Healing Bytes:
Navigating the rewards and risks of smart worlds for health

Danielle Brady
Giulia Torchio

Credit: CANVA

Table of contents

ABOUT THE AUTHORS

Danielle Brady is a Policy Analyst in the Social Europe and Well-Being programme at the European Policy Centre.

Giulia Torchio is a Junior Policy Analyst at the European Policy Centre.

Executive summary

This publication centres on the notion of smart worlds for health, which encompasses existing and emerging technologies such as Artificial Intelligence (AI) along with other digital health tools.

Smart worlds for health offer many potential benefits in areas such as prevention, diagnostics, treatment, health prevention and promotion and advanced research and innovation. However, smart worlds for health are not without challenges with concerns surrounding the overall accessibility of data, which is central to drive forward innovation, and practices of data sharing and re-use, which are notoriously difficult to implement in a fair manner. Further challenges include the need to upskill the healthcare workforce and the digital literacy of the population.

This paper sheds light on the potential for good and for harm that describes smart health and charts the way forward for new technologies setting out a number of recommendations to overcome these challenges:

► Prioritise the implementation of European Health Data Space.

► Invest in digital literacy.

► Invest in smart health education for healthcare professionals.

► Invest in digital and health infrastructure at member state level.

► Ensure diverse high-quality data.

► Prioritise data protection and cyber-security measures.

Introduction: Smart worlds for health

This publication centres on the notion of smart worlds for health, which encompasses existing and emerging technologies such as Artificial Intelligence (AI) along with other digital health tools. Smart worlds, are described as an amalgamation between the physical and digital dimensions aided by numerous systems and devices, called Internet of Things (IoTs) devices. Smart health specially leverages advanced technologies, the internet of medical things (IoMT), sophisticated machine learning algorithms and wireless communication systems.[1] This integration facilitates the creation of interconnected and intelligent environments, which promise to revolutionise modern approaches to health and the healthcare sector by enabling healthcare stakeholders to significantly enhance patient care, optimise resource utilisation, and improve overall health outcomes.

Through the collection and analysis of data in real-time, these systems could empower practitioners and users alike fostering informed decision-making and the simulation of potential impacts. Moreover, the integration of AI and machine learning technologies could also enable the creation of personalised experiences that cater to individuals' specific needs and preferences.

In addition to its potential to improve access to healthcare and enable telemedicine, enhanced drug design, and quicker diagnoses, smart worlds could also contribute to increasing the overall resilience of the health sector. Advanced prevention systems, as well as early detection and outbreak assessment tools could help society be better prepared for future pandemics and public health threats.

Despite the significant potential of smart worlds to improve healthcare, and the European Commission's efforts to spearhead innovation through strategic communications and initiatives, the path forward is not without obstacles. There are fundamental concerns surrounding the overall accessibility of data, which is central to drive forward innovation, and practices of data sharing and re-use, which are notoriously difficult to implement in a fair manner.

Despite the significant potential of smart worlds to improve healthcare, and the European Commission's efforts to spearhead innovation through strategic communications and initiatives, the path forward is not without obstacles.

This research aims to shed light on the potential for good and for harm that describes smart health and to chart the way forward for new technologies. For this reason, this discussion paper is structured in the following manner: The first section introduces the main dynamics that have contributed to the increase of digitalisation in healthcare. Then, partly drawing from the expertise of healthcare professionals, researchers, representatives of the private sector and other relevant stakeholders who have taken part in a series of events organised by the European Policy Centre with the support of Vodafone Institute for Society and Communications, the second and third sections discuss the main benefits and challenges of smart worlds for health. Lastly, policy recommendations sketch the necessary next steps to tap into smart health's potential for Europe.

COVID-19: AN ACCELERATING CATALYST FOR DIGITAL HEALTH

While the digitalisation of health has been part of the Commission's strategic agenda for some time the impact of the COVID-19 pandemic significantly helped to create momentum for digital health and e-health policies. Given the ubiquitous spread of the virus beyond national borders, solutions such as telemedicine and digital consultations, which had not been popular previously in some member states, had to be established and implemented rapidly.

These solutions became vital in the fight against COVID-19 as they made health services available to more patients while also minimising the risk of contagion. Mobile apps, websites, robots, and chatbots swiftly supplanted traditional face-to-face consultations, aided the rapid dissemination of crucial information and facilitated remote medical visits, primary care services, e-prescriptions, remote patient monitoring, real-time screening, risk assessment, and triage before hospital admission.[2]

However, for most of these tools, swift legislative changes or adaptations at the member states level were required. For example, Austria, Belgium, Estonia, and the Czech Republic, lacked national legislation, strategies, or policies regarding telemedicine, promptly enacting measures to enable provider reimbursement for telehealth consultations and clarify regulatory frameworks. Countries like France, Luxembourg, and Poland, where telemedicine was already established, eased existing restrictions or introduced new platforms to facilitate patient and provider access to remote consultations. Furthermore, Belgium, Estonia, Greece, and Ireland permitted the issuance and electronic access of prescriptions and sick leave certificates.[3] These changes displayed the need for regulation and legislation to support the adoption of the digital tools at the onset of the pandemic.

At the EU level, the Commission established the EU digital COVID-19 vaccination certificate. In doing so, it created a standardised digital format for documenting vaccination status, which aimed to streamline the process of verifying individuals' immunity to the virus across the Union.[4] These certificates played a crucial role in assisting member states to reinstate cross-borders travel.

Hence, by quickly breaking down barriers and making the swift adoption of digital tools across the health ecosystem a matter of life or death, the pandemic served as a catalyst for health digitalisation.

Digitalising health in the EU

Partly building on the momentum spurred by the COVID-19 pandemic, in 2020 the EU Commission included digitalising health among its key policy priorities to ensure that Europe is fit for the digital age. A second catalyst was the value that data has come to play in the digital economy, and the Commission's reckoning that the EU produced significant quantities of it, which could result in increased innovation in many different fields. Hence, tapping into the potential of this data has suddenly become a priority for Europe.

The digital and data pillars of the broader "Europe fit for a digital age" strategy aims to do precisely that. They set the objectives to enhance the EU's digital sovereignty and drive forward innovation by creating a fair, single market for data. This effort is supported by two main policy initiatives: (i) the Digital Governance Act (DGA), setting up the infrastructure of the single market for data,[5] and (ii) the Data Act (DA), focusing instead on setting clear and fair rules on data access and re-use.[6]

Adding to these efforts, the Commission also pushed for a gradual integration of further digital tools, such as the Electronic Health Records (EHRs), and telemedicine into standard clinical practice across Europe. This not only allows a shift beyond the traditional means of delivering health and the overall functioning of health systems, but also promotes the use of population health data for societal good. However, other relevant factors play a role and potentially undermine the benefits of digital health, such as accessibility and digital literacy.

THE COMMON EUROPEAN DATA SPACES AND THE HEALTH DATA SPACE

Together with the legislative framework set by the DA, some of the major building blocks of the digital Single Market are the Common European Data Spaces (CEDS) created under the DGA as part of the relevant digital infrastructure. In the Commission's vision, these digital spaces spanning fourteen highly specific sectors, such as mobility, public administration, the Green Deal, and skills[7] will help unleash the potential of data-driven innovation by facilitating data access and sharing data.

Among the CEDS, the European Health Data Space (EHDS), which establishes a data-sharing framework for health data across the EU, is set to become the first data space to be rolled out and to become a pillar of the European Health Union (EHU).[8] In particular , by providing guidelines, shared standards, infrastructures, and a governance framework, the EHDS contributes to facilitating cross-border data-sharing among stakeholders across the EU. This in return results in larger volumes of better-quality data for patient care, research and innovation. Additionally, it affords the EU the chance to become a frontrunner in the global arena setting benchmarks for health data.[9]

By providing guidelines, shared standards, infrastructures, and a governance framework, the EHDS contributes to facilitating cross-border data-sharing among stakeholders across the EU.

However, significant disagreements among those stakeholders emerged during the negotiations of the regulation overseeing the EHDS. These differences centred on patient consent to data sharing for primary and secondary uses and, on how to strike the right balance between data protection principles and fostering research and innovation.[10] While privacy advocates pushed for a nuanced approach to data consent through detailed opt out mechanisms, data holders voiced their concerns that such a provision could result in an additional burden for them and suggested a "blanket consent" approach. Some experts also pointed out that different populations could have different feelings towards data sharing and, therefore, implementing an opt out mechanism could lead to skewed data sets.[11]

Eventually, the Council and European Parliament achieved a provisional political agreement on the proposal of the EHDS, mandating that patients have the right to opt out of both primary[12] and secondary data use,[13] with few exceptions related to the protection of the vital interest of the subject or another patient, or for public interest, policy-making, or statistical purposes.[14] This development is welcomed overall as it promotes a granular approach to consent that is in line with the General Data Protection Regulation (GDPR).

The recent agreement now shifts the attention to a significant challenge: implementation.[15] Successfully implementing the EHDS necessitates cross-border infrastructure for health data exchange that, in return, underscores the importance of investing in semantic interoperability[16] and fostering cooperation.

To do so, the Commission has put measures in place under "EU4health," which is part of the Digital Europe Programme, and measures under Horizon Europe. These foresee the introduction of cross-border infrastructures that will facilitate electronic health data exchanges and support health data reuse, and account for an estimated investment of EUR 800 million under the current multi-annual financial framework (MFF).[17] However, to be successful, these initiatives are also dependant on the cooperation of member states, which will need to prioritise the implementation and build the necessary environment for the EHDS to reach its potential.

Other than the EU progress related to the roll-out of the CEDS and the EHDS, and other regulatory efforts that are also relevant to the healthcare sector are advancing. Recent technological leaps in the field of AI, as we will see later in this research, could add to the benefits offered by digital health tools. This is because AI has great potential to integrate with already existing technologies and revolutionise health by offering innovative, tailored approaches to patient care that are more affordable. There is, however, no innovative technology where the benefits are not balanced by equally serious risks and, as such, AI needs to be effectively regulated too.
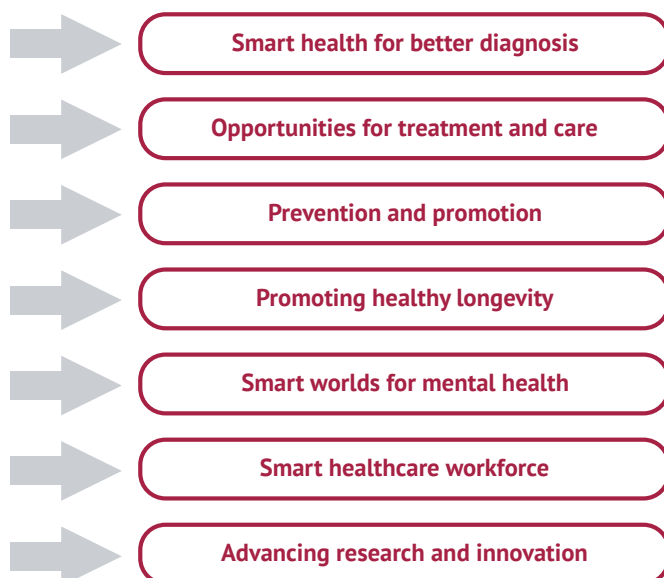
On this note, the Parliament and the Council recently reached a historic agreement on the world's first comprehensive AI regulation, the EU AI Act. The legislation essentially sets to regulate AI systems as products and to create harmonised standards across the EU to ensure a fair, trustworthy and human-centric adoption of AI. In terms of regulatory approach, instead, the AI Act is described by a tiered approach, distinguishing among uses based on their associated risks. There are three categories of risk – unacceptable, high, and limited – each characterised by different sets of obligations and reporting requirements.[18] When it comes to healthcare, most of its AI applications will fall under the high-risk category and hence will have to meet further requirements before they can be put on the market.[19]

Harnessing the potential of smart worlds: Opportunities for health

Smart worlds for health offer potential across the entire health ecosystem, from health prevention tools to diagnostics and treatment. Harnessing the potential of AI and digital tools can render positive outcomes and promote healthy populations across the EU. Reflecting on the insights received during the roundtable discussions, several potential opportunities were identified:

HARNESSING THE POTENTIAL OF SMART WORLDS: OPPORTUNITIES FOR HEALTH

- Smart health for better diagnosis
- Opportunities for treatment and care
- Prevention and promotion
- Promoting healthy longevity
- Smart worlds for mental health
- Smart healthcare workforce
- Advancing research and innovation

SMART HEALTH: USING AI FOR BETTER DIAGNOSIS

The integration of AI into healthcare brings forward significant advancements, notably in the recognition of intricate patterns, which lays the groundwork for sophisticated image-based detection and diagnostic systems.[20] Clinical Decision Support Systems, used to assist the decision-making process in the healthcare sector[21] are -emerging as crucial tools in healthcare and health systems in Europe, with the potential to significantly reduce diagnostic errors and enhance decision-making processes. These systems aid the efficient extraction and documentation of data within EHRs,[22] further streamlining healthcare workflows. Moreover, advancements in computational techniques, including natural language processing (NLP), pattern identification, and the development of efficient search algorithms, are at the forefront of propelling AI capabilities.

The concept of a smart health world promotes the use of digital innovations to enhance diagnostic processes and treatment strategies. AI plays a crucial role, especially in analysing diagnostic images like X-rays and MRIs, supporting physicians in disease identification and therapy planning. For instance, AI algorithms have been developed to identify signs of cancer in mammograms with remarkable accuracy, enabling quicker diagnostic and treatment decisions.[23]

AI algorithms have been developed to identify signs of cancer in mammograms with remarkable accuracy, enabling quicker diagnostic and treatment decisions.

A notable example includes a breast cancer prediction algorithm trained on 38,444 mammogram images from 9,611 women. This pioneering model uniquely combines imaging with EHR data and related health information to forecast the likelihood of malignancy in biopsies and to differentiate between normal and irregular screening outcomes effectively.[24] By doing so, it achieves diagnostic precision on par with professional radiologists and offers significant potential in reducing the rate of overlooked breast cancer diagnoses.

The benefits of smart health and AI tools have been highlighted in Europe's Beating Cancer Action Plan.[25] The EU's efforts to combat cancer strives to integrate resources and databases into an open, accessible, and user-friendly infrastructure for cancer imaging data, ensuring accessibility to all stakeholders. By utilising anonymised images, a diverse array of parties, ranging from hospitals to researchers and innovators, will have access to a vast repository of data. This wealth of information harbours the potential to refine AI tools through training, thus enhancing their precision and dependability.[26] Leveraging real-world electronic records facilitates seamless sharing of clinical insights among various healthcare professionals involved in cancer management, including nurses, oncologists, radiologists, and surgeons.

SMART HEALTH: OPPORTUNITIES FOR TREATMENT AND CARE

The positive impact of smart health for diagnostics is complemented by additional benefits, such as enhanced access and availability of treatment and care. AI-driven medical applications offer promising avenues for treating conditions more effectively and efficiently, including prevalent diseases like heart disease and cancer, and rare disorders such as cystic fibrosis.[27] By tailoring medication timing and dosages to individual patient needs or selecting patients for screening based on personalised health profiles rather than generic criteria like age and sex, AI technologies could pave the way for better preventive care, and more precise treatments. This advancement not only has the potential to save lives but also to optimise the use of healthcare resources more effectively.

This should also result in a reduction in care fragmentation where a patient's care is divided among multiple providers without proper coordination, which can lead to inefficiencies, suboptimal experiences, and increased risks of harm. Digital health solutions play a pivotal role in integrating data across care providers, particularly benefiting patients with complex health needs, such as those with multiple chronic conditions. By enabling better data integration, these technologies help reduce fragmentation and improve care continuity.[28]

For example, smart worlds for health hold the potential to improve medication adherence through health digitalisation. A study examining AI smartphone apps revealed a significant 67% absolute enhancement in drug adherence among users, with daily monitoring via the AI platform resulting in 100% adherence compared to 50% in the control group.

HOLISTIC APPROACH: SMART HEALTH FOR PREVENTION AND PROMOTION

Smart worlds aim to bring benefits to those who have been diagnosed with conditions and provide many opportunities for prevention and health promotion. Tailoring health promotion strategies can yield better results and promote a shift from broader health promotion initiatives to more precise interventions targeting specific communities, whether they are geographically bound or linked digitally.

Studies have highlighted the merit of a personalised approach to health promotion. For instance, in a study focusing on dietary habits and weight management, researchers found that implementing self-monitoring diets through mobile app-based food tracking, coupled with tailored feedback, effectively spurred positive behavioural changes. Over six months, participants managed to curtail their consumption of energy-dense and nutrient-poor foods, leading to weight reduction and a decreased risk of future chronic diseases.[29]

Within a smart world, AI algorithms can also aid clinicians in making informed decisions regarding patient nutritional needs, disease prevention, and management by analysing large datasets to uncover novel associations between diet and disease outcomes. This empowers clinicians to provide evidence-based nutritional recommendations. Moreover, smart health promotes the utilisation of AI-powered devices and applications for tracking dietary intake, providing feedback, and encouraging healthier food choices.[30]

PROMOTING HEALTHY LONGEVITY IN SMART WORLD FOR HEALTH

At the core of smart worlds for health is the opportunity to move towards a more personalised approach to health and treatment. It transcends clinical, hospital, and primary care settings to encompass home care, offering further opportunities. Home monitoring plays an important role in the self-management of chronic diseases, particularly among the elderly, involving tasks such as medication management, dietary adjustments, and the oversight of health devices. The potential benefits extend to enhancing independence and facilitating ageing at home through the monitoring of physical spaces and fall prevention. Given Europe's changing demographics and ageing population, the issue of healthy longevity will only become more salient and here smart worlds can play an important role. Tools such as software, smartphones, and mobile applications empower patients to take control of a significant portion of their healthcare, streamlining interactions with the healthcare system.[31]

Given Europe's changing demographics and ageing population, the issue of healthy longevity will only become more salient.

SMART WORLDS FOR MENTAL HEALTH

Furthermore, the digitalisation of health systems could have positive implications for mental health through the prevention and treatment of issues. AI tools, for instance, can identify at-risk populations, leading to faster intervention and possibly averting severe mental illness. They also recognise, evaluate, and predict stress levels, such as signs of cognitive impairment which can affect mental health over time, and resort to digitised healthcare, which enhances clinicians' comprehension of the underlying causes of intricate disorders.[32] AI could enhance mental health care accessibility, and function as a primary resource, offering information and services to those seeking help.[33]

SMART HEALTHCARE WORKFORCE

Smart health should not just lead to improved quality care but also has the potential to bring benefits for the functioning of entire health systems by improving clinical procedures and streamlining administrative tasks, benefiting healthcare professionals. One key aspect is automating routine administrative functions like appointment scheduling and insurance claims processing using AI-driven systems. This approach enables healthcare organisations to reduce costs significantly and enhance efficiency. Automated appointment scheduling optimises resource utilisation, reduces wait times, and boosts patient satisfaction. Consequently, integrating AI into administrative tasks results in a more efficient and cost-effective healthcare system, ultimately enhancing patient care quality.

SMART WORLDS IN ADVANCING RESEARCH AND INNOVATION

Research and innovation can also benefit from a smart world for health. The availability of data can enhance research. In this sense the implementation of the EHDS offers much potential in driving forward research within Europe by providing a standardised, secure framework for health data across Europe. This facilitates easier data sharing, enabling researchers to access diverse health data and develop personalised medicine approaches. Additionally, it promotes collaboration among researchers, healthcare providers, and policymakers, accelerating research processes and supporting evidence-based policy decisions.

The incorporation of AI in research and innovation can yield benefits in areas such as drug discovery and development where substantial transformations have been noted. By harnessing AI algorithms, researchers can now simulate and forecast the interactions between potential drugs and viral protein. AI also contributes to drug development by automating multiple tasks, thus cutting down on the expenses and time linked with preclinical and clinical trials. Further benefits include the use of AI to overcome challenges presented by Antimicrobial Resistance (AMR). For example, researchers at MIT have developed an algorithm that can predict the probability that a patient's UTI can be treated with different antibiotics.[34]

Overcoming the obstacles: The costs and challenges of a smart world for health

While smart worlds have many benefits for health across the health ecosystems, many challenges exist concerning the transition in health. Accessing the costs and overcoming the challenges will be essential to harness the potential of smart worlds. It is also essential to ensure that the potential of smart worlds is harnessed for all ensuring access and availability to reduce inequalities rather than exasperating existing ones or create new ones. Drawing on the discussions during the roundtables organised in the context of the project several challenges have been identified:
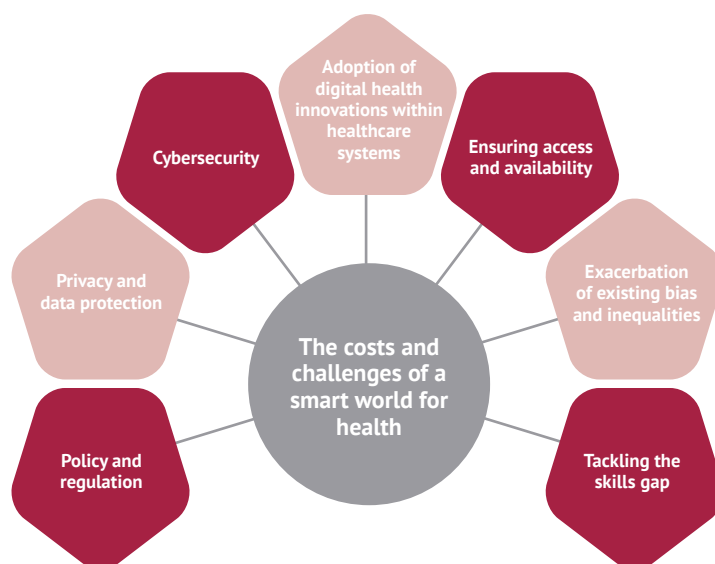
ENSURING THE CONDITIONS FOR SMART HEALTH: POLICY AND REGULATION

Ensuring the necessary conditions for smart health requires navigating several challenges and considerations across various domains. Firstly, in terms of policy, governments at the various levels of governance play a pivotal role in shaping the regulatory landscape and competencies within healthcare systems. Robust frameworks and regulations are essential to guide the integration of digital health technologies and ensure that they align with ethical standards and patient privacy rights. This requires a delicate balance between fostering technological advancements and mitigating potential risks and disparities that may arise. As already highlighted, the current Commission mandate has witnessed great advances in providing necessary regulation and legislation to allow for the advancement of health digitalisation and the transition towards smart worlds for health. While the EHDS and AI Act hold much potential and signal progress for digitalisation and AI in healthcare, challenges remain.

Questions persist on the right to opt out contained within the EHDS regulation and on how to mitigate further potential digital inequalities that might arise from data use to the detriment of the patients. According to the provisional agreement reached in March 2024, member states can decide whether to grant citizens with the right to "opt-out" of data sharing and re-sharing, with the exception of situations of "vital interest".[35] However, ambiguity arises regarding the definition of 'vital interest' and the specific beneficiaries of this interest. An additional concern is the potential fragmentation that this decision to leave the choice on the implementation of the right to opt out of member states could lead to.

To address these concerns, some experts are pointing to solutions revolving around solidarity-based data governance. Simply put, data solidarity supporters propose to regulate data use through an evaluation of the risks and benefits associated with data sharing. If it poses more risks than benefits for people and communities, then it should not be allowed, and companies violating this principle should be heavily sanctioned. By suggesting to wage law to its full potential to prevent harmful practices and to implement heavy sanctions for offenders, data solidarity aims to fairly redistribute the benefits and costs associated with new digital practices.[36]

However, data sharing is not the only issue associated with the rollout of the EHDS. There is also an issue of lack of trust among citizens, which stems from data privacy concerns which, if not addressed, could undermine the successful implementation of the EHDS. Therefore, the EU must provide reassurance to citizens to gain their trust and prompt them to buy in data sharing to unlock the benefits that the EHDS offers in terms of care for patients but also concerning the advancement of research and innovation agenda in Europe.

Therefore, striking the right balance between data privacy and the need for data-driven innovation remains a critical challenge that policymakers, healthcare providers, and technology developers must navigate.

PRIVACY AND DATA PROTECTION

Data privacy and security emerge as paramount concerns in the era of smart health, as the widespread digitisation of health information raises questions about the confidentiality, integrity, and ownership of personal health data. It also emerged during the roundtables organised by the EPC, as part of the smart health project supported by Vodafone Institute for Society and Communications, citizens harbour concerns about their data, which could potentially be misused or accessed by unauthorised actors with malicious intents.[37] If not addressed, these concerns could undermine attempts to tap into the potential of smart health. For this reason, it is of the utmost importance to make privacy and data protection measures in the infrastructure needed to digitise health. Only by doing so can we maximise trust and harness the potential benefits that technological strategies can offer in smart healthcare.

CYBERSECURITY

Cybersecurity can be viewed almost as a complementary concern when it comes citizens' fears surrounding the use of AI and other digital tools for health and in healthcare systems. The threat of cybersecurity attacks increases with greater use of and sharing of data within health systems.

The threat of cybersecurity attacks increases with greater use of and sharing of data within health systems.

Analysis from the European Union Agency for Cybersecurity (ENISA) shows that between the period of January 2021 to March 2023, the EU health sector witnessed a high frequency of cyberattacks, with 53% affecting healthcare providers and 42% targeting hospitals. Ransomware emerged as a major threat, implicated in 54% of the incidents and often leading to data breaches or theft, impacting nearly half of all reported incidents.[38] The analysis also highlights the special vulnerability of patient data, which constituted the most targeted asset, showing both the high stakes and ongoing risks in the health sector's cybersecurity challenges.[39]

Therefore, ensuring protection against such risks will be essential not only to avoid data breaches or theft but to also build trust amongst citizens who may be reluctant to buy into smart worlds for health due to fears related to the threat of cyberattacks and theft of data especially given the sensitive nature of health data. A potential solution to this issue of trust in the context of cybersecurity of medical smart devices could be a thorough vetting of new technologies and their manufacturers, including searching for any history of non-compliance with EU standards.

ADOPTION OF DIGITAL HEALTH INNOVATIONS WITHIN HEALTHCARE SYSTEMS

Ensuring health systems are adequately prepared enabling smart health is essential. Healthcare systems have been slow to embrace digital health innovations, including AI. While the adoption of telemedicine increased during the COVID-19 pandemic, the healthcare sector still lags behind other industries in implementing and scaling up innovation.[40] A key reason for this slow adoption is concern over safety and potential harm from new technologies. Additionally, the fragmented data infrastructure poses a challenge, making it difficult to scale up innovation and realise the full potential of technology investments, particularly for AI which relies heavily on quality data for training.[41] Standardising digital health data is crucial to ensure compatibility and interoperability across different systems and devices, allowing for seamless data exchange and analysis. Moreover, investing in robust digital infrastructure is essential to support the scalability and sustainability of smart health solutions, especially considering the diverse needs and capacities of different healthcare settings.

ENSURING ACCESS AND AVAILABILITY

In addition to the challenge of ensuring health systems are prepared for smart health, investment must also be placed across the health ecosystem to ensure smart health can be adopted most holistically. Therefore, connectivity plays a central role. Ensuring access across the EU will be essential to avoid the risk of exacerbating already existing inequalities and the creation of new ones whereby the absence of necessary infrastructure prevents the equitable rolling out of smart worlds for health. Health digitalisation and the deployment of AI tools within the context of smart worlds should only be deemed a successful endeavour if it ensures greater access and availability of healthcare to all populations.

Without the necessary infrastructure and associated investment both across and within all member states there is a risk that digital health solutions and the smart world for health will not be accessible to all, therefore, broadening already too wide health inequalities in both within and between EU countries.

Smart worlds for health are not confined within the parameters of the EU or Europe but there are many opportunities for health at the global level. The application of AI and other digital technologies holds the potential to vastly enhance global access and improve the availability and quality of care, rendering better patient outcomes the regions across the world. However, data ownership, respect for personal data privacy and the establishment of global data spaces are required to harness the potential of digitalisation effectively across all regions and to address new inequalities and biases proactively.[42]

EXACERBATION OF EXISTING BIAS AND INEQUALITIES

Additional obstacles hinder the realisation of the advantages of smart worlds for health and, in fact, pose further dangers of perpetuating existing disparities. Inadequate and biased data pose a significant risk, as current inequalities in healthcare can seep into the conception, development, and deployment of AI and other digital tools. Bias may manifest during data collection, algorithmic design, and human interpretation, particularly in machine learning where existing biases in training data can be replicated. Ensuring data diversity throughout all stages of AI development is crucial to prevent the perpetuation of inequalities. Nonetheless, challenges arise regarding data inclusivity, as datasets utilised to train, assess, and refine AI models often lack representation of diverse populations, such as ethnic minorities, migrants, and socioeconomically disadvantaged individuals, who may have limited or irregular access to healthcare systems.[43]

Without AI models trained using data sets from diverse regions, there is a risk that under-resourced regions will not fully benefit due to an inadequate algorithmic service.

The use of health data from diverse regions for areas such as treatment, surveillance and research is also crucial to ensure the benefits of emerging technologies and enhancement of existing ones are reaped globally in areas such as treatment, surveillance and research. Without AI models trained using data sets from diverse regions, there is a risk that under-resourced regions

will not fully benefit due to an inadequate algorithmic service to these populations and, consequently, a global shortfall in algorithmic efficacy. Thus increased efforts must be made to avoid the exacerbation of inequities and biases between regions and shift towards integration overcoming the challenges of data fragmentation of data collection platforms.[44]

ADDRESSING HEALTH LITERACY

Additionally, health literacy emerges as a fundamental consideration in the context of smart health, particularly given the rapid pace of technological innovation. The lack of digital health literacy, especially among older populations, poses a significant barrier to the adoption and effective utilisation of digital health technologies. The 2023 Digital Decade report identifies increasing digital skills in the population as one of the biggest challenges of the EU, highlighting that 46% of Europeans do not possess the basic skills required for everyday tasks and access to online services.[45] In this context the EU has set targets to improve basic digital literacy under the digital decade policy programme. It aims to ensure that 80% of the population possesses basic digital literacy by 2030.[46]

The lack of digital health literacy, especially among older populations, poses a significant barrier to the adoption and effective utilisation of digital health technologies.

Without significant improvements in digital literacy the true impact of smart worlds will not be felt and the benefits not reaped by populations across the EU. Improved digital health literacy leads to better health outcomes by empowering individuals to use technologies to understand their health conditions, follow treatment plans accurately, and engage in preventive health behaviours. Improving digital literacy levels will also help broker trust towards digital tools as enhanced knowledge coupled with skills to wield the tools could foster confidence in their use, highlighting the benefits they can bring.

TACKLING THE SKILLS GAP

Patients must be afforded the adequate skills to use digital tools, but healthcare professionals must also be equipped with the necessary skills and knowledge. While AI and digital tools offer the potential to ease the burden placed on healthcare professionals, without the necessary skills and knowledge, there is a risk that these tools will end up doing the exact opposite. In the

context of an informal meeting of health ministers, the Belgian Presidency[47] outlined that the advent of new technologies present difficulties in ensuring that healthcare professionals possess adequate digital skills. Discussions regarding task delegation and the incorporation of technologies such as AI underscore the complexities involved in reshaping healthcare delivery.[48]

With Europe's health systems facing shortages and issues with attraction and attrition of healthcare workers, it is paramount that digital skills are prioritised to ensure their benefits are felt. There are several initiatives at the EU level, which aim to address digital skills gaps including projects such as the EU's Bewell
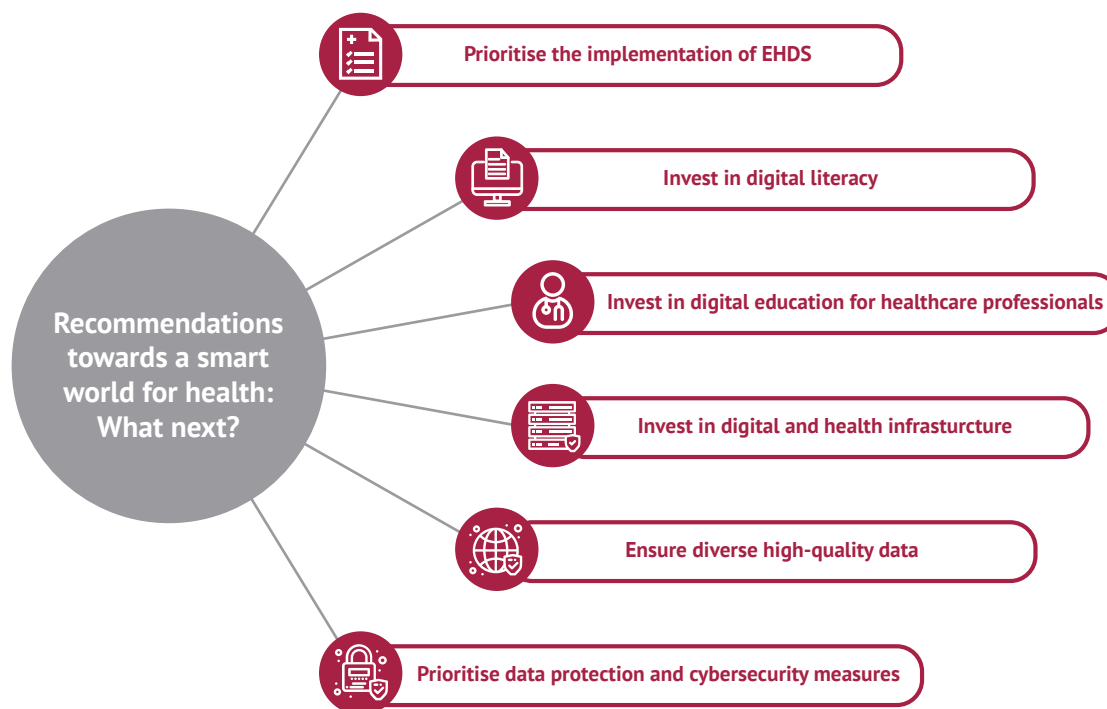
project[49] and further initiatives under the Public Health Programme, EU4Health and joint actions under the remit of DG SANTE. The Recovery and Resilience facility has also played a role in supporting the digitalisation of healthcare in member states . It has provided funding and resources to enhance digital infrastructure, develop advanced health technologies, and improve data management systems. Additionally, it has focused on upskilling healthcare professionals. However, the skills gap persists. The ever-evolving nature of health technologies requires a long-term approach to upskilling and reskilling, otherwise the technological advancements will be futile.

Recommendations

TOWARDS A SMART WORLD FOR HEALTH: WHAT NEXT?

Adopting a smart world approach can yield numerous benefits. However, realising these benefits necessitates overcoming the challenges outlined. Underpinning each of the outlined challenges is trust. Therefore, tackling each of these challenges is important not only to address the individual issue itself but to also create

the correct conditions to build trust and obtain buy-in from populations. Otherwise, smart worlds for health will remain merely an idea or concept, rather than becoming a true reality. As such a number of actions are required at both the EU and member state level. Building on the input received during the roundtable discussion, we set out a number of recommendations to overcome the outlined challenges and transition towards a smart world for health.

Recommendations towards a smart world for health: What next?

- Prioritise the implementation of EHDS
- Invest in digital literacy
- Invest in digital education for healthcare professionals
- Invest in digital and health infrasturcture
- Ensure diverse high-quality data
- Prioritise data protection and cybersecurity measures

PRIORITISE THE IMPLEMENTATION OF EHDS

While we can acknowledge the strides made during the current mandate, the focus must now shift to the importance of the implementation of the EHDS across member states:

► Member states must place emphasis on the implementation of the EHDS. With member states starting at different points of departure is essential so that those who lag behind prioritise the implementation of the EDHS.

► The EU needs to provide sufficient support to member states in the rolling out of the EHDS in terms of funding to allow for investment in the necessary infrastructure and support in knowledge building and sharing of best practices. Some positive examples can be observed with the support DG REFORM has offered member states and regions with regards to health digitalisation more broadly.

► Alignment between these initiatives and existing legislation such as GDPR is essential. Complementarity between the EHDS and AI Act is also crucial for effective implementation.

INVEST IN DIGITAL LITERACY

Increasing digital literacy levels across the EU is essential for the success of smart worlds for health and to indeed ensure the digital transition needs nobody behind. Meeting the European Commission's digital decade target of equipping 80% of the population with basic digital skills by 2030 are non-negotiable:

► Member states must ensure adequate and accessible opportunities for all segments of society to guarantee that digital literacy will not impede smart health and result in widening access to healthcare and in turn health inequalities.

► At the EU level ongoing initiatives such as the European Skills Agenda and Digital Education Action Plan must be leveraged to ensure the target is met.

INVEST IN SMART HEALTH EDUCATION FOR HEALTHCARE PROFESSIONALS.

Healthcare professionals are essential to ensuring the potential of smart worlds for health. However, they must be equipped with the necessary skills and knowledge:

► Member states must ensure that entry-level training circulars include a strong digital component to ensure those entering the healthcare workforce are provided with the digital skills and knowledge required for future-proof health systems, of which AI and other digital tools will be a strong feature.

► An EU-level skills programme should be adopted and incorporated into the European Health Union to facilitate cross-border training for healthcare professionals across the health ecosystem. Digital skills should be central to this to bolster the exchange of expertise and best practices ultimately contributing to diminishing healthcare disparities across the EU. The forthcoming Skills Strategy, a component of an ongoing Erasmus+ initiative, could serve as a guiding framework to tackle existing skill deficiencies across all 27 EU member states.

INVESTMENT IN DIGITAL AND HEALTH INFRASTRUCTURE AT MS LEVEL

Smart worlds for health require digital infrastructure which necessitates investments. A shift in thinking is required whereby health spending is viewed not as a cost but as an investment:

► Member states must prioritise their health spending, avoiding cost cuts in budget reviews. Instead, investment in health spending should be prioritised, especially around health prevention and promotion. Smart worlds have the potential to reduce burdens on health systems but without adequate investment, they will be unable to do so.

► At the EU level, efforts must be made to streamline healthcare spending across EU initiatives such as the RRF and the European Semester. Initiatives targeting prevention and health promotion should be recognised as investments across member states, fostering sustainable and inclusive economic growth through investment and reform.

ENSURE DIVERSE HIGH-QUALITY DATA

Without diverse quality data, smart worlds for health are likely to reproduce the existing health inequalities. To avoid this, emphasis must be placed on data quality through the life cycle of smart worlds, starting from research through design and conception of tools, up until their utilisation. Obtaining diverse, high-quality data requires:

► A common EU framework should be established to define data quality standards for research and innovation across member states. The FAIR data principles[50] should be used a basis for such framework. This would provide member states with guidance to ensure quality representative data.

► Collaboration must be prioritised between the EHDS and other health data spaces to promote the collection and use of diverse data. For example, close collaboration should be established between the EHDS and the development of an African health data space.

PRIORITISE DATA PROTECTION AND CYBER-SECURITY MEASURES

► Thoroughly check devices applied in the medical sector and vet their manufacturers. Devices should be extensively checked for potential risks before entering the market, as IoT could easily be hacked if not well protected. Likewise, manufacturers should also be thoroughly vetted to check for any history of non-compliance with EU health and digital acquis.

► IoT devices should follow the principle of privacy by design and by default to minimise vulnerabilities in the technology.

► Ensure that adequate consent mechanisms are in place when it comes to data health sharing and re-use. Member states should guarantee granular rights, as opposed to a blanket consent approach. Citizens should be allowed to decide among which data collection practices they want to consent to and which they would instead prefer to opt out of. Only by doing so they will be able to increase trust among the population and to potentially collect bigger volumes of data.

Digital healthcare systems need to be heavily encrypted to ensure the anonymisation of data and minimise the chances of severe data leaks caused by cyber-attacks.

1   Ghulam Muhammad, Fatima Alshehri, Fakhri Karray, Abdulmotaleb El Saddik, Mansour Alsulaiman, Tiago H. Falk (2021) "A comprehensive survey on multimodal medical signals fusion for smart healthcare systems" *Information Fusion*, Volume 76 pp 355-375.

2   Brady Danielle (2022) "Building public trust to successfully deploy AI in EU healthcare", Brussels: European Policy Centre.

3   Organisation for Economic Co-operation and Development/European Union (2020), Health at a Glance: Europe 2020, Paris: Organisation for Economic Co-operation and Development.

4   European Commission, "EU Digital COVID Certificate", Official Website, 2024.

5   European Commission, "European Data Governance Act", Official Website, February 27, 2024.

6   European Commission, "Data Act", Official Website, April 4, 2024.

7   European Commission, "Shaping Europe's digital future", Official Website, 22 May 2024.

8   European Commission, "European Health Data Space", Official Website, 2024.

9   Brady Danielle & Elizabeth Kuiper (2023), "Is the European Union ready for the challenges of the 21st century", Brussels: European Policy Centre.

10 Greenacre, Martin, "Proposal on health data access for research falters over patient consent", *Science Business*, 12 March 2024.

11 *Ibid*.

12 Primary use refers to the sharing of patient data with medical personnel.

13 Secondary use refers to the sharing of patient data with other parties for research purposes.

14 European Parliament (2024) "EU Health Data Space to support patients and research", Press Release, 15 March 2024.

15 European Commission, "Political agreement on European Health Data Space", Official Website, March 15, 2024.

16 Semantic interoperability refers to ability of systems or services used for data exchanges to understand and preserve the format of the information.

17 Mauer Nicole & Dimitra Panteli (2023) "Implementing digital solutions and AI", Brussels: European Observatory on Health Systems and Policies.

18 DIGITALEUROPE (2021), "DIGITALEUROPE's initial findings on the proposed AI Act", Policy Paper, 10.

19 European Commission, "AI Act", Official Website, 6 March 2024.

20 Bekbolatova Molly, Johnathan Mayer, Chi Wei Ong & Milan Toma (2024) "Transformative Potential of AI in Healthcare: Definitions, Applications, and Navigating the Ethical Landscape and Public Perspectives. Healthcare" Healthcare (Basel). Volume 12, Number 125.

21 Science Direct, (2022) "Clinical Decision Support System" (accessed May 24 2024).

22 Johnson KB, Wei WQ, Weeraratne D, Frisse ME, Misulis K, Rhee K, Zhao J, Snowdon JL. (2021) "Precision Medicine, AI, and the Future of Personalized Health Care" Clinical and Translational Science.

23 Pinto-Coelho Luis (2023). "How Artificial Intelligence Is Shaping Medical Imaging Technology: A Survey of Innovations and Applications", Basel: Bioengineering, Volume 18, Number 10.

24 Johnson KB, Wei WQ, Weeraratne D, Frisse ME, Misulis K, Rhee K, Zhao J, Snowdon JL. "Precision Medicine, AI, and the Future of Personalized Health Care" (2021) Clinical and Translational Science.

25 European Commission (2021)"COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL Europe's Beating Cancer Plan" Brussels.

26 European Commission "European Cancer Imaging Initiative" (accessed 12 December 2023).

27 Van der Schaar Mihaela (2023) "AI-powered personalised medicine could revolutionise healthcare (and no, we're not putting ChatGPT in charge)", The Guardian.

28 OECD (2023), Health at a Glance 2023: OECD Indicators, Paris: OECD Publishing.

29 Kerr Deborah A. *et al*, (2016) "The connecting health and technology study: a 6-month randomized controlled trial to improve nutrition behaviours using a mobile food record and text messaging support in young adults" Int J Behav Nutr Phys Volume 21, Number 52.

30 Bond Ashley, Kevin Mccay & Simon Lal (2023) "Artificial intelligence & clinical nutrition: What the future might have in store"Clinical Nutrition ESPEN, Volume 57.

31 Karim Lekadir (2022) "Artificial intelligence in healthcare Applications, risks, and ethical and societal impacts" Brussels: European Parliament

32 World Health Organisation, (2023) "Artificial intelligence in mental health research: new WHO study on applications and challenges" (accessed 23 April 2024).

33 Ettman Catherine & Sandro Galea (2023) "The Potential Influence of AI on Population Mental Health". JMIR Ment Health, Volume 16, Number 10.

34 Conner-Simons Adam & Rachel Gordon, (2020) "Algorithm reduces use of riskier antibiotics for UTIs" *MIT News*.

35 Council of the EU (2024) "European Health Data Space: Council and Parliament strike deal" (accessed 20 April 2024).

36 Prainsack, Barbara, et al., "Data solidarity: a blueprint for governing health futures", *The Lancet*, November 2022.

37 Towards European Health Data Space, "Qualitative study to assess citizens' perception of sharing health data for secondary use and recommendations on how to engage citizens in the ", Report, 31 March 2023.

38 Theocharidou Marianthi & Ifigeneia Lella (2023) "ENISA THREAT LANDSCAPE: HEALTH SECTOR" European Union Agency for Cybersecurity.

39 Theocharidou Marianthi & Ifigeneia Lella (2023) "ENISA THREAT LANDSCAPE: HEALTH SECTOR" European Union Agency for Cybersecurity.

40 Anderson Brian &. Eric Sutherland (2024), "Collective action for responsible AI in health", Paris: OECD Publishing, Paris.

41 *Ibid*.

42 Fransen Lieve, Danielle Brady & Elizabeth Kuiper (2024) "Global health 2.0: paving the way for the future" Brussels: European Policy Centre.

43 Brady Danielle (2022) "Building public trust to successfully deploy AI in EU healthcare", Brussels: European Policy Centre.

44 Fransen Lieve, Danielle Brady & Elizabeth Kuiper (2024) "Global health 2.0: paving the way for the future" Brussels: European Policy Centre.

45 European Commission (2023) "Report on the state of the Digital Decade" European Commission.

46 European Commission "Europe's Digital Decade: digital targets for 2030" (accessed 25 May 2024).

47 Belgian Presidency Council of the European Union (2024) "Informal meeting of health ministers" (accessed 27 April 2024).

48 Belgian Presidency Council of the European Union (2024) https://belgian-presidency.consilium.europa.eu/en/events/informal-meeting-of-health-ministers-23-244/"Informal meeting of health ministers" (accessed 27 April).

49 Bewell "Blueprint alliance for a future health workforce strategy on digital and green skills" (accessed 23 May 2024).

50 FAIR data is data which is findability, accessibility, interoperability, and reusability.

The **European Policy Centre** is an independent, not-for-profit think tank dedicated to fostering European integration through analysis and debate, supporting and challenging European decison-makers at all levels to make informed decisions based on sound evidence and analysis, and providing a platform for engaging partners, stakeholders and citizens in EU policymaking and in the debate about the future of Europe.

The **Social Europe and Well-being Programme (SEWB)** is dedicated to achieving a stronger Social Europe fit to address the social, environmental, economic and political challenges facing the Union today. It focuses on policies that prioritise strong and resilient healthcare systems; modern and inclusive labour markets; eradicating inequalities; investing in the health and well-being of people; making European welfare states and social protection systems fit for the future.

The **Europe's Political Economy Programme (EPE)** is dedicated to covering topics related to EU economic governance, the single market, industrial and digital policies, and strategic autonomy in a context of deep geo-economic and technological shifts. The Programme has contributed actively to these debates over past years, leveraging its convening power, analysis and multistakeholder taskforce model. EPE analysts pioneered the concept of a 'wartime economy' following Russia's invasion of Ukraine, and the Programme is currently running projects focusing on the EU's ambitions and the private sector's capacity to deliver on the "triple" green, digital and economic security transitions. As fast-advancing components of 'economic security', digital and emerging technologies, such as quantum, are priority areas of focus. Linked to the changing international context, the Programme also focuses on trade policy, the transatlantic agenda, notably the EU-US Trade and Technology Council, China, and the EU's close economic partnerships (UK, EEA, Switzerland). The EPE Programme consists of a young and dynamic team, with recent recruitments bolstering analytical capacities linked to economic growth and crises, resilience and recovery, emerging tech and cybersecurity.