Quarterly of the European Observatory on Health Systems and Policies

EUROHEALTH

RESEARCH • DEBATE • POLICY • NEWS

› Digital Health Systems

- Charting the future of digital health systems
- Secondary use of (big) data
- Developing effective policy to support Artificial Intelligence in health and care
- E-Prescription success in Estonia
- The national Danish e-Health Portal
- The future development of digital health in Kazakhstan
- Digital health driven prevention as a clinical reality

Volume 25 | Number 2 | 2019

European Observatory on Health Systems and Policies
a partnership hosted by WHO

EUROHEALTH

Quarterly of the
European Observatory on Health Systems and Policies
Eurostation (Office 07C020)
Place Victor Horta/Victor Hortaplein, 40/10
1060 Brussels, Belgium
T: +32 2 524 9240
F: +32 2 525 0936
Email: contact@obs.who.int
http://www.healthobservatory.eu

Eurohealth is a quarterly publication that provides a forum for researchers, experts and policymakers to express their views on health policy issues and so contribute to a constructive debate in Europe and beyond.

The views expressed in *Eurohealth* are those of the authors alone and not necessarily those of the European Observatory on Health Systems and Policies or any of its partners or sponsors. Articles are independently commissioned by the editors or submitted by authors for consideration.

The Observatory is a partnership, hosted by WHO/Europe, which includes other international organizations (the European Commission, the World Bank); national and regional governments (Austria, Belgium, Finland, Ireland, Norway, Slovenia, Spain, Sweden, Switzerland, the United Kingdom and the Veneto Region of Italy); other health system organizations (the French National Union of Health Insurance Funds (UNCAM), the Health Foundation); and academia (the London School of Economics and Political Science (LSE) and the London School of Hygiene & Tropical Medicine (LSHTM)).The Observatory has a secretariat in Brussels and it has hubs in London at LSE and LSHTM) and at the Berlin University of Technology..

Design and Production: Steve Still

ISSN 1356–1030

LSE Health

List of Contributors

Olzhas Abishev • Ministry of Healthcare, Republic of Kazakhstan

Ran Balicer • Clalit Research Institute, the WHO Collaborating Center for NCD Research Prevention and Control, Israel

Noa Dagan • Clalit Research Institute, the WHO Collaborating Center for NCD Research Prevention and Control, Israel

Nick Fahy • Nuffield Department of Primary Care Health Sciences, University of Oxford, United Kingdom

Clayton Hamilton • Division of Health Systems and Public Health, World Health Organization Regional Office for Europe, Denmark

Indra Joshi • NHSX, United Kingdom

Hans Kluge • Division of Health Systems and Public Health, World Health Organization Regional Office for Europe, Denmark

Karin Kõnd • Estonian Health Insurance Fund, Estonia

Anett Lilleväli • Estonian Health Insurance Fund, Estonia

Jessica Morley • University of Oxford and NHSX, United Kingdom

Morten Elbæk Petersen • sundhed.dk, Denmark

Nadav Shimoni • Clalit Research Institute, the WHO Collaborating Center for NCD Research Prevention and Control, Israel

Yerbol Spatayev • Social Health Insurance Project, Republic of Kazakhstan

Gemma A Williams • European Observatory on Health Systems and Policies, United Kingdom

Eurohealth is available online at: http://www.euro.who.int/en/about-us/partners/observatory/publications/eurohealth and in hard-copy format. If you want to be alerted when a new publication goes online, please sign up to the ***Observatory e-bulletin:*** http://www.euro.who.int/en/home/projects/observatory/publications/e-bulletins

To subscribe to receive hard copies of *Eurohealth*, please send your request and contact details to: bookorder@obs.euro.who.int

Back issues of *Eurohealth* are available at: http://www.lse.ac.uk/lsehealthandsocialcare/publications/eurohealth/eurohealth.aspx

CONTENTS

GUEST EDITORIAL

I am delighted to have the opportunity to introduce this digital health themed edition of *Eurohealth.* The contribution of digital health in the complex landscape of health systems strengthening and reform is significant and Member States in the European Region are moving rapidly on implementing their national digital health strategies.

The *WHO Symposium on the future of digital health systems,* which was hosted by the WHO Regional Office together with the Norwegian Centre for eHealth Research in Copenhagen earlier in 2019 brought together over 350 participants from Member States to hear 90 thought leaders highlight key trends, discuss impacts and help shape the future directions of health systems digitalization. This was combined with an impressive living demonstration of the Danish health system in action in Healthcare Denmark's *Patientville* exhibition.

The key messages arising from this event were revealing. Firstly, it was clearly demonstrated that **digitalization is challenging our understanding of how and where health care can be delivered and is driving a transition to predictive and preventative models of care**. There were several impressive examples illustrating this transformation in practice from which you will learn more in the articles that follow.

Secondly, there was a message underlining the comprehensive ability of digital health to *disrupt* health systems, service delivery models, care processes and public expectations. That is, **digitalization of health systems is not simply a notion of "continuing what we're doing now, faster and more efficiently"** but is putting the individual at the centre of their own health and well-being, addressing how the rights and consent of individuals can be respected and acted upon, and harnessing the value of data for health.

Finally, an expression of the **importance of digital health in achieving universal health coverage** was conveyed through more efficient and effective modes of providing quality and equitable access to health for all. However, it was agreed that the path towards a safe future enabled by digital health will require strong public health engagement and Member States to concretely link their investments for digital health to the achievement of public health policy goals. This is particularly pertinent in light of the increased focus on the role of digital health in the context of supporting Primary Health Care as enshrined within the Declaration of Astana and ratified by Member States during the Global Conference on Primary Health Care, Astana, Kazakhstan, in October 2018.

It was clear from many of the questions raised during the symposium that the barriers to progress in the digitalization of health system are often human, not technological. Allocating finances, integrating data, agreeing on common open standards, and ensuring the workforce is ready to embrace change were common hurdles voiced by Member States. In this context, it was noted that digitalization is likely to remove the need for certain specialisations and change the nature of others, though this did not imply job losses. Health and data literacy were also identified as key factors to be addressed: helping professionals and individuals to understand what health data is, what it means for people's health, and how and why to react to it.

Digitalization also has an important governance component that requires urgent attention. Credibility and public trust are essential to the success of digital health. New standards and regulatory approaches are needed to ensure security and transparency, so individuals understand and are confident in the use of their data and technical solutions. Building this trust requires time and the political will to take responsibility and ensure that wrongful uses of technology are prevented.

In looking to the future, linking digital investment to public health and health promotion and prevention goals needs new strategic approaches and organisational changes based on identified needs. Without such a focus, digitalization efforts may inadvertently introduce new inequities, creating divides where resources are not aligned with social needs. Continuing dialogue and studies of success in digital health are crucially important - particularly around the role of the private sector, and how to balance the different, competing interests which exist.

I hope you enjoy this edition of *Eurohealth*, and that it provides you with an interesting oversight of the key issues surrounding the digitalization of health systems and how together, we can leverage the benefits of digital health to support WHO's mission to *promote health, keep the world safe, and protect the vulnerable*.

Hans Kluge, Guest editor

Director, Division of Health Systems and Public Health

WHO Regional Office for Europe

Cite this as: *Eurohealth* 2019; 25(2).

CHARTING THE **FUTURE OF DIGITAL HEALTH SYSTEMS** IN THE WHO EUROPEAN REGION

By: Clayton Hamilton

Summary: A key agenda item for European health system decision makers is the role of digital health in reforming and modernising health systems and health service delivery. Only a small number of European Member States have made significant progress in reorienting their health systems to capitalise upon the advantages which digital health and high-quality data can offer. This article seeks to highlight the directions and influences in the digitalization of national health systems, examine the contribution of public health approaches, and offers recommendations on the future of health service design and delivery.

Keywords: *Digital Health, Digitization, Health Systems Strengthening, Public Health Approach*

Introduction

Digital health* and its role in reforming and modernising health systems and health service delivery has become a key agenda item for European health decision makers. The current level of intensity surrounding digital health and its development is palpable – with several major events on this topic taking place across Europe weekly, each casting a focus on the latest trends and advances in the development of digital services and device offerings for the health sector. Most notably, the recent emphasis on the potential for data-driven technologies, such as Machine Learning and Artificial Intelligence, to disrupt and reform clinical care environments has been a recurring feature of conference headlines and keynote speeches. Undoubtedly, we are seeing these technologies mature at an unprecedented rate, driven by both substantial private sector investment and a renewed interest by Member States in leveraging the full power of data flowing through their health systems. This, in turn, is rekindling interest in the importance of having timely access to high-quality health data and a re-examination of sources and methods for the capture, codification, storage and exchange of such data.

To many, the unique appeal of digital health lies in its potential to tackle entrenched inefficiencies in health systems and to create a new, tactile paradigm of health care – one in which individuals are empowered through choice; where health-related information is more accessible and actionable, and health services are more transparent and personalised.

* Defined as a broad umbrella term encompassing eHealth as well as developing areas such as the use of advanced computing sciences (in the fields of, for example, "big data", genomics and artificial intelligence).

Clayton Hamilton is Technical Officer, Digitalization of Health Systems, Division of Health Systems and Public Health, World Health Organization Regional Office for Europe, Denmark.
Email: hamiltonc@who.int

Coupled with this vision is a discourse surrounding a shift away from reactive care environments (enabled by digital technologies, big data and genomics-based approaches) to modalities of prediction and disease prevention.

> strategic focus must remain centred on developing and contextualising the fundamental building blocks of digital health

While a handful of countries in Europe have made significant progress in reorienting their health systems to capitalise upon the advantages which digital health and high-quality data can offer, the reality of the situation across the majority of European countries is a starkly different one. Health systems are still often fraught with piecemeal technology implementations, data interoperability across institutional and regional boundaries is poor, governance and financing for digital health is lacking and health care professionals often feel ill equipped in their use of the available technologies (in addition to feeling overwhelmed by the burden of data entry). Ensuring that these complex, systemic barriers are appropriately addressed by national digitalization programmes requires that the strategic focus remains centred on developing and contextualising the fundamental building blocks of digital health, that investments are aligned to key health policy objectives, and that the trust of health care professionals and the public in their use of digital solutions is well-established.

This article seeks to highlight the directions and influences in the digitalization of national health systems, examine the contribution of public health approaches, and offers recommendations on the future of health service design and delivery.

A public health approach to the digitalization of health systems

As digital health services become more widespread in Europe, a holistic, public health approach to the design of future health systems becomes highly relevant in ensuring that solutions remain safe, accessible and affordable by all segments of the population.

The actions of the World Health Organization (WHO) in developing digital health in countries are anchored in the UN Sustainable Development Goals and in particular, in national targets for Universal Health Coverage (UHC). Mobilising this agenda is taking place through the articulation of WHO's ambitious triple billion target: one billion more people benefiting from UHC; one billion more people better protected from health emergencies; and one billion more people enjoying better health and well-being. Under this framework, WHO seeks to advise countries on how to best position themselves in terms of digitalizing their health systems and data and leveraging the capacity of both, for the delivery of population-wide services and interventions. The notion of digital health as an enabler of public health action is rooted in the understanding that good health and well-being is primarily a function of equity. As such, the delivery of equitable health services is largely dependent upon countries developing well-designed and governed health systems that increase quality and accessibility of health services and facilitate the flow and use of health information at all levels of the system – including transparently to citizens.

The public health approach also acknowledges that significant influences and impacts to our health originate from outside the sphere of influence which care systems provide. Accordingly, the WHO/Europe Health 2020 policy framework has, for many years, advocated for an intersectoral approach to health that transgresses the silos of government portfolios and funding – calling for shared ownership of strategic goals for health and well-being between multiple stakeholders within and beyond the health domain. Successful efforts for national digital health service development often seek to mirror this intersectoral approach, engaging stakeholders from health and social care, civil society, patient representative groups, Information and Communication Technology (ICT) ministries and the private sector.

Translating goals into action in European Member States

As a vehicle for delivering public health impact in digital health, the WHO/European Regional Office has created the *Digitalization of Health Systems initiative* which seeks to accelerate the safe implementation of digital health in European Member States for the achievement of better health and well-being for all. The initiative includes five overarching dimensions of public health action and support for digital health:

- Designing the future of health service delivery and access;
- Empowering individuals to better manage their own health and well-being through technology;
- Improving the operational efficiency and responsiveness of the health system;
- Enabling the transition to integrated, person-centred models of care and facilitating the move from treatment to prevention;
- Technology and innovation facilitating achievement of key public health initiatives.

Framed under these five dimensions, and in line with the ongoing development of a WHO Global Strategy for Digital Health, the WHO/Europe is developing a roadmap for the digitalization of national health systems that will identify and unpack the key factors contributing to the design of safe, effective and accessible digital health services.

The future of health is digital and personal, but the path remains uncertain and the public health benefits unclear

The rapid expansion and uptake of digital health brings with it many challenging questions to be considered by health decision makers. These include uncertainties regarding approaches to evaluating the safety, efficacy and long-term sustainability of digital solutions in health care; appropriate methods of obtaining and applying consent for the use of health data in different contexts; training of the health workforce; and models of public-private sector engagement that keep the best interests of populations at heart. This is in addition to existential questions being raised as to the influence of technology on the future value base of health systems and their operation.

The reality is that while we are seeing a significant increase in interest in digital health and many efforts to fund and accelerate progress, at the same time, we are observing an increase in solution complexity, new risks appearing, new public concerns emerging, new partnerships, modalities of engagement and methods of value creation. Consequently, governing this landscape requires a new generation of leaders who are adept in the management of continuous change and who can successfully navigate the complex, fluid, multi-faceted, multi-stakeholder environments of digital health.

We are only at the very beginning of seeing the effect of large-scale population-based data analytics being incorporated back into primary health care settings for diagnostics and risk factor identification in individuals. Combined further with omics-based precision medicine approaches that rely "on both biological individuality and population knowledge to provide tailored health care",[1] we will begin to see an entirely new level of consistency, accuracy and personalisation in predicting, diagnosing and treating disease. This combination represents an incredibly powerful and significant shift in our understanding of what is possible in health care and will correspondingly require restructuring of health systems and services to leverage the massive quantities of data required for these approaches. We can also expect to see new roles in health care and public health emerge – specifically medical data scientists who configure and apply data analyses to population data sets, and other hybrid medical-technology roles that are capable of actioning such data and developing appropriate care pathways upon this basis.

> Governing this landscape requires a new generation of leaders who are adept in the management of continuous change

It is important to note that several, critical questions still remain as to the potential cost implications to public budgets of implementing such approaches and whether or not they will serve to increase or decrease the overall cost of health care and/or overmedicalise health in the long term. As such, we must also consider how to ensure that these approaches do not introduce new inequities and social divisions in our societies, and that benefits are widely and evenly distributed among populations. Further independent research is required to examine the social return on investment of the approaches described above in contrast to, or combination with low-cost public health interventions.

The value of strategic partnerships for digital health

The need to invest further in bold, innovative and far reaching partnerships for digital health cannot be over-emphasised. The momentum of big political interventions and agreements must be exploited if we are to accelerate progress uniformly in digitalizing European health systems. This includes leveraging partnerships between state actors; patients and representative groups; with young people; with donors and development agencies; with academics and researchers; with developer communities and with the private sector (who are the leaders of innovation). Some examples of the work of partners within the European digital health context include the work done by the European Commission,[2] through its Digital Single Market Strategy, eHealth Network, and Digital Service Infrastructure approach, which has developed significant national capacity for digital health and cross-border data exchange between EU Member States, the Global Digital Health Partnership[3] which represents an independent "collaboration of governments and territories, government agencies and the World Health Organization, formed to support the effective implementation of digital health services" and the OECD[4] through its agenda for next generation of health reforms which provides recommendations for "Adapting health systems to new technologies and innovation."

Creating synergies for digital health can only occur when we unite around shared goals for health and well-being. Sustainable Development Goal 17 provides unique momentum to accelerate partnerships, including for digital health, and action within this context should be made to identify trends and best-of-breed approaches, develop evidence on the effectiveness of digital interventions and to define new methods of measuring the performance of digital health systems.

Preparing for the future of digital health systems

To adequately prepare for the future of digital health, Member States are encouraged to embed a public health approach into their national digitalization efforts to ensure that "no one is left behind" in the impending transformation of health services and that social and cultural factors underpinning transformative change in health are taken into consideration in addition to governance, technical, organisational,

financial and process-based requirements. Digitalization is important, but not at any cost. Safety and ethics in digital health are key and there needs to be a clear fundamental caveat of "do no harm" applied to all forms of technology adoption in health.

In designing the future of digital health systems, action by Member States is needed to:

- Develop more concrete approaches to enhancing the digital capabilities of the health workforce, coupled with an open dialogue on inclusive gender approaches and changing roles and responsibilities of health care professionals.
- Build upon the significant achievements already made in the area of standards adoption and interoperability for digital health. This includes development of guidelines on data quality and consent, and clear policy for the use of public health data by private sector entities.
- Focus on the development of broad-scale programmes for digital health literacy.
- Place particular attention on digitalization initiatives deployed in primary health care settings, ensuring that solutions do not place undue burden on health care professionals and guarantee continuity of care as individuals move through the health system.

> Member States are encouraged to embed a public health approach into their national digitalization efforts

The development of future health systems in Europe will undoubtedly be shaped in large part by digital technologies. The challenge for digital health and public health communities will be to work together to ensure that the benefits of digitalization are shared equitably and that services are designed to include and protect the most vulnerable groups in society.

References

1 Tebani A, Afonso C, Marret S, Bekri S. Omics-based strategies in precision medicine: Toward a paradigm shift in inborn errors of metabolism investigations. International Journal of Molecular Sciences 2016;17(9):1555. doi: 10.3390/ijms17091555. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5037827/

2 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 2018. Available at: https://ec.europa.eu/newsroom/dae/document.cfm?doc_id=51628

3 Global Digital Health Partnership (GDHP) website. Available at: https://www.gdhp.org

4 OECD Ministerial Statement. The next generation of health reforms. Available at: http://www.oecd.org/health/ministerial/ministerial-statement-2017.pdf

Spain: Health system review

By: E Bernal-Delgado, S García-Armesto, J Oliva, et al.

Copenhagen: World Health Organization, 2018 (on behalf of the Observatory)

Number of pages: 179; **ISSN:** 1817-6127

Freely available for download: http://www.euro.who.int/__data/assets/pdf_file/0008/378620/hit-spain-eng.pdf?ua=1

The underlying principles and goals of the Spanish national health system continue to focus on universality, free access, equity and fairness of financing. The evolution of performance measures over the last decade shows the resilience of the health system to macroeconomic conditions, although some structural reforms may be required to improve chronic-care management and the reallocation of resources to high-value interventions.

Life expectancy in Spain is the highest in the EU. Inequalities in self-reported health have also declined in the last decade, although long-standing disability and chronic conditions are increasing due to an ageing population. After decreasing in 2009–2015, public health care spending is on the rise with public sources accounting for over 71.1% of total health financing. Yet private spending, mainly related to out-of-pocket payments, has increased over time, and it is now above the EU average.

Primary care remains the core element of the health system. Public health efforts over the last decade have focused on increasing health system coordination and providing guidance on addressing chronic conditions and lifestyle factors such as obesity. Health system-specific measures to maintain the sustainability of the Spanish health system were implemented in the last decade, with no short-term impact on health outcomes. Structural measures, however, are needed to improve resource allocation and technical efficiency as well as patients' participation in decisions on their care.

BUILDING AND MAINTAINING PUBLIC TRUST TO SUPPORT THE SECONDARY USE OF PERSONAL HEALTH DATA

By: Gemma A Williams and Nick Fahy

Summary: Large-scale availability of personal health data, together with improved data analytic capabilities presents enormous opportunities to transform health services and improve patient and population health. Capturing the benefits of this data revolution requires the secondary sharing of personal health data, which raises concerns over data protection, privacy and security. Successfully addressing these concerns while facilitating secondary data use is complex and relies on establishing and sustaining trust at the individual and societal level. Trust can be secured through clear data governance, public and health practitioner engagement, developing comprehensive consent procedures where needed, and implementing technical solutions to safeguard cyber security.

Keywords: *Secondary Data Use, Data Sharing, Cyber Security, Data Governance*

Introduction

Rapid proliferation in the use of health applications of information and communication technologies ('eHealth') such as electronic health records, mHealth smartphone applications and wearable devices, alongside greater availability of genetic, genomic and proteomic data has led to unprecedented, large-scale accumulation of personal health data. Simultaneous advances in health analytics, machine learning and artificial intelligence have the potential to transform capabilities to handle and analyse this complex data. This data revolution is generating new insights and knowledge that have immense potential to improve patient and population health through the development of precision medicine and the delivery of more efficient and higher-quality health care services.[1]

One of the challenges to realising the potential benefits from these technologies and applications is that they depend on personal information being shared and used in ways that were often not originally intended, with outcomes enjoyed by more people than the original data subject.[2] Data may be shared with researchers to support academic and clinical research, with health providers to support delivery of health services and public health activities, or with commercial organisations involved in developing and

Acknowledgments: Nick Fahy is supported by the National Institute for Health Research (NIHR) Oxford Biomedical Research Centre.

Gemma A Williams is Research Fellow, European Observatory on Health Systems and Policies, London, UK; **Nick Fahy** is Senior Researcher, Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford, UK. Email: g.a.williams@lse.ac.uk

implementing new health technologies or delivering health care services. Yet, while there are many potential benefits for such secondary data use, there are also concerns among health professions, patients and the wider public over data protection, personal privacy and security and the purposes to which such data may be put.

Successfully addressing these concerns and establishing principles and processes for the secondary use of personal data that can command public and patient trust is fundamental to facilitate continued data sharing and will be essential to realise the potential of these technologies. Building trust at the individual and at the societal level can help encourage patients and research subjects to provide consent to share data where required. Lack of trust can lead to patients adopting privacy protecting behaviours such as not seeking care, providing inaccurate or incomplete information or changing health providers, which can affect the accuracy, type and amount of health data collected.[3] More broadly, there is a tension between the key role of technology companies as important partners in the development and use of many digital health technologies on the one hand, and lower public trust in use of secondary data when profit-making entities are involved on the other.[4]

Building trust by developing clear legal frameworks

A clear legal framework that safeguards personal data and ensures it is only shared where appropriate and under conditions that protect individual privacy is central to societal trust in the secondary use of health data. At the European Union (EU) level, the General Data Protection Regulation (GDPR) enacted in 2018 provides a firm legal basis governing the use of personal data, including health, biometric and genetic data.[5]

On the face of it, GDPR Article 9 makes specific legal provision for the secondary use of health data for research purposes "in the public interest, scientific or historical research purposes or statistical purposes",[5] and also makes clear that consent is not always needed to process data. However, these provisions leave exact legal requirements over the use of sensitive personal information for research up to individual Member States or subject to other EU regulations, such as those governing clinical trials or mandatory reporting of some infectious diseases. Variations in national governance frameworks and confusion about what they mean in practice lead to great differences between Member States in terms of the extent of health data linkage and the availability of health data for research purposes.

As the use of personal data has become both more widespread and more widely discussed, this confusion has not only undermined the potential of future applications of secondary use of data, but also destabilised existing consensus. For example, cancer registries had been operating effectively and with a broad base of public support for years before questions about appropriate secondary use of data undermined some of those registries, with significant consequences for the use of data for registries.[6]

> Openness and transparency form a pivotal component of public engagement strategies

In discussing restrictions imposed by the GDPR on the secondary use of personal data, it is important to distinguish between anonymised data and fully identifiable or pseudonymised data. With identifiable and pseudonymised data, it is possible to identify individuals, making it subject to strict data sharing constraints. Fully anonymised data, on the other hand, cannot be linked back to an individual and is not subject to the same restrictions. It can therefore be shared with fewer constraints, subject to national regulations, making it a powerful data source for research. However, while sharing of anonymised data creates fewer legal considerations, it still raises ethical concerns over the appropriate use of health data, along with practical concerns as full anonymisation is difficult to achieve and is not sufficient for certain types of research and statistics. Even where data are anonymised, there are still expectations as specified by the GDPR, that data will only be shared for specified, explicit and legitimate purposes.[5] Interpretations of what may classify as legitimate use of health data vary between potential data processers, making it important that national, regional and institutional guidelines on ethical and legitimate sharing of health data are developed to ensure data is only shared when appropriate and under circumstances likely to bring benefits to patients and the wider public.

Building trust through public engagement

Part of developing legal frameworks that can sustain public support depends on effectively communicating and engaging with the public.[7] Public engagement can improve awareness and understanding of the benefits of data sharing, how data will be used beyond improving personal care, anonymisation procedures, privacy risks, data security, the involvement of private companies and protection options pertaining to personal data, and can help to develop frameworks that reflect broader societal consensus. Developing knowledge on the role that commercial companies may play in analysing secondary data is likely to play a crucial role in any public engagement strategy. For while the public is broadly supportive of personal health data being used for research purposes by universities and other non-commercial entities, they are less supportive of sharing data with companies to help them improve their products or services, even if it may be beneficial to public health.[8]

In their review of 'Health Data Governance Privacy, Monitoring and Research', the OECD proposed three key elements of a successful health data public engagement strategy (**see Box 1**).

Box 1: Key elements of a successful health data public engagement strategy

1. Regular, clear and transparent communication with the public about the collection and processing of personal health datasets including the benefits of the processing, the risks of the processing and the risk mitigations

2. Public information, such as a website, that describes personal health datasets at a national level, including the content of the datasets and the dataset custodians

3. Public information, such as a website, that describes applications for approval of the processing of national personal health datasets, including dataset linkages, as well as approval of the decisions

Source: [7]

Successful engagement should be ongoing and involve opportunities for the public to feed-back on data sharing initiatives, privacy concerns and how benefits of research will be captured by patients and the public. Openness and transparency over the use of data and research findings form a pivotal component of public engagement strategies. Patient or public representatives should also participate in developing solutions to overcome any issues that may be encountered.[9]

Building trust by developing clear consent procedures

Where consent is required, lack of clarity on data use and options to opt-out of data sharing can also erode public trust in secondary data use. As noted, while people are often comfortable and supportive of their health data being used for research purposes, they may be less keen to share data if it is to be processed by private companies, even where this may ultimately lead to health benefits and improved health and care services. Developing and communicating clear consent procedures to patients, research participants and the public is therefore central to building support for secondary data use.[10] One option includes taking advantage of new technologies to support the consent process itself by enabling consent to be dynamic; to change over time. This can help to reduce the weight of decisions about consent at a specific point in time, if people know that they can change their mind later.[11] Making patients aware of their rights surrounding privacy and consent options at the time of registration in a primary care facility or referral to secondary care and communicating opt-out options to the public are also key to developing informed consent procedures. Under the GDPR, consent must be freely given, based on properly explained information, recorded, provided for specific purposes and can be refused or easily withdrawn at any time.[5]

Building trust by engaging and guiding health workers

Health care workers are a critical link in developing patient and public trust in data sharing. As the individuals most trusted to use and share patient data appropriately, they can play a key role in helping patients navigate the complex world of health data and are in a unique position to effectively communicate and make clear the benefits of sharing personal information.[9] This requires health workers to be supportive of the re-use of health data and to have appropriate knowledge of fundamental issue such as how and why patient data might be used, together with the potential benefits to the patient and society more widely. Health workers themselves must also be confident in sharing sensitive and confidential patient data for secondary purposes, provided a request meets legal requirements. An understanding of legal and practical considerations over what data can be shared and under what conditions is therefore necessary.

Establishing national codes of conduct or good practice guidelines aimed specifically at health practitioners are important tools that can help develop the required knowledge among health workers to facilitate secondary sharing of health data. One example in practice includes 'Good Practice Guidelines for GP Electronic Patient Records' from the United Kingdom that offer advice on governance issues relating to sharing electronic patient records, including data ownership and control[12] These Guidelines are supported by British Medical Association (BMA) principles on Disclosing Data for Secondary Purposes which aim to assist Local Medical Committees and General Practitioners in determining how to respond to secondary data access requests.[13]

> reduce the weight of decisions about consent at a specific point in time

Building trust by ensuring cyber security and resilience

Building public trust on data sharing not only depends on assurances that data will be used appropriately, but also on confidence that data will be held and shared securely. Health information, as with other personal data, is at great risk from data breaches and cyber-attacks that may see data stolen and sold, deleted or corrupted.[14] This not only violates individual privacy but has the potential to cause direct harm to patients and may make data unavailable when needed. The cyber security threat posed to digital health systems was recently brought to the fore by the WannaCry malware attack that targeted a number of large corporations and entities globally, including the English National Health Service (NHS) where critical systems were compromised, preventing health staff from accessing patient records and other services.[14]

Developing digital health infrastructure that is resilient to cyber-attacks is critical to ensuring the security of patient data. Although a complex challenge, many countries have already taken significant steps to ensure the integrity of networks, systems and data through the development or adapted use, of existing technology

platforms. Perhaps one of the most famous examples is the development of Keyless Signature Infrastructure (KSI) Blockchain technology in Estonia, which underpins the digital e-services ecosystem in the country, including the secure use of eHealth records, eAmbulance and ePrescriptions.[15] In essence, blockchain technology is a tool through which a continuously growing list of records are linked and secured using cryptology into a permanent database. Once entered, data cannot be changed by anyone, including system administrators, the government or hackers[15] and information can only be accessed using signatures from people with appropriate credentials. Depending on the intended use of an access request, approval can then be granted by the patient or relevant practitioners. As well as enhancing cyber security, this system also means that a patient can, when requested or required, have full access to their own data and can choose the participants they would like to share it with.

Putting in place robust digital infrastructure is vital to ensure cyber resilience, but is not sufficient on its own. As noted by Ghafur et al,[14] a large share of data breaches in the health sector are due to employee behaviours such as covertly abusing data access or clicking on infected email links. Training on cyber security and actions that can be taken to mitigate security risks therefore plays a crucial role in reducing risks from cyber incidents. Strong oversight and regulatory frameworks, with in-built monitoring, evaluation and accountability processes are also fundamental to improve cyber resilience. Mechanisms at the local and national level should be in place where any cyber security risks can be assessed and cyber-attacks or inappropriate use of data can be reported,[14] with financial penalties imposed for any unauthorised use of data.

Conclusion

The secondary use of health data for research and big data analytics brings unprecedented opportunities to transform health care and improve patient and public health. Although there is widespread support for the sharing of personal data for appropriate secondary uses to improve health or health care, concerns remain about lack of clear principles and processes, particularly when commercial organisations are involved. Engaging with concerns surrounding the re-use of sensitive data and sustaining public trust remain key to facilitating continued data sharing. Building public trust requires public engagement to raise awareness of the benefits of secondary data sharing, understandings of opt-in and opt-out consent options, privacy, data security and legality. This can help individuals have more control over their own information, to become active participants in the future use of health data, rather than passive suppliers of data. Clear legal frameworks and effective technical solutions are also required to meet expectations that data will be safeguarded and only shared when appropriate and under conditions that maintain privacy. Maintaining public trust and confidence in data sharing is an ongoing exercise that will evolve as population expectations, knowledge and health literacy improve and technological advances progress.

References

1 Kersting K, Meyer U. From big data to big artificial intelligence? Algorithmic Challenges and Opportunities of Big Data. *Künstl Intell* 2018;32(3).

2 Evans H. Using data in the NHS: the implications of the opt-out and GDPR. *Technology and Data*. The King's Fund, 2018. Available at: https://www.kingsfund.org.uk/publications/using-data-nhs-gdpr

3 Malin BA, El Emam K, O'Keefe CM. Biomedical data privacy: problems, perspectives, and recent advances. *Journal of the American Medical Informatics Association* 2013;20(1):2–6.

4 Hill EM, Turner EL, Martin RM, Donovan JL. "Let's get the best quality research we can": Public awareness and acceptance of consent to use existing data in health research: A systematic review and qualitative study. *BMC Medical Research Methodology* 2013;13(1):1.

5 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) *Official Journal of the European Union*. 2016;119(1)

6 Coleman MP, Evans BG, Barrett G. Confidentiality and the public interest in medical research – Will we ever get it right? *Clinical Medicine* 2003;3(3):219–28.

7 OECD. Health Data Governance Privacy, Monitoring and Research. *OECD Health Policy Studies,* 2015. Available at: http://www.keepeek.com/Digital-Asset-Management/oecd/social-issues-migration-health/health-data-governance_9789264244566-en#page116

8 Royal Statistical Society. Royal Statistical Society research on trust in data and attitudes toward data use/data sharing. *Data, evidence, decisions,* 2016. Available at: https://www.statslife.org.uk/images/pdf/rss-data-trust-data-sharing-attitudes-research-note.pdf.

9 Kostkova P, Stevenson O, Valho R. Who owns the data? Open data for healthcare. *UCL Public Policy Briefing,* 2015. Available at: https://www.ucl.ac.uk/public-policy/sites/public-policy/files/migrated-files/open-data-for-healthcare.pdf

10 National Data Guardian for Health and Care. Review of Data Security, Consent and Opt-outs. *Caldicott Report,* 2016. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/535024/data-security-review.PDF

11 Kaye J, Whitley EA, Lund D, Morrison M, Teare H, Melham K. Dynamic consent: A patient interface for twenty-first century research networks. *European Journal of Human Genetics* 2015;23(2):141–6.

12 British Medical Association (BMA), Department of Health, Royal College of General Practitioners (RCGP). The Good Practice Guidelines for GP electronic patient records, 2011, *Version 4*. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215680/dh_125350.pdf

13 British Medical Association (BMA). Disclosing data for secondary purposes, 2016. Available at: https://www.bma.org.uk/advice/employment/ethics/confidentiality-and-health-records/disclosing-data-for-secondary-purposes

14 Ghafur S, Grass E, Jennings NR, Darzia A. The challenges of cyber security in health care: the UK National Health Service as a case study. *The Lancet Digital Health* 2019;1(1):PE10–12.

15 e-estonia. Building Blocks of e-estonia, 2019. Available at: https://e-estonia.com/solutions/

DEVELOPING EFFECTIVE POLICY TO SUPPORT ARTIFICIAL INTELLIGENCE IN HEALTH AND CARE

By: Jessica Morley and Indra Joshi

Summary: The increased availability of data has enabled the development of Artificially Intelligent Systems (AIS) for health, but implementing these systems and capitalising on the associated opportunities is not straightforward. To mitigate these risks, outdated governance mechanisms need to be updated and key questions answered. To achieve this, whilst still supporting innovation, a new joint organisation for digital, data and technology in the English NHS (NHSX) is developing a 'principled proportionate governance' model that involves focusing on proactively and objectively evaluating current AIS technology and regularly involving all those who rely on and serve the health and care system.

Keywords: *Digital health, Artificially Intelligent Systems, Machine Learning, NHS, England*

Introduction

Compared to other industries, it might appear that health care has been slow to respond to the 'data revolution'.[1] However, over the last few years this has changed significantly. The increased availability of data has enabled the development of Artificially Intelligent Systems (AIS) for diagnostics, drug discovery, public health and epidemiology, operational efficiency, and 'P4' (predictive, preventive, personalised and participatory) Medicine.[2,3,4]

Implementing these systems and capitalising on the associated opportunities is, however, not straightforward. The fall-out from the care.data scheme* demonstrates the challenge we face in trying to find a balance between investing in the development of data-driven technologies that have the potential to improve the quality of health and care services, whilst respecting ethical values such as autonomy, transparency, confidentiality and privacy.[5] Poorly designed AIS for health could result in

Jessica Morley is Research Assistant, Oxford Internet Institute, University of Oxford and AI Lead, NHSX, London, United Kingdom; **Indra Joshi** is Digital Health and Clinical Lead, NHSX, London, United Kingdom. Email: Jessica.morley@nhsx.nhs.uk

* Care.data was a programme intended to create a national database of patients' medical records that could be used for the purposes of research and ensuring consistency of care across primary and secondary care. However, it failed to win clinician and patient trust and was shut down in 2016.

significant harm to individuals, groups, or society, ultimately resulting in a loss of public trust.

To mitigate these risks, outdated governance mechanisms (policies, standards and regulations) need to be updated and key questions answered in terms of: liability in cases of medical error; doctors' and patients' understanding and control over how AIS produce predictions or recommendations that are used in treatment plans; and access to and protection of patient data.[6] In order to do this, whilst still supporting innovation that can deliver genuine system and patient benefit, NHSX (the central governing arm of the English NHS related to digital transformation) is developing a 'principled proportionate governance' model focused on: (1) guiding principles and best practice; and (2) safe, effective and proportionate regulation.[7] This involves focusing on proactively and objectively evaluating current AIS technology to ensure best practices are developed and implemented in an evidence-based manner[8] and with regular involvement from all those who rely on and serve the health and care system.

It is hoped that by adopting this approach, NHSX can encourage the development of AIS in a way that secures patient and health care practitioner trust, serves the public interest, and strengthens shared social responsibility.[9] What follows are some examples of how NHXS is doing this. The intention in outlining these is not to imply that it has 'solved' the problem of how to foster the development and implementation of AIS in health and care in a safe, ethical and robust manner, but to provide examples of what can be done and to encourage an open and collaborative approach to policymaking.

> proactively and objectively evaluating current AIS technology to ensure best practice

Guiding principles and best practice

First, building on existing frameworks, such as the Department for Digital, Culture, Media and Sport *Data Ethics Framework*,[10] is the Code of Conduct for Data-Driven Health and Care Technology. The Code aims to promote the development of AIS for health and care in accordance with the Nuffield Council on Bioethics' principles for data initiatives (i.e. respect for persons, respect for human rights, participation, accounting for decisions[11]) by clearly setting out the behaviours that the central governing organisations of the NHS expect from those developing, deploying and using AIS for health and care.

NHSX developed the Code, which is a series of 10 principled behaviours, using a Delphi methodology and published the first draft on 5 September 2018 along with a questionnaire for members of the public to offer feedback. It combined the feedback gleaned from this survey with that gathered from an extensive period of face-to-face engagement with industry experts, academics, regulators and patient representative organisations over the last quarter of 2018, to produce a revised version of the Code in February 2019 (**see Table 1**).

For the most part, these principles reflect behaviours that are already required by regulation, such as the Data Protection Act 2018, or existing NHS guidance, such as the NHS Digital Design Manual. However, principles 7 and 8 (and 10 although not discussed here), are entirely new and required further supporting policy work.

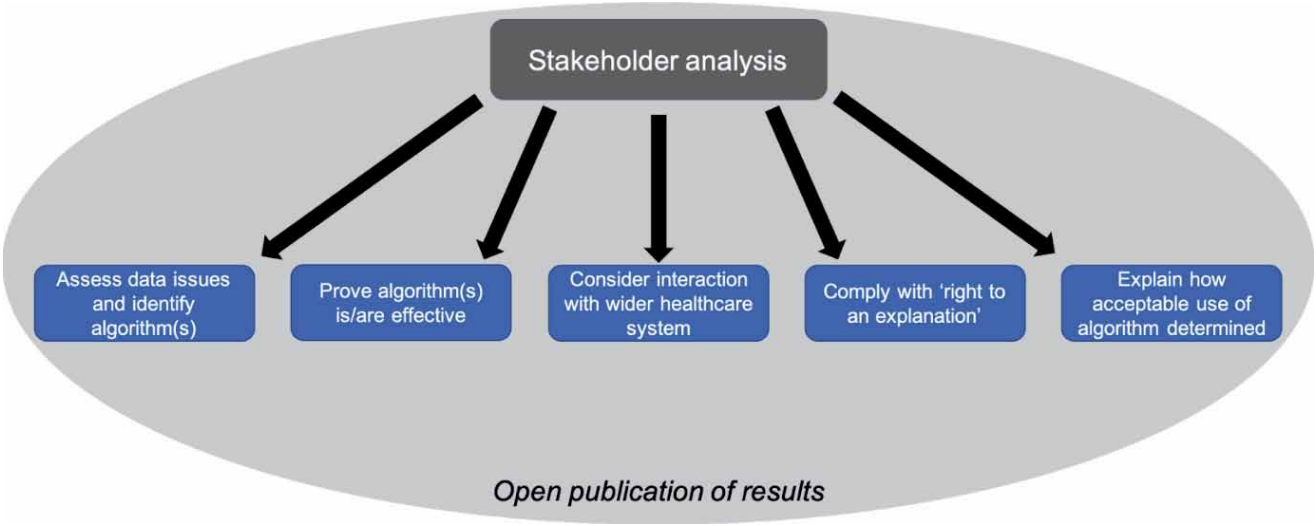
For principle 8, NHSX worked with the National Institute for Health and Care Excellence (NICE), Public Health England, and Med City (the life sciences sector cluster organisation for the Greater South East of England), to create the *Evidence Standards Framework for Digital Health Technologies*.[13] The

Table 1: The 10 Principles in the Code of Conduct for Data-Driven Health and Care Technologies, May 2019

1	Understand users, their needs and the context
2	Define the outcome and how the technology will contribute to it
3	Use data that is in line with appropriate guidelines for the purpose for which it is being used
4	Be fair, transparent and accountable about what data is being used
5	Make use of open standards
6	Be transparent about the limitations of the data used
7	Show what type of algorithm is being developed, or deployed, the ethical examination of how the data is used, how its performance will be validated, and how it will be integrated into health and care provision
8	Generate evidence of effectiveness for the intended use and value for money
9	Make security integral to the design
10	Define the commercial strategy

Source: [12]

Figure 1: A schematic outlining the different components of the principle 7 'how-to' guide



Source: Produced by Matt Fenech, Olly Bostrum and Nika Strukelj of Future Advocacy.

framework establishes the evidence of effectiveness and economic impact required before digital health interventions can be deemed appropriate for adoption by the health and care system. In keeping with its principled proportionate approach, the framework is based on a hierarchical classification determined by the functionality (and associated risk) of the tool, which indicates the level of evidence required so that a more complex tool (such as one providing diagnosis) requires considerably more evidence than one simply communicating information.[14]

> "ethical and behavioural principles are necessary but not sufficient

Following from this, for principle 7, NHSX is currently working with a number of think tanks, academic, industry and patient groups, to create a 'how-to' guide. The guide takes the form of a set of processes that NHSX will encourage developers to undertake. The processes are divided into two: i) recommendations for general processes that apply across all aspects of principle 7; and ii) recommendations for specific processes that apply to certain subsections (**see Figure 1**).

In both cases, the intention is to make it very clear to developers not only *what* we expect them to do in order to develop AIS for use in health and care, but *how* they might go about doing it. This is because, as has been pointed out several times recently,[15] ethical and behavioural principles are necessary but not sufficient to ensure the design and practical implementation of responsible AI. Indeed, this is why NHSX has turned the entire Code into a self-assessment workbook which, much like the assessment list included in the European Commission's Framework for Trustworthy AI,[16] aims to operationalise responsible AIS for health and care.

NHSX is currently piloting the workbook with a series of public and private companies to assess how it can be tailored in a proportionate manner, where it needs further development and where, like with principles 7 and 8, NHSX might need to provide more detailed guidance on translating between the *what* and the *how*. Once it has been tested, NHSX will be able to embed it into existing assessment processes, such as the Government Digital Service spend controls process, and the Digital Assessment Questionnaire for the NHS Apps Library, to provide us with a mechanism for conducting algorithmic assurance.

Safe, effective and proportionate regulation

NHSX believes that as the Code of Conduct, and its associated guidance, is strengthened over time it will significantly improve the governability of AIS developed, deployed and used within the health and care sector in the UK. Nevertheless, NHSX also believes that this will not provide sufficient protection for higher risk systems. For these systems, harder governance mechanisms will be needed. To develop these, NHSX is conducting two parallel processes: (a) assessing the supply of and demand for AIS and (b) strengthening the existing regulatory framework as part of an ongoing process involving all of the health and care regulators (Information Commissioner's Office, Care Quality Commission, Medicines and Healthcare products Regulatory Agency, Health Research Authority) and the Better Regulation Executive, to assess the gaps in the existing framework and transition it to one of 'regulation as a service.' †

† This particular programme of work is led by Adrian Price in the Department of Health and Social Care.

First, to assess the supply of AIS, NHSX is conducting a nationwide survey (available to all in the UK), in collaboration with the Academic Health Science Network AI Initiative, to answer key questions such as: (i) what outcomes are developers of data-driven technologies expecting to achieve for their identified user(s)?; (ii) where in the system do developers anticipate their data-driven technology to be deployed and how far away from that being a reality do they feel?; (iii) where and how are data-driven technology developers accessing data for training, testing, validation and evaluation?; and (iv) have the resultant models been assessed for possible issues of bias, optimised (in terms of architecture, procedures and outcomes) for fairness and designed with explainability in mind?

Second, to assess demand, NHSX is working with the Academy of Medical Royal Colleges, think tanks and social research groups, to conduct qualitative research with staff in hospital trusts to understand: (i) the primary issues they face on a daily basis that may prevent them from delivering the high standard of care NHSX expects; and (ii) the barriers that might be preventing them from using an available AIS to overcome relevant issues. NHSX hopes that the results from these two projects will provide the evidence that NHSX requires to determine where to invest next in the development of AIS and which areas of regulation it should focus on strengthening first.

Conclusion

The above provides a brief and non-exhaustive snapshot of the work that the central governing organisations of the NHS are leading on to develop effective policy to support Artificial Intelligence in health and care. The constantly developing nature of AIS means that these will not be one-off exercises, but part of an ongoing programme of work. Nor is it work that NHSX has been, or is planning to, conduct alone. The implications of the implementation of AIS in health and care are so significant, that close collaboration with regulators, with innovators, with patients (who must be seen as part of the solution, not a problem to be overcome),[17] with commissioners, with policymakers and with those on the frontline will continue to be essential if NHSX is to successfully embed the values that matter to all voices in the NHS into AIS from the very beginning. NHSX will continue to regularly assess whether it is striking the right balance between supporting innovation and protecting patient safety whilst creating a trusted environment that is in alignment with the NHS Constitution.

References

1 Oborn E, Barrett SK. Digital health and citizen engagement: Changing the face of health service delivery. *Health Services Management Research* 2016;29(1–2):16–20. https://doi.org/10.1177/0951484816637749

2 De Fauw J, Ledsam JR, Romera-Paredes B, et al. Clinically applicable deep learning for diagnosis and referral in retinal disease. *Nature Medicine*;24(9):1342–50. https://doi.org/10.1038/s41591-018-0107-6

3 Fleming N. How artificial intelligence is changing drug discovery. *Nature* 2018;557(7707):S55–7. https://doi.org/10.1038/d41586-018-05267-x

4 Velasco E. Disease detection, epidemiology and outbreak response: the digital future of public health practice. *Life Sciences, Society and Policy* 2018;14(1). https://doi.org/10.1186/s40504-018-0071-4

5 Sterckx S, Rakic V, Cockbain J, Borry P. "You hoped we would sleep walk into accepting the collection of our data": controversies surrounding the UK care.data scheme and their wider relevance for biomedical research. *Medicine, Health Care and Philosophy* 2016;19(2):177–90. https://doi.org/10.1007/s11019-015-9661-6

6 Ngiam KY, Khor IW. Big data and machine learning algorithms for health-care delivery. *The Lancet Oncology* 2019;20(5):e262–73. https://doi.org/10.1016/S1470-2045(19)30149-4

7 Sethi N, Laurie GT. Delivering proportionate governance in the era of eHealth: Making linkage and privacy work together. *Medical Law International* 2013;13(2–3):168–204. https://doi.org/10.1177/0968533213508974

8 Mittelstadt B. The Ethics of Biomedical 'Big Data' Analytics. *Philosophy & Technology* 2019;32(1):17–21. https://doi.org/10.1007/s13347-019-00344-z

9 Floridi L, Cowls J, Beltrametti M, et al. AI4People – An Ethical Framework for a Good AI Society: Opportunities, Risks, Principles, and Recommendations. *Minds and Machines* 2018;28(4):689–707. https://doi.org/10.1007/s11023-018-9482-5

10 Department for Digital, Culture, Media & Sport. *Data Ethics Framework,* 2018. Available at: https://www.gov.uk/government/publications/data-ethics-framework/data-ethics-framework

11 Nuffield Council on Bioethics. The collection, linking and use of data in biomedical research and health care: ethical issues, 2015. Available at: http://nuffieldbioethics.org/wp-content/uploads/Biodata-a-guide-to-the-report-PDF.pdf

12 Department of Health and Social Care. *Guidance Code of conduct for data-driven health and care technology,* 2019. Available at: https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology

13 NICE. *Evidence standards framework for digital health technologies,* 2019. Available at: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies

14 Greaves F, Joshi I, Campbell M, Roberts S, Patel N, Powell J. What is an appropriate level of evidence for a digital health intervention? *The Lancet* 2018;392(10165):266–7. https://doi.org/10.1016/S0140-6736(18)33129-5

15 Morley J, Floridi L, Kinsey L, Elhalal A. From What to How. An Overview of AI Ethics Tools, Methods and Research to Translate Principles into Practices, 2019. *ArXiv:1905.06876 [Cs]*. Retrieved from http://arxiv.org/abs/1905.06876

16 European Commission. *Ethics Guidelines for Trustworthy AI,* 2019. Available at: https://ec.europa.eu/futurium/en/ai-alliance-consultation

17 Aitken M, Tully MP, Porteous C, et al. Consensus Statement on Public Involvement and Engagement with Data-Intensive Health Research. *International Journal of Population Data Science* 2019;4(1). https://doi.org/10.23889/ijpds.v4i1.586

DIGITAL HEALTH DRIVEN PREVENTION AS A CLINICAL REALITY

By: Nadav Shimoni, Noa Dagan and Ran Balicer

Summary: The increasing burden that non-communicable diseases (NCDs) inflict on health care systems has continued to rise in recent decades. As many NCDs are preventable, early identification and intervention is key. Progress in the fields of data science and analytics, including recent utilisation of artificial intelligence (AI) in health care, have been identified as game changers in making preventive endeavours effective. Yet, the use of digital health at scale in practice is limited. Based on the experience of an integrated health care payer-provider system in Israel, several key attributes to successful prediction-based preventive proactive interventions have been identified.

Keywords: *Prevention, Prediction, Causal inference, Digital Health, Israel*

Introduction

NCDs are a leading cause of mortality and place a growing burden on the health care system, with global incidence and prevalence increasing.[1] With a rise in the numbers of patients who are ageing and have multi-morbidities, health systems are facing growing demands, which available resources are unable to meet. Effective prevention measures can reduce this burden and extend healthy life expectancy through the execution of proactive interventions, but realising this paradigm at a population level is challenging both financially and logistically.[2]

The increasing availability of longitudinal digital health care data, together with advancements in data science and most notably in AI, create new opportunities to analyse, augment, and alter health care delivery to provide more efficient preventive and proactive medicine.[3] As a by-product in the past few years, there has been a surge in new digital health tools for diagnosis, prognosis, therapeutics, care management, and care delivery.[4]

Yet, despite a plethora of readily available digital health tools, including hundreds of thousands of mobile health applications, with hundreds more launched on a daily basis,[5] successful attempts at harnessing AI to improve health care at scale in clinical practice are rare.[6,7] Creating predictive models with strong predictive performance, for example, is far from enough to ensure their use and acceptance by health care providers.[8]

Nadav Shimoni is Business Development Manager and Public Health Resident; **Noa Dagan** is Chief Data Officer & Researcher; **Ran Balicer** is Founding Director, Clalit Research Institute, the WHO Collaborating Center for NCD Research Prevention and Control, Israel. Email: nadavshi@clalit.org.il

Creating and integrating predictive models in the Israeli health care system

The prediction models in use within health organisations in Israel provide examples from which it is possible to learn about their design, implementation, and ability to scale up. In Israel, all citizens have universal access to health care through one of four payer-provider health care organisations. The largest of these organisations, Clalit Health Services (Clalit), serves over 4.4 million members, which constitute over half of the Israeli population. Clalit benefits from being a fully integrated system consisting of 14 hospitals, over 1,500 primary care clinics, while also operating its own laboratories, pharmacies, imaging services and other facilities. Coupled with an extremely low annual member attrition rate (less than 2%) and capitation-based budget, an embedded economical and operational incentive for long-term preventive care has been created.[9]

> critical steps are overlooked

Data on all Clalit members are recorded in individual electronic health records (EHRs), which date back to the 1990s. All socio-demographic and administrative data, inpatient and outpatient details, health care utilisation, medical history information, and medical encounters are also recorded in the EHRs. The longitudinal data has been extremely influential in creating data-driven tools and a "living lab" in which to implement them.

Data derived from the EHRs, coupled with the work of a multi-disciplinary group of physicians, epidemiologists and data-scientists from the Clalit Research Institute (CRI), has allowed Clalit to create predictive models, and the integration within Clalit made it possible to implant them into actual practice at scale, for over a decade. Such predictive proactive prevention plans aim at tackling and preventing key diseases associated with the global burden of disease, including chronic kidney disease progression, asthma attacks, onset of type-2 diabetes among pre-diabetics, acute deterioration of geriatric patients, 30-day readmissions and winter morbidity (pneumonia and influenza).[9] This work serves as a basis for CRI's work as the WHO Collaborating Center on Non-Communicable Diseases Research Prevention and Control.

Understanding the key challenges

While prediction tools have great potential to enable proactive and preventive interventions, it is essential to understand their limitations. Our experience suggests that several key factors impact this process, and in too many of these suggested new interventions these critical steps are overlooked.

Workflow engineering and stakeholder involvement

The first step, and often the most critical component, in designing a new prediction-based intervention is workflow engineering to allow the process to be streamlined with the daily work of practising clinicians. It is also critical to involve all stakeholders in ensuring that the intervention addresses a well-defined unmet need for administration as well as the end-user. When designing the readmission prediction model that was implemented in parallel in the ambulatory and inpatient setting, it was an outcome of intense deliberations with clinical staff, including key opinion leaders and practising staff, as well as administrators at all levels of the system. This has proven immensely important in establishing a clear new workflow in each of the settings and allocating resources when it required adjustment.

It is important for administrators to be aware that predictive proactive models of population health eventually get translated into intervention lists, which are essentially a new workload for clinicians. It is of value to address the issue of "impactability"– i.e. the likelihood of the intervention to positively affect the selected individuals, and not only risk. Carving out the likely low-impact sub-groups from top risk tiers reduces the burden of the unduly long lists and reduces the frustration of physicians facing patients that may be at risk but are unlikely to benefit from any intervention as the deterioration of their chronic condition is intractable or non modifiable.

> process to be streamlined with the daily work of practising clinicians

Select simple models when possible

Another key challenge in introducing prediction tools into practice is current pushback from the care providers who should use these tools on a daily basis. There is a fine balance between the need to create prediction tools with explainable methodologies, (i.e. why a certain decision was made, namely, "white box models", such as simple decision trees or logistic regression) and the motivation to utilise the more complex prediction algorithms that can sometimes produce better performance but are more difficult to explain ("black boxes" such as random forests or neural networks, that can use the entire medical history data).

Over the years, Clalit has deployed models of both kinds. The factors that affected the choice of model type usually were due to the clinicians' opinions, as well as relative performance of the different model types. When the differences in performance between simple and complex models are minor, the simpler model is always preferred. It is also critical not to be only data-driven, but to collect key features from the clinical experience of the end-users, and see if those can be reasonably included in the prediction to increase its face validity through the lens of these same end-users.

It is likely that over time, clinicians will learn to trust prediction models, and thus more black box models could be integrated into practice. In the meantime,

simpler models are often good enough, or alternatively technologies that explain the leading features in black boxes models, such as the SHAP (SHapley Additive exPlanations) method, can be used to gain clinicians' trust.

Identify when a different toolset is necessary

Finally, it is important to be very cautious when the challenge to tackle with a predictive model is prescriptive rather than predictive – i.e. when the aim is not to classify patients based on their risk but rather to predict the most favourable impact among several treatment options. The latter requires a different methodological toolset, one which stems from the rapidly developing field of causal inference, and simple predictions may lead to erroneous recommendations. Unlike prediction models, where the performance of the model can be evaluated using test and validation sets, it is far more complicated to determine the performance of a causal inference algorithm when based on observational data. Even when employing multiple statistical techniques to minimise the amount of confounding on the casual effect including minimising differences between the exposed groups, there is always considerable residual confounding.

When properly used, these 'counterfactual assessment' models can serve as strong motivators in changing patient behaviour. CRI is using causal inference in several prescriptive models that are delivered directly to patients in their mobile application, to see how different behavioural changes (e.g. smoking cessation or weight reduction) can alter their life course and reduce their risk of morbidity.

Conclusion

Being able to utilise prediction models more effectively, while also more accurately understand the anticipated impact of different interventions for a specific individual before testing them in practice, requires understanding causal effects. Deducing from massive longitudinal retrospective data such causal effects of where and how it is preferable to intervene by weighing alternative outcomes will further transform health care in the coming years. These processes will contribute substantially to reaching the next milestone in achieving effective and affordable population health maintenance at scale.

References

1 WHO. *10 facts on noncommunicable diseases,* 2013. Available at: https://www.who.int/features/factfiles/noncommunicable_diseases/en/

2 WHO. *Noncommunicable diseases country profiles 2018*. Available at: https://www.who.int/nmh/publications/ncd-profiles-2018/en/

3 Topol E. High-performance medicine: the convergence of human and artificial intelligence. *Nature Medicine* 2019;25:44–56.

4 *Classification of digital health interventions v1.0: a shared language to describe the uses of digital technology for health*. World Health Organization, 2018. Available at: https://www.who.int/reproductivehealth/publications/mhealth/classification-digital-health-interventions/en/

5 Mathews C, McShea J, Hanley C, Ravitz A, Labrique A, Cohen A. Digital health: a path to validation. *npj Digital Medicine* 2019;2:38.

6 Schulman K, Richman D. Toward an Effective Innovation Agenda. *N Engl J Med* 2019;380:900–1.

7 Keane P, Topol E. With an eye to AI and autonomous diagnosis. *npj Digital Medicine* 2018;1:40.

8 Kappen T, van Klei W, van Wolfswinkel L, Kalkman C, Vergouwe Y, Moons GM. Evaluating the impact of prediction models: lessons learned, challenges, and recommendations. *Diagnostic and Prognostic Research* 2018;2:11. https://doi.org/10.1186/s41512-018-0033-6

9 Choen-Stavi CJ, Balicer RD, Leventer Roberts M, WHO Europe. Innovation in health care for proactive care delivery and strategic clinical decision-making: integrating research, technology and practice. *Public health panorama* 2018;04(03):470–4. World Health Organization. Regional Office for Europe. Available at: https://apps.who.int/iris/handle/10665/324939

E-PRESCRIPTION SUCCESS IN ESTONIA: THE JOURNEY FROM PAPER TO PHARMACOGENOMICS

By: Karin Kõnd and Anett Lilleväli

Summary: Estonia has introduced the world's most innovative solutions for prescribing medicines and the future possibilities are incredibly promising. A move from paper to digital prescriptions and additional features that will help both the doctor and patient are already present in the health system.

Keywords: *E-Prescription, Cross Border Health Care, Estonia*

Introduction

Estonia's health care system is one of a kind with innovative e-solutions available for both patients and doctors. One of the key innovations in Estonia's cutting-edge e-health system is e-prescription.

The Estonian e-prescription system was launched in 2010 by the Estonian Health Insurance Fund. E-prescription is a country-wide, centralised and paperless system used by all doctors, patients and pharmacies. A year after launching, 84% of prescriptions were issued digitally. The preparation of the system took five years and involved a number of partners including: governmental bodies responsible for different data registries, hospitals, pharmacies and software providers among others. E-prescription has enhanced openness and transparency in the field of prescribing medicines and more importantly opened a whole new method for future developments which aim to share information and statistics, and improve medical care and the quality of decision-making. In 2019, 99.9% of prescriptions are issued digitally, about 10 million prescriptions each year, which translates to a significant amount of time saved for all parties.[1,2]

The primary benefits of e-prescription

E-solutions are expected to enhance the efficiency of public services. E-prescription aims to benefit the patient, pharmacist, state and physician. From patient perspective, the main benefit is convenience. From the state point of view, the main benefit is big data collection that enables the updating of policies based on thorough data analysis.

All health care service providers and pharmacies are connected to the central e-prescription system, which helps the physicians and pharmacists monitor and manage the issuing of prescriptions. After prescribing a medicine, the e-prescription system stores the incoming prescription and it becomes accessible immediately in every pharmacy's information system on request. The pharmacist identifies the person using his/her ID card and retrieves the prescription from the central database.

Karin Kõnd is Project Manager; **Anett Lilleväli** is Chief Specialist, Estonian Health Insurance Fund, Estonia. Email: Karin.Kond@haigekassa.ee

It is thought that doctors spend less time issuing prescriptions and make less mistakes. They have access to a patient's full medicine history and will get feedback if the medicine has been over- or misused. The e-prescription system also enables the automatic calculation of the correct rate of reimbursement on medications covered by the Health Insurance Fund.

Another major advantage is that physician visits are no longer needed for routine, repeat prescriptions. Patients can contact the doctor by e-mail or by phone and then collect the medicine from the pharmacy. Another advantage is that patients don't need to worry about carrying a paper prescription or losing it. Through the patient portal they can have a complete overview of their medicines and also a data log for every prescription.

> drug-drug interaction alert service integrated in the prescription centre

Pharmacies spend significantly less time entering less data into the system and can pay more attention to serving clients. The vast majority of necessary prescription data is already entered into the e-prescription system by the doctor; the pharmacist only has to add that the medication was actually dispensed to the patient.

Improving the quality of pharmaceutical care – drug-drug interaction alert

The e-prescription system provides an overview of all prescriptions issued for a patient and with this information it is possible to evaluate any interactions between pharmaceuticals prescribed by different doctors. Since June 2016, all Estonian physicians are using the drug-drug interaction (DDI) alert service integrated in the prescription centre. The service is based on the INXBASE database[4] which provides checks for interactions and displays respective notifications.

The alerts for different DDIs are divided according to clinical significance and generated automatically for the user. Automatic information is also displayed when there are no interactions.[5]

In addition to DDI alerts, e-prescription data are used in monitoring and enhancing the quality of pharmacotherapy. For example, various indicators are embedded into the family physicians' quality bonus system, which monitors a doctor's adherence to treatment guidelines (e.g. type-2 diabetes, post myocardial infarction management, etc.) For every family physician, tailored specific feedback about his/her prescribing pattern in comparison with peers is also available.

Crossing borders

Due to people becoming more mobile, the need for e-services to be available outside the country's borders is growing. As a result of the active cooperation in e-governance, Estonia and Finland were the first countries in the European Union to launch a cross-border e-prescription service. It is based on the European eHealth Digital Service Infrastructure (eHDSI).

So far, it has been possible to buy prescription medicines abroad using paper prescriptions. Since 21 January 2019, e-prescriptions issued in Finland can be retrieved in Estonian pharmacies.

The opportunity to use e-prescriptions abroad will benefit citizens by making the management of medications treatment easier, while pharmacies benefit from the improved data quality for their activities because digital prescriptions issued in another country will become available in a standardised form and in the local language.

The launch of a cross-border e-prescription service is the first step on a long road to facilitate the transmission of health data across borders so that, in case of a health problem in a foreign country, the physician would also have access to a summary of the medical history for the provision of better quality treatment.

> 99.9% of prescriptions are issued digitally

The future of e-prescription – pharmacogenomics

In medical sciences, Estonia is leading in the research field with the Estonian Biobank located at the University of Tartu. The biobank holds more than 152,000 people's DNA, which is about 12% of the adult population of Estonia. Collecting genetic data is an important step towards preventive medicine, transforming to personalised health care and enabling people to receive better and timely treatment in the future.

The field of pharmacogenomics (PGx) is gradually shifting from the reactive testing of single genes towards the proactive testing of multiple genes to improve treatment outcomes, reduce adverse events and decrease the burden of unnecessary costs for health care systems. Despite the progress in the field of PGx science, its implementation into routine medical care is difficult. Nevertheless, the number of studies on the implementation of PGx has increased in recent years and scientists are working on genetic association studies looking for new practical medical benefits from genetic information.

Estonia is leading the way towards developing practical solutions for health care from genomic data, and the Government of Estonia is supporting projects to find new practical ways to implement personalised medicine into action.

The project is divided into different steps and the next step forward is to integrate genetic data into the e-prescription system as a part of routine medical care,

taking into account the personal genetic information when prescribing drugs. The first developments will be ready by 2022, when a patient-specific drug-gene interaction alert system is integrated into e-prescriptions.

Conclusion

Next year, 2020, will be the 10th anniversary of the e-prescription service. In a decade Estonia has gone from paper prescriptions to e-prescriptions with additional features such as DDI-alerts and the cross-border exchange of prescription data. By 2022, the e-prescription is envisioned to involve PGx recommendations based on patients' genetic data, which will offer enhanced opportunities for personalised care.

References

1 E-estonia Healthcare web site. Available at: https://e-estonia.com/solutions/healthcare/e-prescription/

2 Project highlights: Estonian e-prescription software development. Helmes. E-estonia web site. Available at: https://www.helmes.com/reference/estonian-e-prescription/

3 Ilves L. New Digital Prescription Service: drug-drug interaction *(Digiretsepti uus teenus: ravimite koostoime kontroll. – Eesti Arst.) Eesti Arst* 2016;95(5):282–4. Available at: https://ojs.utlib.ee/index.php/EA/article/viewFile/12921/8004

4 INXBASE Interaction Database web page. Availbale at: http://www.medbase.fi/en/professionals/inxbase/

5 Drug-drug Interaction e-service: Interacting with Notifications Displaying a Hospital or family doctor information system *(Ravimite koostoimete e-teenus: koostoime teadete kuvamine haigla või perearsti infosüsteemis*). Available at: https://www.haigekassa.ee/sites/default/files/IT_juhised/koostoimete_kuvamine_infosusteemis.pdf

Morten Elbæk Petersen is CEO, sundhed.dk, Copenhagen, Denmark. Email: mep@sundhed.dk

ACHIEVING BETTER HEALTH AND WELL-BEING VIA THE **DANISH E-HEALTH PORTAL** SUNDHED.DK

By: Morten Elbæk Petersen

Summary: An overview of prescription medications, laboratory test results, vaccination data, a historical overview of treatments, Electronic Health Records from hospitals, and large volumes of highly qualified information about health, prevention and disease provide examples of the data and digital services available 24–7 to citizens and health care professionals via the Danish e-Health portal, www.sundhed.dk. Sundhed.dk was launched in 2003 and is an integrated part of national economic negotiations and national eHealth strategies.

Keywords: *eHealth Portal, Personal Health Data, Patient Empowerment, Public Information, Denmark*

Introduction

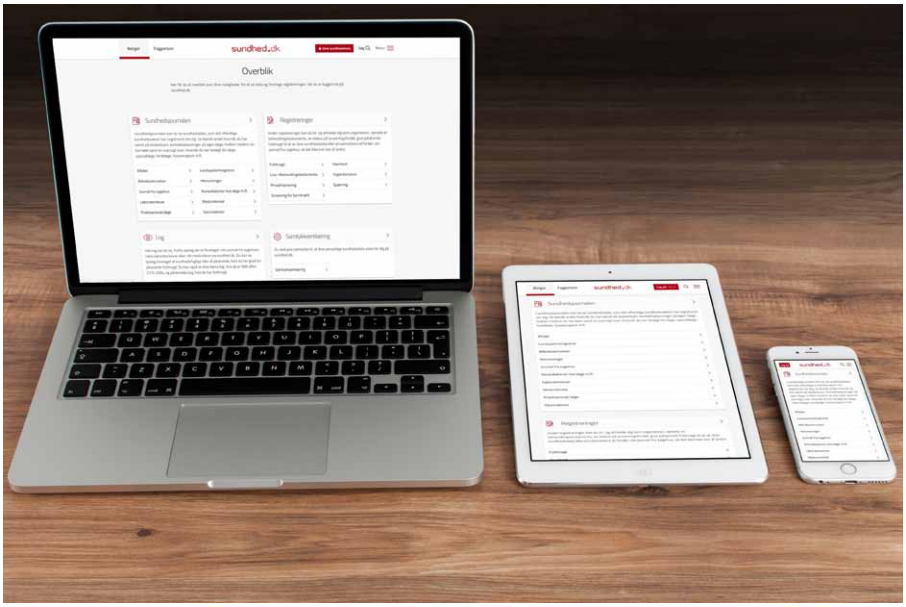
A multitude of data and digital services are available to citizens and health care professionals in Denmark via the national, publicly-owned, Danish eHealth portal, sundhed.dk.[1]

As part of the Danish health care sector, sundhed.dk plays a crucial role in supporting transparency and patient empowerment and providing health professionals with the possibility to access patient health data residing outside of local systems and *across* sectors and boundaries. This contributes greatly to the delivery of more coherent and effective health care for Danish citizens.

Launched in 2003 as a collaboration between the state, the regions and the municipalities, sundhed.dk is an integrated part of national eHealth strategies.

The most recent Danish national Digital Health Strategy 2018–2022 – *A Coherent and Trustworthy Health Network for All*,[2] highlights that sundhed.dk will continue to serve as "a single point of national entry where patients can access their health data provided by the hospital, General Practitioner (GP) and municipal health service." This "one trusted source" approach contributes directly to the national strategic goal for strengthening

Figure 1: A view of sundhed.dk



Source: [1]

the health system through more coherent treatment pathways, across national, regional and local levels.

> Denmark is a pioneer when it comes to eHealth

Furthermore, sundhed.dk is governed by its own political board with representatives from each of its partner organisations. This model ensures that handling of data takes place in a fair and democratic setting, that the agenda about personal health data is set by political will, and that it reflects the demands and expectations from the population rather than being driven by commercial interests. This model also helps maintain the high credibility of the portal and directly contributes to establishing cultures of trust.

The functionality of sundhed.dk has been regularly extended and improved with the inclusion of new services and information. As a result, there has been a clear and measurable increase in the use of sundhed.dk such that in the first quarter of 2019, there was an average of 3.9 million total visits per month (from citizens and health professionals combined) (**see Figure 2** overleaf). This represents a significant portion of Denmark's population of 5.8 million people who are accessing the portal each month.

In terms of technical design, sundhed.dk is based on a federated IT-architecture that integrates with local systems. That is, sundhed.dk displays data from more than 120 different sources without storing or duplicating data. This ensures that timely, efficient and secure requests to display citizen health data are achieved as well as high accessibility to the portal across different end-user platforms (PC, tablet and mobile phone).

Sundhed.dk services and features

Sundhed.dk offers 24-hour access to personal health data and general information about health prevention and diseases for citizens and health professionals.

It is structured in two spaces: an 'open space' and a 'closed space'. The 'open space' offers free, evidence-based information (free from commercial influence). Products made available in this space include the Medical Handbook – a tool providing Clinical Decision Support to doctors, and a "light version" of the same information for patients and the general public. This is widely used to increase health literacy and to explain terminology that may appear in Electronic Health Records (ERNs) or other medical literature. Also offered is an overview of health promotion tools to assist citizens with, for example, smoking cessation and weight loss.

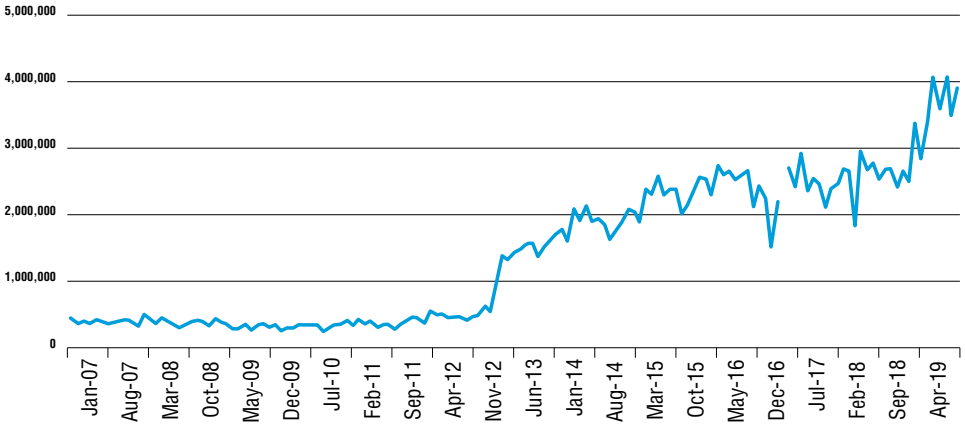
The 'closed space' is accessible by secure login only and provides access to personal health data. Citizens log into "My Health" which provides an oversight of an individual's prescribed medicines, EHRs, notes from hospital visits, descriptions of x-rays and scans, and an overview of vaccinations. In addition, any laboratory test results and consultations with hospitals and other primary health care professionals, including dentists, are available.

A recently added feature is the ability to give authorisation to a relative or other trusted people to access an individual's personal health record. This enables family members and informal carers to provide the necessary support when required. It also reinforces sundhed.dk's goal regarding patient empowerment when it comes to 'giving a helping hand' to relatives and loved ones.

> easy access to personal health data makes sundhed.dk the most innovative and significant digital solution in Denmark

Another notable feature is the "My log" function, which shows the list of organisations that have accessed a patient's data via the portal. This kind of transparency is very important from a security and trust perspective.

Figure 2: Monthly visits to sundhed.dk, 2007–2019



Source: [1]

Health care professionals are provided with access to personal health data *across* sectors and boundaries. Data from local health care providers (GPs) and regional EHR systems (hospital clinicians) are accessible via sundhed.dk for patients receiving treatment within the system.

Health care professionals can additionally access clinical information and guidelines as well as patient data that are not accessible in their own systems. For example, GP's can access EHRs from hospitals, waiting lists, and contact information of other health care professionals.

Sundhed.dk foundations

To understand the positioning and popularity of sundhed.dk, it is necessary to highlight some of the core factors underpinning its success: a public health care sector built within a democratic setting and financed by state taxes, a long tradition in Denmark for registration of health data, a high level of IT-maturity and a trust-based culture.

The Danish national health care system is tax-financed, universal and based on the principles of free and equal access to health care for all citizens. Accordingly, the use of sundhed.dk is free of charge.

It operates across three political levels: the state, the regions and the municipalities, organised in two structures: 'the primary health care sector' (GPs, home care, pharmacies) and the 'secondary health care sector' (hospitals). GPs play a crucial role in this structure as 'gate keepers', keeping patients in the primary sector whenever possible, and away from the more expensive hospital settings. In addition to the economic benefits of this approach, supporting this gatekeeping function and empowering citizens have been key aims of the portal development since its inception.

Integrating health information across the health sector through sundhed.dk has additionally allowed for an increased focus on prevention and treatment at home. At the same time, having a national digital solution that offers citizens insight into their own personal health data, has proven to be very effective.

Denmark also has some of the world's most comprehensive and quality assured health data. This is based on a long tradition of registration and collection of health data and disease dating back to World War II. A unique and important building block in the Danish health care system that facilitates accurate data collection is a unique personal identifier – the Civil Registration Number (CPR) – introduced in 1968, which is issued to every citizen at birth.

With regards to digitization of public services, Denmark is a global frontrunner having developed a very high level of IT-maturity and is seen as a 'role model' for eHealth innovation in Europe.[5] In both the recent European Commission report on European Digital Public Service: *Digital Economy and Society Index (DESI) 2019*[3] and the United Nations e-Government survey (2018),[5] Denmark not only ranks among the top among EU Member States but also among all 193 UN Member States.

A democratic setting, high credibility and Safe Harbour

The democratic setting upon which the Danish health care system is founded is a fundamental contributor to the success of the public health portal. In Denmark, the principle of 'public ownership and handling of health data' mostly goes hand in hand with high credibility and a culture of trust. Sundhed.dk is, in many ways, seen as a Safe Harbour for health data and the public interest in a sometimes chaotic eHealth market. This is due to a high degree of confidence in public sector institutions in Denmark and trust in the well-established security mechanisms utilised by sundhed.dk. Trust is further enhanced by confidence in a health care sector governed by democratically elected politicians at national, regional and local levels.

International attention

Denmark is a pioneer when it comes to eHealth and a world leader measured in terms of a vast majority of parameters, such as IT systems at hospitals and GP clinics and digital communication between different segments of the health sector.

Since its inception, sundhed.dk has drawn international attention. Today, sundhed.dk's leadership is reflected in different awards such as the eEurope Award (2004) and the Computerworld Honors Program (2007), as well as being highlighted as the leading national health portal by the Information Technology & Innovation Foundation (2009) and the HIMSS Europe eHealth Leadership Award (2015). Notable international success has also included profiling of sundhed.dk at the German International Forum in Berlin in dialogue with German Chancellor, Angela Merkel, as well as in the G20 Summit Briefing Books as a best practice example, in Hamburg (2017), Argentina (2018) and in Osaka, Japan (2019). The CEO of sundhed.dk frequently features as a keynote speaker in international conferences and events.

It is also important to note that a continuous dialogue and engagement with the World Health Organization (WHO) has been taken over the years, in order to share the design and benefits of sundhed.dk with regional and global audiences. Most recently, sundhed.dk showcased at the WHO Symposium on the future of digital health systems in the European Region in March 2019.

Further, the CEO of sundhed.dk takes a seat in different international advisory boards including, more recently, the independent International Scientific Advisory Board (SAB) of the MII (Medizin Informatik-Initiative) funded by the Federal Ministry of Education and Research in Germany.

Concluding remarks and new strategic ambitions

The many opportunities and easy access to personal health data makes sundhed.dk the most innovative and significant digital solution in Denmark to support patient empowerment, as well as contributing to cost reduction and work flow improvements for health care professionals.

Sundhed.dk is an example of exploiting opportunities in the spread of digital technologies to provide citizens with transparency and openness about their own data. This subsequently drives changes and improvements in the health care sector. The success of sundhed.dk reinforces the significant role which digital health has in achieving key public health priorities. Maintaining the high level of success for sundhed.dk can only be achieved through a cycle of continuous innovation. As such, in 2018 and 2019, the team at sundhed.dk and its partners have sought to create a new strategy for the next period of development from 2019 to 2022.

A main feature of this work has been an open and inclusive process to ensure that sundhed.dk, in close dialogue and collaboration with all stakeholders, can set new, ambitious goals for the further development of the portal. This includes engagement of health care professionals, patient associations, the IT industry and many others. This approach has been, and probably always will be, of vital importance in achieving ownership and anchorage of systemic change in health, and is a prerequisite to implementation and reaching strategic goals across sectors.

The new strategy set four strategic benchmarks for further development of the portal:

- Citizens as active players & participants
- Health & prevention
- Seamless health services – cross-sectorial coherence
- Security & trust of personal health data

The new strong focus on increased prevention, and the inclusion of citizens own lifestyle and prevention data – in addition to the health care sector's own "system data" – is expected to usher in a radical change for the further development of digital health, the health care sector in general and to contribute to better health and well-being for all Danish citizens, both now and in the future.

References

1 Sundhed.dk. *Your health portal*. 2019. Available at: https://www.sundhed.dk/

2 The Danish Ministry of Health, the Danish Ministry of Finance, Danish Regions, and Local Government *Denmark. A Coherent and Trustworthy Health Network for All: Digital Health Strategy 2018–2022*. Copenhagen, 2018. Available at: https://www.healthcaredenmark.dk/news/listnews/danish-digital-health-strategy-2018-2022-now-available-in-english/

3 HIMSS Analytics Annual European EHealth Survey 2018. Available at: https://www.himss.eu/himss-analytics-annual-european-ehealth-survey

4 Available at: https://www.himss.eu/himss-analytics-annual-european-ehealth-survey-2018

5 The Digital Economy and Society Index (DESI). Available at: https://ec.europa.eu/digital-single-market/en/desi

6 United Nations E-Government Survey 2018. Available at: https://publicadministration.un.org/egovkb/Portals/egovkb/Documents/un/2018-Survey/E-Government%20Survey%202018_FINAL%20for%20web.pdf

THE FUTURE DEVELOPMENT OF DIGITAL HEALTH IN KAZAKHSTAN

By: Olzhas Abishev and Yerbol Spatayev

Summary: Digitalization is currently considered one of the most important instruments for the development of health care systems. At the same time, it requires significant efforts and inclusive measures coordinated at a national level. The current strategy on electronic health care development of the Republic of Kazakhstan forms a sustainable foundation for further development and offers a vision of the next steps for the national programme. Evaluation of results already achieved and future plans can contribute to the development of a consensus and recommendations for other countries to guide development of digital health services.

Keywords: *Electronic Health, Health Digitalization, Standards, Information Model, Republic of Kazakhstan*

The global context of health care digitalization

Digital data and digital processes have facilitated revolutions in all spheres of human existence by transforming not only familiar information exchange methods, but business-processes and even whole industries. Industry 4.0, which is characterised by the deep penetration of information and communication technologies, carries a number of risks, but also enormous expectations for societal transformation. In these conditions, the task of the government to help facilitate digital transformation encompasses developing the necessary environment to facilitate innovation, such as through the implementation of legislative reforms and generating timely responses to the challenges related to digitalization in all spheres, including health care.

The application of information and communication technologies (ICT) to health care began several decades ago; however, the rapid growth in technology implementation started after 2000.[1] At the same time, the role and functions of eHealth have been continually redefined on the basis of accumulated knowledge and experience.

Case studies show that health ICT can: 1) increase the safety of medical care; 2) improve workflows by facilitating tasks such as medication reconciliation and by bringing decision support systems to the point of care; 3) reduce operating costs of clinical services; 4) reduce administrative costs; 5) achieve "transformation" of care by: effectively providing means to implement changes that are otherwise difficult, improving access to care (via telemedicine), improving chronic

Olzhas Abishev is Vice Minister of Healthcare, Ministry of Healthcare of the Republic of Kazakhstan; **Yerbol Spatayev** is Specialist on eHealth, Social Health Insurance Project, Astana, Republic of Kazakhstan.
Email: abishev_o@ezdrav.kz

care, multiple service delivery and care coordination, and improving feedback on the quality of care.[2]

When implementing transformative digital health projects, governments face a number of significant difficulties, such as the lack of legislation or regulatory base, lack of human, financial and technological resources, lack of unified standards, low quality of data and difficulty in linking data collected from different sources, among others. These challenges have become insurmountable obstacles in relation to the full application of ICT in some countries. This is particularly true where there is an absence of an inclusive national level strategic approach, which ensures the relevance of digitalization for all beneficiaries and encourages cooperative collective efforts to solving health care tasks.[3]

The experience of electronic health care development in Kazakhstan

In the last decade, the Republic of Kazakhstan made a significant breakthrough in the field of health care informatisation by transitioning from ad hoc developments based on a "stimulus-reaction" principle to the subsequent implementation of a long-term strategic vision. In the framework of the *National eHealth Development Strategy for 2013–2020*, the focus shifted from the collection of analytic data, to the formation of an integrated information environment, which facilitates involvement and access to the necessary information for all major beneficiaries, including the population, health care and medicine providers, as well as management and financing bodies.

The first step to achieving this vision was identified as the formation of a favourable environment for the development and introduction of medical information systems that compete with each other (towards a decentralised and de-monopolised eHealth open market). Learning from international experience, regulation of the market for eHealth solutions was planned by forming a set of national and international standards, to enable the creation of an interoperable data model and integration mechanisms. The concept of national level Electronic Health Records (EHRs) was established as a practical implementation of standards and a tool for unification of not only information systems, data and the flow of information, but all health care actors, including the patients themselves.

Strategy implementation required significant institutional reforms. Following the principle of inclusive development, the Ministry of Healthcare of the Republic of Kazakhstan rejected their informatisation monopoly and concentrated efforts on policy development, regulation and standardisation, ensuring the development and implementation of integrated mechanisms at the national level, including the development of systems and services for health care management and financing. Separate structures and organisations for the implementation of different aspects of informatisation – from the introduction of standards to management of projects at the national level were created. The necessary legislative and regulatory bases were formed and national registers and integrated services, which are the enablers of a unified information space for the health care system, were developed. The introduction of national services, like ePrescriptions and eReferrals for planned hospitalisation, was ensured.

The implementation of medical (hospital) information systems in all medical organisations of the country was ensured on a local level. The process of shifting to paperless medical data with fully digitized patient records was initiated. Services and mobile applications for patients were actively introduced. The network of telemedicine that allows patients from distant rural areas to access consultations with specialists from large regional and national medical centres was deployed.

Despite considerable progress, a number of challenges in developing digital health solutions in Kazakhstan remain, many of which are being experienced by other countries. Health and health care data collected in electronic form are still fragmented. At the local level, clinical data are limited within the frames of a specific medical organisation, or several organisations which use the same information system with a single database. At the national level, analytic data are distributed between different databases, including disease-specific registers, as well as databases of national services for ePrescriptions and eReferrals. This in turn causes problems with the verification of data and difficulties with data linkage that prevents deeper analysis of health care processes and performance.

Moreover, despite the first steps towards the digitalization of medical information, paper forms are still the primary tool used to capture medical data. Clearly, even after digitalization of health care data is achieved for medical centres (e.g. achieving *paperless hospitals and polyclinics*), the next stage of development – a *paperless health care system* – will require additional tools, resources and time.

Future development

The current national strategy's aim is to create a complex, integrated informational infrastructure that provides all health care actors, including the patient, with all necessary medical and administrative information. However, despite understanding the significant role of ICT in health care, ICT within the framework of the current strategy is assigned a passive, supportive role. At the same time, the contemporary paradigm of digitalization implies the application of digital technologies to change existing processes and models of care and provide new opportunities for achieving goals and getting value. Within the framework of digitalization, ICT plays the role of proactive tools and is the driver of qualitative transformation.

These challenges necessitate the development of a new vision that establishes new long-term objectives and tasks. Within any new vision it is important that the Kazakhstani strategic approach towards informatisation maintains systematic complex development. While the infrastructure for *collecting* digital medical data has been created, the next stage will require the development of infrastructure with the purpose of ensuring the functions of *sharing* and advancing the *application and use* of data.

In the short-term, the development of an integrated platform at the national level which helps to integrate local and regional

medical information systems is planned. The platform contains instruments and services that ensure interoperability through the application of the unified set of registers and classifiers across the whole space of digital health care. This includes an EHR repository; storage of analytic data with the instruments of Business Intelligence, and a portal for patients.

It is expected that after the implementation of the Platform in 2020, national level EHRs will become a central source of verified data to support clinical and political decision-making. An informational model of EHRs, built on the principles of standard ISO 13940:2015 "Health informatics-System of concepts to support continuity of care",[4] will become the core of an informational model of the whole care provision system and a starting point to facilitate the move towards a paperless health care system.

By functioning as a central element of interoperability, and hence comprehensive support of patient-centred care, EHRs will provide clinically relevant information to all permitted individuals as and when needed. The capture of key data about the patient's health according to the information model standards will provide all participants involved in the organisation and provision of care with a minimum set of information that ensures the highest possible level of knowledge about public health, utilisation of health resources, monitoring of care, patient's care management and interactions between involved parties.

Another long-term goal is to digitalize the patient's route through the health care system. Its achievement requires the full interoperability of all health information systems and resources. This will provide clinical decision-making in real time at all levels of care. It means reducing barriers between levels of care or to health care facilities, as well as coordination of the patient's route in outpatient and inpatient settings by Primary Health Care doctors aimed at the prevention or management of chronic diseases. Such a unified, integrated patient route is monitored through recommendations provided by clinical guidelines and ensures efficient and effective use of health care resources. The final result of this goal is to support seamless care, meaning timely, predetermined, planned and automated transfer of activities and information from one health care provider to another based on programmes and plans of care. A fully interoperable digital health ecosystem should be created at this stage, including, in addition to national and subnational level information systems, telehealth and mobile health devices and tools.

Digitalization of both clinical processes and patient routes requires the development and implementation of a new digital method of data collection. All health and health care data must be collected and exchanged not just in digital form, but with the observance of the principles of support for the evolving clinical context. A unified data collection policy will need to cover all clinical data needs for all possible uses without the need for subjective interpretation. This means that any digital record must contain primarily machine-readable data that can be processed and interpreted by a computer.

In addition to the digital data access tools described above, technologies will be introduced that support clinical and policymaking decisions regarding the health of the individual, groups of people, and the population as a whole. Innovative data processing technologies will be used to search for patterns, correlations, and cause-effect relationships in relation to public health, personalised medicine and the effectiveness of the health care system.

Conclusion

Despite the many examples of successful implementation of individual technologies, the complex digitalization of health care systems is a challenge which has not yet been solved by any country.[5] Based on rising expectations and growth in expenditure for ICT, the World Health Organization pays particular attention to the lack of a systematic approach to monitoring and evaluating national health system digitalization programmes.[3] In the absence of generally accepted techniques for the evaluation of digitalization results, developing procedures to estimate the clinical and economic effectiveness of ICT should become one of the main priorities for national strategies.[6]

The accumulated experience of Kazakhstan demonstrates the importance of developing a strategic approach and ensuring the sustainability of results in an environment where the pace of development and obsolescence of technology is constantly increasing. To achieve sustainability, one must create a favourable environment, develop an institutional framework and provide investment in standards, data and use-cases, rather than in a particular informational system or technology.

References

1 WHO. *Building foundations for eHealth: progress of member states: report of the Global Observatory for eHealth*. WHO, 2006. Available at: https://apps.who.int/iris/handle/10665/43599

2 Joint Action to support the eHealth Network. *Report on Overview of OECD Studies on eHealth and Core Outcome*. JAseHN, 2016. Available at: https://webgate.ec.europa.eu/chafea_pdb/health/projects/677102/outputs

3 OECD. Strengthening Health Information Infrastructure for Health Care Quality Governance. *OECD Health Policy Studies*, 2013. Available at: http://www.oecd.org/publications/strengthening-health-information-infrastructure-for-health-care-quality-governance-9789264193505-en.htm

4 International Organisation for Standardisation. *ISO 13940:2015 Health informatics – System of concepts to support continuity of care*. ISO, 2015. Available at: https://www.iso.org/standard/58102.html

5 WHO. Atlas of eHealth country profiles: the use of eHealth in support of universal health coverage: based on the findings of the third global survey on eHealth 2015. WHO, 2016. Available at: https://www.who.int/goe/publications/atlas_2015/en/

6 Bergmo TS. How to Measure Costs and Benefits of eHealth Interventions: An Overview of Methods and Frameworks. *Journal of Medical Internet Research* 2015;17(11):e254.

NEW PUBLICATIONS

Strengthening health systems through nursing: Evidence from 14 European countries

Edited by: AM Rafferty, R Busse, B Zander-Jentsch, W Sermeus, L Bruyneel

Copenhagen: World Health Organization (acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies), 2019

Number of pages: 163; **ISBN:** 978 92 890 5174 3

Freely available for download: http://www.euro.who.int/en/about-us/partners/observatory/publications/studies

'Who is a nurse?' and 'What is nursing?' seem to be simple questions yet the answers are strangely elusive. This book explores the variations in structure and organisation of the nursing workforce across the different countries of Europe. This diversity, and the reasons for it, are of more than academic interest. The work of nurses has always had a critical impact on patient outcomes. As health systems shift radically in response to rising demand, the role of nurses becomes even more important.

This book (Part 1 of 2) provides a series of national case studies drawn from 12 countries which were chosen as the subject of a large EU-funded study of nursing (RN4Cast) along with Lithuania and Slovenia which were added to provide broader geographical and policy reach. Part 2, to be published later in 2019, will provide thematic analysis of important policy issues such as quality of care, workforce planning, education and training, regulation and migration.

The lessons learned from comparative case-study analysis demonstrate wide variation in every dimension of the workforce. It examines what a nurse is; nurse-to-doctor and nurse-to-population ratios; the education, regulation and issuing of credentials to nurses; and the planning of the workforce. While comparative analysis across countries brings these differences into sharp relief, it also reveals how the EU functions as an important 'binding agent', drawing these diverse elements together into a more coherent whole.

Contents: *Foreword; Author affiliations; List of figures and tables; List of abbreviations; Acknowledgements; Introduction; Belgium; England; Finland; Germany; Greece; Ireland; Lithuania; the Netherlands; Norway; Poland; Slovenia; Spain; Sweden and Switzerland.*

Poland: Health system review 2019

By: C Sowada, A Sagan, I Kowalska-Bobko, et al.

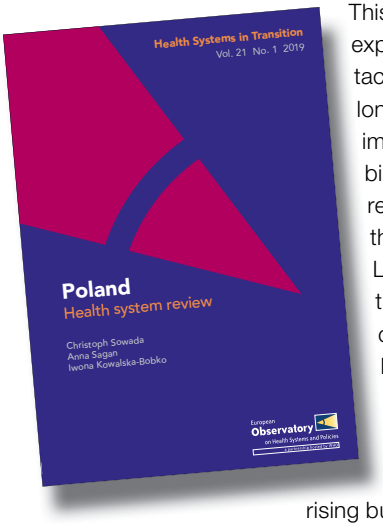
Copenhagen: World Health Organization (acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies), 2019

Number of pages: 235; **ISSN:** 1817–6119

Freely available for download: https://tinyurl.com/y6qdne6y

The new Poland HiT review provides many useful insights into the Polish health system. In 2017, Poland devoted 6.7% of its GDP to health, a share that was lower than in most EU Member States. Private financing (mainly out-of-pocket spending) accounts for 30% of current spending on health and its role is much larger in Poland than in most EU Member States. The government has pledged to increase public spending from 4.6% of GDP in 2017 to 6% by 2024. This will present an opportunity to address mounting health challenges as well as tackle longstanding problems and structural imbalances.

Governance of the public health system is divided between the Minister of Health and three levels of territorial self-government. This fragmentation can help to explain the slow progress in tackling important and longstanding problems and imbalances. Life expectancy at birth has been increasing but remains three years lower than the EU average. Likewise, preventable and treatable mortality rates have decreased but are much higher than the average rates in the EU.



Health challenges include high rates of obesity, a rising burden of mental disorders and population ageing, and are likely to increase demand for health and social care. Provision of care remains skewed towards inpatient care and there are acute shortages of both doctors and nurses. These structural imbalances will continue to pose a major challenge for the effective delivery of care.

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

HSPM COUNTRY NEWS

The Observatory's Health Systems and Policy Monitor platform provides systematic descriptions of country health systems and features up-to-date information on ongoing health reforms and policies. See individual country pages for these news items and more: http://www.hspm.org

Compiled by Gemma Williams based on January-June 2019 reform logs.

Austria: Use of electronic vaccination records to improve immunisation coverage

A series of measles outbreaks attracted public attention in early 2019. Health authorities urged the population to check their vaccination record and when necessary, update vaccination status at every age, to close immunisation coverage gaps. Austria has relatively low vaccination rates. In 2015, measles vaccination coverage rates for children aged between two and five years at first dose reached 92% and about 82% at second dose. It was estimated that about half a million people aged between 15 and 30 years were not protected against measles. In June 2018, government authorities and social health insurance funds agreed to replace paper-based vaccination records with electronic records. The Electronic Health Record Institution (ELGA Ltd.) responsible for the electronic patient record is conducting a pilot of an electronic vaccination record (e-Impfpass) until 2020.

Belgium: Evaluation of the performance of the Belgian health system

In April 2019, the fourth edition of the Health System Performance Assessment (HSPA) for Belgium was published. The report uses 121 indicators that facilitate the analysis of five transversal dimensions (accessibility, quality, efficiency, sustainability, and equity) and five specific topics (prevention, mental health, care for older people, end-of-life care, and care for mothers and newborns). The report concluded that quality of care was considered "good to average", but some issues were highlighted such as the number of nosocomial infections (safety) and the overconsumption of antibiotics (appropriateness). The Belgian health system is "accessible", but indicators on sustainability, which relate to the availability of General Practitioners, pose questions on the ability of the Belgium system to cope with the ageing population. Mental health services, prevention and end-of-life care were identified as areas needing improvement.

Estonia: Advances in the country-wide digital registration system

After years of development, a centralised system for making electronic appointments is available for patients. "Digiregistratuur", a national digital registration application in the patient portal, allows individuals to book, cancel and change appointments for specialist ambulatory care visits. The system shows patients an overview of all appointments available at the health care providers that have joined the system. The patient can see all valid and unused digital referral letters and can easily book a suitable appointment time based on this information. Patients can only make one appointment per digital referral, thereby avoiding double booking. North-Estonian Medical Centre was the first to join the system, with other ambulatory health care expected to join during 2019. In the future, patients will be able to make primary care and dental care appointments if the provider has joined the digital registration system.

Finland: Failure of proposed health and social care reforms

In March 2019, the Finnish Parliament stopped the proceedings related to proposed health and social care and regional government reforms. The move triggered the government's resignation one month before the general elections. Since the government submitted the first reform bill to the Parliament two years ago, the reform proposals have undergone several iterations and continued to be the subject of a contentious debate. The three major aspects of the reform (freedom of choice model, which increases the role of the private providers; strict cost containment measures; and administrative reform establishing 18 counties tasked with service provision) remain unresolved. While it is expected that the health and social care reform will continue, the content of the reform may change depending on the outcome of the elections.

Ireland: The HPV vaccination programme has been extended to cover boys

The WHO recommends the human papillomavirus (HPV) vaccine to protect against HPV infection for both men and women. In 2010, the HPV vaccine was introduced for all Irish teenage girls. It has been offered to HIV-positive men and women under the age of 26 since 2016 and since 2017, to men who have sex with men aged 16 to 26 years. The Health Information and Quality Authority recommended the extension of the HPV vaccine to boys concluding it is clinically and cost effective. In 2018, funding was allocated to extend HPV vaccines to boys and it is in the HSE (Health Service Executive) 2019 service plan.

Israel: Further expansion of the roles and responsibilities of specialist nurses in the community

In May 2019, the Ministry of Health issued a new circular that expanded the role and responsibilities of specialist nurses (SN) working in primary care. The SN's main role is to be a "case manager", who will follow patients during the treatment period, continue the treatment and management of chronic diseases, treat mild acute

health problems, provide palliative care, and promote health. The objective of this change is to strengthen multidisciplinary team working in primary care clinics. SNs will continue to work under the direction of the physician in charge of the clinic, with physicians responsible for establishing and approving the role of the SN in the treatment of each patient. The physician has no obligation to provide the SN with all the responsibilities allowed by the circular.

Italy: A new national waiting list has been approved

After nine years, a new National Waiting List Plan went into effect in July 2019. Among the new features, maximum waiting times are indicated for all health care services (as opposed to 58 in the previous edition), including planned outpatient care. Schedules, managed through regional Unique Booking Centres (CUPs), will be accessible and updated in real-time through on-line platforms. Chronic patients will follow a specific path, different from "first access" patients and non-chronic ones, and will be assisted throughout their therapy. Health care facilities are required to guarantee monitoring of waiting times for both institutional services and private practice activities. The latter must be used only when waiting times exceed those accepted by regional standards (with volumes being subject to ceilings), and patients are required to contribute through co-payments.

Lithuania: Increase in funding for mental health services

In line with the 2014–2021 EEA "Health" financing programme, more than €9 million will be allocated to implement a set of actions on improving child, adolescent and family mental health in Lithuania by 2024. Measures that will be implemented include home visits by trained nurses to assist pregnant women and mothers of children under the age of two years; development of adolescence-focused mental, social and health care services at municipalities level; assistance to children with behavioural problems and their families, in collaboration with the Ministry of Social Care and Labour; developing methodologies for preventive services in child day-care and school settings; and creating a role for welfare consultants to assist people with early symptoms of depression and anxiety.

Malta: Development of health care services for transgender individuals

A Government document on Transgender Healthcare Services launched in 2018 is one of the first of its kind in Europe and presents the policy direction and way forward for the development of transgender inclusive healthcare services in Malta. These services aim to enable transgender persons to change their physical appearance to align this better with their felt gender identity. The vision was to develop a trans-inclusive health care system and to organise gender affirmative care for transgender persons using a person-centred approach that tends to the physical, mental and social aspects of care of the individual while respecting the person's gender identity. Care is provided by means of a specialised multidisciplinary team of endocrinologists, surgeons, mental health professionals, social workers, speech and language pathologists and a nurse coordinator- to enable transgender persons to transition in a supportive and evidence-based environment.

Netherlands: Changes in the basic benefit package in 2019

New treatments were added to the benefit package in 2019. Lifestyle interventions were included for people with moderate health risks due to overweightedness. The intervention is directed towards a sustainable change towards healthier food and more activity. Patients that need taxi transportation to go to their treatment can now get reimbursement for travel costs for consultation, tests and check-ups that are related to the treatment. Formerly, only the travel costs for the actual treatment could be reimbursed. Remedial therapy for chronic obstructive pulmonary disease (COPD) patients is now reimbursed from the first treatment (formerly, the first 20 treatments had to be paid out-of-pocket). Paracetamol (1000mg per pill), Vitamin D and calcium are no longer reimbursed. They can be bought over-the-counter at pharmacies or drugstores.

Spain: A new strategic framework to enhance primary care

In April 2019, the Minister of Health presented to the Council of Ministers "The Strategic Framework for Primary and Community Care" that aims to meet the current needs and challenges facing Primary Care (PC). The Strategic Framework, resulting from a consensus process between regional representatives, health professionals and users, consists of six strategic lines: reinforcing the Interterritorial Council commitment to PC leadership; consolidating the budget and human resources policies to guarantee PC effectiveness and quality; improving quality of care and coordination of PC with other levels of assistance; reinforcing community orientation, health promotion and prevention; and promoting education and research in PC. The six strategic lines are reflected in 23 objectives and 100 action proposals. One action expected to start in 2019 is guaranteeing non-urgent consultations in less than 48 hours.

United Kingdom (England): England's new general practice contract five-year framework

The new general practice contract framework marks some of the most significant changes in over a decade, and has the potential to act as a lever to increase the sustainability of general practice and community services. The contract framework commits £1 billion (€1.1 billion) to the capitated contracts held by individual general practices over the next five years, with an additional £1.8 billion (€2 billion) to flow through a new 'network contract' for geographically-mandated networks of practices called 'primary care networks' (PCNs). The contract framework commits to developing expanded teams of community-based health professionals attached to PCNs by 2023/24 and promises to modernise the pay-for-performance 'quality and outcomes framework' introduced in 2004, by retiring many indicators and creating a new quality improvement domain. The most visible patient-facing change will be increased access to primary care via digital technology (either provided by their practice or sub-contracted to an online General Practitioner provider).

EHFG 2019

A healthy dose of disruption?

Transformative change for health and societal well-being

EUROPEAN
HEALTH FORUM
GASTEIN

2–4 OCTOBER
BAD HOFGASTEIN
AUSTRIA