MOVING BEYOND THE HYPE

EPHA Reflection Paper on Big Data and Artificial Intelligence

November 2019

epha

european
public health
alliance

Table of content

Introduction

Over the last few years, there has been an important shift in the policy discussion about digital health, not least due to the orientation of the European Commission's (EC) 2018 Communication on the digital transformation of health and care[1] which steered it away from the introduction and deployment of e/mHealth tools towards data-driven technology. Alongside many other developments, so-called Big Data, supported by Artificial Intelligence (AI), lies at the heart of this latest phase. The EC regards AI in particular as "one of the most strategic technologies of the 21st century", which is being likened to the steam engine or electricity[2]. The question is now how to best harness their potential for improving the quality of healthcare, whether diagnostics, decision-making or by offering more tailored options for prevention and treatment responding to the complex needs of patients, professionals and health systems.

However, the increased involvement and reliance on actors tasked with programming algorithms, storing and securing data, and performing health analytical tasks, means that the public health community needs to be vigilant to ensure that long-held values, rights and responsibilities are being protected and respected: "bigger", more ubiquitous data coming from multiple sources does not automatically equal better decision-making or health outcomes. Clearly, the data trend in healthcare does not occur in isolation and is linked to broader shifts related to the widespread uptake of Information and Communication Technology (ICT) solutions in all spheres of life, which has many positive, but also some negative implications for public health. Challenges posed by "fake news", deliberate disinformation (e.g. about vaccination) and biased algorithms provide examples. In addition, changing attitudes towards data protection and privacy, consent, decision-making and the responsibilities of individuals and professionals need to be addressed.

The purpose of this paper is to reflect on Big Data (a focus area of the outgoing EC) and AI (a priority of new EC President von der Leyen) from a public health perspective. It outlines actual and potential uses, describes the effects they exert on health systems and healthcare, and highlights a number of concerns to ensure that data use and governance occurs in the most ethical and fair way possible. In the context of the Finnish

Presidency's Council Conclusions on a European economy of wellbeing[3], the paper presents a few recommendations to ensure that the technologies involved in the digitalisation of health are conceived as effective and inclusive supporting tools for policymakers, healthcare planners, professionals, patients and society at large. This will only be the case if European values are upheld and the rights to access and control one's personal data and to privacy are maintained. Clarity and transparency, coupled with responsible oversight, is required to protect solidarity in the EU. **As stated in EPHA's response to the digital transformation of health and care[4], it is imperative to look beyond the hype of digitalisation by adopting an end user perspective to meet the real health and social needs of today.**

What are Big Data and Artificial Intelligence?

Although there is no universally accepted definition of Big Data in healthcare, the OECD refers to the more general description offered by De Mauro et al (2016), which states that "Big Data is the information asset characterized by such a high volume, velocity and variety to require specific technology and analytical methods for its transformation into value." Volume, velocity and variety are thus keywords indicating that such large quantities of real-time data exceed the human capacity to aggregate, analyse or process them. Others have added two further V's – variability and veracity – as being intrinsic characteristics, hinting at the challenges involved[5]. The EC, in its study on Big Data, Telemedicine and Healthcare[6], proposed the following definition: "Big Data in Health refers to large routinely or automatically collected datasets, which are electronically captured and stored. It is reusable in the sense of multipurpose data and comprises the fusion and connection of existing databases for the purpose of improving health and health system performance. It does not refer to data collected for a specific study."

Big data sources are varied and could include human or machine coded information, but also transaction data, biometrics as well as web and social media data[7]. They can be structured, semi-structured, or unstructured, and the interrelationships can be highly complex (involving e.g. syntactic, semantic, social, cultural, economic, and organisational differences) as a consequence[8]. Moreover, regardless of whether humans or machines are

taking decisions based on the data analysed, the latter can be tarnished by erroneous, duplicate or incomplete records (e.g. related to date, age, gender, etc.), as well as by irrelevant information, a caveat that should not be underestimated.

The prominence of Big Data goes hand in hand with the rise of Artificial Intelligence (AI) in many healthcare domains, including diagnostics, therapeutics and clinical decision-making, enabled by recent advances in computer technology and the proliferation of social media and connected devices, objects and sensors forming part of the "Internet of Things". AI techniques include machine learning for structured data (including deep learning, which permits classification of objects) and natural language processing for unstructured data, together providing the ability to unlock data that is otherwise hidden in the ¬vast amount of information generated.[9] The EC defines A.I. as follows: "(...) Systems that display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals. AI-based systems can be purely software-based, acting in the virtual world (e.g. voice assistants, image analysis software, search engines, speech and face recognition systems) or AI can be embedded in hardware devices (e.g. advanced robots, autonomous cars, drones or Internet of Things applications)."[10]

The Independent High Level Expert Group on AI refers to it as a scientific discipline on one hand and a technology on the other.[11] Put simply, AI can support health stakeholders by making sense of and establishing associations between different types of data including from medical images, wearables (e.g., physical activity) and apps, genetic testing, consultation notes, demographic statistics, etc. In combination, it can help predict whether and when the condition of a patient is likely to deteriorate. AI-powered devices and services are said to function more responsively and autonomously.[12]

Conversely, in order to make sense of the generated data, context-specific analytics skills are required: a growing challenge for health systems given the currently low level of high-performance computing systems and data-trained health professionals. This has opened the door to private companies, including multinational IT and pharmaceutical players, entering a growing market in which expertise is scarce yet the value of data is high. The Economist even called data today's most valuable resource, surpassing oil.[13]

Technologies such as blockchain, algorithms, virtualisation, high-performance / cloud computing, neuromorphic chips, and data-sharing tools are helping to operationalise Big Data and AI. As a potential solution to alleviate growing societal fears over data security following scandals involving data misuse and hacking operations, a blockchain represents a time-stamped series of immutable records of data managed by a cluster of decentralised computers. Secured in blocks and cryptographically stored, data inside the chain cannot be altered but they are traceable in a transparent way. According to the EC, the decentralised nature of record keeping in combination with encryption of data enhances users' trust, while enabling traceability and security for storing and transmitting data.[14]

How are Big Data and AI reshaping healthcare?

Data-driven solutions and AI are already commonplace in European healthcare although this may not be obvious to ordinary people. A range of tools and platforms for analysing data are widely used in hospitals and other healthcare settings, and they underpin many Internet-based and mobile solutions. As disruptive technologies, AI and Big Data hold great potential for improving certain healthcare functions, e.g. routine screening and diagnostics, avoiding medication errors and adverse reactions, understanding disease transmission pathways, supporting chronic disease management and improving patient safety. They also boost a precision medicine approach with the promise of identifying the best treatments for patient sub-populations and individuals.

Medical data management is the most widely used application given the need to compile increasingly detailed patient data from various sources (e.g. medical records, patient histories). Where available, Electronic Health Records (EHRs) might include patients' medical records including laboratory tests results, medical reports, and drug prescriptions, allowing for easier recording and access to patient data. Moreover, EHRs can be easily modified in real-time and shared between doctors, patients and other health professionals.

In some settings, robots are deployed to provide support to healthcare workers, inter alia by collecting, storing, reformatting and tracing large quantities of data to provide faster access.

By making use of AI techniques in data mining, important trends, patterns, correlations, and anomalies can be recognised to support decisions, make predictions, and conduct quantitative investigations. Similarly, analysing information from tests, X-Rays, CT scans, data entry, and other routine tasks can be done faster and more accurately by machines. Cardiology and radiology are two disciplines where the amount of data is staggering and time consuming.

In image analysis, machines have the potential to analyse 3D scans in real-time, supporting physicians and specialists. Although not always fully reliable, AI has strong X-ray interpretation abilities, which is useful for screening diabetic retinopathy, tuberculosis or fractures. Telemedicine and radiology might benefit from smartphone pictures sent by patients (e.g. skin rashes) to speed up diagnosis, enable healthcare for people living in remote or rural areas, and avoid emergency visits -provided that applicable guidelines and standards for telemedicine are applied. In addition, the knowledge base in many specific disease areas could be advanced, and predictions about the likelihood of contracting as well as detection of life-threatening diseases - cancer, stroke, neurological and cardiovascular – and conditions arising from bacterial infections (e.g. sepsis) can be given to allow early intervention and reduce mortality.

The benefits of healthcare data analytics are thus threefold as they comprise the organisational and professional sphere (e.g. telemedicine, predicting patient volumes and staffing needs, better strategic planning, combating fraud/corruption, improving data security, integrating medical imaging), the patient sphere (active engagement as data owners and collectors, safety via remote monitoring and real-time alerts, reduction of hospital visits), as well as the biomedical sciences and public health research.

From an end user perspective, it is particularly important that healthcare professionals using data-driven technologies retain the responsibility for taking decisions. The technologies in question should empower healthcare professionals, individuals and communities to engage in a fruitful dialogue and ultimately achieve better quality care.

The following list provides further examples:

- By enabling healthcare professionals and patients to record and access more ubiquitous amounts of relevant health data, better coordination and continuity of care can be achieved, with shared access to EHRs as a cornerstone.

- Making use of robotics in clinical settings, e.g. for providing precision support during surgeries to reduce complications. Robotic prostheses can provide patients with higher levels of mobility. Robots can also assist people in their homes, which could contribute to healthy and active ageing by helping people to remain independent and active for longer.

- AI-based wearables are not only useful for real-time monitoring of patients but they also make possible sensory substitution, e.g. by giving blind people accurate, verbal information about their surroundings, an experience akin to vision.

- In healthcare institutions, data-driven solutions can detect workflow inefficiencies to ensure health workers spend their limited time in the most productive way. They can also help avoid unnecessary patient hospitalisations, reduce duplication of tests and administration, time delays (important for saving lives), thereby potentially improving cost effectiveness.

- Prescription support can be provided via predictive models that reveal potential drug dependencies, side effects, and co-morbidities.

- Data analysis can identify trends or interpret genetic information that would predispose someone to a particular disease. With the help of AI, body scans can detect diseases early and predict the health issues people might face based on their genetics.

- In epidemiology, AI could help in improving early warning and detection, as well as finding viable responses, in the fight against cross-border healthcare threats including severe communicable diseases (e.g., Ebola) and antimicrobial resistance. Progress relies on effective surveillance involving the tracking and sharing of high quality, comparable data and their analysis beyond the national level.

- Population health analytics, e.g. to provide the possibility of optimising the healthcare pathways of a specific target population[15]

- A growing number of apps use AI based on personal medical history and common medical knowledge, giving recommendations based on the users' medical history. Patients report their symptoms into the app, which accesses a database of illnesses, informs about and monitors medication management, and determines the need to see a doctor.

- The patient selection for clinical trials could be based on DNA profiling, which provides biomarkers for targeted treatment. Selecting individuals with the same genetic features could lead to more precise drug development, reductions in sample size and reduced variability. Furthermore, genome sequencing could support greater diagnostic sensitivity and hence more suitable treatment. Big Data analytics can also be used for more accurate genotypic and phenotypic data to support investigations of causality. Genetics and genomics look for mutations and links to disease from the information in DNA.

- The development of new medicines with real added value can be fostered and potentially accelerated as informed decisions about market access and pricing can be taken based on data showing long-term and real-world outcomes.

- In health research, easy access to structured, high quality data is vital. Linked databases provide opportunities to analyse disease patterns, detect associations between exposures (e.g. behaviour or services received) and outcomes (e.g., acute events such as heart attacks or onset of chronic diseases such as Alzheimer's), and potentially identify causal relationships that can foster new therapies. Already in 2014, the EC identified a growing number of Big Data studies in disease areas including dementia cancer, gastroenterology and rare diseases.[16] Big Data enables connecting exiting clinical research networks and, at system level, a "learning culture" could be enabled by constant availability and flow of data.

- Big Data could be a tool for reducing health inequalities, e.g. by linking relevant data collected by different types of service providers (e.g. social welfare, health and emergency care) to gain a better insight into the use patterns of disadvantaged groups and make service improvements. Quality linked data could also broaden the range of research questions and help uncover risk factors.

Regardless of the intended use, it will be important to gain people's trust and confidence in using enlarged amounts of aggregated data. Especially where underserved subpopulations are concerned, there need to be very tight rules in place stipulating who may collect the data, for what purpose, and the permissible uses / restrictions, which must be shared and understood by individuals. This involves informed consent and opt-out possibilities. Data quality, security, privacy and portability, but also international or cross-sectorial data governance deserve attention.

European, international and national perspectives

The EC's 2018 Communication on the digital transformation of health and care envisages that existing databases containing health information will increasingly be linked to enable data sharing across the European Union (EU). Its three pillars include citizens' secure access to and sharing of health data across borders; better data to advance research, disease prevention and personalised health and care; and digital tools for citizen empowerment and person-centred care. Big Data provide a natural key to achieving this ambition.

Already in 2014 the EC began a strategic reflection process about the uses of Big Data in health[17], and in 2016 an EC-commissioned study was published[18] which describes the added value of priority projects in various MS and presents an in-depth analysis of potential policy actions. This resulted in ten policy recommendations formulated to stimulate EU and national level deployment of Big Data without compromising people's privacy and safety.

The "Big Data for Better Outcomes" (BD4BO) programme[19] under the Innovative Medicines Initiative (IMI) public-private partnership aims to create re-

search platforms and networks for various disease areas including Alzheimer's, haematology and cardiovascular to combine and expand existing data sources, build analytic capacities, and establish common standards. For example, the IMI-funded BigData@Heart project[20] accesses and harmonises European-wide data sets from various sources with the aim of designing prognosis algorithms that can predict the evolution of cardiovascular disease in individuals.

In June 2019, the Joint Action supporting the eHealth Network that was created under the Cross-border Patient's Rights Directive 2011/24/EU published a report on policy action on innovative use of Big Data in health.[21] The eHealth Network's work also enabled the introduction of cross-border ePrescription and patient summaries between participating countries as use cases of the European eHealth Digital Service Infrastructure (eHDSI)[22], with a longer-term goal of developing a European exchange format for EHRs, as outlined in a 2019 EC Recommendation[23].

Many other EU initiatives are underway under the banner of the Digital Single Market Strategy, particularly in the area of cloud computing, supporting the "free flow of data" in an economy in which an immense amount of personal and non-personal data is routinely collected.[24]

At the national level, a number of countries already operate extensive health data and/or patient registries including the United Kingdom, the Nordic Countries and Estonia. Although often decentralised, these data can be quite comprehensive and structured. The EC Communication on AI highlights that, in Denmark, emergency services are able to diagnose cardiac arrest and other conditions based on voice recognition, while in Austria radiologists can detect tumours by comparing x-rays with a vast amount of medical data[25]. The cross-sectoral appeal of Big Data and AI was confirmed in 2018, when French President Macron called for a Europe-wide Big Data strategy[26]. Germany also recently announced investing €3bn to boost the nation's AI capabilities and research over the next six years[27].

Following the EC's flagship Communication on AI which maps out its vision as part of a European Initiative on AI[28], the Political Guidelines issued by incoming EC President von der Leyen[29] contain a dedicated chapter on "A Europe fit for the digital age" as a joint task for several Commissioners, co-ordinated by Executive Vice-President Vestager and under the guidance of the new Commissioner of the Internal Market, Thierry Breton, who will also oversee the evolution of Europe's cybersecurity strategy following the 2019 Cybersecurity Act[30]. The development of a legislative European approach on the human and ethical implications of AI, coupled with the ambition to attract increased investment in the sector and boost SMEs, is a priority for the first 100 days of the new EC.

Regarding the ethical dimension, the EC's AI Communication led to the establishment of a European AI Alliance, a multi-stakeholder forum whose members are encouraged to interact with the High Level Expert Group on Artificial Intelligence, respectively tasked with drafting ethics guidelines and advancing policy and investment recommendations[31]. Although not specifically focused on health, the Horizon 2020 research and innovation programme funds two projects covering ethical aspects of AI: SHERPA, which analyses how AI and big data analytics impact ethics and human rights[32] and SIENNA, which will develop ethical protocols and codes for human genomics, human enhancement and AI & robotics[33].

The EU work in this area will be accompanied by a new Digital Services Act envisaged to update eCommerce rules and create a regulatory framework for the digital ecosystem. Moreover, progress has been proposed on digital literacy across the life-course. A European data space has already been carved out as part of the Digital Single Market strategy.[34]

At international level, the WHO, engaged in an international consultation on the ethics of Big Data and AI with the aim of issuing comprehensive guidance[35]. The Recommendation of the OECD Council on Health Data Governance argues in favour of processing health data within countries and across borders for health-related public policy objectives, while minimising risks to privacy and security[36].

Europe may be slow adapting to and investing in data-driven and AI technologies compared to the United States or China, a gap which represents a pressing economic concern for the EC. However, European health systems are quite different from those in the US or China as they are characterised by an approach that values solidarity over individual responsibility. Hence, only a gradual, evidence-based and fair implementation will contribute to achieving the EC's overall objective to "be

Only a gradual, evidence-based and fair implementation will contribute to achieving the EC's overall objective to "be the champion of an approach to AI that benefits people and society as a whole".

the champion of an approach to AI that benefits people and society as a whole".[37] It is important to ensure that Big Data and AI initiatives at EU and national level will be linked more strongly with public health objectives and key functions so that the information derived from the data can be translated into new and effective interventions that can generate concrete improvements to physical and mental health outcomes for all, in line with the principles of the European Pillar of Social Rights[38] and Europe's commitment to the health-related Sustainable Development Goals (SDGs).

Challenges and ethical considerations

The effective utilisation of Big Data / AI is dependent on a number of factors, including the removal of current obstacles such as data fragmentation (e.g. due to silos and legacy systems) and lack of interoperability (which could be at institutional, regional, national and supranational level) which prevent compatibility and effective use[39]. Considerable differences remain between European countries regarding the uptake of technology and these discrepancies also appear to widen the gap between standards, competences and practices.

Of equally great concerns are the absence of an appropriately balanced regulatory structure, the lack of a public health-driven approach to digitalisation and, arguably, lack of informed public discussion about the implications of these developments in the broader framework of "personalised medicine"[40].

Given the importance of the human relationship between health professionals and patients, which is based on mutual trust, it must be acknowledged that certain qualitative aspects of health – such as context-specific and historical variables of an individual's health throughout the life-course, e.g. related to socio-economic and other determinants and risk factors – are difficult If not impossible to capture by data. Therefore, decisions about eligibility, e.g. to obtain access to health services, insurance and reimbursement should never be taken based on databases alone but they must be appraised by qualified professionals and take into account the life context of individuals.

Another concern relates to intellectual Property Rights rules, which are potentially threatened by the entry of commercial players in European healthcare systems as companies could change their privacy policies to significantly enlarge the parties who could access personal medical information, including in locations operating under different data protection regimes.[41]

Although it has been said that the healthcare professions will not be majorly impacted by the data revolution compared to other sectors[42], it is clear that more abundant data, whether collected by automation, during examinations or by patients themselves, will considerably enlarge the information they can draw on to diagnose and treat patients, and to identify processes and courses of action. In their European Statements, EPHA members the European Association of Hospital Pharmacists call for the active involvement of the profession in the design, specification of parameters and evaluation of ICT within the medicines processes[43]. Similarly, community pharmacists have pointed out that increasing numbers of patients are seeking their advice as accessible health professionals on how to interpret information acquired from various sources, while pharmacies are providing digital point-of-care tests in many countries. The expansion of activities in the digital realm is opening up questions about reimbursement schemes related to the deployment and professional recommendations of data-driven e- and mHealth tools and the linking of commonly used data such as EHRs and ePrescribing systems.[44] Similar concerns apply to other healthcare professions.

Inevitably new skills will be required to analyse ever growing volumes of data, and while healthcare professionals cannot be expected to be data specialists, an adaptation of study and training curricula would enable them to take better decisions, as EPHA members representing European students of the medical[45], pharmacy and public health disciplines have argued.

Although it may not always be possible to grasp exactly how and why the data support certain recommendations, understanding the underlying processes is key to enabling effective human-technology interplay. This presupposes a certain level of knowledge of how an algorithm works internally, of the types of data decisive in producing certain results, and of how to assure data quality within complex systems. Also, the person to whom the data refer must have the right to receive an explanation of how a decision has been generated.

However, Big Data and AI must not drastically alter

functions but they should augment professionals' expertise by providing a fuller picture of patients' health, a view supported by leading multinationals[46].

It will be equally important to educate society at large about what data-driven healthcare means in practice. For instance, the blurred line between solutions certified as medical devices and those classified as consumer "health and wellbeing" products is confusing and public health objectives must be at the heart of digital health and care. The formal validation of apps within health systems is one example of reassuring the public and weeding out low quality products. Technology moves much faster than regulatory frameworks, which is why the rapid and blind adoption of solutions could threaten the attainment of the SDGs, especially if the benefits only reach segments of society who already receive good quality healthcare.

At the same time, advancing population health also depends on the possibility to make best use of data for research. Personal health data are often donated by individuals eager to contribute to the societal good, as long as their privacy is protected. EPHA members have repeatedly underlined the need to ensure the implementation of a robust General Data Protection Regulation (GDPR) framework that does not hinder the ability to use data for research, including secondary use, within well-defined boundaries.

While the GDPR is undoubtedly an important vehicle for protecting personal data, including "by design" and "by default", it was also designed to enable the free flow of data. Despite provisions giving data subjects the right to be provided with meaningful information about the logic behind decision-making based on automated processing[47], the GDPR may not be sufficient to cover all applicable instances in which patient health data might come into play with sophisticated data-driven technologies and AI (i.e., circumstances going beyond the GDPR provisions), and it may be necessary to consider an additional regulatory regime as data become more ubiquitous and influential.

Similarly, it has been argued that the most underserved and marginalised groups could potentially gain the most from Big Data and AI, which could function as important tools to ensure that "no one is left behind in the digital transformation", which is another EC objective[48]. For example, the linking of relevant administrative datasets of homeless people using different social welfare and health services could enable better observational studies, predictive analytics (e.g. service-use patterns), and testing the effectiveness of interventions.[49] Insights into the factor shaping the health of other disadvantaged populations, such as Roma or migrant communities, would benefit from collecting more comprehensive data on ethnicity (which is currently not possible in some MS) as they could help illuminate the complex, intersectional reality of discrimination and exclusion.

At societal level, the wind of change is palpable in many sectors as vast amounts of money are invested in transforming entire industries, professional roles and hierarchies; examples include driverless cars, drones, and robots. There is growing concern that the jobs created are primarily for IT-literate elites. Another concern relates to the fact that few digital solutions are successfully scaled up to the level of widespread deployment, which Is dependent on a critical mass based on the perceived usefulness and meaningfulness of new technology.

In a world in which populists and other actors are exploiting digital tools to blur the lines between truth and fiction, it could also be that the insights offered by big data may not be taken seriously. More worryingly, they could be instrumentalised by undemocratic forces, coupled with increased fears over large-scale cybersecurity threats.

The EC's Big Data vision includes health and non-health data, such as information derived from social media. In other words, traces left by individuals that could reveal clues about their health, whether offered consciously or without intent. Analysing such data is questionable given the difficulty to obtain a person's explicit consent for this purpose in spontaneous social media environments, but it is also dangerous given that individuals might exaggerate or downplay their real mental and physical health online. The relevance, veracity and reliability of such data, while providing anecdotal insights, does not reflect the complex reality of an individual's health, linked to personal histories and the agency one has to act upon available information and opportunities.

In a recent report, the French National Consultative Committee on Ethics (CCNE) highlights further dimensions that need to be addressed, including the increased mixing of the public and private sphere (e.g. geo-localisation of smartphone users) and that the quality and adequacy of data select-

ed to train algorithms needs to reflect the problem under investigation.[50] Moreover, the CCNE underlines that sharing data too widely would represent a menace to fundamental human rights given the impossibility to control all instances where patient consent is violated, the quality of the data themselves, and how and by whom they are stored and reused. EPHA members AGE have pointed out that older people are particularly volatile to abuses to their dignity, liberty and security[51].

EPHA members the European Institute of Women's Health have pointed out that algorithms are not gender neutral: programmed primarily by men, the underlying data often ignore the biological and physiological characteristics of women[52]. Given the striking lack of diversity in Silicon Valley and other high-tech hubs, it Is even less likely that programmes take into account the needs of ethnic minorities or non-binary people. Advocacy in this area is important as it raises awareness of diversity, promotes virtuous competition, compliance with legal requirements and agreed standards, and encourages a collaborative "end user approach" stimulating meaningful innovation.

Also, if intelligent machines are able to provide answers more accurately than people, this might relegate healthcare professionals to the realm of case management. The CEEE highlights three ethical principles that could be hampered: medical secrecy (as certain data do not stem from the medical sphere), responsible decision-making (due to the risk of placing too much faith in automation) and the relationship between professionals and patients as the latter might morph into a "mass of data" to be analysed rather than individuals with unique problems.

Similarly, the increased importance assigned to genetic testing as part of examinations and prescribing entails a narrow view. Selective data collection and analysis could lead to increased pressures on individuals to responsibly "manage" their behaviours. In the context of "personalised medicine" patient groups with suitable genotypes could be favoured over the rest of the population, which begs questions about equity and justice and could have implications for access to medicines if R&D models only consider these groups. Moreover, to make treatment decisions, genetic information will need to be shared with experts and administrators, which means that privacy and confidentiality are inevitably a relative notion. Some people may not wish to know their genetic susceptibility towards

certain diseases, whether due to personal preference or faith. It has also been argued that health systems would not be able to absorb the costs arising from pharmacogenetics and the associated demand for genetic counselling[53], and it remains difficult to interpret genetic information to support treatment choices.

There as thus a number of ethical and regulatory challenges the public health community must engage with[54]. Europe has a long tradition of creating and adhering to values and rights that support health for all and that are reflected in the EU Charter of Fundamental Rights[55]. Globally, they are vital for achieving the SDGs and universal health coverage, especially in the poorest countries affected by severe health worker shortages[56]. It is important that policymakers and the private sector recognise and support a vision of Big Data and AI as a social good that could help nurture sustainability. Like all technologies, they can be used in inclusive ways to improve universal health coverage, but they can also exacerbate the inequalities of people lacking tools to lead healthy lives.

Conclusions

What makes Big Data/AI particularly complex is the fact that the data sources are so diverse, including professionals, patients, and machine-generated information. A corollary of having so much more data available is that there could also be more loopholes for misusing the data, which is why ethical behaviour must be strengthened.

As has been noted in a joint EPHA-EC article, "Big data holds the potential to transform and benefit public health in the future, but it will be no longer only about providing access to health care services, institutions and medication, but about the bigger picture in which society understands digital technology, also taking into account the socio-behavioural aspects that influence quality of life".

In practice this means that it is not necessarily about the size of the data but about meaningfulness and utility. All health stakeholders should be involved in harnessing their full potential. Data only tell part of the story: the ethical concerns over the digitalisation of society are serious and real. Advocacy for maintaining the very foundation European health systems are based on – solidarity – is urgently needed. Investments in prevention and health promotion measures can reach all segments of soci-

Data only tell part of the story: the ethical concerns over the digitalisation of society are serious and real.

ety, whether actively involved in data generation or not. While increased engagement of individuals in their health is positive – although caution must be exercised when it comes to patient self-management - changing behaviours is a long-term process. People might in fact rely even more on the guidance of doctors to make informed choices as evidence from Sweden suggests.[57] To safeguard Europe's rights-based approach to health, and ensure tangible benefits for end users. the oversight and policies of governments concerned about the health and inclusion of all members of society is critical.

The examples provided above highlight that Big Data and AI do indeed hold much promise for improving healthcare. But recalling the five V's of Big Data and the many possibilities to hack, distort, alter, manipulate, misuse and erase data, it will be increasingly important to develop binding policies and legislation that can keep up with the pace of innovation to protect people's safety, privacy and fundamental rights.

The Finnish Council conclusions espouse the potential of digitalisation while stressing they must be deployed to benefit people and promote digital inclusion[58]. in the context of a post-2020 Europe that respects the principles of the European Pillar of Social Rights, EPHA proposes the following recommendations to supplement those advanced by the EC[59]:

- The integration of Big Data and AI technologies must be accompanied by regular updates of legislation and rules that protect the fundamental rights of individuals, their privacy and personal data including health data. The GDPR and other legislation (e.g. the evolving ePrivacy framework) will need to remain "fit-for-purpose" and keep up with rapid digital innovation and new ethical concerns arising from their deployment.

- The public health community, including civil society and NGOs, must be given a voice in the policy debate to ensure that the future of European public health, including the financing of national health systems, corresponds to people's needs and preferences. Solidarity and population health must remain key values as the commercialisation of health will further diminish social cohesion and exacerbate inequalities

- Better information about digitalisation of healthcare needs to be disseminated across Europe to launch a wide-ranging societal debate about where we are headed – or not.

- Research involving Big Data and AI techniques should be driven by the needs of health systems, professionals and individuals as part of a rights-based, end user-centric, public health friendly approach.

- In order for healthcare professionals and individuals to be able to reap the best possible benefits from data-driven solutions, it will be increasingly important to include them in educational and professional programmes and to invest in health literacy initiatives that take into account different levels of education and agency.

The next step for EPHA will be to explore more deeply the opportunities and threats involved in the digitalisation of areas that exert a direct or indirect influence on how public health is conducted. Hence, in 2020, we will commission a study to develop further and more specific policy recommendations.

Notes

1. EC COM(2018) 233 final, available at https://ec.europa.eu/digital-single-market/en/news/communication-enabling-digital-transformation-health-and-care-digital-single-market-empowering
2. EC COM(2018) 237 final, Artificial Intelligence for Europe, p.1
3. (insert 24 Oct version)
4. EPHA (2018), https://epha.org/wp-content/uploads/2019/02/enabling-the-digital-transformation-of-healthcare.pdf
5. Raghupathi W. & Ragupathi V. (2014), Big Data analytics in healthcare: promise and potential. Health Inf. Sci. Syst. 2:3, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4341817/
6. European Commission (2016), Big Data in Public Health, Telemedicine and Healthcare, https://ec.europa.eu/health/sites/health/files/ehealth/docs/bigdata_report_en.pdf
7. Raghupathi & Ragupathi, op. cit.
8. Benke K. & Benke G. (2018), Artificial Intelligence and Big Data in Public Health, International Journal of Environmental Research and Public Health
9. Jiang, F. et al (2017), "Artificial Intelligence in healthcare: past, present and future", Stroke and Vascular Neurology 2017:2, pp. 230-242.
10. EC COM(2018) 237 final, op, cit., p.1
11. https://ec.europa.eu/digital-single-market/en/news/definition-artificial-intelligence-main-capabilities-and-scientific-disciplines
12. EC COM(2017) 228 final, "A Connected Digital Single Market for All"
13. https://www.economist.com/leaders/2017/05/06/the-worlds-most-valuable-resource-is-no-longer-oil-but-data
14. See e.g. the "My Health, My Data" project, https://ec.europa.eu/digital-single-market/en/news/blockchain-enable-medical-data-be-stored-and-transmitted-safely-and-effectively
15. See Buttigieg, Stefan (2017), Population Health for Europe – why not?, posted at https://www.himss.eu/himss-taxonomy-topics/population-health
16. EC (2014), The use of Big Data in public health policy and research, p.3
17. https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20141118_co07b_en.pdf
18. EC / Gesundheit Oesterreich (2016), Study on Big Data in Public Health, Telemedicine and Healthcare
19. https://www.imi.europa.eu/projects-results/project-factsheets/bd4bo
20. https://www.bigdata-heart.eu/
21. https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20190611_co4422_en.pdf
22. https://ec.europa.eu/health/ehealth/electronic_crossborder_healthservices_en
23. EC, C(2019) 800 final
24. EC COM (2017) 9 final, Building a European Data Economy)
25. EC COM(2018) 237 final, op. cit., p.1
26. https://www.ft.com/content/e451e1d4-f5de-11e7-88f7-5465a6ce1a00
27. https://www.ft.com/content/fe1f9194-e8e3-11e8-a34c-663b3f553b35
28. EC COM(2018) 237 final, op.cit.
29. von der Leyen, Ursula (2019), A Union that strives for more – My agenda for Europe.
30. Regulation (EU), 2019/881, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0881&from=EN
31. https://ec.europa.eu/digital-single-market/en/high-level-expert-group-artificial-intelligence
32. https://www.project-sherpa.eu/
33. https://www.sienna-project.eu/
34. https://ec.europa.eu/digital-single-market/en/policies/building-european-data-economy
35. https://www.who.int/ethics/publications/big-data-artificial-intelligence-report/en/
36. https://www.oecd.org/els/health-systems/health-data-governance.htm
37. EC COM(2018) 237 final, op. cit., p.2
38. In particular principle 3 on equal opportunities, principle 12 on social protection, principle 16 on health care and principle 20 on access to essential services, but other principles are also relevant. https://ec.europa.eu/commission/priorities/deeper-and-fairer-economic-and-monetary-union/european-pillar-social-rights/european-pillar-social-rights-20-principles_en
39. EC (2014), op. cit.
40. Arnason, V. (2012), The Personal is Political: Ethics and Personalised Medicine, Ethical Perspectives 19, no.1, pp. 103-22.
41. Booth, Phil (2019, England's NHS is embracing 'big data' – But who's really benefiting?, https://www.opendemocracy.net/en/ournhs/the-nhs-is-embracing-big-data-but-whos-really-benefiting/
42. See https://epha.org/no-need-to-worry-digital-health-is-progressing-but-health-workers-needs-will-determine-its-success/
43. https://ejhp.bmj.com/content/21/5/256
44. PGEU (2019), Position Paper on Big Data & Artificial Intelligence in Healthcare, https://www.pgeu.eu/wp-content/uploads/2019/04/PGEU-Position-Paper-on-Big-Data-Artificial-Intelligence-in-Healthcare.pdf
45. https://epha.org/digital-health-literacy-a-prerequisite-competency-for-future-healthcare-professionals/
46. Microsoft (2018), Healthcare, Artificial Intelligence, Data and Ethics – a 20130 vision.
47. EC COM(2018) 237 final, op.cit., p.14
48. EC COM(2018) 237 final, op.cit., p.2
49. Culhane, Dennis (2016), The Potential of Linked Administrative Data for Advancing Homelessness Research and Policy, European Journal of Homelessness, Volume 10, No 3.
50. CCNE (2019), Avis 130. Données massives et santé : Etat des lieux, prospective et nouvelles questions éthiques
51. https://epha.org/digital-health-and-care-listen-to-what-older-persons-think/
52. https://epha.org/gender-and-ehealth/
53. Arnason (2012), op. cit.
54. Benke K. & Benke G. (2018), op. cit.
55. See Article 35: https://fra.europa.eu/en/charterpedia/article/35-health-care
56. https://www.ft.com/content/4b13402a-f65a-11e9-9ef3-eca8fc8f2d65
57. http://lakartidningen.se/Klinik-och-vetenskap/Originalstudie/2019/10/Natvardsanvandare-i-Skane-kontaktade-oftare-vardcentral/?utm_source=dlvr.it&utm_medium=twitter#.Xal7N4RPYvA.twitter
58. 13171/19, Draft Council Conclusions on the Economy of Wellbeing, https://data.consilium.europa.eu/doc/document/ST-13171-2019-INIT/en/pdf
59. EC (2016), op. cit.

european public health alliance