currently being gathered is to be put to the best possible use. The project will be supported by a robust communication strategy to inform all stakeholders in and outside the project about developments and results, as well as issues that need to be addressed in order to achieve the project’s goals.

### **BigData@Heart**

The most recent BD4BO topic is titled “Increase access and use of high quality data to improve clinical outcomes in heart failure (HF), atrial fibrillation (AF), and acute coronary syndrome (ACS) patients”. The expected impact of the proposed project (titled “*BigData@Heart*”) is better and safer treatment paradigms for patients with AF, HF, and ACS. In more direct terms, the project is expected to improve understanding of the risks of serious outcomes in these patients compared to the general population. The existing knowledge should be further improved on how these patients are treated in the real world and what affects outcomes with more efficient surveillance of safety and effectiveness in real world settings. Further expectations include: improving information on the importance

of adherence to treatment, the role of risk factors, comorbidities, genetics and lifestyles; improving awareness of quality of life aspects that are important for patients; evaluation and testing of tools that may be useful for predictive analytics and surrogate markers for cardiovascular outcomes; developing strategies to use these predictive analytic tools and surrogate markers to improve clinical care pathways and support innovative drug development that provide relevant improvement of outcomes that are important for patients.

### **Prostate cancer**

Another further topic on prostate cancer, with the primary objective of increasing the body of evidence to improve prostate cancer outcomes, will aim to identify and broaden the relevant outcome measures: epidemiological, clinical, economic, and patient reported outcomes. This includes screening, diagnosis and predictive factors that may have an impact on these measures (including complications and adverse effects) across all stages of disease through collection and analysis of available data.

### **Impact on research environment for big data**

The BD4BO programme ambition is to invest in four key enablers that will support the evolution towards outcomes-focused and sustainable health care systems. In addition, the BD4BO programme will endeavour to impact on the use of big data in the research environment. Researchers will have the opportunity to benefit from the improved quality of data sets in these specific disease areas, stakeholder agreement of clinical outcomes and endpoints to improve health care services and accelerate the development and availability of innovative medicines, and a wealth of patient reported outcome measures from digital solutions for data mining to develop preventative and personalised approaches to patient care.

The BD4BO has a coordination and support action (CSA) project (titled *DO→IT*) that will facilitate programme coordination of current and future projects, develop a repository for sharing knowledge and insight for use by health

care stakeholders, lead communication and engagement, and address data privacy issues in the development of informed consent forms for use within clinical, non-clinical and biobanking research. As a European-wide project, the value of the CSA project is that it will harmonise activities and the acceptability of outcome measures, and leverage the breadth of experience in member states from different stakeholders towards sustainable health care systems and patient access to innovative and safer medicines.

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# HEALTH PRIORITIES OF THE 2017 MALTESE EU PRESIDENCY

By: Natasha Azzopardi-Muscat, Antoinette Calleja, Charmaine Gauci, Hugo Agius-Muscat and Stephen Mifsud



MALTA EU2017

**Summary:** Malta is at the helm of the EU between January and June 2017. The Maltese Presidency intends to continue to build on the work of previous Presidencies to tackle important priorities for which there is clear added value for action at EU level. To this end Malta has identified childhood obesity and structured cooperation between health systems as its two main thematic priorities. HIV, eHealth, Rare Diseases, medicines, cancer and antimicrobial resistance will also be on the agenda. Through a series of expert and political meetings, the Maltese Presidency aims to bring forward specific actions on the identified health priorities.

**Keywords:** Maltese EU Presidency, health systems, childhood obesity, eHealth, HIV

## Introduction

In January 2017, Malta assumed the Presidency of the Council of the European Union (EU) for the first time since it acceded to the EU in 2004. This Presidency comes at a delicate moment in the history of the EU since it will have to tackle key issues that have developed at a European level, including Brexit. Nonetheless, the Maltese Presidency has identified six main priorities which it aims to push forward during its Presidency. These are: migration, the single market, security, social inclusion, Europe's neighbourhood and the maritime sector.<sup>1 2</sup>

Although health policy does not feature as one of these major themes, the health and well-being of European citizens can also be positively impacted through the adoption of strategies in some of these key priority areas. More specifically, the Maltese Presidency has put together an ambitious programme of events for the health sector. The overall goal is that of highlighting issues that need cooperation across health systems for an effective

response to be mounted by Member States. The approach taken is one where needs should be identified by evidence and driven through a bottom up cooperation process between Member States, with the support of the European institutions. The Maltese Presidency is emphasising the need for the EU to prioritise social aspects and the pursuit of health and well-being for European citizens is an important component of this objective.

## Legislative agenda

The Maltese Presidency will continue to work on the Proposals put forward by the Commission, namely to amend Regulation (EC) No.726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

Besides convening the regular meetings in Brussels and in Malta, a programme of specific themed events has been developed

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around the main priorities identified. These events are expected to inform the development of Council Conclusions on childhood obesity and structured cooperation between health systems.

### The Presidency health priorities

In the field of health, the Maltese Presidency will continue to build on the work carried out by the Netherlands and Slovakia as part of the Trio Presidency. It will also, however, seek to forge links with the upcoming Trio Presidency and therefore contribute to identifying the health priorities for the EU in the coming years. The main thematic priorities which will link up with planned Council Conclusions are, childhood obesity and structured cooperation between health systems. In addition, the Maltese Presidency will focus on several other topics through the organisation of specific Malta based events. These include HIV, eHealth, Rare Diseases and Cancer. Furthermore, the Maltese Presidency will follow up on the work carried out by previous Presidencies on the issues of antimicrobial resistance (AMR) and access to medicines.

#### Childhood obesity

Childhood obesity has reached epidemic proportions across the globe. The negative impacts that childhood obesity bears on health, productivity, quality of life, longevity and the significant related social and economic costs are well known. Malta has one of the highest rates of childhood obesity in the world.<sup>4</sup> The key objective is to halt the rise in overweight and obesity in children and young people (0–18 years) by 2020. The Maltese Presidency aims to tackle the rise in childhood obesity by taking a strategic approach to support Member States in identifying good practices and key areas where further action is required. Malta aims to highlight the findings of the mid-term evaluation of the *EU Action Plan on Childhood Obesity 2014–2020* and to identify key areas that call for further actions.

Since children spend a large proportion of their time in schools, this presents an opportunity to alter their eating habits by exposing them to healthy and nutritious food. In the absence of procurement guidelines, many public bodies and



Launch of the new HiT health system review on Malta on 28 February: (left to right) Josep Figueras and Elias Mossialos (European Observatory), Maltese Health Minister Chris Fearne, HiT author Natasha Azzopardi-Muscat and Martin Seychell (EU Commission).

entities are obliged to go for the lowest priced contractor; however, this may give rise to children being provided with unhealthy meals. For this reason, the Maltese Presidency, in collaboration with the European Commission and Member States through members of the High Level Group on Diet and Physical Activity, the Joint Research Centre and the Regional Office for Europe of the World Health Organization, have developed evidence-based guidelines for procurement of school food that is healthy and suitable for children.

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an ambitious  
programme of  
events for the  
health sector

#### Structured cooperation between health systems

The health systems of Member States face common challenges which can be mitigated when Member States work together in synergy. The Maltese Presidency is working to identify mechanisms of voluntary structured cooperation between health systems to support Member State health systems

and provide tangible benefits for health professionals and patients. The Maltese EU Presidency has chosen to focus on the scope of voluntary structured cross-border cooperation between Member States to ensure access to innovative medicines and technologies as well as access to highly specialised health services. The needs of small populations, referring both to populations of smaller countries, as well as patients with Rare Diseases, are highlighted.

Structured cooperation between Member States can enhance capacity, increase equity and also improve quality and efficiency of health system interventions. Policy briefs synthesising the evidence on collaboration in the procurement of health technologies and health workforce challenges related to highly specialised health care have been prepared in collaboration with the European Observatory on Health Systems and Policies.<sup>4 5</sup> Access to medicines and other medical technologies is still a problem in Europe, especially for small, lower income countries and or products with a small demand. These challenges are partly related to the manner in which pricing and procurement are being organised. In this area, the Maltese Presidency will seek to follow up on the Council Conclusions adopted under the Netherlands Presidency in 2016 by seeking to identify the mechanisms which will promote sustainable cooperation in the processes

of procurement of innovative medicines and technologies with a view to improving access and affordability.

The launch of the European Reference Networks (see news section of this issue) provides an opportunity to build strong cross-border professional networks to support the provision of highly specialised services and interventions for patients with Rare Diseases. Patient mobility can be completed by structured mobility of health professionals. The development of opportunities for structured cross-border medical specialist training may assist to overcome various challenges being faced by Member States in ensuring retention and development of their specialised health workforce. Ensuring good quality training opportunities across the EU will also indirectly improve access and continuity of care for European citizens.

These themes will be discussed by experts and recommendations for priority areas in which structured cooperation can support Member States' health systems, underpinned by the appropriate mechanisms that respect health system diversity, will be put forward in Council Conclusions.

### eHealth

*Data for Health: the key to personalised sustainable care* is the central theme underpinning eHealth Week, 10–12 May 2017<sup>1</sup> organised by the Maltese Presidency, the European Commission and HIMSS–Europe, in collaboration with the World Health Organization. eHealth Week 2017 will gather more than 1,300 stakeholders from around the globe to address current international topics related to health care IT.

The following issues have been earmarked for discussion during eHealth Week: patient access to and sharing of health data; security and privacy of health care data; sharing personal health data across country borders; IT support for European Reference Networks; improving the effectiveness, safety and privacy of mHealth applications; scaling up digital innovation for health and care; smart environments and integrated care; data management analytics for personalised medicine and public health policy; IT

support for reform of health care systems; and new roles and shifting balances in health care. High-level delegates will also discuss the health-related objectives of the Digital Single Market.

### HIV/AIDS

Although there have been impressive gains in reducing the number of AIDS diagnoses during the last decade, the burden of HIV infection remains unacceptably high in Europe. Each year about 30,000 people are newly diagnosed with HIV in the EU/EEA, and almost another 110,000 people are known to be infected in the broader European Region. Europe is the region with the fastest growing rate of infection in the world.<sup>2</sup> There is good evidence on what works to effectively prevent and control HIV. In order to reverse the HIV epidemic in the EU/EEA, countries need to scale up: HIV prevention, both in terms of coverage and uptake, especially those targeting men who have sex with men, migrants and people who inject drugs; HIV testing to reduce the undiagnosed fraction and ensure early linkage to care for people living with HIV (PLHIV) and HIV treatment and to ensure that the proportion of PLHIV with an undetectable viral load is increased, both for their personal benefit as well as to reduce future HIV transmission.

The Maltese Presidency recently brought together leading experts on HIV prevention and control from across the EU to discuss how Europe can improve its response to HIV and these ideas were summarised in a technical declaration.

### Other health priorities

A series of meetings being held in Malta will focus on a number of other priority areas. Foremost amongst these is the event on Rare Diseases co-organised with EURORODIS and the research and development aspects associated with orphan medicines. The closing meeting of the CANCON project brings together years of important work carried out in the area of cancer at EU level. The need to sustain such valuable initiatives is highlighted within the overall thematic priority on structured cooperation. The Maltese Presidency has also placed medicines as a key focus area. Here meetings will discuss the need to find

ways to address the issue of high prices for innovative medicines in view of the changing nature of the industry and the need to ensure that European citizens can gain access to important medicines in a timely and affordable manner. The Maltese Presidency will also continue to follow up on the work carried out on the important topic of AMR in order to ensure that the follow up actions envisaged are being duly implemented.

### The future

Throughout the dialogues on the respective priorities being discussed during the Maltese Presidency, the importance of determining the role that Member States would like the EU to play, both in taking forward work in the area of public health concerns, as well as supporting Member States to address common health system challenges, will be a key underlying consideration. The Maltese Presidency has the ambition of leaving a robust legacy in the area of health at EU level, mirroring the value and importance that health and health systems are given at a national level.

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# REFORMS TO INPATIENT CARE IN SLOVAKIA

By: Anne Spranger, Martin Smatana, Peter Pažitný, Daniela Kandilaki, Michaela Laktišová, Monika Palušková, Darina Sedláková and Ewout van Ginneken

**Summary:** The Slovak health system has undergone several episodes of ambitious reforms over the last 15 years. One important area of reform has been the inpatient sector. Acute care beds have been decreased by roughly 30% since the 1990s and are to be decreased further until 2030 as outlined in the Strategic Framework. A Slovenian Diagnosis Related Group (DRG-) based hospital payment is expected to become fully operational by 2022. These reforms also targeted the financial stability of the Slovak inpatient sector that has been characterised by underfunding, recurrent hospital debts and ageing infrastructure.

**Keywords:** Hospital Reforms, Inpatient Care, Hospital Payment, DRGs, Slovakia

## Introduction

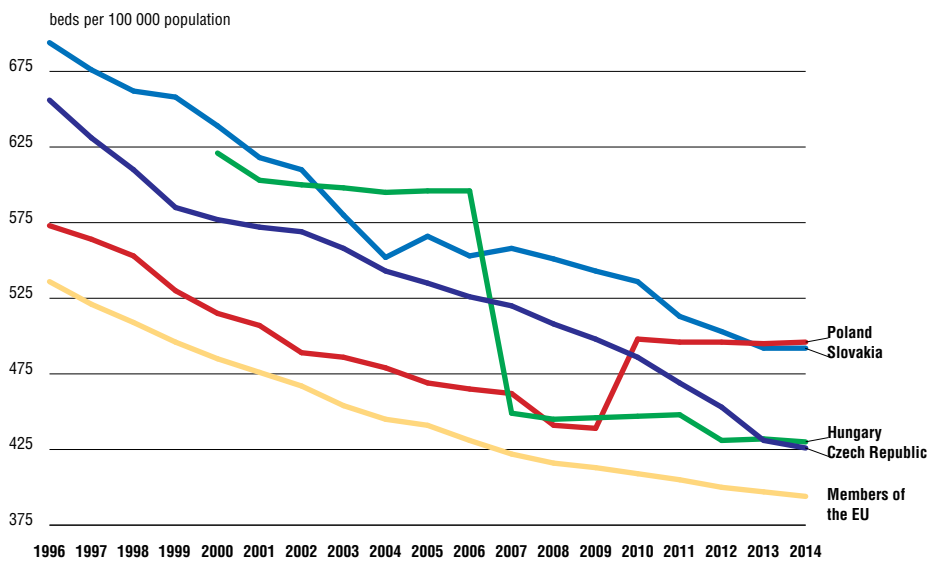
In the early 1990s, Slovakia re-introduced a statutory health insurance system, in which nearly all hospitals were in state ownership and established as budgetary contributory organisations (a Slovak form of not-for-profit legal entities established by the central government, regional government or municipality in order to perform tasks in the public interest). The Soviet legacy of oversupply of acute beds and lack of chronic care beds, medical technology and inefficient coordination proved difficult to change. Any attempts to reduce the number of hospital beds were opposed by the hospitals, as well as by local authorities.<sup>1</sup> The financial situation of hospitals (and their poor financial management) further deteriorated as some privately-owned hospitals entered the market with protests by health workers for higher wages in 2001. Confronted with highly indebted hospitals, as well

as recurrent allegations that hospital managers were engaging in corruption, the Slovak health system underwent a major reform between 2002 and 2004. The reform installed market principles for health insurance and health provision and as a result, responsibility for contracting health service provision was moved away from the state towards health insurance companies (HICs). Other major aims were to improve efficiency in acute inpatient care and achieve a more effective utilisation of resources.<sup>2</sup>

This article describes the most important reforms targeting acute inpatient care in Slovakia since 2010. These reforms did not merely aim to reduce bed capacity, but also targeted the efficiency and financial sustainability of inpatient care through changes in payment mechanisms and strategic hospital planning.

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**Figure 1:** Reducing the density of acute hospitals beds but not closing the gap with the EU average



Source: <sup>3</sup>

## Reforming acute inpatient care

Although transforming acute inpatient care had been addressed in previous reform programmes, the 2002–2004 reforms in Slovakia received much more international attention. This was also due to several controversial elements of the reform, such as transforming public hospitals into joint-stock companies, a process that has been halted twice in 2006 and after 2012 and the resulting confusion about the long-term direction of the reforms. Nonetheless, acute inpatient care in Slovakia was finally reformed following concerted efforts by HICs, the Ministry of Health and the Health Care Surveillance Authority (HCSA).

Since the early 1990s, many European countries have aimed to reduce inpatient capacity because advances in medical technology have allowed faster discharge of patients and treatment in day care settings. In line with the countries of the *Visegrád 4* group, which includes the Czech Republic, Poland and Hungary, Slovakia has been able to reduce bed capacity considerably (see Figure 1). In 2014, there were 4.9 acute care beds per 1000 population in Slovakia, reaching a comparable level to that of Poland, but still above the EU-28 average. Indeed, the Slovak Republic started out with 6.9 acute care beds per 1000 population

in 1996 and was able to decrease capacity by roughly 30% by 2014. The Strategic Framework for Health 2014–2030 aims to decrease acute care beds by another 50%.<sup>4</sup>

## A hospital sector plagued by underfunding

The hospital sector has been characterised by underfunding and ageing infrastructure. Although, the Slovak Ministry of Health had used several approaches (e.g. installing an agency called *Veritel* for the consolidation of health care debts), hospital debts kept accumulating and had to be settled in several “rounds” by the Ministry of Health (for an overview see Figure 2). Since 2011, debts have been creeping up again to reach a high of €592 million in June 2016. Debt is a multi-causal problem based on underfunding, but also failing governance, lack of transparency and the introduction of minimum wages for physicians in 2011.

In theory, capital renovation of inpatient care is also covered through reimbursements by HICs to hospitals. Yet hospital infrastructure has been deteriorating. Indeed, health care capital formation was found to be well below that of neighbouring countries. Estimates of the additional investments needed in order to meet EU-15 averages range from

€3.9 billion by the Ministry of Health<sup>5</sup> up to €8.3 billion in the worst case scenario of an independent think-tank.<sup>6</sup>

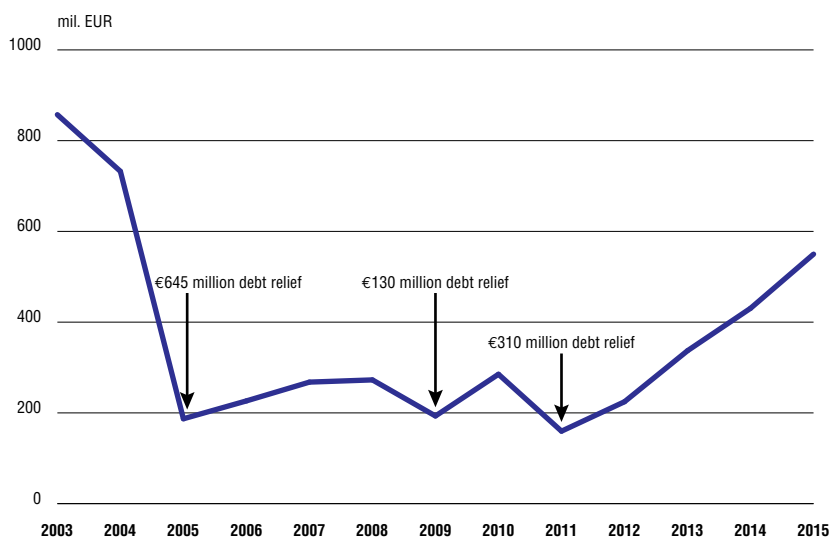
## Reining in hospital debt

To remedy the situation, in 2017, the Ministry of Health announced plans to improve hospital governance by introducing higher compliance standards to non-debts.<sup>7</sup> Furthermore, Slovakia opted for a DRG-based payment mechanism for inpatient care. Since 2010, the implementation process has been governed by the HCSA using the German DRG-system as a base. The SK-DRG system is expected to become fully operational by 2022.

Since 2016, hospitals have been informed of the respective DRG payment for each performed procedure, but are still reimbursed according to the ‘old’ reimbursement scheme. Currently, DRGs are implemented through HICs contracts, applying various safety nets (from global budgets to a combination of old and new payment systems). This scheme is mainly based on per hospitalisation case payment for a completed case differing by specialty, but also among hospitals. The basic payment rate will be harmonised over a five year period, from individual rates in 2017 and 2018 to a single rate in 2022. Once the SK-DRG system is fully operational, hospital financing is expected to bring a higher degree of harmonisation in payments. Therefore, DRGs could help raise comparability among Slovak providers and confer important information about utilisation of resources in inpatient care.

## Ambitious plans to reduce inpatient care capacity

Inpatient care is jointly planned by HICs and the Ministry of Health. First, HICs contract individual providers specifying volumes and prices for inpatient care. In 2016, there were three HICs operating in the Slovak market: two privately run HICs and one publicly owned HIC (*GHIC*). Given this highly concentrated health insurance market, HICs have large market power and can reduce acute bed numbers by not contracting providers or hospital departments. For instance, the GHIC did

**Figure 2:** Chronology of debt settlements in the Slovak health care sector since 2002Source: <sup>1</sup>**Table 1:** Regional variance of distribution of bed capacities in Slovakia, 2014

NUTS 2 regions	Number of hospital beds (per 1000 population)	Curative care beds in hospitals (per 1000 population)	Rehabilitative care beds in hospitals (per 1000 population)
Slovakia	5.8	4.9	0.15
Bratislavský kraj	7.6	6.8	0.24
Západné Slovensko	4.7	4.1	0.09
Stredné Slovensko	5.8	4.8	0.15
Východné Slovensko	6.2	5.2	0.16

Source: <sup>9</sup>

not contract several hospital departments during 2010–2011 which resulted in a nationwide reduction of 3000 beds. It should be noted, however, that the HICs are legally obliged to guarantee sufficient availability. Second, strategic planning by the Ministry of Health sets medium to long-term goals for inpatient care. In 2002, the Ministry of Health implemented a Bed Reduction Plan, resulting in a cut of 6000 acute beds. In 2014, the Ministry of Health targeted inpatient care by setting targets in the first Slovak Strategic Framework. By 2030, the goal is to achieve an occupancy rate of 85% (in 2014 it stood at 69%, well below the EU-28 average of 77%) and 2.5 acute beds per 1000 inhabitants through a combination of reduced bed capacities and lower inpatient cases through strengthened primary care. <sup>2 3</sup>

### Some providers are seen as crucial to ensure accessibility

An exception to the principles above is the so-called compulsory network of providers, which was re-introduced in 2012. This network is based on calculations of a minimum number of hospital beds for each of the eight self-governing regions and in 2016 consisted of 36 hospitals, specialised institutions and medical institutions. Minimum capacities are calculated per capita, but they do not consider the specific health care needs and resource use of the population. <sup>4</sup> Enlisted hospitals have to be contracted by all HICs, irrespective of their quality and effectiveness. Critics say this regulation undermines the market and that it was only established to improve the bargaining

power of public providers. <sup>5</sup> Indeed, all but one provider in the compulsory network are state-owned. <sup>6</sup>

Despite the compulsory network, strong regional variance in inpatient care capacities in Slovakia persists (see Table 1 for an example). This highlights that the compulsory network does not ensure regional equality in access to inpatient services. The region around the capital, Bratislava, has about 60% more beds per capita than more rural areas in the Western Slovakia (*Západné Slovensko*).

### Waiting lists remain a point of concern

Although there seems to be ample capacity as outlined above, perhaps ironically, waiting lists are a persistent problem in certain areas and for certain specialties. The government that took office in March 2016 made reducing waiting times a policy priority. <sup>10</sup> Waiting times in inpatient care have caused several heated debates in previous elections. In 2010, legislation on public reporting of waiting times was supposed to increase transparency and collect data for several procedures and all hospitals. In general, waiting lists should not exceed 12 months, as monitored by the HCSA. Subordinate legislation issued by the Ministry of Health regulates only three types of waiting list (hip and knee replacements, cataract surgeries and heart surgeries). The impact of this decree is difficult to estimate precisely, but according to HCSA the average waiting times in 2014 decreased compared to 2013 by 14–53%. <sup>11 12</sup> However, only one HIC (*Dôvera*) publishes information on waiting times and discloses this information to their insured population. Waiting times are also fuelled by weak patient management and gatekeeping by GPs. A vast majority of consultations end with a referral to a specialist or hospital, which also relates to the GP's limited medical competences resulting from legislation in 2012. GP competences were limited to basic and administrative tasks and have been gradually broadened (e.g. pre-operative examinations and chronic care) since 2014. Furthermore, there are still ways to see specialists without a referral even though this has been required since 2013. <sup>13</sup>



## Conclusions

Hospital reforms in Slovakia have mainly focused on financing and strategic planning of care as a way to increase efficiency and sustainability of the sector. As the implementation of some key reforms, e.g. the introduction of the Slovak DRG system, strengthening hospital governance and improving primary care, are still ongoing, it is too early to judge whether they will achieve their goals. Some challenges remain: the HICs have to contract the compulsory network providers which may affect their ability to increase the efficiency of the system. Moreover, decreasing waiting times while simultaneously reducing beds sounds paradoxical but could be achieved by stronger gatekeeping and better patient management. How this plays out will need close monitoring and perhaps additional reforms.

Other countries seeking to reform the hospital sector can learn from the Slovakian experience. It shows that a multipronged approach is needed that not only reduces beds or reforms payment methods. First, primary care reform should go hand in hand with reducing inpatient care overcapacity. This not only includes improving the gatekeeping function and reducing unnecessary referrals, but also broadening the competences of GPs. Second, data collection on health service usage needs to be improved before it can be used to increase transparency and accountability of inpatient providers. Third, improving (financial) governance

of hospitals has been an often overlooked issue, although there remains great potential to make improvements. Taken together, attention to these areas can pave the way to further promote quality of inpatient health services.

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## Pharmaceutical policy in China: Challenges and opportunities for reform

**By:** Elias Mossialos, Yanfeng Ge, Jia Hu and Liejun Wang

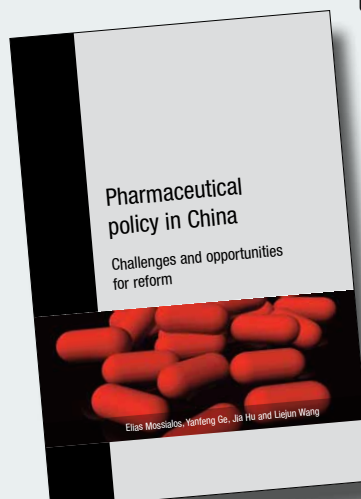
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China has a complex pharmaceutical system that is currently undergoing significant reforms. This book provides a comprehensive overview of China's pharmaceutical system and covers key topics such as drug approvals and quality regulation, expenditure trends, pricing and reimbursement, irrational prescribing, traditional Chinese medicine, industrial policy, and the role of hospitals, primary care, and pharmacies.



# THE TRUMP ADMINISTRATION LAUNCHES AMERICAN HEALTH LAW CHANGES INTO HEAVY SEAS

By: Timothy Jost

**Summary:** As promised, the Trump administration and congressional Republicans have begun an effort to repeal and replace the Affordable Care Act. While Republicans hope to pass legislation for President Trump to sign in April, they face political, procedural, and practical difficulties.

**Keywords:** *US Health Care Reform, Affordable Care Act (ACA)*

## A slow start to repeal

Rarely if ever has health policy in the United States undergone as revolutionary a change as has occurred in the first two months of 2017. As of 19 January, the last day of the Obama administration, the Department of Health and Human Services (HHS) was still actively urging Americans to enrol in health insurance coverage through the Affordable Care Act (ACA) before the 2017 open enrolment period ended on 31 January. HHS was issuing report after report documenting how the ACA, and in particular the ACA's expansion of Medicaid coverage for low-income Americans and its ban on the exclusion of insurance coverage for pre-existing conditions, were benefiting Americans. President Obama himself and Sylvia Burwell, the departing HHS Secretary, sung the praises of the ACA in their final remarks to the country.

On 20 January, Donald Trump was inaugurated as president of the United States. His first official act was to issue a sweeping executive order entitled,

“Executive Order Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal”. The executive order directed the departments and agencies that oversee the ACA to:

- “waive, defer, grant exemptions from, or delay the implementation of any provision,” of the ACA in order to minimise costs and regulatory burdens imposed on states, private entities, and individuals;
- “provide greater flexibility to States”; and
- “encourage ... a free and open market in ... healthcare services and health insurance”.

The Executive Order led to apocalyptic speculation about actions the Trump administration might undertake to undermine the ACA, but had little immediate effect. In fact, executive orders have no immediate legal effect outside the government; they rather state policy and aspiration, and this one was no different.

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During the week following inauguration – the final week of the 2017 open enrolment period – the Trump administration withdrew advertisements urging people to enrol in ACA coverage. ACA marketplace enrolment, which had been running ahead of 2016, flat-lined in the final week, causing 2017 enrolment to come in at 12.2 million, slightly behind 2016. The Trump administration's final enrolment report rejoiced in the shortfall. The Internal Revenue Service also announced that it was not initiating a planned new programme to tighten up collection of penalties under the ACA's individual responsibility provision, which penalises people who do not have health insurance or qualify for an exemption, but it acknowledged that the penalty was still in force.

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 Republicans do  
 not have a repeal  
 plan that all of  
 them can  
 approve

But President Trump's revolution in health policy is starting slowly. Nearly a month into the new administration, the major health programmes of the US are functioning much as they always have. Former Congressman Tom Price, President Trump's designee to head the Department of Health and Human Services, which administers the Medicare, Medicaid, and ACA health subsidy programs, and a sworn enemy of the ACA, was confirmed by Congress on 10 February.

But the first rule proposed by the new HHS, issued on 15 February, is billed as an attempt to stabilise the individual insurance markets, which were hit with high premium increases and insurer withdrawals for 2017 and could collapse under the threat of ACA repeal for 2018 without help from the Trump administration. The rules would reduce the open enrolment period for 2018, reduce opportunities for consumers

to enrol outside of the open enrolment period and increase eligibility verification requirements for those who do, reduce oversight of and requirements for insurer provider networks, allow insurers to refuse to cover consumers who owed premiums from prior years, and allow insurers to sell cheaper plans. The proposed rule largely responds to demands that insurers have made for their continued participation in the individual market for next year. The rules will harm some consumers, but they are not revolutionary.

### Congress begins work

As the Trump administration settles in, Congress has begun work on repealing parts of the ACA. The Republicans have controlled the House of Representatives since 2012 and have voted dozens of times to repeal the ACA. The Republicans only have a 52 to 48 majority in the Senate, and under the arcane rules that normally govern Senate action, need 60 votes to move major legislation if the Democrats object to it. The party holding the majority in the Senate, however, is able to move legislation affecting the revenues and expenditures of the United States in the Senate by a simple majority vote through a special procedure called budget reconciliation. The Republicans began work on repealing the ACA through the budget reconciliation process by enacting a budget resolution in mid-January instructing the jurisdictional committees of the House and Senate to begin drafting repeal legislation.

### Republicans are divided over the new legislation

At this point, however, the Republicans have run into four problems. First, they do not have a repeal plan that Republicans across the political spectrum can approve. For nearly seven years they had been in opposition without a chance of repealing the ACA as long as President Obama was in office and could veto any legislation they adopted. (In fact, he did veto repeal legislation in 2016.) As long as the Republicans were in opposition, they could vote for repeal without actually having a plan for replacement. But now that they actually have the possibility of repeal, they must find a consensus clear way forward.

The House Republican leadership introduced legislation on 6 March 2017 that is now proceeding through Congress, but it is not clear that it can pass. It would repeal \$600 billion (€562 billion) (over 10 years) in taxes that the ACA imposed on health insurers, pharmaceutical companies and wealthy Americans; roll-back the ACA's Medicaid expansions and change Medicaid from an open-ended federal entitlement programme to a programme in which state funding was capped; end the penalties the ACA imposed on individuals for being uninsured and on large employers for not offering health insurance; require individuals to maintain continuous coverage or face a premium surcharge, and abandon the ACA's income-based tax insurance affordability tax credits in favour of age-adjusted fixed-dollar tax credits. The most conservative members of the House are demanding more dramatic changes in the ACA while the more moderate members urged patience while a consensus replacement plan is worked out. The Republicans hope to pass legislation for President Trump to sign in April.

### The procedural complexities of repeal are significant

As the Republicans have proceeded, the procedural complexities of repeal and replace have become glaringly apparent. Budget legislation, subject to a simple majority vote, can only be used to enact provisions that affect the revenues and outlays of the government. This is clearly the case for legislation affecting the premium tax credits that fund coverage for low- and moderate-income individuals through the ACA's marketplaces, and even for the penalties that enforce the requirement that individuals be insured, qualify for an exemption, or pay a tax. But the ACA's provisions that ban insurer exclusions of pre-existing conditions or health status underwriting do not clearly affect government expenditures or revenues, and thus probably cannot be repealed, much less be replaced, through reconciliation. Although Republicans are hungry to repeal as soon as possible the taxes the ACA imposed on the wealthy and on health insurers and providers which fund the ACA's premium tax credits and Medicaid expansions, they realise that they will need revenue from those taxes to



finance their own assistance programmes. At the time of writing it remains to be seen how they can accomplish this, although they seem to hope that they can cut federal Medicaid funding enough to cover the tax cuts.

### The popularity of the ACA has been rising

Third, although the ACA has rarely enjoyed a net favourable rating in opinion polls during its seven years in force, its popularity has trended upward with the threat of repeal looming. Over twenty million Americans are currently covered under the ACA, and they are unlikely to get a better deal from the Republicans. Republican members of Congress returning to their districts in February have faced mobs of angry constituents. Congressional switchboards are being flooded with calls demanding that members protect their constituents' coverage. As congressional discussion has included major changes in the Medicaid and Medicare programmes, the leaders of states, which depend heavily on Medicaid, and senior citizens, who are dependent

on Medicare, have also expressed their concerns to Congress. Major medical and hospital associations have come out against the Republican reforms. For seven years Republicans have made political hay out of opposition to the ACA. It may be the Democrats turn to benefit from talk of repeal.

### Individual insurance may become unavailable to millions of Americans

Finally, it has become clear that the individual insurance market is quite fragile. Precipitous withdrawal of federal subsidies from the market, particularly if insurers are required to cover consumers with serious health problems, could make the sale of individual insurance coverage untenable. The Congressional Budget Office (CBO) earlier projected that repeal without replace, even if repeal were delayed for a couple of years, would lead to 32 million Americans losing coverage and individual insurance being unavailable in three quarters of the country in ten years.<sup>1</sup> At the time of writing, the CBO has not weighed in on the present proposals.

### The response to changes is uncertain

The Republicans in Congress continue to assert that they will repeal and replace the ACA, and they likely will in some fashion. The replacements they are now debating would very likely increase the number of uninsured, cut taxes dramatically for the wealthy (\$7 million (€6.55 million) each annually for the 400 highest-income families) while raising the cost of health insurance and health care dramatically for low-income Americans, shift costs from the federal to the state governments, and reduce the cost of insurance coverage for the young and healthy while increasing the cost for consumers who are older and have health problems. Whether these changes will be popular or unpopular, and with whom, remains to be seen.

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## Health system efficiency: How to make measurement matter for policy and management

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Efficiency is one of the central preoccupations of health policy-makers and managers, and justifiably so. Inefficient care can lead to unnecessarily poor outcomes for patients, either in terms of their health, or in their experience of the health system. What is more, inefficiency anywhere in the system is likely to deny health improvement to patients who might have been treated if resources had been used better. Improving efficiency is therefore a compelling policy goal, especially in systems facing serious resource constraints.

The desire for greater efficiency motivates a great deal of decision-making, but the routine use of efficiency metrics to



guide decisions is severely lacking. To improve efficiency in the health system we must first be able to measure it and must therefore ensure that our metrics are relevant and useful for policy-makers and managers. In this book the authors explore the state of the art on efficiency measurement in health systems and international experts offer insights into the pitfalls and potential associated with various measurement techniques.

The authors use examples from Europe and around the world to explore how policy-makers and managers have used efficiency measurement to support their work in the past, and suggest ways they can make better use of efficiency measurement in the future.

# HEALTH CARE REFORM IN KOSOVO

By: Aferdita Ademi Osmani, Dorjan Marušič, Ramadan Halimi, Robert Muharremi and Valentina Prevolnik Rupel

**Summary:** Kosovo has one of the youngest populations in Europe. The death rate is almost half of the European average, accompanied by a low life expectancy of 72 years for females and 68 years for males. It has launched wide-ranging and ambitious health care reforms built on the introduction of a mandatory health insurance system, reforming the functions of the Ministry of Health, establishing chambers of health care professionals and changing the organisational structure of the health system.

**Keywords:** Health Care Reform, Health Insurance, Organisational Structure, Kosovo

## Introduction

Kosovo has a GDP (Gross Domestic Product) per capita of €3,084 (in 2014); one of the lowest levels in Europe (see Box 1 for more key facts about Kosovo). A World Bank poverty assessment report<sup>1</sup> indicates that 45% of Kosovo's population lives below the poverty line, with another 15% living in extreme poverty. The organisational structure of the health care system is composed of the public health care network and facilities in private ownership. Public health institutions are organised into three levels: primary, secondary and tertiary.

The current health care reforms started in 2010 and consist of four pillars. The first introduces universal health insurance with all the necessary organisational structures. The second pillar introduces the Kosovo Hospital and University Clinical Services (KHUCS) as a coordinating body for the delivery of health care in health care institutions. The last two pillars change the administrative role of the Ministry

of Health (MoH) to a strategic one and establish chambers (or associations) for key groups of health professionals to develop their practice.

### Box 1: Key facts about Kosovo

- Kosovo is located in the Western Balkans in south-eastern Europe
- It has a land area of 10 908 km<sup>2</sup> and a population density of 177 inhabitants/km<sup>2</sup>
- It is administratively divided into 38 municipalities
- According to the Kosovo Agency of Statistics (KAS) estimations, the resident population is approximately 1.78 million
- 28% of the population is under 14 years old and 7% are over 65
- Life expectancy at birth in 2011 was 74.1 years for males and 79.4 years for females.<sup>2</sup>

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## The current health system

The state in Kosovo is the owner of all public health institutions which are organised into three levels:

- Primary health care with a network of family health centres;
- Secondary care, with seven regional hospitals for in-patient care and specialist services, professional mental health services with nine community based mental health centres and nine integrated houses; and
- Tertiary care comprising the University Clinical Centre Kosovo (UCCK), National Institute of Public Health with the Regional Institute for Public Health, Centre for Sports Medicine, Telemedicine Centre, Institute for Occupational Medicine, National Centre for Blood Transfusion and Dentistry University Clinical Centre.

In 2014, the private health care network consisted of 1,069 licensed institutions, 305 (28.5%) of which are dental practices (see Box 2).

### Box 2: Physical and human resources in the health sector

In 2014, there were 3,767 public beds (2020 in secondary care and 1,747 in tertiary institutions) and 325 beds (8%) in private institutions, resulting in a total of 4,092 beds or 2.2 per 1000 inhabitants, which is less than half of the EU average of 5.3 beds per 1000 inhabitants.

In primary care, there are 1,068 doctors, in secondary care 546 and in tertiary care 1,050. In the private health care network, there are 3,024 employed health professionals, out of which 1,457 (48%) are doctors. There are 2.2 medical doctors per 1000 population, which is far below the EU27 average of 3.4 doctors per 1000 citizens.<sup>3</sup>

Currently, the health sector in Kosovo is largely tax-funded from general and municipal taxes and direct payments. In Kosovo, total health expenditure in 2013 was estimated at 6.6% of GDP. Public (government) sector spending on health was only 2.7% of GDP, while 3.9% was private (out-of-pocket). Most of the

out-of-pocket expenditure has occurred in the private sector and in payment for medicines.

In 2014, there were only 0.57 outpatient visits per citizen performed in public hospitals in Kosovo, which is far below the EU25 average of 6.3 visits. However, taking into account that the EU figure also includes data from private hospitals and not knowing the number of outpatient visits in private clinics in Kosovo, we could conclude that in Kosovo this figure should be higher due to visits to private providers. There are multiple reasons for this: most importantly, the role of primary care is not yet fully functioning. Furthermore, the gate-keeping function of general practitioners (GPs) is not performed efficiently and a referral system is not yet in place.

“the government is committed to modernising the health system”

In public hospitals, there were 175,016 discharged patients, 93,599 from regional hospitals and 81,417 from the UCCK (in 2014). With a hospitalisation rate of 94.88 patients treated per 1000 inhabitants, Kosovo was far below the EU28 average of 173 in 2012.<sup>4</sup> While that number excludes patients treated in private hospitals, the difference is still substantial. One could conclude that activity levels in public hospitals in Kosovo are low.<sup>5</sup>

With 4.9 days average length of stay (ALOS) in regional hospitals and UCCK together (data is from 2012), this is one of the lowest in the region; in regional hospitals the ALOS was 4.1 and at the UCCK 5.9 days. In contrast, the average ALOS in EU28 was 7.8 (2012). While low ALOS implies efficient provision of services, without precise data on diagnosis and severity of illness, reaching a conclusion on this point about Kosovo is not possible.

The average daily bed occupancy rate in Kosovo is low: for regional hospitals and UCCK it was 62% (in regional hospitals it was 51.9% while at the UCCK it was 75.1% in 2014). In hospitals in 2014 there were on average 973 empty beds daily, which is much higher than 861 in 2009.<sup>6</sup>

## Reform goals

The new Government (elected in June 2014) recognises health as a priority sector and is committed to modernising the health system. The main goals of the current reform package are to:

- improve financial protection and access to health care for the population, especially for vulnerable groups; and
- improve quality, appropriateness and efficiency of health service delivery

The four key elements of the reform to achieve these goals are presented below.

### Health financing reform and universal coverage

The goal of improving financial protection and access to health care will be addressed by the introduction of mandatory health insurance (MHI) from 2017, with a single statutory Health Insurance Fund (HIF). Until the HIF starts its operations, its function will be carried out by the Health Financing Agency (HFA), established as an executive agency of the MoH. The payment of contributions (called ‘premiums’ in Kosovo) is planned to start during the second half of 2017. The contribution will be paid by all employees. A wide range of groups are exempt from paying such contributions: poor families under social assistance, prisoners, individuals who are living in state institutions (eg. children in foster care and guardianship), older people and those with disabilities, repatriated people during the first year of repatriation, war casualties and their spouse and children, trafficking victims during the first year after their official registration, permanent residents of informal settlements in Kosovo who are not registered and victims of domestic violence.

Citizens will be entitled to health care services defined under a basic benefit package (BBP). The basic health care



services covered by the HIF will be determined at the beginning of every fiscal year by a technical committee appointed by the HIF Steering Board and approved by the Government in compliance with available financial resources and the health needs of the population. Broadly, the BBP could potentially include: protection and improvement of citizens' health through prevention and early diagnosis of diseases and other health disorders; medical procedures aimed at early diagnosis of diseases, treatment and monitoring of citizens' health conditions; treatment of diseases, injuries and other health disorders; in-patient and out-patient hospital treatment; use of drugs and other medical supplies from a defined essential medicines list; use of dental and prosthetic aids; use of orthopaedic and ortho-prosthetic aids and other medical supplies and aids.

“more capacity building is needed for the MHI system to become fully operational”

The price-list for basic health care services will be applicable to all health care providers in the public sector. Supplementary health care services, i.e. health care services outside of the BBP, will be provided at market prices, with patients paying out-of-pocket unless they are covered under private health insurance schemes.

As of July 2016, some of the activities related to the MHI have already been implemented: the HFA has established the price list for in- and out-patient services as well as for BBP services for secondary and tertiary health care. Quality indicators have been prepared and implemented through the contracting system which began in 2013. The MoH also piloted the introduction of performance contracts with

all public hospitals during the first quarter of 2013 and has subsequently implemented them permanently.

The next steps in implementing this pillar of the reform include the HFA undertaking further planning, fully defining the BBP, undertaking contracting with health care providers, monitoring the performance of services and collecting contributions. However, more capacity building is needed for the MHI system to become fully operational. The task needs to be supported by a health information system and staff training to analyse collected data in order to adjust care processes within health facilities to meet needs. Moreover, the implementation schedule for MHI and the introduction of criteria to define vulnerable groups (through a specific legislative procedure) needs to be clearly established.

#### ***Re-organisation of health care institutions***

As a second pillar of the reform, the establishment of the KHUCS in 2014 is designed as a unitary health institution composed of all secondary and tertiary health care facilities which have the status of autonomous units within it. The definition of the role, obligations, responsibilities, supervision, norms, standards, strategies and the policies of the KHUCS should be developed by the MoH and defined by statute. KHUCS as an operative body can cover negotiations, management, analyses, planning and monitoring, quality and safety. The KHUCS is responsible for providing quality health care services by focusing on performance, efficiency, effectiveness, and transparency in health care provision. It is intended to create synergistic effects through the coordination of specialised health care services, and ensure the transfer and sharing of professional knowledge and experience.

The KHUCS<sup>9</sup> is directed by a Managing Board comprised of seven members who are appointed by the Government after proposal by the Minister of Health. A General Director, appointed by the Managing Board, manages the operational affairs of KHUCS and is responsible for its professional and financial performance. KHUCS is expected to support management, planning and administration

within its constituent hospitals and separate the providers from the purchaser of services: currently, such operational issues are undertaken by the MoH.

As the re-organisation of health facilities is intended to split the purchaser-provider role, it is seen as one of the biggest elements of the reform. The HFA—and eventually HIF—will be the purchaser in the system and KHUCS will be the coordinator of public hospitals in the negotiation process. However, as a transitional measure, since January 2015, the KHUCS has been a budgetary organisation and receives budget allocations directly from the Ministry of Finance. Therefore, the HFA currently does not act as the purchaser, contrary to the main goal of the reform.

Another shortcoming at the moment is that KHUCS lacks an institutional development and operational plan; thus, there is a lack of clarity about the relationship between the KHUCS and the health care institutions it is tasked to co-ordinate. Overly complex and unclear management structures within the KHUCS, coupled with a lack of staff experienced in the establishment and operation of performance-based contracts has led to the KHUCS operating at a sub-optimal level. Consequently, the MoH plans to clarify the roles and responsibilities of each institution in the operationalisation of KHUCS. Above all, the priority is to transfer the health budget from the KHUCS to HFA/HIF so that the latter may begin to operationalise its role as the main purchaser in the health system.

#### ***Re-designing the functions of the MoH***

The premise for the current reform process is the need for the MoH to shift from being an operational government institution to one that is a strategic policy making entity that governs and has oversight of the whole health sector. To actively play its role as a steward and regulator, the MoH has assigned new roles to several organisations such as the Health Inspectorate, the Pharmaceutical Inspectorate, KHUCS, (new) Medical Chambers, and the HFA. To support the new developments and new responsibilities, the institutional and organisational capacities of the MoH need to be further strengthened.

Unfortunately, this part of the reform is lagging behind schedule, to some extent due to political reasons.

### **Establishment of Health Professional Associations**

Five chambers (or associations) of health professionals have been established for: doctors, dentists, pharmacists, physiotherapists and nurses, midwives and other health care professionals. The chambers are entrusted with several functions, namely licensing, implementing professional supervision, verifying the legality of the specialisation processes, organising specialisation exams, organising and supervising sub-specialisations, planning and implementing continuous professional education.

“effective monitoring and evaluation is needed to ensure full and co-ordinated implementation

The chambers will be financed from the central budget for a three-year transitional period and then will be financed from membership fees, charges and fees for licensing certifications and other sources. Technical assistance and secondary legislation needs to be prepared to enable the full operationalisation of the chambers. In addition, the role and relationship between the chambers and other organisations in the health system needs to be clearly defined.

### **Progress so far and the way forward**

The various pillars of the reform have attained different levels of policy attention and have reached varying levels of development. The sequencing and synchronisation of actions in all four pillars has not been well coordinated. Given the health system's current

capacities and ability to absorb change, launching such ambitious and wide-ranging reforms simultaneously has impacted on the overall stability and continuity of the current regulatory arrangements and service provision. It is our view that an effective monitoring and evaluation mechanism is needed in all four areas to ensure that the reform is fully implemented in a coordinated way.

Moreover, the overly complex and unclear management structures within the KHUCS, as well as staff capacity challenges, present a high level of risk to completing the reform process. The same concerns apply to the HFA/HIF. At the MoH, where people are facing changes in their positions and responsibilities, there is also a risk of the MoH focusing exclusively on policy formulation and supervision and it may refrain from intervening in operational aspects of the KHUCS and the HFA should these not proceed adequately. The main concern here is that the MoH may be moving forward with establishing the legal and institutional framework for MHI without devoting the necessary attention and resources to building the required human and structural capacity for implementation. Meanwhile, public support for the reform could diminish if improvements in public health care services are not visible.

More broadly, in order to introduce performance-based management a fundamental restructuring of the health care institutions is required, not only in terms of structure and process, but also in the mindsets of its managers and employees, to be customer-, and performance-oriented. Therefore, the MoH and KHUCS should make more efforts to develop required capacities.

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# WHAT DOES BREXIT MEAN FOR HEALTH IN THE UK?

By: Nick Fahy and Tamara Hervey

**Summary:** The EU has a significant impact on health and social care, and Brexit will create major issues in this sector. A Parliamentary inquiry has identified six areas: the health and social care workforce, reciprocal health coverage, regulation and research on medicines and medical devices, public health, funding and wider market and trade rules. The major impact on health, though, is likely to come from the economic cost of Brexit putting even more pressure on financing an already stretched health and social care system.

**Keywords:** *Brexit, Health, Social Care, Impact, United Kingdom*

## Introduction

Of all the areas that will be affected by Brexit, it's tempting to think that health and social care will escape largely unscathed. Indeed, one of the most visible slogans of the official Leave campaign in the referendum was to divert money supposedly sent to the EU into the National Health Service (NHS) instead, so some people may even think that the NHS will end up with more money after the UK leaves the EU. Unfortunately, neither of these two things is correct. The EU has a much greater impact on health than is often recognised, meaning Brexit will have major effects here, too; and leaving the EU seems likely to harm the finances of the NHS, not to improve them. The Health Committee of the House of Commons of the UK Parliament is investigating the impact of Brexit on health and social care in the UK, and this has already thrown light on a wide range of areas of concern.

## The EU has a greater impact on health than is often recognised

It is often said that health and health care is not an EU competence; indeed, this was recently repeated by the UK's Secretary of State for Health,<sup>1</sup> question 2\*. Repetition, however, does not make it true. The EU has wide-ranging competences affecting health and health care, ranging from legislation affecting health determinants such as the environment, food safety and living and working conditions, to detailed regulation and licensing procedures for medicinal products and medical devices.<sup>2</sup> This is widely misunderstood in part because the EU's impacts on health arise from EU powers in a range of areas. But this does not diminish their impact.

The Health Committee's inquiry has identified six major areas of concern where leaving the UK is likely to have an impact on health in the UK:<sup>3</sup>

\* Question numbers refer to the specific question given in the oral evidence.

**Note:** Both authors are specialist advisors to the Inquiry on Brexit and health and social care by the Health Committee of the House of Commons of the UK Parliament.

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1. The UK's health and social care workforce – both those that are here now, and those that the UK will need in the future;
2. Reciprocal health care coverage and cross-border health care;
3. Medicines, medical devices, clinical trials and wider health research;
4. Public health, including environmental protections and communicable diseases;
5. Resources, including EU agencies, funding programmes, networks and health in overseas aid; and
6. Market functioning and trade agreements.

### Some key issues: medicines licensing and health workforce

Two particular issues that have emerged from the inquiry so far concern medicines licensing and the health workforce. The UK Secretary of State for Health has made clear that the UK will be leaving the European Medicines Agency as part of Brexit,<sup>[1], question 67</sup>, so the UK will have to put in place its own licensing regime for medicines. This is likely to mean some tricky choices, such as:

- does the UK try to remain closely aligned with the EU licensing system, effectively granting power over regulatory standards to an EU system over which the UK no longer has influence?
- does the UK deliberately diverge, attempting to create a regulatory system that is attractive in different ways to pharmaceutical companies, and what might that mean?
- or does the UK simply accept getting drugs a few months or years later than elsewhere in Europe?

The UK also faces acute challenges with its health and social care workforce. The UK is unusually dependent on overseas workers in health and social care,<sup>[1]</sup> with 90,000 EU staff working in social care in the UK and 58,000 in the NHS,<sup>[1], question 9</sup>. There's no evidence of significant numbers leaving the UK yet, but social care in particular is experiencing lower numbers of applications,<sup>[1], question 214</sup>. Whilst doctors are the kind of skilled

professionals who seem likely to be able to come to the UK under future immigration rules, the position for nurses is already much more difficult, and social care is exactly the kind of low-wage employment where immigration restrictions would be expected to bite hardest. In his evidence to the Health Committee, the Secretary of State offered reassurances that this would not be the case,<sup>[1], question 50</sup>, but without proposing any concrete ways forward. Even the best immigration status would not match the entitlements of EU law, or its administrative conveniences. Government narratives about immigration have not helped health and care workers from the rest of the EU feel unwanted, like mere 'bargaining chips'.

### The impact of Brexit on funding for the NHS

Potentially the biggest impact on health and social care will be the impact on funding arising from the consequences of Brexit on the wider economy. Much solace has been taken from relatively good economic performance since the referendum. But this is misleading; legally, nothing has happened yet – not even the formal notification of the UK's intention to leave, and certainly not the departure itself. The UK has significant liabilities to the EU, and there seems likely to be a substantial 'exit bill'. Moreover, the UK is likely to lose investment from EU funds, including the European Investment Bank, which has invested over £3.5bn into the British health system.<sup>[5]</sup>

We will only be able to see the economic consequences of Brexit after the Article 50 process is completed and the terms of the UK's departure are clear. The most likely scenario remains a significant deterioration in the UK economy overall and its public finances, putting additional pressure on all aspects of public expenditure, including health and social care.<sup>[6]</sup> Health was a central issue in the referendum campaign, with frequent complaints about people not being able to see their doctor or get timely health and social care. But these are actually symptoms of an over-stretched and under-funded set of health and social care services, not of liabilities to the EU or restrictions imposed by EU law.

Leaving the EU's procurement rules may result in some differences in contracting arrangements for medical equipment and devices, although if European standards are no longer recognised in the UK, the cost of these will go up. Contracting for health services is already effectively excluded from the scope of EU law: the choice to introduce private providers into the NHS was a national one, not forced by Europe, although this is often misunderstood by those who experience frustrations arising from the 'privatisation of the NHS'. If Brexit does indeed reduce resources still further, then the frustrations and unmet needs are likely to worsen, not to improve.

“leaving the EU seems likely to harm the finances of the NHS”

### Impact on health for the rest of the EU

Of course, Brexit does not only affect the UK, but the whole of the rest of the EU, too. As well as the personal impact on those who might have come to study or work within the UK or Britons living elsewhere in the EU, there are wider issues of cooperation; on pandemics and communicable disease, for example, which are no respecters of borders. The Secretary of State was clear that the UK will aim to remain part of such public health cooperation,<sup>[1], question 97</sup>, but only time will tell how feasible this is in practice from the UK's future relationship with the EU.

More broadly, the UK has historically played a strong role within Europe in biomedical research, with British universities at the centre of research generating new treatments and health research in general under research and development funded by the EU. If research and development in health becomes more fragmented across Europe after Brexit, this will have consequences throughout Europe, not only for the UK. If on the

other hand the UK takes active steps to secure its place as a world leader, for instance through investment in the sector, openness to recruitment of ‘the best’,<sup>1</sup> question 226, and continued participation in EU-funded research and development programmes,<sup>2</sup> there may be continued, or possibly even greater opportunities for collaboration.

## Conclusions

It is still impossible to know what the impact of Brexit will be. Negotiations are just about to begin, and the British Government has been studiously unforthcoming about what new relationship with the EU they are seeking. But even in an area such as health, often thought of as being a purely national matter, the UK’s departure from the EU raises a wide range of concerns, and precious few opportunities, as the Health Committee has identified. These range from the personal uncertainties of those working in the health system and those depending on health care and rights both in the UK and elsewhere, to the regulatory challenges of devising new licensing systems, and the overall

challenge of finding sufficient funding for health and social care after the economic consequences of Brexit become clear.

This article has focused on the short-term; the immediate challenges thrown up by the Brexit process. In the longer term, though, Brexit will mean that the current policies will be thrown open to change regarding – well, everything. That will create both risks and opportunities for health, as John Middleton and Mark Weiss highlighted in a previous article in Eurohealth.<sup>3</sup> It will be vital to ensure that alongside attention to the drama of the Article 50 negotiations, attention is also given to shaping the future health policies of the UK for a future outside the EU. It is also vital that the EU seizes the opportunity to develop its health policies for a future without the UK.

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## Slovakia: Health system review

**By:** Martin Smatana, Peter Pažitný, Daniela Kandilaki, Michaela Laktišová, Darina Sedláková, Monika Palušková, Ewout van Ginneken, Anne Spranger

**Copenhagen:** World Health Organization 2016 (on behalf of the Observatory)

**Number of pages:** 210 pages; **ISSN:** 1817-6127

**Freely available to download at:** [http://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0011/325784/HiT-Slovakia.pdf?ua=1](http://www.euro.who.int/__data/assets/pdf_file/0011/325784/HiT-Slovakia.pdf?ua=1)

The Slovak health system is based on universal coverage, compulsory health insurance, a basic benefit package and a competitive insurance model with selective contracting of health care providers. However, 14 years after the introduction of a competitive insurance model, some health indicators, such as life expectancy, healthy life years and avoidable deaths, are troubling. This hints at persistent room for improvement in the delivery of care, especially primary and long-term care. Additionally, inequity in the distribution of health providers needs to be addressed, especially given the ageing workforce.

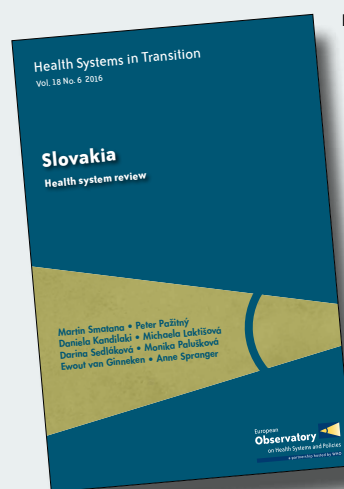
Allocative efficiency also remains a challenge for the Slovak health system. For instance, the parallel systems of health

insurance companies, and the lack of data sharing capacity, promote repetitive testing and this contributes to the second highest spending on ancillary services in the EU in 2013. On the one hand, there is a strong will to improve the Slovak health system, for example the current strategic documents and

reform efforts by the Ministry of Health aim at a complete overhaul of enduring inefficiencies in the Slovak health system. On the other hand, health policy has been unstable over the last years and characterised by two rigid ideological positions.

**Contents:** Preface, Acknowledgements, Abstract, Executive summary, Introduction, Organisation and governance, Financing,

Physical and human resources, Provision of services, Principal health reforms, Assessment of the health system, Conclusions, Appendices.



# NEW PUBLICATIONS

## How can structured cooperation between countries address health workforce challenges related to highly specialized health care?

**By:** M Kroezen, J Buchan, G Dussault, I Glinos, Matthias Wismar

**Copenhagen:** World Health Organization, 2016

**Observatory Policy Brief 20**

**Number of pages:** 36; **ISSN:** 1997–8073

**Freely available for download:** [http://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0008/331991/PB20.pdf?ua=1](http://www.euro.who.int/__data/assets/pdf_file/0008/331991/PB20.pdf?ua=1)

This Policy Brief draws on the experience of different cross-border collaborations in highly specialised health care in order to address health workforce challenges that countries face. It identifies the factors that can enable or block structured cooperation and describes the institutional framework in place. It also examines the policy implications for supporting structured cooperation in the EU.

Key messages include: resolving health workforce challenges and improving cooperation between health professionals will make it



more likely that patients will receive high-quality specialised care in their own country. Voluntary structured cross-border cooperation can help address the health workforce challenges that currently force patients to travel to find appropriate care. Structured cooperation works at different levels (linking countries, health care or training bodies, and/ or clusters of organisations and individuals) but is always influenced by the institutional and the underlying policy frameworks. Evaluation of different models is still scarce, but policy-makers can enhance the chances of structured cooperation succeeding by reviewing the five main groups of factors that can enable or block success. The ways in which policy-makers can support structured cooperation and address health workforce challenges in highly specialised care are also discussed.

**Contents:** Acknowledgments; Key terms / Key messages; Executive summary; Policy brief; Conclusions; References.

## How can voluntary cross-border collaboration in public procurement improve access to health technologies in Europe?

**By:** J Espín, J Rovira, A Calleja, N Azzopardi-Muscat, E Richardson, W Palm, D Panteli

**Copenhagen:** World Health Organization, 2016

**Observatory Policy Brief 21**

**Number of pages:** 28; **ISSN:** 1997–8065

**Freely available for download:** [http://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0009/331992/PB21.pdf?ua=1](http://www.euro.who.int/__data/assets/pdf_file/0009/331992/PB21.pdf?ua=1)

This Policy Brief examines the legal framework put in place by the EU to foster voluntary cross-border collaboration in the field of



public procurement of health technologies. It looks at recent experiences and developments in cross-border collaboration across Europe and explores the challenges and opportunities that such collaboration presents.

Key messages include a growing interest in further developing cross-border collaboration in the field of health. This is supported by EU legislation and policies, and extends to improving access

to health technologies. Changes in health technologies markets, such as the generalisation of managed entry agreements and the prevailing lack of price transparency, require different approaches to those applied in the past. There is a sound rationale for increased voluntary collaboration between countries in procurement of health technologies; however, in practice, developing sustainable collaboration seems challenging. Experiences are still limited and too recent to really allow clear lessons to be drawn about effectiveness and impact. Nevertheless, it is clear that in order to succeed initiatives would require strong political commitment and mutual trust between purchasing partners.

**Contents:** Acknowledgments; Key messages; Executive summary; Policy brief; Findings; Discussion; Conclusions; References.

*These policy briefs were produced to inform discussions under the Maltese EU Presidency in 2017*



# NEWS

## International

### European Reference Networks (ERNs) begin work

ERNs are new innovative cross-border cooperation platforms between specialists for the diagnosis and treatment of rare or low prevalence complex diseases. 24 thematic ERNs, gathering over 900 highly specialised health care units from 25 EU countries and Norway, began work on 1 March on a wide range of issues, from bone disorders to haematological diseases, from paediatric cancer to immunodeficiency. A conference on ERNs was held in Vilnius on 9 March to celebrate their launch and discuss how to maximise their benefits and impact. The hope is that bringing together expertise on this scale will benefit thousands of patients with diseases requiring a particular concentration of highly specialised health care in medical domains where the expertise is rare. There should also be economies of scale allowing resources to be used in a more efficient way.

The ERNs are virtual networks that have been set up under the EU Directive on Patients' Rights in Healthcare (2011/24/EU). They will develop new innovative care models, eHealth tools, medical solutions and devices, as well as strengthening research through large clinical studies and development of new medicines. ERNs are not directly accessible to individual patients. However, with patients' consent, and in accordance with the rules of their national health systems, cases can be referred to the relevant ERN member in their countries by their health care providers. The ERNs will be supported by European cross-border telemedicine tools, and will be able to benefit from a range of EU funding mechanisms including the EU research programme "Horizon 2020".

**A full list of ERNs is available at:** [http://ec.europa.eu/health/ern/networks\\_en](http://ec.europa.eu/health/ern/networks_en)

### Antimicrobial resistance remains high: new EU report

Bacteria found in humans, animals and food continue to show resistance to widely used antimicrobials, says the latest report on antimicrobial resistance (AMR) in bacteria by the European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control (ECDC). The findings underline that AMR poses a serious threat to public and animal health. Infections caused by bacteria that are resistant to antimicrobials lead to about 25,000 deaths in the EU every year. The report highlights that countries in northern and western Europe generally have lower resistance levels than those in southern and eastern Europe. This may be due to differences in antimicrobial use across the EU. The report is accompanied by a data visualisation tool, which displays data by country on AMR levels of some bacteria found in foods, animals and humans.

**The report and data visualisation tool are available via** [http://www.efsa.europa.eu/en/interactive\\_pages/AMR\\_Report\\_2015](http://www.efsa.europa.eu/en/interactive_pages/AMR_Report_2015)

### EU-OSHA launches visualisation tool on safety and health of Europe's ageing workforce

By 2040, almost 27% of the EU's population is expected to be over the age of 65. This has serious implications for workers, employers and society as a whole. The objectives of a three-year project, carried out by the European Agency for Safety and Health at Work (EU-OSHA) at the request of the European Parliament, were to examine the safety and health of older workers and to identify ways of ensuring sustainable work. Among other things, the project highlighted examples of workplace safety and health strategies that consider workforce ageing, and the drivers and barriers to the implementation of such strategies. The results aim to inform policy development in this area.

A final overview report combines all of the project's findings and discusses their policy relevance. It includes a user-friendly, interactive visualisation tool. Users can examine existing policies, strategies

and programmes and compare policy development and approaches in different European countries. Country profiles provide an at-a-glance visual summary of the situation in 31 European countries. In addition, in-depth reviews, reports and case studies on rehabilitation and return-to-work strategies are available. The project also examined specific issues facing women in the context of an ageing workforce.

**The report is available at:** <http://tinyurl.com/glr2qpq>. **The interactive tool is available at:** <https://visualisation.osha.europa.eu/ageing-and-osh#!/>

### Kyrgyzstan: policy options to reduce out-of-pocket payments for medicine

A new WHO/Europe report examines the causes of high out-of-pocket payments for prescription drugs in Kyrgyzstan and presents ways to address the problem through policy reform. WHO/Europe conducted a study of prescription drug costs in Kyrgyzstan between 2013 and 2015. During this time, co-payments for reimbursed medicines in outpatient care increased by 20% in the country. The report proposes a number of recommendations to limit and bring down high out-of-pocket payments, including: regulating the price of medicines reimbursed by public health insurance; regulating retail sector margins; updating legislation on the criteria and processes for adding or removing medicines from the list of reimbursed medicines; and improving data collection on reimbursement prices.

**The report is available at:** <http://tinyurl.com/hwpppha>

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