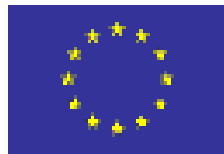


ENABLING THE DIGITAL TRANSFORMATION OF HEALTHCARE

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Overview

In April 2018 the European Commission published a Communication on enabling the digital transformation of health and care in the Digital Single Market, empowering citizens and building a healthier society (European Commission 2018a). In this document EPHA responds to the Communication, identifying the adoption of an end-user perspective as the core challenge facing the Commission's plans. The sections which follow outline the contents and context of the Communication, explain what is meant by an end-user approach and why it is important, and offer an end-user perspective on some of the Communication's key points. Finally, a set of recommendations is offered, taking account of the role of digital health in the pursuit of universal healthcare.

The Communication: priorities and planned actions

In its Communication, the Commission outlines a vision to: (a) promote health, prevent and control diseases, address unmet medical need and universal access to high quality care, (b) make health systems resilient and sustainable, (c) stimulate growth and promote industry (European Commission 2018a, 4). In pursuit of this vision, the Communication groups the Commission's priorities and planned actions under three headings.

Citizens' secure access to and sharing of health data (point iii of the Communication) speaks to the overarching principle that citizens should be able to access all of their health-related data, share it with whomever

they choose, and do so across borders. As such, it focuses primarily on electronic health records (EHRs) and ePrescription systems.

The Commission plans four actions:

1. Clarify the role of the eHealth network in the eHealth Digital Service Infrastructure (eHDSI), so as to improve citizen access to data;
2. Adopt a Recommendation on a common technical specification for EHR formatting;
3. Support the use of eHDSI in new areas, such as public health and research;
4. Mobilise funding, from the Connecting Europe Facility (CEF), Horizon 2020 and the next Multiannual Financial Framework (MFF), for collaboration between member states and regions.

Better data to promote research, disease prevention and personalised health and care (point iv of the Communication) is primarily about the use of genomic and other health data for research and personalised medicine. It therefore focuses on technical specifications for access and exchange of data, as well as incentives for research and pilot projects. The Commission plans four actions:

1. Establish a voluntary coordination mechanism for sharing of genomics and other data;
2. Support the creation of technical specification for access and exchange of datasets for research;
3. Launch pilot actions to test the practical application of cross-border health data exchange;
4. Mobilise the above actions with funding



from the CEF, Horizon 2020 and the next MFF.

Digital tools for citizen empowerment and for person-centred care (point v of the Communication), discusses the need to shift to a prevention-based model, to focus on well-being (rather than disease) and to integrate care. It acknowledges the considerable barriers to this shift in terms of investment and knowledge and, therefore, focuses its four planned actions more closely on stimulating industry and building capacity in authorities:

1. Promote common principles for validating and certifying health technologies;
2. Support the exchange of best practice, capacity building and technical assistance, using funds from Horizon 2020, the Structural Reform Support Programme (SRSP), the third Health Programme and the next MFF;
3. Raise awareness about innovation procurement and investment in health digitalisation;
4. Promote knowledge and skills in citizens, patients and healthcare professionals (HCPs) in collaboration with health professional organisations and academia.

The Communication was published in response to a set of Conclusions adopted by the Council of the EU in November 2017 (Council of the EU 2017). These identify a lack of infrastructure and technical interoperability as the underlying barrier to the digitalisation of health and care across Europe. As such,

they urge Commission and member state action to develop interoperable systems for sharing data, adopt common specifications, indicators and guidelines, and to cooperate in pooling knowledge and resources, sharing best practice and facilitating ‘necessary convergence’. The Conclusions also highlight the relevance of health literacy, patient empowerment and HCP capacity as crucial determinants of the efficacy of digital health systems. The Council draws attention to differences in digital and health literacy, which need to be considered ‘in order to avoid creating further health inequalities’ (Council of the EU 2017, point 23), to the need for skills development for HCPs and to the importance of putting citizens at the centre of the development of digital health.

The Conclusions themselves were adopted in the context of the EU eHealth Action Plan 2012-2020 (EHAP) and the mid-term review of the Digital Single Market strategy (which replaced the mid-term review of the EHAP). The former is based on exploiting market opportunities for digital health tools and targeting barriers to their wider deployment, whilst the latter noted their potential for improving peoples’ health and increasing the sustainability of health systems. However, as EPHA noted at the time, none of these frameworks goes far enough in recognising and accounting for the importance of inclusivity and accessibility in the development of digital health (EPHA 2018).

The Communication maintains the EHAP’s vision for a digitalised health sector which promotes health and well-being, prevents



disease, addresses unmet medical need and fosters universal healthcare but, regrettably, also mirrors the EHAP's lack of concrete actions to implement this vision. The various commitments made focus upon technical barriers and serve the objectives of improving cross-border implementation and market development much more closely than those around health promotion and disease prevention. The Communication also follows the EHAP in making minimal reference to digital literacy and training as core requirements for wider uptake of digital health technologies. By contrast to the Council Conclusions, which specifically recognise the need to ensure that measures in the area of digital health do not 'creat[e] further health inequalities' (Council of the EU 2017, point 23) the Communication notes the risk of a 'digital divide' but offers no strategies for mitigation. Moreover, both the Communication and the Council Conclusions fail to reflect the notion of a digital divide in their understanding of digital health end-users. They refer to citizens, patients, HCPs and public authorities (different end-user 'roles') but not the elderly, migrants, the disabled, or other 'non-traditional' users of digital health (different end-user 'groups'). In doing so, they overlook a crucial dimension of both end-user involvement and the inequalities which can be exacerbated by digital health technologies.

In sum, whilst the Communication presents a comprehensive and action-focused approach, it does not provide the necessary follow-up to the EHAP. The concrete actions it identifies are almost exclusively

in the domains of market development and technical infrastructure; by contrast, actions on promotion, literacy and inequalities are minimal and vague, without tangible plans for implementation. Moreover, the Communication does little to address the fundamental governance issue and create a digital health arena that is led by and concerned with health objectives, rather than market actors and commercial interest.

The challenge: adopting an end-user perspective in the development of digital health

As the Digital Health Society notes, a recent and influential set of recommendations on research and innovation in the EU highlights the importance of involving end-users in research projects, so as to ensure that outputs have the maximum impact (Mazzucato 2018). This section examines what it means to adopt an end-user perspective on digital health and how it can be achieved in practice.

What is meant by an end-user perspective?

'Meaningful involvement of end users means establishing an effective co-creation process for digital health tools, in order to ensure that the development and implementation of digital health policy is driven by actual health and practical needs of people...rather than by the demands of the market.' (EPHA 2017)

By end-users, we refer to anyone making use of the technologies designed, manufactured, procured and regulated by the network



of research, industry and public authority stakeholders that makes up the digital health arena. This includes patients, consumers and citizens – the individuals whose care journey or health status is the subject of data collection – as well as carers and HCPs – who must make use of this data to facilitate care and adapt to its role in care models – and healthcare providers, system managers and the health system itself, into which the use of such tools must be integrated. These clusters of actors comprise our traditional understanding of digital health end-users.

However, drawing on the work done by the eHealth Stakeholder group (EHSg), which emphasised in its 2014 Health Inequalities and eHealth report the needs of ‘non-traditional’ digital health users, we can expand this traditional understanding. Taking the different end-user roles (patient, professional, provider / system) as one dimension, we can see a second dimension which accounts for the different end-user groups. As noted by the EHSg, these might include, among others: people with disease-specific conditions, older people and children, people with disabilities, people with mental illness, people who have had less educational opportunity, those affected by poverty and unemployment, migrants and ethnic minorities, those living in geographically excluded areas and individuals wishing to ‘opt out’ of such care tools (eHealth Stakeholder Group 2014). The health needs of these groups, as well as the opportunities for and barriers to digital health implementation among them, differ greatly from those which are highlighted when considering end-user roles alone.

Adopting an end-user perspective therefore means taking into account:

- The needs, preferences and priorities of end users in different roles – citizens, consumers, patients, carers, HCPs, health system managers, local authorities and providers.
- The needs, preferences and priorities of end users in different groups or situations – such as those with specific conditions, of ethnic minorities, living in poverty or without access to necessary infrastructure.

The perspectives of different end-user roles and groups can be included and involved at any point in the digital health development process. Thinking about the creation of the technologies and tools themselves, users might be incorporated at the very start, acting as partners in the design; at the other end of the process, users might be invited to test and trial an end product (Birnbaum et al. 2015). Beyond the design of the specific tools and interventions, end-users can also be fruitfully involved in the development of regulation and policy around digital health, especially in areas such as privacy, security and portability.

Why is it important to account for end-user perspectives?

Adopting an end-user perspective is a clear and actionable way to address many of the weaknesses and risks of the current digital health agenda. By understanding end-users in the holistic manner outlined above – taking account both of different roles and of different



groups of end-users – planned actions can better account for health inequalities, facilitate more appropriate governance of digital health and strengthen existing mechanisms for end-user involvement. This is because:

- Focusing on different groups of end users, rather than just different roles, highlights the potential for exacerbating inequalities and establishing a ‘digital divide’ in health.
- The various end-users identified above have in common a concern with health – either their own personal health status or the functioning of the health system and provision of care – thus providing a stronger health ‘steer’ and ensuring that digital health does not develop in a separate silo from other health issues.
- Taking a more holistic view of end-users will prompt a more holistic approach to their involvement, ensuring that end-users are included at every step of the conception, design, implementation and evaluation cycle, as well as in accompanying processes of regulation, policy-making and resource allocation.

There is also a wealth of evidence which confirms the importance of adopting an end-user perspective when developing digital health technologies and illustrates the advantages of doing so. Such an approach has been shown to increase the engagement of patients in their care (Steinhubl, Muse, and Topol 2013, Barelllo et al. 2016), improve their health outcomes (Hibbard et al. 2007) and

result in the design and creation of better digital health technologies (Slater et al. 2017). Moreover, research suggests that a lack of attention to users’ needs and perspectives hinders the uptake of digital health technologies (Campling et al. 2017).

An end-user response to the Commission Communication

A comprehensive analysis of the Communication from the perspective of end-users is beyond the scope of this report but the sections below use the Communication’s main themes to offer some indication and examples of how the incorporation of end-user perspectives might inform the priorities and actions of the EU’s digital health agenda.

Citizens and their data: ePrescriptions, EHRs and cross border care

The Communication recognises – in its links to the General Data Protection Regulation, among other initiatives – that trust in the system of data collection, storage and exchange is key to encouraging uptake of digital health technologies. Inherent to this is *literacy and informed consent*. Users need to understand when they are consenting to share their health data, what health data they are sharing, and with whom. HCPs need to have confidence that the data they are sending will reach its destination securely, and that the data that they are receiving is genuine in its origin. This implies that digitalisation needs to be accompanied not only by a rigorous regulatory framework for security and privacy, but also by a programme of education and awareness raising. Moreover, when learning about how digital



health systems work, end-users need to be confident that they serve health interests. If the tools and applications involved are designed with commercial or economic objectives in mind, end-user trust will be weakened from the outset.

The expansion of the eHealth Digital Service Infrastructure to encompass EHRs, as well as ePrescriptions and Patient Summaries, is an important and valid next step in the digitalisation of healthcare cross Europe. It is also vital to the facilitation of cross border healthcare and the mobility of patients, professionals and health services. However, in establishing the infrastructure to support coordination and care between member states, the construction of robust, end-user focused domestic EHRs must not be overlooked. Expansion should take a two-stage approach.

1. Developing strong domestic EHR systems.

EHR systems need first to function and improve outcomes in the domestic health system, providing practical benefit to all end-users. Though not attributable to any single issue, research has found that this benefit is unclear, in some cases, to HCPs. Responding to a study in the US, clinicians report that EHRs do not help them to accomplish 'high-level tasks', such as communication and coordination of care between teams (Unni et al. 2016). A project in New Zealand found that, with the right educational and training support, community nurses and nurse leaders / managers can use digital health tools very effectively. However, the study also highlighted that, when asked about

their views on the system and its efficiency, nurses cited problems with duplication of paper and electronic records, multiple logins for different systems (resulting in shared and lost passwords) and difficulties with accessing patient notes in some settings (Walker and Clendon 2016). Seeking to learn from these kinds of mistakes, a new Constructive eHealth evaluation mechanism has been trialled in Denmark. It included clinicians, IT professionals, administrators, and vendors in the development of EHRs across 4 case study hospitals, and showed '...a need for a) Early involvement of clinicians, b) The best possible representation of clinicians, and c) Workload reduction for those involved' (Høstgaard, Bertelsen, and Nøhr 2017, 12). Moreover, the study concluded that '[t]he consequences of not providing this were a lack of ownership of decisions and negative attitudes towards the clinical benefits related to these decisions'. Though individual settings vary, it is clear that HCPs need to be more closely involved in the development of EHR systems to ensure wider acceptance.

Research on patient, as opposed to HCP, perspectives on EHRs is scarce (indicating a more general oversight in this area of digitalisation) but there is some indication that patients and consumers are most concerned about privacy, data breaches and medical identity theft. Moreover, patients in the US express concern about conflicting regulatory regimes between state and federal level (Mathai, Shiratudin, and Sohel 2017), suggesting that patients might favour an EU level regulatory framework to divergent national regimes if they feel that this creates



a more secure system for EHR storage and sharing.

As critical as security and operability, but more often overlooked, is the content of EHRs. End-users need to be closely engaged in the development of EHR systems – inputting into initial design and feeding back on day-to-day operation – to ensure that they contain the information that patients, HCPs and health systems need to deliver high quality care. Does the record include the necessary, disease-specific fields needed to treat patients with particular conditions? Does it contain the information necessary to ensure continuity of care that is culturally and socially appropriate for a particular patient? Is there space for non-medical or non-clinical information that is relevant to treatment or diagnosis? Involving end-users, from different roles and groups, in design and evaluation of EHRs can help to ensure that they serve real and practical needs.

2. Supporting cross-border healthcare.

The development of strong, trusted and accessible EHR systems at national level will underpin the establishment of an EU-wide EHR system, essential for cross-border care. ‘Mobility of data’ has been described by the Commission as the fifth freedom of the EU, alongside capital, goods, people and services (European Commission 2016). The Patients’ Rights in Cross-border Healthcare Directive, adopted in 2011 to clarify patients’ rights when receiving care in another member state, also establishes voluntary mechanisms for the development of digital health technologies, emphasising their centrality in facilitating

cross border care. The European Reference Networks (ERNs), for instance, rely upon telemedicine and remote networking of HCPs and system managers to share knowledge in the treatment of rare diseases. For patients, care abroad is facilitated by initiatives to harmonise and exchange EHRs, ePrescription systems and patient summaries.

The advantages and benefits of this digitalisation of cross-border care are similar to those of digitalising in-country, domestic care. For patients and HCPs fewer medication errors, improved prescribing practices and greater coordination of care are promised; for health systems, streamlined billing processes and fewer errors offer efficiency incentives (see Menachemi and Brooks 2006). For patients needing or seeking cross-border care, and the professionals and health systems delivering it, such benefits are magnified. Findings from the epSOS (European patient smart open services) project, which developed and tested a set of cross-border digital health services, suggest that physicians and pharmacists foresee benefits for communication, clinical safety and patient management. Moreover, the project specifically identifies language barriers and concerns / inconvenience around lost or incomplete paperwork as areas where EHRs facilitate better care, and the provision of complete medical histories as enabling HCPs to feel more confident when treating patients (Almazán et al. 2015).

The Commission’s latest report on the implementation of the Patients’ Directive suggests that the reported minimal uptake by



patients continues to be attributable to lack of information or legal certainty, rather than to any digital barrier (European Commission 2018b). As such, the focus should continue to be upon making patients aware of their rights vis-à-vis cross-border care, and on ensuring HCPs are equipped (primarily through access to relevant medical information in the appropriate language) to treat patients from other member states to the same high standard as domestic patients. However, given its role in facilitating this care, it is also important that digital health solutions such as EHRs are advanced with interoperability and collaboration in mind. In addition to improving care outcomes and efficiency in national systems (as seen in the Estonian EHR system as a strong example of how this can be done well), EHRs can help address language barriers, fragmentation of paper health records, challenges to continuity of care, and many other barriers to seeking cross-border care.

Data, research and personalised medicine

‘Personalised medicine: a move away from a “one size fits all” approach to the treatment and care of patients with a particular condition, to one which uses new approaches to better manage patients’ health and target therapies to achieve the best outcomes in the management of a patient’s disease or predisposition to disease.’ (NHS England 2016, 6)

From a patient perspective, personalised medicine holds the potential to improve (NHS England 2016, 12-13):

- Prevention: genomic technologies offer

the possibility to identify those most at risk of particular diseases, to intervene before symptoms have presented.

- Diagnosis: rather than being based purely on symptoms, diagnosis in the personalised medicine model can be based on a variety of other information, such as particular molecular and cellular processes. This presents the potential to make much more accurate diagnoses of what exactly is causing the symptoms and the effects that they are having.
- Treatment: With better diagnosis comes more targeted treatment. Personalised medicine offers an opportunity to reduce reliance on ‘trial-and-error’ prescribing, which can have unpleasant side-effects for patients, to better informed interventions and prescriptions.
- Participation: at each of the above stages, a greater range and higher quality of information can help inform better discussions between patients and healthcare professionals. Technologies can provide rapid and real time data for use at the point care, whilst predicting risk can prompt engagement with the health system at an earlier stage.

As such, personalised medicine should, by definition, involve end-users more closely than traditional models of care. However, in reality this depends on the scope and cost of the personalised intervention proposed and the knowledge capacity / health literacy among end-users.



Big data for population-based personalised medicines. Though personalised medicine is commonly understood to refer to interventions at the level of the individual, it also has a population-level form, whereby data for large numbers of people is aggregated and used to design better-targeted interventions for particular groups – such as those in defined regions or at a specific life-stage. The development of big data presents a wealth of new information for use in public health but also presents a risk. Such data is detached from the data subject and, as such, does not necessitate end-user involvement in the product / intervention development process. This exclusion makes it less likely that the resulting tools and actions will respond to genuine needs, or produce positive health outcomes. However, population-level personalised medicine may be viewed as a more equitable investment of health system resources, depending upon the focus of the intervention, than individualised medicine.

Literacy for individualised interventions.

As with any kind of healthcare, end-users can only participate fully in personalised medicine programmes if they are sufficiently well informed and skilled to do so. There is little research on end-user experiences with genomic data but a recent study, which explores the expectations of cancer patients receiving genomic-sequencing, finds that most are unfulfilled. 'At baseline, the vast majority of patients expected to receive several potential direct benefits from [genomic] study participation, including written reports of sequencing findings (88%),

greater understanding of the causes of their cancer (74%), and participation in clinical trials for which sequencing results would make them eligible (84%). In most cases, these benefits were not realized' (Roberts et al. 2019). Another study reports a similar level of uncertainty in patients undergoing genomic-sequencing, indicating a need to reinforce end-user understanding of the development and implementation of this technology (Hyland et al. 2018). Moreover, there is even less evidence of HCP perspectives on personalised medicine. One HCP commentary indicates that much genomic data adds little to the care process and thus clinicians see minimal added value in using it – the exception here is deemed to be pharmacogenomics (the study of predictors of response to treatment), which has the potential to drastically alter, and improve, care through better prescribing (Kitsios and Kent 2012).

From a health systems perspective, the introduction of digital health technologies and personalised medicine must take account of both direct and indirect impact. A genomic test increasing detection of bone development abnormalities in infants might soon reduce the demand for orthopaedic surgery, for instance, but might also mean that such surgeries are no longer available, except in specialist centres. This indirectly reduces access for those still requiring such services (The Topol Review 2018). From a HCP perspective, digital health technologies might provide access to valuable, real-time data about patients' condition since their last home visit, facilitating personalised care,



but can also reduce the amount of ‘face-to-face’ time as consultations become centred on screens and devices (NASEM workshop summary 2016).

Though involvement of different end-user roles is inconsistent, personalised medicine is an area where the needs of different end-user groups could, at least in theory, be directly and productively accounted for. Population-level personalised interventions could target those with particular conditions (diabetes, respiratory diseases, mental health conditions), those from particular age groups (the elderly, children, adolescents), those from particular regions, cities or geographical areas (urban / rural), and many other specific groups. Even individual interventions could prioritise patients from within particular groups, to ensure that they have access to the benefits of digital health. Personalised medicine thus has the potential, with the right data and the necessary will, to be a digital health application that highlights and addresses health inequalities, rather than one which risks their exacerbation. However, in rapidly changing, data-driven health environments there is a danger that disadvantaged groups might fall further behind, which is why EPHA uses the term with caution.

Citizen empowerment and person-centred care

The World Health Organization defines patient empowerment as: ‘A process in which patients understand their role, are given the knowledge and skills by their health-care provider to perform a task in an

environment that recognizes community and cultural differences and encourages patient participation’ (World Health Organization 2009). Though research is hindered by the lack of a common understanding of ‘patient empowerment’ in the digital health context (Risling et al. 2017), digital health technologies are considered to increase empowerment by better informing patients about their health and the care that they receive, by giving them the capacity to take action (for instance, by reporting a new symptom or development in real time) and, in some cases, by facilitating more appropriate care (using information designed for a specific cultural group, for example). When thinking of digital health technologies as tools for empowerment, then, we are primarily referring to a sub-category of more consumer-focused technologies – mHealth apps, telemedicine, wearable sensors and monitors, etc. – rather than genomic therapy or nanomedicine, for instance.

The Communication identifies digital health technologies as an important part of strengthened citizen empowerment and a tool for person-centred care. It also recognises that digital health literacy and adequate training are crucial to facilitate empowerment. In order for digital health technologies to be empowering – i.e. to give patients a more central role in their care and enable them to work in partnership with their HCPs – both patients and HCPs need access to the necessary training and support. The Communication commits the Commission to ‘promot[ing] knowledge and skills of citizens, patients and healthcare professionals



in using digital solutions' but provides no concrete plans for implementation. This is a fundamental weakness of the Communication.

Beyond the absence of adequate implementation mechanisms, there is an extent to which the use of digital health technologies as a tool for empowerment could prove detrimental to equity in and access to healthcare. At the most fundamental level, the use of the term 'citizen empowerment' is problematic. Disparities in access to care and existing health inequalities will be exacerbated where empowerment of citizens is pursued to the exclusion of those groups which increasingly struggle to access the mainstream health system. In various parts of Europe, the long-term unemployed, those living in poverty, those without homes, Roma communities and growing numbers of undocumented migrants face barriers to accessing traditional care. Though there is evidence to suggest that digital health technologies might help to address some of these divides – for instance by providing healthcare of appropriate linguistic and cultural specificity – the language that we use to espouse the aims and objectives of digitalisation should be inclusive (being especially cautious about 'citizens' as the focus of empowerment), and should seek to help groups at risk of vulnerability specifically.

Disparities in access stem from differences in wealth, deployment of technology and its acceptability, and are particularly acute in non-traditional groups of end-users (eHealth Stakeholder Group 2014). Development

should therefore take careful and specific account of the needs of these populations. Moreover, deployment of digital care models must (a) consider different roles and groups of end-users and (b) not view these populations as discrete. Two indicative examples can be highlighted:

1. Use of digital health technologies to treat *mental illness* is based on the notion that these can be more acceptable to users, have advantages in terms of reach, anonymity and cost, and may enhance the treatment experience (Fuller-Tyszkiewicz et al. 2018, 2). However, digital health interventions in this area face greater drop-out rates than face-to-face interventions, in part because they are not always designed with end-users in mind. For instance, one clinician involved in an evaluation study noted that apps for self-management of depression needed to have a flexible alerts system, since a common symptom in those suffering with the illness is to sleep in late; setting alerts to engage with treatment that are activated in the early morning is thus unhelpful (Fuller-Tyszkiewicz et al. 2018, 8).
2. Previous efforts to engage *elderly end-users* have been criticised for treating this group as homogenous and technology-resistant when, in reality, a range of needs, abilities and preferences exist within elderly patient groups (Campling et al. 2017, 5). In a project which brought elderly patients with hearing impairments into the design process for digital tools to assist them, they were able, along



with their clinicians, to advise of the kind of training that they might need to be able to make best use of such technology. They requested, for instance, that this be differentiated for ‘beginners’, ‘intermediate’, and ‘advanced’ technology users, and include patients’ ‘significant others’, rather than assuming that all elderly users would require the same amount of technological support (Nielsen et al. 2018).

In both of these examples, end-users are (dis)empowered according to the extent of their involvement in the design and development of digital health solutions and the extent to which they are considered as a homogenous user group. Where end-user perspectives are not taken into account – particularly those of non-traditional end-user groups – access to and equity of digital healthcare will be negatively affected, resulting in empowerment for a select group of end-users (or citizens) and widening health inequalities.

Recommendations: using digital health to empower end-users

The analysis above demonstrates that the goal of universal access to healthcare – as established by the Sustainable Development Goals and committed to by European governments and the EU institutions – can only be achieved if digital health technologies are available to and meet the specific needs of all groups. This can only be guaranteed by ensuring the inclusion of end-users at each stage of the development process. On this basis, EPHA offers the following recommendations.

Citizens and their data

1. Continue to invest in national EHR systems, putting greater emphasis on the involvement of end-users to ensure that both the functionality and the content of EHRs meet practical need.
2. Prioritise the creation of a mechanism for taking account of the very specific circumstances facing care sought / received in other member states and involve end-users closely to ensure that EHRs contribute to the facilitation of cross-border care.

Data, research and personalised medicines

3. Explore, support and incentivise the use of personalised medicine as a tool for reducing health inequalities, in close partnership with end-users.
4. Establish mechanisms to ensure that both the direct and indirect impacts of personalised medicine are taken into account when implemented. Citizen empowerment and person-centred care
5. Supplement the planned action on training and literacy with concrete programmes and initiatives, seeking end-user involvement to ensure that these serve practical need.
6. Focus such initiatives on non-traditional end-user groups to ensure that ‘empowerment’ is available to all and not an additional / exacerbated facet of health inequalities.

General recommendations

7. When involving end-users in the



development of digital health, ensure that the whole patient journey – from primary and secondary care, GP practices and pharmacies, through to supported living, home care and preventative measures – is considered.

8. Frame and understand digital health as a supplement and companion to traditional healthcare. Plan its adoption in a way which does not compete with the traditional healthcare sector, which will continue to require sizeable and continuous investment.

9. Integrate digital health solutions carefully and, ensuring that this does not provide added burden for an already overstretched health workforce.

10. Design the objectives of ‘online’ and ‘offline’ health so that they support one another, and so that health interests drive the development of both sectors.

11. Ensure that the development of digital health is supported by a strong regulatory framework, particularly around mHealth and consumer-facing products. Such a framework should start from the premise that all patients are vulnerable, by virtue of their need, and so must be protected from misleading or damaging information.

More fundamentally, there is a need to broaden the scope of the EU’s digital health remit. As the digital health agenda has developed, two parallel groups of problems have emerged. On the one hand, issues of organisation – integrating digital tools, engaging and involving end-users, ensuring coherence with goals of access, quality and solidarity – have begun to undermine

the uptake of digital health. On the other, technical barriers to interoperability and compatibility have been exacerbated by a lack of common protocols and infrastructure (Høstgaard, Bertelsen, and Nøhr 2017, 2). Whilst the latter set of problems has been the focus of the EHAP, the Council Conclusions and now the Commission Communication, the former have continued to be underrated and inadequately addressed. The Commission should take steps to redress this balance and adopt a more encompassing and holistic approach to digital health.



REFERENCE LIST

Almazán, Cari, Marie Decool, Montse Moharra, Anna-Lena Nilsson, Natalia Allegretti, and Merik Seven. 2015. "Implementation of a cross-border health service: physician and pharmacists' opinions from the epSOS project." *Family Practice* 32 (5):564-567. doi: 10.1093/fampra/cmz052.

Barello, Serena, Stefano Triberti, Guendalina Graffigna, Chiara Libreri, Silvia Serino, Judith Hibbard, and Giuseppe Riva. 2016. "eHealth for Patient Engagement: A Systematic Review." *Frontiers in psychology* 6:2013-2013. doi: 10.3389/fpsyg.2015.02013.

Birnbaum, Faith, Dana Lewis, Rochelle K. Rosen, and Megan L. Ranney. 2015. "Patient Engagement and the Design of Digital Health." *Academic Emergency Medicine* 22 (6):754-756. doi: 10.1111/acem.12692.

Campling, Natasha, David Pitts, Paul Knight, and Richard Aspinall. 2017. "A qualitative analysis of the effectiveness of telehealthcare devices (i) are they meeting the needs of end-users?" *BMC Health Services Research* 17 (1). doi: 10.1186/s12913-017-2408-8.

Council of the EU. 2017. Council conclusions on Health in the Digital Society — making progress in data-driven innovation in the field of health. Brussels: Official Journal of the EU.

eHealth Stakeholder Group. 2014. Health inequalities and eHealth.

EPHA. 2017. Discussion Paper on the power of digital solutions for health and disease management. Accessed 3 February 2019.

EPHA. 2018. Health and care in the Digital Single Market: enabling equal access to quality care in Europe?

European Commission. 2016. Presentation on Mobility in Healthcare and the role of data: UEMS.

European Commission. 2018a. Commission Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society. Brussels.

European Commission. 2018b. Report on the operation of Directive 2011/24/EU on the application of patients' rights in crossborder healthcare.

Fuller-Tyszkiewicz, Matthew, Ben Richardson, Britt Klein, Helen Skouteris, Helen Christensen, David Austin, David Castle, Cathrine Mihalopoulos, Renee O'Donnell, Lilani Arulkadacham, Adrian Shatte,



and Anna Ware. 2018. "A Mobile App–Based Intervention for Depression: End-User and Expert Usability Testing Study." *JMIR Ment Health* 5 (3):e54. doi: 10.2196/mental.9445.

Hibbard, Judith H., Eldon R. Mahoney, Ronald Stock, and Martin Tusler. 2007. "Do Increases in Patient Activation Result in Improved Self-Management Behaviors?" *Health Services Research* 42 (4):1443-1463. doi: 10.1111/j.1475-6773.2006.00669.x.

Høstgaard, Anna Marie Balling, Pernille Bertelsen, and Christian Nøhr. 2017. "Constructive eHealth evaluation: lessons from evaluation of EHR development in 4 Danish hospitals." *BMC Medical Informatics and Decision Making* 17 (1):45. doi: 10.1186/s12911-017-0444-2.

Hyland, Robyn, Maureen Smith, Laura Rasmussen-Torvik, and Sharon Aufox. 2018. "Great expectations: patient perspectives and anticipated utility of non-diagnostic genomic-sequencing results." *Journal of community genetics* 9 (1):19-26. doi: 10.1007/s12687-017-0314-8.

Kitsios, Georgios D., and David M. Kent. 2012. "Personalised medicine: not just in our genes." *BMJ: British Medical Journal* 344:e2161. doi: 10.1136/bmj.e2161.

Mathai, N., MF. Shiratudin, and R. Sohel. 2017. "Electronic Health Record Management: Expectations, Issues, and Challenges." *Journal of Health and Medical Informatics* 8: 265. doi: 10.4172/2157-7420.1000265.

Mazzucato, Mariana. 2018. *Mission-oriented research & innovation in the European Union: A problem-solving approach to fuel innovation-led growth.* edited by DG Research and Innovation. Luxembourg.

Menachemi, Nir, and Robert G. Brooks. 2006. "Reviewing the Benefits and Costs of Electronic Health Records and Associated Patient Safety Technologies." *Journal of Medical Systems* 30 (3):159-168. doi: 10.1007/s10916-005-7988-x.

NASEM workshop summary. 2016. "Roundtable on the Promotion of Health Equity and the Elimination of Health Disparities." *The Promises and Perils of Digital Strategies in Achieving Health Equity*, Washington DC.

NHS England. 2016. *Improving outcomes through personalised medicine.* Medical Directorate, NHS England.

Nielsen, Annette Cleveland, Sergi Rotger-Griful, Anne Marie Kanstrup, and Ariane Laplante-Lévesque. 2018. "User-Innovated eHealth Solutions for Service Delivery to Older Persons With



Hearing Impairment.” *American Journal of Audiology (Online)* 27 (3S):403-416. doi: http://dx.doi.org/10.1044/2018_AJA-IMIA3-18-0009.

Risling, Tracie, Juan Martinez, Jeremy Young, and Nancy Thorp-Froslic. 2017. “Evaluating Patient Empowerment in Association With eHealth Technology: Scoping Review.” *Journal of Medical Internet Research* 19 (9):e329-e329. doi: 10.2196/jmir.7809.

Roberts, J., Michele Gornick, Lan Q. Le, Natalie J. Bartnik, Brian Zikmund-Fisher, Arul Chinnaiyan, and for the MiOncoseq Study team. 2019. *Next-generation sequencing in precision oncology: Patient understanding and expectations*. Vol. 8.

Slater, H., Jm Campbell, Jn Stinson, M. M. Burley, and Am Briggs. 2017. “End User and Implementer Experiences of mHealth Technologies for Noncommunicable Chronic Disease Management in Young Adults: Systematic Review.” *Journal Of Medical Internet Research* 19 (12). doi: 10.2196/jmir.8888.

Steinhubl, Steven R., Evan D. Muse, and Eric J. Topol. 2013. “Can mobile health technologies transform health care?” *JAMA* 310 (22):2395. doi: 10.1001/jama.2013.281078.

The Topol Review. 2018. *Preparing the healthcare workforce to deliver the digital future*. edited by Health Education England: NHS.

Unni, P., C. Staes, H. Weeks, H. Kramer, D. Borbolla, S. Slager, T. Taft, V. Chidambaram, and C. Weir. 2016. “Why aren’t they happy? An analysis of end-user satisfaction with Electronic health records.” *AMIA ... Annual Symposium proceedings*. *AMIA Symposium 2016*:2026-2035.

Walker, Léonie, and Jill Clendon. 2016. “The case for end-user involvement in design of health technologies.” *Journal of Telemedicine and Telecare* 22 (8):443-446. doi:10.1177/1357633X16670479.

World Health Organization. 2009. “Patient empowerment and health care.” accessed 5 February 2019. <https://www.ncbi.nlm.nih.gov/books/NBK144022/>.





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