



European
Commission



ASSESSING THE IMPACT OF DIGITAL TRANSFORMATION OF HEALTH SERVICES

Report of the
**Expert Panel on effective ways of
investing in Health (EXPH)**

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EXPERT PANEL ON EFFECTIVE WAYS OF INVESTING IN HEALTH

(EXPH)

Opinion on
Assessing the impact of digital transformation of health services

The EXPH adopted this Opinion at the 12th plenary on 20 November 2018
after public hearing on 13 November 2018

About the EXpert Panel on effective ways of investing in Health (EXPH)

Sound and timely scientific advice is an essential requirement for the Commission to pursue modern, responsive and sustainable health systems. To this end, the Commission has set up a multidisciplinary and independent Expert Panel which provides advice on effective ways of investing in health (Commission Decision 2012/C 198/06).

The core element of the Expert Panel's mission is to provide the Commission with sound and independent advice in the form of opinions in response to questions (mandates) submitted by the Commission on matters related to health care modernisation, responsiveness, and sustainability. The advice does not bind the Commission.

The areas of competence of the Expert Panel include, and are not limited to, primary care, hospital care, pharmaceuticals, research and development, prevention and promotion, links with the social protection sector, cross-border issues, system financing, information systems and patient registers, health inequalities, etc.

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The opinions of the Expert Panel present the views of the independent scientists who are members of the Expert Panel. They do not necessarily reflect the views of the European Commission nor its services. The opinions are published by the European Union in their original language only.

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SUMMARY

The impact of digitalisation of health services has been profound and is expected to be even more profound in the future. Like for other services, it is important to evaluate the impact of such digital health services. Decisions to adopt, use or reimburse new digital health services, at different levels of the health care system, are ideally based on evidence regarding their performance in the light of health system goals.

In order to evaluate this, a broad perspective should be taken. Attainment of the broad health system goals, including quality, accessibility, efficiency and equity, are objectives against which to judge new digital health services. These goals are unaltered by the process of digitalisation. Evaluations should be designed and tailored in such a way as to capture all relevant changes in an adequate manner. We do not provide a full evaluation framework in this Opinion, but we do reflect on important elements. Monitoring can also complement evaluations by observing general trends in how health systems evolve, also as a consequence of digitalisation.

Many different categorisations of digital health services can be used in the context of their evaluation. We distinguish between interventions for care users, health care providers, for health systems or resource managers, and data services. Moreover, we distinguish between centralised and decentralised decision-making. We advise to start any evaluation with a full description of the relevant digital technology, its use and aims, addressing elements like the ones above to give a full overview of the technology, its intended use, costs and consequences, and its most relevant comparator, in order to be able to select an appropriate evaluation strategy and key parameters to include.

Important frameworks and practical guides for the evaluation of digital health services have been proposed. We especially highlight the recent Jasehn and WHO frameworks. These can serve as a starting point both for practical evaluation studies and for further development of evaluation frameworks. In evaluations, the development phase of the digital health service as well as implementation of it, are crucial elements. Combinations of different evaluation types may be required to provide relevant information to decision makers at different moments. Careful selection and justification of applied methods is warranted. Further investment in the development of methodologies and a European repository for evaluation methods and evidence of digital health services is encouraged.

When evaluating digital health services many specific aspects need to be considered. We illustrate some of the specificities of evaluating digital health services, including creating a suitable policy context, rules for setting HTA priorities, and using appropriate outcome measures.

Governments could play a more active role in the further optimisation both of the process of decision-making (both at the central and decentral level) and the related outcomes. They need to find a balance between centralised and decentralised activity. Moreover, the broader preparation of the health care system to be able to deal with digitalisation, from education, through financial and regulatory preconditions, to implementation of monitoring systems to monitor its effects on health system performance, remains important.

We discuss data sources, broader considerations (including cybersecurity, privacy and market power), and provide recommendations for dealing with the digital transformation.

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BACKGROUND

European countries typically pursue health systems goals that include high quality, efficiency, equity, affordability and accessibility of health care (EXPH, 2014). Balancing and optimizing these goals is a continuous process, due to developments both within and outside the health care domain. It typically involves trade-offs between (potentially conflicting) goals, like affordability and quality, requiring normative judgments from relevant decision makers and citizens. One of the factors influencing the performance of health care systems in achieving this goal is technological change, including the ongoing process of digitalisation of health services. The latter process may have large consequences for the future of health care delivery and health systems. Many countries struggle with the desire to, on the one hand, stimulate digitalisation and the adoption of digital services, in light of their promise to improve health system performance, and, on the other hand, to steer the process of digitalisation in the desired direction and evaluate whether it actually improves health care and health system performance. In that context, it needs to be asserted that the benefits of the process of digitalisation of health services outweighs the associated costs (in the broadest sense of the word).

Digital technologies and the digital environment offer new opportunities for identifying needs and delivering health care (from prevention and health promotion to curative interventions and self-management). As such, they have the potential to transform healthcare services in ways that may contribute to health system goals. The nature and consequences of digital health services can differ substantially from case to case, emphasising the complexity of evaluating their contribution.

The results and outcomes of digital transformation of health services (which is further defined later in the Opinion) will importantly depend on the quality of the process and the involved stakeholders. This includes end-users of digital health services (be it professionals, care users or citizens), developers of digital health services, producers of health services and governments. The success of digital transformations requires a sound understanding of the two basic interacting components, i.e. "the health service" and "the digital", at all these different levels. The full process of their development, production, funding, implementation and evaluation requires careful consideration in this context.

The innovative solutions that some digital health services represent can, if designed purposefully and implemented in a cost-effective way, provide better health outcomes and contribute to the sustainability of health systems. However, while digital health services *can* have this effect, they *need* not always have it. Evaluations and monitoring should establish whether this is the case for specific digital health services. The scope of such evaluations and monitoring needs to be set appropriately. This is underlined by the fact

that, like other technologies, digitalisation in health care normally affects certain goals or certain groups positively, while at the same negatively affecting others.

EU policies have consistently emphasised the importance of digital solutions such as eHealth and have accentuated positive aspects of how digital innovations can improve integration of care through up to date information channels and deliver more targeted, person-centred (or personalised), effective and efficient healthcare, reducing errors and length of hospitalisation. However, a balanced view of the effects of digitalisation remains needed and not all forms of digitisation may result in improved care and health system performance. Put differently, a health care service is not good (or bad) *just because* it is digital.

Public expenditure on health and long-term care has been increasing over the last decades in all EU Member States and is expected to rise even further. In 2015, it accounted for 8.5% of GDP in the EU and could reach up to 12.5% of GDP in 2060.¹ A substantial part of the increase has been attributed to the introduction and funding of new technologies in health care, including digital ones. In this context, there is a growing need for robust evidence to support arguments that digital health solutions (Car et al., 2008; WHO, 2016) - and the related new organisational models replacing the old - can bring better health outcomes for citizens and contribute to improving the effectiveness, accessibility and resilience of health systems. Given the diverse forms, usages and impacts of digital technologies in health care (ranging from general use of computers to algorithms designed to assist radiologists and radiotherapists in detecting and treating cancers, from robotic surgery to computer aided decision models, and from mobile device apps helping patients to self-manage their disease to electronic health records), this requires evaluations on different levels.

Systematic assessment and evaluation of the impact of digital health services is, therefore, needed. To date, such assessments are relatively scarce, especially those addressing the transformative aspects of healthcare delivery on the organisational and operational level.

The literature on the impact, for example, of telehealth solutions for chronic conditions suggests that telehealth in some cases may reduce hospital admissions and mortality patients suffering from chronic heart failure, may improve blood pressure control in patients with hypertension, may reduce hospital admissions for chronic obstructive pulmonary disease and may improve glycaemic control in diabetes (e.g. Brettle et al., 2013; Inglis et al., 2015; Flodgren et al., 2015).² However, the evidence-base concerning cost-effectiveness can be less clear as is the generalisability of such results. The same

¹ European Commission's Joint Report on Health Care and Long-term Care Systems and Fiscal Sustainability (7 October 2016)

² NHS England. TECS evidence base review. Findings and recommendations. NHS England, April 2017

holds for equity impacts of introducing digital services, which has the risk of increasing the 'digital divide'.

Models for assessing the value of telemedicine, like MAST,³ have been developed and used (e.g. Sorknaes et al., 2013), but their use may still be considered limited. The lack of robust evidence on cost-effectiveness is partly due to the absence of available data collected over long periods of time and may also be related to regulations and requirements for funding and reimbursement as well as to difficulties in determining cost-effectiveness in this context. This is especially the case when the introduction of some digital technology changes organisational structures. For some changes, it may not only take several years to see a clear impact at the health system level, but it may also be highly difficult to isolate the costs and effects of such changes in a developing health care environment. There are indeed examples which have demonstrated cost-effectiveness, for instance regarding telehealth, and even cost-savings (e.g. Darkins et al., 2015).⁴ Again, the generalisability of such findings, as well as the quality and breadth of the evaluations performed, are important to consider. There are also examples of less favourable or more mixed results for digital health services (e.g. Maddison et al. 2015).

A framework for the assessment of the digital transformation of health services and its impact is vital to generate the evidence required for decision-making on stimulating, using and/or funding digital health strategies at various levels in the health care system. In this Opinion, this issue is further addressed based on the terms of reference highlighted next. With it, we hope to support EU member states with decision-making in the domain of health, social and fiscal policies. Moreover, we also aim to help the Commission to shape further activities toward a better uptake of the digital health services at the EU level.

³ <http://www.mast-model.info/>

⁴ Joint Improvement Team for the Scottish Government, An Assessment of the Development of Telecare in Scotland 2006-2010, 2010 & European Commission, European Innovation Partnership on Active and Healthy Ageing Reference Sites: Excellent innovation for ageing - A European Guide, 2013

TERMS OF REFERENCE

The Expert Panel is requested to provide its analysis on the following:

- a) What are the systematic methods available for assessing the impact of the digital transformation of healthcare with regard to health objectives: access, outcomes, patient participation, use of resources, and sustainability? Are the existing methods best tailored for assessing the value of digital transformation of health services? Is there a need for modification of existing methods or for the development of new ones to assess and evaluate the impact of digital health services?
- b) What types of data are available and required to assess the value of digital health services?
- c) What impacts of digitalisation of health services should be assessed systematically? Should this impact be considered with regards to health outcomes, health systems, the wider society, or all of these? Or should other dimensions be considered instead or in addition?
- d) How could the impacts on wider fiscal and social policies, beyond the health sector, be assessed?

1. OPINION

1.1. Digitalisation and health

Health technologies, in the widest meaning of the word, have changed continuously ever since the early stages of medicine. Increasing knowledge and diagnostic, preventive, treatment and rehabilitation possibilities have altered the content of health care systems. In turn, health systems have also evolved into complex entities with changing roles and responsibilities for patients, health professionals, payers and regulators. The 'digital transformation of health services' is seen as an important and influential process, that has already had a substantial impact on current health care and health systems and is expected to have a further fundamental impact on health care and health care delivery in the future.

It is also immediately acknowledged that 'the digital transformation of health services' is a complex and multifaceted issue. The scale of impact, areas affected and complexity of the interactions of the digital with health service provision are illustrated in the topic tree shown in Figure 1. This topic tree was based of clustering concepts obtained from online available texts containing the terms "digital transformation" and "health services".

Digitalisation refers to that use of digital technologies in the context of the production and delivery of a product or service. Such digital technologies allow health care services to be organised, produced and delivered in new ways. Digitalisation is therefore less of a 'technical' process (like digitisation), it is also an organisational and cultural process. (See Textbox 1).

Textbox 1: Digitalisation is more than a technical process

A service is a joint interaction of tools, processes, power and people.

Human evolution is the result of changes in all these categories. The "power" has changed only four times in history, from manpower, through horsepower, the power of steam to finally electric power. Every new power needed the modification of tools, processes and behaviour of people in order to improve services and productivity. With "digital transformation" the power has not changed (still electricity), the only thing that has changed (and led to transition from industrial society into information society roughly in 1990) is our ability to more efficiently manipulate "objects" we were able to transform into a digital format. Thus in some situations we are able to produce "artefacts" not by directly doing this with our hand in the place we are, but perform this digitally, and at a distance. This can be used/misused in all situations where we are able to digitise without loss of content and context. The potential loss of context and resulting loss of meaning is especially important in the area of health services provision.

Digitalisation, ranging from the use of computers and electronic health records to home monitoring of patients, electronic medical devices, and the application of computer aided visualisation and decision support systems, has affected and is expected to affect many aspects of health care systems in terms of structure, culture, professions, treatments and outcomes. This is sometimes referred to as the "**digital transformation**", which indicates that health care services and systems are in a transition in which more health services and processes will be digitalised. The digital transformation encompasses the instrumented effort to meaningfully introduce new digital information and communication technologies and corresponding new processes into the health care sector. Some of this digitalisation is health care specific, another part is a consequence of the broader digitalisation trend in society. Both can lead to changes and innovations in health technologies and health care delivery processes, and thus impact health, health care, and health systems. The digital transformation in some of its aspects therefore represents a fundamental change in the mode and culture of care delivery of organisations (see also EXPH, 2016a).

Much of the digitalisation process and its products (the digital and virtual environment) are relatively novel and some aspects may be difficult to observe or properly understand (e.g.,

artificial intelligence). The speed of developments may give individuals, professionals, systems and decision makers little time to adapt, understand, and develop the appropriate behaviours in relation to these new technologies and possibilities. While this already complicates our understanding of the intended and desired consequences of the new technologies, new tools, programmes, processes, devices etcetera, can also have unintended consequences, like the transition of the industrial revolution had unintended direct health effects (e.g. labour safety) and indirect environmental effects (e.g. pollution). The digital transformation is likely to have both intended and unintended effects, which need to be taken into account when evaluating digital services. This increases the need for evaluation as well as caution in adopting unevaluated digital solutions.

In order to address the terms of reference in the mandate, we focus in this Opinion on digitalisation of health services and the questions that need to be addressed in evaluating this digitalisation. Following the definition of the World Health Organisation, we define **health services** as *“the whole spectrum of care from promotion and prevention to diagnostic, rehabilitation and palliative care, as well all levels of care including self-care, home care, community care, primary care, long-term care, hospital care, in order to provide integrated health services throughout the life course.”* (WHO⁵) (See also Textbox 2).

⁵ http://www.who.int/topics/health_services/en/

Textbox 2: Health Services⁶

Besides the WHO definition provided, other definitions of health services exist. For instance, in the Australian Privacy Act a health service is described as:

“(a) an activity performed in relation to an individual that is intended or claimed (expressly or otherwise) by the individual service provider or the organisation performing it—

(i) to assess, maintain or improve the individual’s health; or

(ii) to diagnose the individual’s illness, injury or disability; or

(iii) to treat the individual’s illness, injury or disability or suspected illness, injury or disability; or

(b) a disability service, palliative care service or aged care service; or

(c) the dispensing on prescription of a drug or medicinal preparation by a pharmacist”

Such health services have different desired characteristics. According to the Institute of Medicine (IOM) health care (services) should be:

Safe—avoiding injuries to patients from the care that is intended to help them.

Effective—providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse).

Patient-centred—providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.

Timely—reducing waits and sometimes harmful delays for both those who receive and those who give care.

Efficient—avoiding waste, in particular waste of equipment, supplies, ideas, and energy.

Equitable—providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status

Acceptable (Respectful) - the extent to which care is delivered humanely and considerately

Continuity assured – connectedness between the stages along the patient care pathway

Digital health services are defined here as health services that are in part or fully digitalised. These services use digital elements to contribute to the goals of the service (e.g. empowerment of individuals and communities, health promotion, prevention, cure,

⁶ See:

<https://www.alrc.gov.au/publications/62.%20The%20Privacy%20Act%20and%20Health%20Information/definition-%E2%80%98health-service%E2%80%99>

and

<https://www.ncbi.nlm.nih.gov/books/NBK222265/> Crossing the Quality Chasm: A New Health System for the 21st Century. 2001, Berwick DM. A User’s Manual for the IOM’s ‘Quality Chasm’ Report. Health Affairs, 2002; 21(3): 80-90.

care, rehabilitation, etc.). Against this background, one may feel it would be better to speak of digitally supported health services. In this Opinion we will use the term digital health service, to align with common terminology and to accommodate the option of fully digital services.

Digital health services may enhance person- and people-centeredness of care, and ideally should strengthen the relevance, access, equity, quality, cost-effectiveness, sustainability and innovation of health services. In order to do so, these services should be integrated in the broader health system in a comprehensive way, which again emphasises the cultural aspect of the digital transformation and the connectedness of this transformation to the full health system.

Digital health services in this report encompass a broad array of services with different (overlapping) names, such as eHealth, mHealth, telemedicine, telecare, imaging, artificial intelligence, electronic health records, etc. Recently, WHO provided a classification of digital services, by dividing them into four categories as shown in Figure 2, based on main users of the services.

Figure 2: WHO classification digital health services



INTERVENTIONS FOR CLIENTS: Clients are members of the public who are potential or current users of health services, including health promotion activities. Caregivers of clients receiving health services are also included in this group.



INTERVENTIONS FOR HEALTHCARE PROVIDERS: Healthcare providers are members of the health workforce who deliver health services.



INTERVENTIONS FOR HEALTH SYSTEM OR RESOURCE MANAGERS: Health system and resource managers are involved in the administration and oversight of public health systems. Interventions within this category reflect managerial functions related to supply chain management, health financing, human resource management.



INTERVENTIONS FOR DATA SERVICES: This consists of crosscutting functionality to support a wide range of activities related to data collection, management, use, and exchange.

Source: WHO, 2018

Finally, it is useful to define the term evaluation here. **Evaluation** is defined in this report as *“The systematic and objective assessment of an ongoing or completed intervention,*

with the aim of determining the fulfilment of objectives, efficiency, effectiveness, impact and sustainability.” (WHO, 2016)

Impact and evaluation of digitalisation

Although much of the digitalisation process has yet to take place, it is expected that the impact of digitalisation on health, health care delivery and health systems can and will be profound. It will likely (further) affect the different phases of health care delivery, including health promotion, prevention, primary care, specialised care, long term care, social care, and self-care. Evidence suggests that current forms of digital health services can already impact the health and wellbeing of patients and the functioning of the health care system in profound ways (e.g. Deloitte, 2015). In this report we focus on the evaluation of digitalisation of health services, not on the process of digitisation. Moreover, we focus on the impact on health care delivery, and less on technical aspects related to digitalisation (like storage of data, etc.). Note that this delineation of this report only indicates our focus, not the relative importance of these issues.

Mobile health services (mHealth) are an example of digital health services that already impact the process of health care delivery. Although more evidence is required, and mHealth in practice takes many forms, there is evidence that it can have a positive impact in certain situations, including asthma treatment and smoking cessation and adherence to therapy, also in low- and middle-income countries (Marcolino et al. 2018; Iribarren et al., 2017).

The World Economic Forum (WEF) has recently indicated their expectations regarding the profound impact digitalisation in health care will have.⁷ For instance, it is expected that: *‘The healthcare system of the future will look very different, with a crucial change being the move to ‘consumer-centric’ healthcare, allowing citizens to have much more responsibility for managing their healthcare and that of their families.’* Such shifts relate to patient empowerment, self-management, shared decision-making and also goal orientation of future health care towards the achievement of life goals of individuals (De Maeseneer & Boeckxstaens, 2012). The directions and diversity of developments relating to digital health services have also been highlighted by the WEF, including aspects like continuous monitoring, connected homes, intelligent treatments, and virtual care teams. Note that more specific forecasting is difficult, certainly when it comes to the expected costs and benefits of new technologies.

⁷ <http://reports.weforum.org/digital-transformation/building-the-healthcare-system-of-the-future/>

As the WEF emphasises, these developments are likely to entail important shifts from diagnosis and treatment, to prevention and management. Moreover, the location of health care delivery may well shift from hospitals and other treatment centres to home and the community. Such shifts, as expected by the WEF, would of course imply fundamental changes in the way health systems are organised and financed, the type of health professionals needed, the role of those professionals and of patients, as well as the health services provided and the process of delivery. All such aspects may also be seen as challenges that need to be overcome in order to facilitate the materialisation of these expectations regarding the future of care.

While such (expected) developments hold the promise of reducing pressure on the workforce, lowering costs and improving patient centeredness and goal-orientation of care, this does not reduce the need for evaluation. Like for other innovations and (new) technologies, such promises may or may not materialise and potential benefits may also be accompanied by unintended and/or negative (side) effects in the short or long term. Hence, the introduction, implementation, use and funding of digital health technologies should be carefully evaluated and monitored. Monitoring and evaluating these technologies appears to be outpaced by the proliferation of digital health technologies (WHO, 2016), partly fuelled by the promise they have to improve health, care and health systems. In the context of publicly funded care systems and public decisions, such evaluation and monitoring are necessary and ideally performed in relation to the goals health systems pursue. In this Opinion, such evaluation and monitoring are central.

Evaluations of digital services, and guidance on how to perform such evaluations, are complex and hampered by a number of fundamental issues, which deserve noting early on in the Opinion. First of all, digitalisation of health care takes many forms. This makes (providing general guidance on) evaluating its impact difficult. Some evaluation strategies may be feasible and desirable in some cases, but not in others. Second, digitalisation takes place in many different areas of the health system, on the level of individual treatments (e.g. eHealth solutions to treat mild depression) to the system level (standardised inter-professional electronic health records). Depending on how one interprets the definition of health services, such system level or organisational level aspects may or may not be seen as services. Here, we will take a broad view, including those types of technologies as at least *indirectly* influencing health services. The diversity in technologies can make the development, implementation and decision processes (and actors) completely different for different digital health services, as well as their informational needs. Third, the (intended *and* unintended) impacts of digitalisation can differ substantially from case to case. While some innovations may directly affect patient health, others may facilitate exchange of

information or reduce administrative burden. Evaluations are ideally tailored in such a way that they capture the relevant impacts of an intervention, both those intended and those unintended (as elaborated on later). Fourth, some elements that may be intrinsic to digital health services (such as the generation, transformation and transportation of information), which may be less prominent in the evaluation of non-digital health services, such as privacy and data-leakage, need to receive sufficient attention in an evaluation of digital health services. The focus in this report, given its aims, will not be on a particular technology or on the set of technologies as available today, but on the essential features that digital technologies have. Thus, we aim to contribute to a framework to evaluate and monitor whether the uptake and use of digital health services contribute to the overall goals of the health care system. This is important because some future developments and technologies may not be foreseeable at this moment. Moreover, the developments in digital health services coincide with the general developments of health systems, which is also enhanced by using digital technology, towards providing proactive, predictive, prospective, preventive, participative and personalised health care / health services (Bourek, 2017).

Evaluating the transformation?

The diverse aspects of the digital transformation as well as the fact that it is an ongoing process also make clear that providing a general answer to the question of whether or not the digital transformation as a whole is or will be beneficial to the health system is difficult, if not impossible to answer. Like many changes in health care delivery, there are good and bad examples of digitalisation of health services. Somehow evaluating the total effect of all these changes at a system level is not only extremely difficult, but it is also unclear as to what the implications of the outcomes of such an evaluation would be, given the underlying variation in digital health technologies. To illustrate this point, take a situation in which the transformation is made up out of the introduction of only two digital health services; one 'good' and one 'bad'. Knowing something about the aggregate of the two (the total 'transformation') is less valuable than knowing which of the two to stimulate and which to terminate. The irreversibility of the general trend of digitalisation makes it also unclear what type of policy implications would be derived from knowledge on the general level of 'the transformation'. Here, we take the view that governments should be more interested in proactively selecting which digital health services contribute best to the overall health system goals *and* in creating an evidence-informed system that is designed to steer towards optimal outcomes.

Promise and practice

The impacts of digitalisation on the health care sector can be large as is the potential of digitalisation to contribute to improving health system performance in the broadest sense of the word. However, over-optimism in this respect, for instance by underestimation of the costs, or overestimation of the benefits of implementing digital health services, or insufficiently acknowledging the risks (e.g. in terms of security) some types of digitalisation may be associated with, should be avoided. The promise of benefits of digitalisation do not always materialise in practice. Implementing new technologies, whether digital or not, should not be based on promise or hope, but on evidence and realism. We see digitalisation therefore, as an instrument to reach health system goals, and such instrument can have positive and negative consequences. Health services are not good/better or bad/worse simply *because* they are digital but can be better or worse than (digital or non-digital) alternatives in contributing to health system goals. Hence, it needs to be evaluated on a case by case basis whether a specific type of digitalisation of health care delivery is deemed desirable or not. In that process, all relevant impacts of services, including long term consequences need to be considered as good as possible. Moreover, by monitoring health system performance, also using indicators (EXPH, 2014), the general development of health sectors and systems can be observed and potentially related to digitalisation.

Who are we informing?

Before turning to the scope of the evaluations and monitoring, it is also good to note that both activities are normally performed to inform a relevant decision maker. This can take place at different levels of the health system. Actually, an important decision context is that to reimburse or fund a health service from collective funds within a health care system. This involves a decision (often at a regional or national level) by a public body. We note here already that not all innovations, including those that are part of the digital transformation, are adopted into the health care system on the basis of centralised decision-making. In many cases, such innovations are decided on at lower levels in the health care system, thus entering the system in a decentralised fashion (although in many cases still collectively financed). While the focus in this report is on the former decision-making context, we will also address the latter situation. Although central governments may not directly be involved in the decision-making processes leading to the adoption of specific health technologies, this does not mean they are not accountable for the functioning and performance of the system in relation to decentralised decision-making. Moreover, they have the ability and role to implement policies that ultimately lead to a well-performing health care system, aligned with the goals of quality, efficiency, accessibility and affordability. Hence, governments may be vital in creating an environment (in terms of education, culture, incentives, etc.) that steers the digital transformation and

health systems in the desired direction. This report aims to contribute to that by stimulating and facilitating Member States to perform routine evaluations and monitoring of digital health services. We also see a role for broader stimulation, facilitation and coordination at the EU level. At all levels, increasing the knowledge base regarding digitalisation and its impact appears to be required.

Concluding remarks

The impact of digitalisation of health services has been profound and is expected to be even more profound in the future. It is important to evaluate whether digital health services contribute to health system goals in an optimal way. This should be done at the level of the service, not the digital transformation as a whole. Decisions to adopt new digital health services, at different levels of the health care system, are ideally based on evidence regarding their performance in light of health system goals.

1.2. Scope of evaluation

The impacts of digitalisation on health, health care and health care delivery can be far reaching and diverse. Hence, it is important to consider these impacts and stimulate digitalisation where it contributes to health system goals and to avoid or mitigate the negative consequences of digitalisation. We do not consider digitalisation to be a goal in itself. As indicated, it is viewed as an instrument that may or may not contribute in a desired way to the overall health system goals. Evaluations and monitoring should demonstrate, as much as possible, whether or not this is the case, at different stages of the development, adoption and use of the service.

Broad perspective

The Panel has always taken a broad perspective on health system performance and goals (e.g. EXPH, 2014). Health system goals include aspects such as quality, access, equity, efficiency, patient empowerment, responsiveness and affordability. A more complete overview is given below. Often, an innovation or policy does not improve the attainment of all goals simultaneously. It may for instance improve quality but, due to higher costs, reduce affordability. Likewise, a new service may improve access but lower efficiency of the health system. In those circumstances, the relevant decision maker needs to trade-off the goals (given the evidence presented) to come to a final judgment regarding whether or not the intervention overall improves or lowers health system performance.

System goals unaltered

Importantly, the digital transformation is not seen as altering the overall goals of health care systems. The goals of quality, efficiency, etc. are believed to be valid also in case of a health care system in, or after, a digital transition. Hence, the transition refers to the way in and extent to which the goals can be achieved, not to the goals itself. Given changes in attainment, the weights of (marginal changes in achieving) the different goals receive in decision-making may also change. Other developments may add to this.

We do note explicitly that digitalisation may add new dimensions and meanings to existing goals. For instance, issues of cybersecurity may be placed under the goals of quality and safety, which did not have this particular dimension before. The goals of patient-centeredness, goal orientation of care and patient empowerment in that context also deserve mentioning, e.g. in order to assess if digitalisation of services leads to a 'digital divide' and new inequities. These aspects are not new but may be strongly affected by the digitalisation process.

Importantly, therefore, when evaluating the impact of the digital transformation on health systems and health care delivery, the traditional goals can still be used, as a broad

indication of health system goals, to judge their appropriateness by. This can also be (implicitly) derived from the Health Technology Assessment (HTA) framework recently proposed in the Joint Action to support the eHealth Network (Jasehn, 2017) as well as from the guidance provided by the WHO (2016).

Diverse impacts on goals

Digitalisation in its diverse forms can impact the attainment of all these goals. First and foremost, it may help to achieve health and wellbeing in the population served. Health, defined as a state of complete physical, mental and social well-being (WHO, 2006) or as the ability to adapt and to self-manage, in the face of social, physical and emotional challenges (Huber et al, 2011), can be directly or indirectly influenced by digitalisation. New treatment options, better adherence and monitoring, and better access are examples of increased possibilities digitalisation may offer. Digital services are used in many parts of the health care system, including health promotion (Free et al., 2011; Harris et al., 2011; Vandelanotte et al., 2007; Bailey et al., 2010), self-management (Pal et al., 2013) and mental health (Arnberg et al., 2014). Some show promising results when evaluated. Still, developments like and treatments options through digitalisation need to be evaluated against the health system goals. Such an evaluation may indicate that the intervention involves improvements in one dimension without negative impacts on others (e.g. lowering administrative costs without affecting patient results or other domains, better diagnosis based on some image due to artificial intelligence at the same costs), which makes a decision to implement or fund such technologies easy. It may also involve improvements or reductions in two or more domains. For example, more efficiency and quality (e.g. shared interprofessional electronic health dossiers reducing repeated tests and providing quicker information) or less of both (e.g., when a digital service is relatively costly and reduces quality, for instance because patients prefer face to face contact to digital contact). Again, when the changes in goal attainment are all in the same direction, a decision to promote, implement, adopt or fund the technology can be relatively straightforward. One may even bundle desired characteristics, so signal this also towards new innovations. For instance, under the Context-Driven Component Evaluation (Ostrovsky et al., 2014), a so-called "Triple Aim Component" includes improving population health, improving patient experience and decreasing per capita cost of care. Whether digital health services indeed qualify this triple aim (without negative side effects), needs to be ensured. Moreover, it is important to consider the impact on 'provider wellbeing', sometimes defined as 'the fourth aim' (Bodenheimer and Sinsky, 2014). Gathering the data to demonstrate costs and benefits of digital health services may be a difficult task.

It needs noting that technology may also involve positive and negative impacts *within* one dimension. For instance, remote contact (email/skype) with a physician may improve access to care services for those living in rural areas, leading to more equitable access. At the same time, however, new communication forms may reduce access for those whose digital ability is lower.⁸ Then, the relevant decision maker needs to trade-off these impacts to come to an overall judgement (if a combination of both technologies is not feasible, serving the total population in a tailored fashion). Most commonly, new health technologies, including digitalisation may lead to changes in two or more dimensions, impacting some positively and others negatively. For instance, by being more expensive yet yielding more health. Again then, a trade-off needs to be made to make an overall judgment. Frameworks to inform this trade-off have been developed and some will be highlighted in this Opinion. The final decision regarding such trade-offs is not up to analysts, but the appropriate decision-making bodies, potentially somehow involving citizens in the process.

Context of change

The context of a change induced by digitalisation can also be important. Some digital health services may offer additional treatment options and work processes *next to* existing ones (see also Textbox 4 below). Other forms may replace current treatment options altogether. Sometimes this replacement is a necessary part of the transformation, sometimes it may be a consequence occurring over time. In case of replacement, old options, professions or skills may be lost (e.g. the skill of recognising heart murmur with a traditional stethoscope when electronic stethoscopes become the standard, or the impossibility to revert back to “old” open surgery from robotic surgery when necessary because no skilled professionals are available anymore). Such losses need not always be negative, but the nature and degree of reversibility of changes can be important to consider when evaluating new technologies (i.e. technology dependence) – even though in practice they are often ignored.

Existing evaluation frameworks

It needs noting that many frameworks for evaluation especially focus on the evaluation of well-defined technologies with a clear place in the treatment chain of particular patient groups, and their impact on health and costs. For at least two reasons, this may be problematic. First, some forms of digitalisation can have a broader impact on health care delivery, diverse patient groups and have only indirect effects on health, care expenditures and other relevant domains. These interventions may target organisational features of

⁸ This is especially the case when the old health service is substituted with the new digital one, rather than being complemented by it. If the new solution complements old solutions, it may improve access for some while not negatively affecting access for others. This highlights the importance of context.

health care delivery rather than specific treatments for specific patient groups. Electronic health dossiers or hospital information systems are examples. Digitalisation, moreover, can impact the way in which professional work is organised more profoundly, potentially leading to new professions (e.g. rehabilitation professionals after vision restoration using digital solutions) or new profiles of existing professions. Such forms of digitalisation may be more difficult to evaluate with standard (HTA) methodology. Second, some forms of digitalisation may primarily aim to influence other aspects than health and costs. For instance, electronic devices or apps may increase patient empowerment through improving self-management and autonomy of patients or elderly, and internet consultations may improve access in remote areas, which can be an important goal (EXPH, 2017a). Such interventions need to be evaluated in light of the relevant, valued changes they bring, for which standardised evaluative frameworks may not always exist.

These examples emphasise that the effects of digitalisation of health services can be diverse and take many forms. This combination can make evaluations difficult, especially in the context of organisational changes (an important part of the digital transformation), which normally do not easily allow RCT designs which would provide most convincing evidence, with diverse appearances and diverse goals, etc.

Scope of Opinion

We cannot provide a fully predefined method for the evaluation of all digital health services and innovations, let alone the full digital transformation. Hence, in this Opinion we will highlight elements that are important in this context, also building on available frameworks. We will present a general framework of thought for how to evaluate digital health services, by determining the fulfilment of health objectives – including access, health outcomes, patient empowerment, efficiency, effectiveness and use of resources. This is aimed to help health policy makers make appropriate decisions, both directly and indirectly steering the digital transformation. Moreover, we will highlight the relevance of looking at the impact on the wider economy and society. Health services can importantly affect broader society, including aspects like fiscal sustainability, social coherence and solidarity. Such broader consequences are important to consider in evaluating health care interventions, whenever relevantly present. Taking a broad societal perspective in (economic) evaluations of health policies and health services is encouraged.

Health system goals

In terms of the health system goals, the Panel previously indicated a set of goals (e.g. EXPH, 2014). These goals include several elements like accessibility, safety, effectiveness,

equity, efficiency, affordability, responsiveness and appropriateness (e.g. Donebedian, 1988; Maxwell, 1992; IOM, 2001).

Evaluations often focus on a subset of these goals, especially safety, effectiveness and efficiency. However, some forms of digitalisation may have a broader impact on the attainment of health system goals, for instance affecting access, equity or responsiveness. Evaluations therefore need to be tailored to include such impacts whenever relevantly present.

Evaluations should be able to assess whether and to what extent a specific intervention (such as adopting a digital service) contribute to these goals. As the Panel wrote before (EXPH, 2014):

"...all services have to be:

1. Effective, and improve health outcomes;
2. Safe, and prevent avoidable harm related with care;
3. Appropriate, and comply with current professional knowledge as well as meeting agreed standards;
4. Patient-centred, and involve patients/people as key partners in the process of care;
5. Efficient and equitable, and lead to the best value for the money spent and to equal access to available care for equal need, utilisation and equal quality of care for all."

This is also true for digital services. Given the nature of some digital services, including the collection, sharing, storage and potential re-use of data, some elements like 'safety' may take a broader meaning or need to be complemented by aspects like privacy or cybersecurity. Such diversity in the exact content from the commonly understood elements of quality of health care services may become more prominent when the services are not directly used in patient care, but for instance in organisational procedures. We encourage researchers to explore these issues further to facilitate definitions of key parameters in line with developments in the health care sector.

Monitoring

Moreover, as highlighted in the Panel's report on Quality of care (EXPH, 2014), evaluation may also be performed on the basis of (systematically) monitoring key indicators of quality of care, including those impacted by the digital transformation. Monitoring may lead to detection of (un)desirable developments that governments and other stakeholders may be able to affect through policies. This will be elaborated on later. First, we will highlight the diversity in types of digital health services.

Concluding remarks

A broad perspective should be taken in evaluations of digital health services. Attainment of the broad health system goals, including quality, efficiency and equity, are objectives against which to judge new digital health services. In principle, these goals are unaltered by the process of digitalisation although their content can be affected when dealing with digital health services. Evaluations should be designed and tailored in a way that captures all relevant changes adequately. We will not provide a full evaluation framework in this Opinion but reflect on important elements. Monitoring can also help in observing general trends in how health systems evolve, also in light of digitalisation.

1.3. Types of digitalisation in relation to evaluation

When wishing to evaluate the effects of digitalisation of health services, it is important to understand the differences in evaluation context and digital health services under evaluation. In terms of the former, an important distinction is which decision maker needs to be informed. Traditionally much of the evaluations performed on health services (and in particular medicines), in the form of Health Technology Assessment (HTA), were aimed at informing central decisions on funding or reimbursement. However, in most health care systems, many technologies enter the health care system without formal evaluations at a central level. Instead, they are introduced based on decentralised decisions (e.g. by individual hospitals or physicians). The type of health service under evaluation is also of importance. Much of the existing methodology for systematically applied evaluations (HTA), was developed in the context of evaluating pharmaceuticals with an emphasis on assessing their health gains and the costs related to their use. This makes clear, also in light of the broad health system goals described in the previous chapter, that this methodology may not be immediately appropriate or complete for use in the context of the evaluation of (all) digital health services.

In this section we touch upon both aspects, to provide a simple categorisation of digital health services that could be used in relation to their evaluation.

Relevant characteristics

There are many possible ways of categorising digital health services, the usefulness of which mainly depending on the way the categorisation is used. One categorisation could be made by directly focusing on the goals of the service (improving health, wellbeing, efficiency, safety, access, etc.). This can help in evaluations but may also prove difficult, for instance when services have more than one goal. Another way of looking at categories of digital technologies is based on the type of technology, e.g., communication, information processing, decision support (including artificial intelligence), imaging, sensors capturing information (e.g. wearables), and implants. A categorisation could also be based on the type of human capabilities a technology enhances, as described in Textbox 3.

Textbox 3: Categories of tools

The development of humankind is closely tied to finding innovative ways of working. Tools or "technologies" we use can, in the most generic way, be divided into four categories based on how they complement or augment our natural human capabilities. The first category helps to increase our physical strength or skills (an example may be the needle, surgical instruments or operating robot), the second category broadens, enhances or complements our senses (microscope, compass, medical digital imaging methods), the third category consists of technologies that help us to modify the nature in order to serve better our needs or satisfy our desires (genetically modified food, contraceptive pill). The fourth category consists of tools multiplying the human intellectual capacity (Glushkov, 1964). These "intellectual technologies" help us to search for and sort out information, formulate and voice thoughts, share know-how and knowledge, measure and evaluate and improve our mental capabilities (Carr, 2010). Speech, writing, typewriter, calculating instruments, printing press, libraries, digital computers, and the Internet fall into this category. In the order these four categories are named here each category offers a rising number of opportunities and hand in hand carries a rising amount of risks. This must be taken into account when devising methods for evaluation of the effects and impact of their utilisation.

Whether new services are complements to existing care or substitutes for that existing care is a relevant characteristic. Textbox 4 elaborates on this. New services may replace old ones for all or some patients, or can be used in addition to or even in synergy with old ones in some or all patients. They may also offer new treatment possibilities that previously were not available. Such distinctions are relevant for the evaluation of technologies, both in terms of *how* to evaluate them as well as in terms of the final judgement about their desirability. We also emphasise the link to market power in this context, an element that is not frequently addressed in common evaluations. Technology and information producers may develop significant market power once their health service is widely used. Especially in those cases where standardisation may result in the selection of few producers, this may lead to market power in the longer run. The irreversibility of decisions and contestability of created markets are examples of elements to be considered in this context.

Textbox 4: Digital health services as support, complement or substitute

“Digital health services support, complement or substitute established health services or offer even entirely new services”.

Examples for **supporting** established health services

1. Tools for managing chronic conditions/ Track and monitor patient status
 - Mental Health
 - Diabetes
 - Respiratory diseases
 - Cardio-vascular diseases
2. Diagnostic decision-support (algorithms)

Examples for **complementing** established health services

1. Radio Frequency Identification (RFID)-Tracking (e.g. of devices, hospital beds etc.)
2. Mobile networking of caregivers
3. Tele-consultation
4. Digital diagnostic tools

Examples for **substituting** established health services

1. Electronic health record
2. E-prescription
3. Internal communication of hospital employees
4. E-referral
5. Automatisation of simple process steps (e.g.
 - a. Monitoring of vital parameters (eICU) (e.g. tele-monitoring vital parameters of intensive care patients)
 - b. Barcode-based administration of medication
 - c. Remote appointments, care over distances

Examples for **new** health services

1. E-Triage (communication and database tool)
2. Robot for hospital logistics
3. Tele-monitoring of chronically ill patients
4. Performance dashboards
5. Routing of the patient flow
6. BigData-based algorithms with treatment recommendations
7. Extended purchaser analysis
8. Medical chatbots
9. Prevention tools (e.g. apps, fitness tracker etc.)
10. Patient-supporting networks
11. Questionnaires
12. E-booking of appointments
13. Telediagnosis

Source: EXPH

It may be useful to consider the place in the health care system of a digital health service, for instance, whether the technology will be used in health promotion or prevention, primary care, long term care, home care, or be used in an integrated way to support the patient pathway, etc. This may also help to target the type of outcomes a technology aims to improve.

Another relevant characteristic is whether the digital health service aims to strengthen the demand side of the health care sector (e.g. by providing more information to patients directly, for instance with monitoring apps on mobile devices) or rather the supply side of the health care sector (e.g. by generating better diagnostic information to specialists and family physicians or make exchange of information between professionals easier). Both types of digital services may change the nature and frequency of interaction between patients and professionals. Some digital services (e.g. facilitating remote contact between demand and supply) focus directly on this interaction. Such distinctions may have profound influence on the type of costs and consequences that could be expected from the adoption of such a technology. In the evaluation of such an intervention, this may determine the elements that need to be focused on as well as the appropriate evaluation strategy.

Some digital services may be aimed at transforming demand (e.g. shifting from primary care to self-management), while others may expand demand (e.g. by providing deprived groups better access to care, or by offering new treatment possibilities where none existed). The distinction between an existing market and a new market is relevant here as well.

Note that categorisations based on such characteristics will likely overlap. It is also unlikely that categorisations can be found that will completely do justice to the digital health technology at hand or fully guide the appropriate evaluation strategy. Hence, we advise to start any evaluation with a full description of the relevant digital technology, its use and aims, addressing elements like the ones above to give a full overview of the technology, its intended use, costs and consequences, and its most relevant comparator, in order to be able to select an appropriate evaluation strategy.

Disruptive innovations

Some forms of digitalisation may be classified as disruptive innovations, whereas others are more gradual improvements of existing (digital or non-digital) services. The Expert Panel (EXPH, 2016a) defines “disruptive innovation” in health care as a type of innovation that creates new networks and new organisational cultures involving new players, and that has the potential to improve health outcomes and the value of health care. This innovation displaces older systems and ways of doing things. The sources of disruptive innovations can include organisation from outside the health care system and patients (see Textbox 5). It is clear that some elements of the digital transformation have the potential of being disruptive in that sense. As previously highlighted, the *“implementation of any (disruptive) innovation should carefully address the issues of relevance, equity (including access), quality, cost-effectiveness, person- and people centeredness, and sustainability. Health*

policy should be designed to encourage enablers for developing and implementing disruptive innovations and reduce the potential barriers.” (EXPH, 2016a).

Textbox 5: Disruptive innovations

Innovations that improve a product or service in fundamental ways can be described as disruptive innovations (EXPH, 2016a). The disruption is usually attributed to a new business model enabled by new technology rather than the technology itself. In health care, disruptive innovations are often believed to come from outside of traditional health care organisations.

A recent survey of executives, clinical leaders and clinicians in the U.S. indicates a great demand for disruptive innovations both regarding health systems and organisations (hospitals, primary care) as such, but also regarding current vendor systems such as electronic health records and clinical decision support systems. Respondents of that survey believe that focused start-ups will lead the way (Dafny & Mohta, 2017).

Another actor is the growing e-patient community where some patients have developed disruptive innovations themselves. For example, Dana Lewis, a diabetes patient who created her own solution to monitor, predict and adapt her glucose levels and enable other patients to build their own pancreas systems using open source technology and tools. Another example is Hugo Campos who programmed his implanted cardiac device and is a patient advocate for the rights of patients to access their health data and become empowered participants in their own health.

See:

Dana Lewis. <https://catalyst.nejm.org/disruptive-innovation-in-healthcare-survey/> (last accessed 2018-11-01)

Hugo Campos. <https://allofus.nih.gov/about/who-we-are/all-us-participant-partners/hugo-campos> (last accessed 2018-11-01)

Such health policies encouraging enablers for developing and implementing innovations, contributing to the aims of health care systems, are clearly relevant in the context of digital health services as well. This emphasises that the role of governments exceeds that of evaluating specific technologies to see whether or not they should be funded and implemented, but also (and perhaps especially) should focus on creating incentives that steer the (decentralised) development, adoption and use of technologies that contribute to health system goals. We will return to this issue below.

In line with EXPH (2016a) a disruptive digital innovation can be characterised by some (or all) of the following capacities:

- Provide improved health outcomes

- Create new services and overcomes challenges regarding accessibility to existing or new services
- Lead to cost-effective methodologies that improve access
- Promote person-centred health delivery
- Empower the patient/person
- Disorder old systems
- Create new professional roles and capacities
- Create new sets of values for the health workforce, patients, citizens and community
- Introduce transformative cultural change

It may be clear that facilitating some of the changes involved (e.g. disorder old systems, creating new professional roles) may be difficult. We refer to EXPH (2016a) for a fuller discussion and policy recommendations.

General categorisation

In the context of evaluating and monitoring the impact of digital health services, we here use a categorisation along two lines. First, we follow the broad categorisation recently proposed by the WHO (2016), which distinguishes between interventions for clients, health care providers, for health systems or resource managers, and finally those for data services (see Figure 2 above). It is expected the first two categories will be closest to technologies that are evaluated with common HTA methods more often (i.e., directly aimed at affecting health or wellbeing), for which more specific evaluative frameworks have been developed.

We will reflect on some previously developed evaluative frameworks in the context of digital health services (e.g. Kidholm et al., 2017; Jasehn, 2017). Most of these are rooted in existing Health Technology Assessment (HTA) frameworks and methodology. In that context, it is useful to distinguish between technologies that change an existing treatment (path) and are standardised and 'self-contained' (Enzing et al., 2018), versus broader interventions that primarily change an organisation, access to care or information exchange. The first two in Figure 2 are more likely to focus on directly improving health or wellbeing than the latter two. This is useful in determining how close to the common HTA methodology an evaluation can be. HTA was primarily developed in the context of curative health technologies, with a special emphasis on evaluating pharmaceuticals, and its common methodology was therefore more specifically developed for that context. In recent years, developments were made to broaden the scope of evaluations to allow the evaluation of public health (e.g. Weatherly et al, 2009), medical devices (e.g. Tarricone et al., 2017), diagnostics (e.g. Severens & Van der Wilt, 1999) and elderly care (e.g. Makai et al., 2014). Still, such broadening poses many challenges, which need to be explicitly

addressed in the current context. It needs to be asserted that the applied methodology is suitable for the questions posed and the questions posed are aligned with the broad goals of health systems. Previous and ongoing projects, including EU funded projects like the MedtechHTA project, aimed and aim to improve HTA methodology to be better fit for this purpose.

Second, the level of decision-making to adopt a technology: centralised or decentralised. In centralised decision-making, the (potential) alignment with public goals of the health care sector can be directly ensured; if the evaluation is broad enough to allow this. It needs noting that centralised decision-making on reimbursement does not automatically guarantee the adoption, implementation or use of an innovation. Possibilities, willingness and incentives at lower levels in the system need to facilitate this. Centralisation of decisions can be demanding in terms of the information required to take a system-wide decision. Moreover, system-wide decisions in some instances may be more difficult to undo, in case they are judged as having been “wrong” ex-post.

Decentralised decision-making may involve other goals and incentives, both from public and private parties, than overall health system goals. With decentralised decision-making, we here refer to those decisions that result in the adoption, implementation and use of digital health services without a formal decision to do so by a public entity on a regional or national level. For example, the decision of an individual hospital to implement a specific electronic health dossier is seen as a decentralised decision. Each hospital makes own choices, some of which may be better than others. Even if they are equally good, the fact that different hospitals use different systems may lead to problems of coordination and interoperability. It is acknowledged that decentralised development, adoption and implementation of digital health services can have both advantages (competition, creativity, several pilots, etc.) and disadvantages (unnecessary experimenting, duplication, suboptimal outcomes on system level, etc.). Governments may therefore need to take a role in this. Also, if decentralised decisions are less aligned with the overall health system goals, this may require additional government intervention to guide the digital transformation in desirable directions. Monitoring, and policies to direct developments in desired directions are crucial in that context, as will be highlighted next. European countries could benefit from developing, implementing and systematically using such evaluation and monitoring systems.

We note that many evaluation and monitoring frameworks are ultimately concerned with informing public policy makers at a national or regional level, i.e. those with system responsibility. In the context of the current report, we do the same.

Concluding remarks

Many different categorisations of digital health services can be used. Here, we loosely use a categorisation which distinguishes between interventions for clients, health care providers, for health systems or resource managers, and data services. Moreover, we distinguish between centralised and decentralised decision-making and will mostly focus on the former. Given the importance of context, we advise to start any evaluation with a full description of the relevant digital technology, its use and aims, addressing elements like the ones above to give a full overview of the technology, its intended use, costs and consequences, and its most relevant comparator, in order to be able to select an appropriate evaluation strategy.

1.4. Evaluating and monitoring

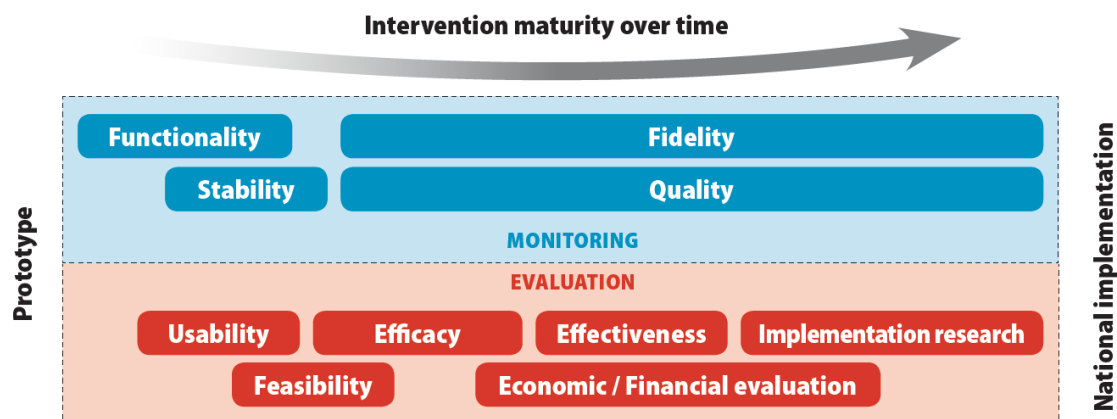
Recently, WHO (2016) provided an important practical guide for the monitoring and evaluation of digital health interventions. We adopt some of the elements of their report in this Opinion. Importantly, the WHO report distinguishes between monitoring and evaluating, which is an important distinction, although the two can be strongly related. In particular, monitoring the impacts of an intervention can provide input into an evaluation of that intervention.

Monitoring

Monitoring is defined as “the continuous process of collecting and analysing data to compare how well an intervention is being implemented against expected results” (WHO, 2016; WHO, 2013). Hence, this entails “the routine collection, review and analysis of data, either generated by digital systems or purposively collected, which measure implementation fidelity and progress towards achieving intervention objectives.” (WHO, 2016). The role and content of both monitoring and evaluating changes with the maturity of an intervention. This is shown in Figure 3.

Figure 3: Monitoring and evaluation in relation to intervention maturity

Figure 1.1. Intervention maturity life-cycle schematic, illustrating concurrent monitoring (blue/upper) and evaluation (red/lower) activities that occur as an intervention matures over time (left to right) from a prototype application to national implementation

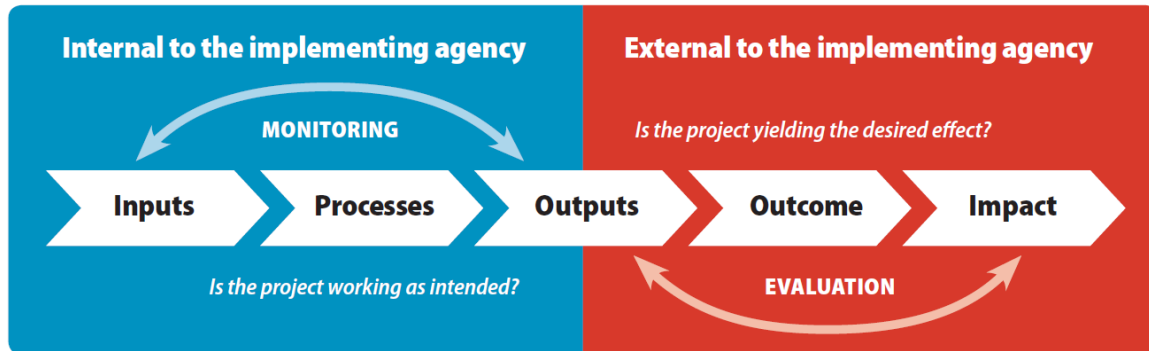


Source: WHO (2016).

Monitoring can be viewed as checking whether the ‘right thing’ (as established with an evaluation) is ‘done right’. Some interventions can still be the ‘right thing’, but if not properly used or implemented, they might not yield the expected or intended benefits. Hence, monitoring could result in doing things better in order to lead to better performance.

The WHO (2016) report acknowledges the intertwined nature of evaluation and monitoring, but frames monitoring somewhat more “internally” and evaluation “externally”. This is highlighted in Figure 4.

Figure 4: Monitoring and evaluation: internal and external



Source: WHO, 2016

While this distinction can be useful, here we see monitoring as the continuous process of collecting and analysing data to compare or evaluate how well an *intervention or system* is performing against *expected or desired* results. This can be done both for ‘internal’ purposes as well as for external purposes. We feel this is important to stress also because monitoring may provide real world evidence regarding the performance of an intervention in practice, which may provide more information not only about its successful implementation but also whether it is the right thing in practice. Moreover, governments may use monitoring of health system performance in key parameters of quality (EXPH, 2014), in order to assess whether improvements are possible or necessary. Monitoring can be used in striving for continuous improvement, also at the system level, which is distinct from case by case decisions based on targeted evaluations. Hence, monitoring is seen here not only as internal but also external to an implementation agency. Monitoring can take place on a system level but also on process and outcome level (including, for instance, fraud checks).

Indicators for measuring e-health: an examples from the Nordic countries

The Nordic countries have progressed far in the development and implementation of national health information systems. The differences in eHealth policies, architectures, and implementation create a fruitful basis for benchmarking and learning from each other. Moreover, together the Nordic countries can function as examples for other European countries.

In 2011, the eHealth group under the Nordic Council of Ministers established the Nordic e-health Research Network (NeRN) to develop, test and assess a common set of indicators for monitoring eHealth in the Nordic countries, Greenland, the Faroe Island and Åland, for use by national and international policy makers and scientific communities to support development of Nordic welfare.

The Research Network published its first report in 2013, where a methodology was presented to generate eHealth indicators, and the first common indicators were tested (Hyppönen et al, 2013). The second report, published in 2015, presented the benchmarking results of altogether 49 common Nordic health IT indicators, for which data were available for 48 indicators from at least some Nordic countries. As such, the report offered a unique view into the state of the art of health IT in the Nordic countries, into continuing work (Hyppönen et al, 2015) on health IT policies, and into support for high-performance health systems and quality and efficiency of health care and services.

In the third report (Hyppönen et al, 2017) options for collecting, analysing, and publishing the benchmarking results and comparisons between the Nordic countries are explored and common indicators that can be used to analyse and compare patients' and citizens' use and experiences of eHealth services are presented. This report illustrates possibilities, challenges and suggestions related to these topics. It offers important lessons to both policy makers and researchers in work towards Nordic and EU-wide data to support evidence-based eHealth policy.

Three contexts

Monitoring is not only important for previously or still to be evaluated interventions, but also for general trends (partly) fuelled by the digital transformation. The case for monitoring system performance (using key indicators) was previously highlighted (EXPH, 2014). If monitoring indicates specific elements in the health system to need improvement, also those that are directly governed by decentralised processes and decisions, governments still have the obligation to see whether and how they can intervene in order to improve.

Hence, three contexts of (monitoring and) evaluation are distinguished here:

(1) Central decisions on funding or implementing a specific digital health service

These evaluations directly inform decisions by public policy makers on the desirability to fund, reimburse or adopt a specific digital health service. This is in line with the common use of HTA.

(2) Central monitoring and evaluating of health system (elements) performance / quality

These activities are directed at monitoring and evaluating by public policy makers whether (elements of) the health system develop in desired directions or require additional policy measures. These activities can be specifically targeted to follow up a decision as informed under (1) or more generally.

(3) Decentralised decisions on funding / implementing digital health services in a public health system

Many investment decisions in digital health services take place at lower levels in the health system. These affect costs and quality of the health system. Hence, there is an overarching interest and responsibility for central policy makers to ensure the alignment with overall health system goals. Specific elements (like interoperability or facilitating aligned decisions) may require central coordination.

We will consider these three contexts below, with an emphasis on (1).

1.5. Frameworks informing centralised decision-making

In order to assess the (potential) impact of a digital health service, an evaluation can take place. This is a central focus point in the current mandate and Opinion. In many ways, evaluating digital health services resembles evaluating the impact of any type of technology (also those non-digital). Moreover, just like with other care, evaluating a single, well-defined intervention is typically easier than several, especially when these are diverse. Here, we first focus on frameworks for evaluating specific digital health services.

In the context of evaluating health technologies, in relation to (some) health system goals, Health Technology Assessment has developed as an important field, informing decision makers about the impact of an intervention relative to a relevant alternative. While applied HTA often takes the form of an economic evaluations, which relates the costs of an intervention to its (health) impact, HTA can include broader considerations regarding organisational, legal, ethical and cultural aspects. The European Network for Health Technology Assessment (EUNETHA) defines HTA as *"a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner."*

A recent report (Jasehn, 2017) describes the development of "A Minimum HTA Inspired Framework to Assess the Value of National eHealth Projects". In that report, which is clearly relevant for the current Opinion, the development of the application of HTA in the field of Telemedicine (leading to the Model for Assessment of Telemedicine (MAST) framework – Kidholm et al., 2012) and broader eHealth applications is highlighted. The WHO elements of evaluation described in (WHO, 2016) are also highlighted in this paragraph.

We emphasise that the below addressed frameworks are important examples of frameworks and that more exist. As we will argue later, further synthesis and development of frameworks is encouraged.

1.5.1. MAST

It is useful to highlight the MAST framework first. The objective of MAST is to provide a multidisciplinary assessment framework consistent with proper scientific standards and guidelines, which could be used by different decision-makers to select the most appropriate technologies that can be applied in the most cost-effective way (Kidholm et al., 2012; Ekeland and Grøttland, 2015; Jasehn, 2017).

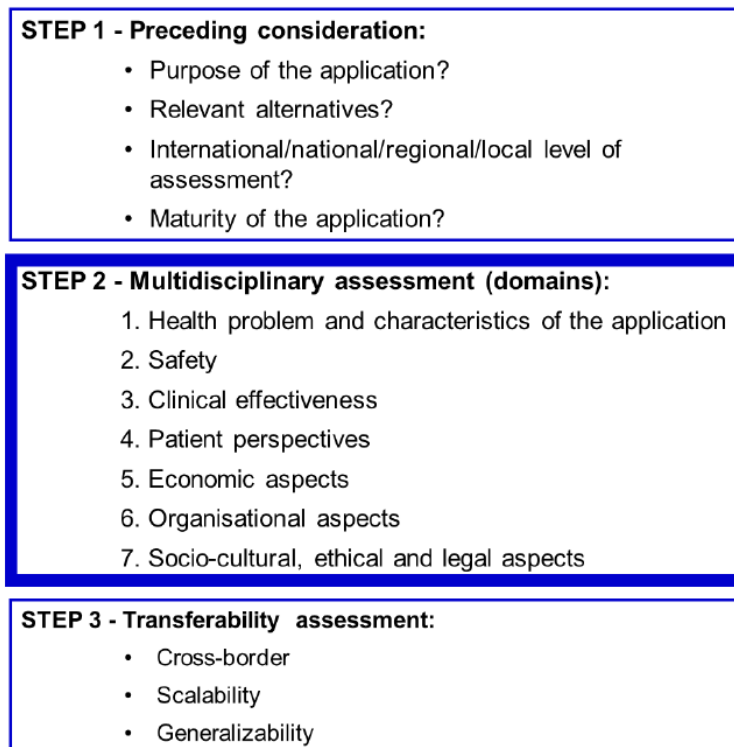
The MAST framework consists of three phases, as shown in Figure 5. Phase 1 consists of preceding considerations. This includes questions regarding the aim of the technology and its alternatives, legislation, reimbursement and maturity of the technology (Kidholm et al.,

2012). In the Jasehn report (2017) it is indicated that that in this phase especially the maturity of the technology and organisation are assessed. The other aspects can be very important as well, as for instance also highlighted in the context of disruptive innovations (EXPH, 2016a). If a technology is not considered to be sufficiently mature, a full assessment should not take place (Kidholm et al., 2012).

In the second phase, a multidisciplinary assessment takes place, organised in seven domains: (1) Health problem and characteristics of the application, (2) safety, (3) clinical aspects, (4) patient perspectives, (5) economic aspects, (6) organisational aspects and (7) socio-cultural, ethical and legal aspects. Kidholm et al. (2012) provide an additional topics for each of these domains to be addressed during the assessment.

The framework ends with phase 3, in which transferability is specifically addressed. One reason for this is *"that implementation of telemedicine in healthcare systems is generally a process which affects the organization. To reach the full potential of telemedicine, adjustments must often be made in the distribution of tasks between different healthcare professions (task shifting) and in communication between professionals."* (Kidholm et al., 2012) Other aspects involve interoperability, scalability and generalisability.

Figure 5: MAST framework



Source: Jasehn, 2017

The MAST framework is relatively frequently used in Europe (e.g. Torbjornsen et al., 2014; Rasmussen et al., 2015; Vis et al., 2015), which suggests that researchers may be aided by the framework. Kidholm et al. (2017) moreover highlight the potential usefulness of the framework for European decision makers (Jasehn, 2017).

The MAST framework was developed for the context of evaluating telemedicine. Broader eHealth technologies originally were not considered when developing the framework. Hence, the MAST-IC framework was developed, to allow evaluation of ICT supported integrated care. In order to allow broader care aspects to be addressed, the wording in three domains in phase 2 (see Figure 5) was changed:

- (1) Health and social situation of the care recipient and characteristics of the service
- (3) Clinical and care effectiveness
- (4) Care recipient perspectives

1.5.2. Jasehn

Recently, a report was published that suggests a minimum HTA framework for evaluating eHealth technology (Jasehn, 2017). The authors write: *"The scope of the suggested framework is, starting from the recommendations of EUnetHTA, to use the accumulated experience from the HTA performed in different European eHealth projects, services and settings, to bring together experience on eHealth assessments and to devise a minimum framework appropriate to assess the value of National eHealth projects intended for patient/citizen use."*

It is important to note that the addition of 'national eHealth projects' indicates the level of projects intended to be evaluated with the framework, which also signals something about the expected audience/users: policy makers at a regional or national level. The authors also indicate that the HTA frameworks that are used in different European countries are aiming to include HTA information into certain policy, governance, reimbursement, or regulatory processes. Hence, the aim is to allow (public) decision makers to make optimal choices in allocating scarce resources by providing information about the (relative) performance of eHealth solutions. As the authors state: *"...the ambition of this framework is to improve the possibilities for decision makers to choose the most appropriate eHealth services to be used in the most cost-effective way by providing a multidisciplinary assessment based on scientific methods and results."*

The proposed framework is intended to be easy to read and use, aligned with earlier recommendations, valid, and appropriate for supporting decisions and resource allocation, technologies targeted at patients and citizens and ICT supported integrated care projects

(Jasehn, 2017). Here, our categorisation of types of digital health services may be relevant again. Interventions directly aimed at clients and health care providers may be more easily evaluated using these frameworks and underlying methodology than for instance digital health services and data services aimed at health systems or resource managers. The latter may require more profound adaptations of the existing HTA framework and methodology.

The proposed Jasehn framework builds on MAST-IC and key principles for HTA conduct, as proposed by Drummond et al. (2008), as shown in Textbox 6. The authors suggest these principles are also relevant in the case of eHealth. Especially in the context of central decision-making this is indeed likely to be the case.

Textbox 6: Principles for HTA proposed by Drummond et al. 2008

A. Principles A – Structure of HTA programs

1. The goal and scope of the HTA should be explicit and relevant to its use
2. HTA should be an unbiased and transparent exercise
3. HTA should include all relevant technologies
4. A clear system for setting priorities for HTA should exist.

B. Principles B – Methods of health technology assessment

5. HTA should incorporate appropriate methods for assessing costs and benefits
6. HTA should consider a wide range of evidence and outcomes
7. A full societal perspective should be considered when undertaking HTA
8. HTA should explicitly characterise uncertainty surrounding estimates
9. HTA should consider and address issues of generalisability and transferability

C. Principles C – Processes for conducting health technology assessment

10. Those conducting HTA should actively engage all key stakeholder groups (such as professional bodies, patient organisations, manufacturers)
11. Those undertaking HTA should actively seek all available data
12. The implementation of HTA findings needs to be monitored

D. Principles D – Use of health technology assessment for decision-making

13. HTA should be timely
14. HTA findings need to be communicated appropriately to different decision-makers
15. The link between HTA findings and decision-making processes needs to be transparent and clearly defined

Source: Jasehn, 2017

Based on these earlier works, the Jasehn framework looks as follows (see Textbox 7).

Textbox 7: The four steps of the Jasehn framework

1. Preceding considerations

- Set the general scope of the HTA according to the PICO (patient/problem, intervention, comparison, outcome) structure
- Justify the choice of comparators and outcomes
- Include a checklist for potential ethical, organisational, patient and social and legal aspects, maybe assessment of maturity of technology
- Include a project plan for the assessment

2. Assess domains and issues

It concerns a multidisciplinary assessment of the outcomes within 5 main and 4 secondary domains.

- Confirm that all main domains of assessment are relevant and can be assessed
- Confirm that secondary domains have been assessed with a checklist during the first step
- Select relevant issues for each domain
- Formulate research questions

3. Collect and analyse data

- Identify potential sources of data
- Literature search
- Quality appraisal
- Effect measures and CIs, Effectiveness vs efficacy
- Define appropriate statistical methodology and modeling techniques to perform the assessment
- Interpret evidence

4. Report

The report should follow the following structure:

- Scope
- Results
- Discussion
- Conclusion

Source: Jasehn, 2017

The Jasehn report (2017) provides more detail on the second phase. The five main domains are equal to the first five domains of the MAST-IC framework, i.e. (1) health and social situation of the care recipient and characteristics of the service, (2) safety, (3) clinical and care effectiveness, (4) care recipient perspectives and (5) economic aspects. The four secondary are the sixth and seventh domains of the MAST-IC framework, i.e. (1) organisational aspects, (2) socio-cultural, (3) ethical and (4) legal aspects.

This framework is considered to be a very useful starting point for the evaluation of eHealth programs on a regional/national level. It can serve as a point of reference for broader future frameworks. It may be complemented by other frameworks, like the Multiple Optimization Strategy (MOST), a methodological approach for building, optimising, and evaluating multicomponent interventions (Collins et al., 2011). We do provide some further suggestions for development and will place this evaluative framework in the broader context of evaluating the digital transformation in the next paragraph.

Before that, we briefly highlight the elements of the WHO evaluation framework (WHO, 2016). Note that we focus here on the evaluation elements, not on the monitoring elements. We consider the WHO guide to be an important source for people involved in developing, implementing, monitoring or evaluating digital health interventions.

1.5.3. WHO

The WHO guide emphasis the different stages of the development of a digital health service, the need to involve different stakeholders in the development, monitoring, evaluation and implementation phases. It also highlights how these phases and processes are connected and provides practical guidance on methods and reporting.

The report emphasises that *“Evaluation is optimally an ongoing cyclical process that informs adjustments and improvements to further intervention planning and implementation. Evaluation activities generate data that can be analysed and interpreted, forming evidence about the likely impact of the intervention.”* A cyclical approach to evaluation (and monitoring), making it fit an environment of continuous improvement (either by adopting, improving or ending programs), is indeed considered to be important, although not often implemented as such in practice.

The authors highlight that at *“the core of every digital health system or intervention is a value proposition – a statement describing the benefits to end-users, with an implicit comparator, which can be a non-digital intervention or an alternative digital product. [...] Value propositions describe (i) which end-user needs are met by the digital health system and how, (ii) why the digital health system is innovative, and (iii) why the digital health system is superior to the standard of care or status quo. [...] Claims about the digital health intervention are based on assumptions about end-user needs and/or the effectiveness of the digital health system.”* (WHO, 2016)

The claims could include aspects like efficacy, effectiveness or cost-effectiveness and can help to design evaluations and monitoring procedures, because they define the key parameters that are expected to be affected by the new intervention. A point of attention is the possibility of ignoring important unintended consequences of an intervention if the

evaluation focuses on the intended and claimed impacts. Hence, a core set of parameters should be included in any evaluation, covering the most important and common impacts. This also increases the comparability of studies.

The WHO report mentions the possibility of linking the claims for a digital health intervention to the Sustainable Development Goals or the Universal Health Coverage goals (which also emphasises the WHO's interest in aiding low- and middle-income countries with their guide), which indicate the potential breadth of the impact of digital health services.

Evaluation is defined as: *"The systematic and objective assessment of an ongoing or completed intervention, with the aim of determining the fulfilment of objectives, efficiency, effectiveness, impact and sustainability."* (WHO, 2016) The evaluation part of the report focuses on evaluating 'effectiveness, value for money and affordability'. WHO highlights the framework for the different stages of evaluation that correspond to the various stages of maturity of the digital health intervention, including:

Feasibility: Assess whether the digital health system works as intended in a given context.

Usability: Assess whether the digital health system is used as intended.

Efficacy: Assess whether the digital health intervention achieves the intended results in a research (controlled) setting.

Effectiveness: Assess whether the digital health intervention achieves the intended results in a non-research (uncontrolled) setting.

Implementation research: Assess the uptake, institutionalization and sustainability of evidence-based digital health interventions in a given context, including policies and practices.

The importance of the latter aspect, implementation research, is emphasised. This is highly relevant to understand, monitor and evaluate the uptake and use of a digital health service in practice. WHO (2016) also gives quite some attention to the aspect of economic evaluation (in its different forms) and some practical pointers. We note here that for instance an aspect like access is covered under monitoring in the WHO report, and hence is not highlighted in the part on evaluation.

In terms of the different forms of evaluation, WHO provides a distinction between and overview of formative and summative evaluations (Figure 6). This distinction can indeed be useful in the context of evaluation of digital health services.

Figure 6: Formative and summative evaluations

Objectives	Illustrative questions asked
FORMATIVE	
Needs assessment	Determines who needs the digital health intervention, how great their need is, and what activities will best address those needs What are the client needs? What intervention activities will best address these needs?
Process evaluation^a	Measures outputs attributed to intervention activities and inputs; this can be done continuously or as a one-time assessment Is the intervention operating as intended?
Implementation evaluation^a	Monitors the fidelity of the intervention or technology system Is implementation occurring in accordance with original study protocols?
SUMMATIVE	
Performance or outcome evaluation	Measures the effectiveness of intervention activities on immediate and intermediate changes in key outcomes, including knowledge, service provision, utilization and coverage <i>Provision:</i> Are the services available? What is the intervention's effect on changes in service delivery? <i>Utilization:</i> Are the services being used? <i>Coverage:</i> Did the digital health system increase coverage of the health intervention? Is the target population being reached?
Impact evaluation	Measures the long-term net effects or impact of the intervention on key health outcomes, including mortality, morbidity and disease risk, at the community level or higher Were there improvements in disease or mortality patterns, or health-related behaviours?
Economic evaluation	Aims to determine a probable value for money from an investment What is the incremental cost–effectiveness of the digital health intervention as compared to existing services?
Secondary analysis	Analysis of existing data to explore new research questions or methods not previously explored Using the database from the International Telecommunication Union (ITU), are there associations between mobile phone ownership and women's literacy? (Questions should be tailored to research objectives)
Meta-analysis	Aims to integrate evidence on the effects (impact) of multiple interventions on key outcomes of interest Overall, across multiple studies, what is the effectiveness (or impact) of this type of intervention on an outcome of interest?

Source: WHO, 2016

The WHO provides practical guidance in numerous aspects of the evaluations in the different stages of the maturity of digital health services. In a general sense, different types of evidence need to be generated depending on the stage of development of a digital health service. Evaluation studies need to answer different questions and address different issues at different stages, e.g. from the initial development phase through to routine use, and therefore, different type of data are required. The following list, adapted from Ammenwerth (2015), outlines the different possible types of questions and methods that can be used to generate the required evidence across the different stages.

Development phase:

- What are the users' needs? (needs assessment)
- Is the digital service free of errors? (test runs)
- Was the digital service built as defined in the requirements? (verification)
- Was the digital service built as wanted by the users? (validation)

- Will the digital service work in practice? (simulation studies)

Pilots and early use:

- Is the technical quality adequate? (performance measurements)
- Is the service user-friendly? (usability tests)
- Is the service sufficiently integrated in the clinical and broader health services processes? (observations)
- Does the service work as intended? (interviews)

Routine use:

- Is the service adopted as intended? (usage pattern analysis, documentation analysis)
- Are the users satisfied? (user survey)
- Is the service cost-effective (cost analysis)
- Does the service lead to errors? (error report analysis)
- What is the impact of the digital health service on efficiency, appropriateness, organisation, or outcome quality of care? (experimental or quasi-experimental studies).

In addition to Ammenwerth's list above, there is also the stage of sustaining and scaling-up digital health services over time and across different implementation sites and systems. The sustainability of digital innovations is dependent on the extent to which health service structures and support systems integrate digital interventions into existing services and systems in a way that supports their long-term stability. This is influenced by contextual factors such as funding, level of organisational support, readiness, capacity and training etc. Interventions delivered at scale need to serve a much more diverse range of service providers working within highly variable and sometimes insufficient service infrastructure and with variable resources (Ogden and Fixsen, 2014). There is, therefore, a need for practical implementation trials that will test evidence-based interventions in more typical resource-constrained conditions before roll-out on a larger scale.

A continuum of evaluation studies employing different methods (both qualitative and quantitative research methods) need to be employed to address the different questions that need to be answered at different stages of the development process. Different types of data will generate evidence that will inform the implementation of digital health services (formative or process evaluation) and strategic decisions concerning their impact and future use (summative or outcome evaluation), including scaling-up on a larger scale. When economic evaluations are required, the overview of types of economic evaluations that could be used in that context provided by WHO (2016) may be useful (see Figure 7).

Figure 7: Types of economic evaluations

	Definition	Costs	Consequences	Illustrative questions
Cost-effectiveness analysis (CEA)	Comparison of two alternatives where consequences of the intervention are measured in natural units	Monetary units	Effectiveness measure: Natural units (e.g. life-years gained, lives saved, cases detected)	Is sending SMS reminders to encourage pregnant women to come for antenatal care more cost-effective than a strategy of not sending messages?
Cost-utility analysis (CUA)	Form of CEA where consequence is measured in terms of healthy years	Monetary units	Utility measure: Quality-adjusted life years (QALYs) or disability-adjusted life years (DALYs)	Health-care providers are sent SMS reminders to notify them if a home birth has occurred. Is this SMS strategy cost-effective compared with a strategy of not sending messages, in terms of increasing the number of healthy years of life for newborns?
Cost-benefit analysis (CBA)	Comparison of two alternatives where consequences of the intervention are measured in monetary terms	Monetary units	Benefit measure: Monetary units	Which digital health option – using SMS or interactive voice response – offers the best net benefit for each client? How does this change over the timescale of the digital health intervention?
Cost-consequence analysis (CCA)	Examination of costs and consequences but without isolating a single consequence or aggregate consequences into a single measure	Monetary units	Consequence measure: Natural units	How does the digital health intervention make a difference to the rate of: provision of perinatal care in the home to pregnant women; trained attendants present at birth; newborns fully vaccinated; adequate postnatal care for mothers; and improved education and development due to better health?
Cost-minimization analysis (CMA)	Comparison of relative costs of interventions with equivalent effects	Monetary units	Consequences are assumed to be equivalent	You want to provide tetanus toxoid immunizations to 1000 pregnant women. Which strategy will cost the least to achieve this result – (i) having a community health worker promote and refer pregnant women, or (ii) using a digital health strategy of sending SMS reminders to pregnant women to attend ANC?

Source: WHO, 2016

As indicated, the WHO gives elaborate attention also to implementation research, which importance is stressed here. WHO (2016) quotes Peters et al. (2013) that implementation research “*seeks to understand and work in real-world or usual practice settings, paying particular attention to the audience that will use the research, the context in which implementation occurs, and the factors that influence implementation*”.

Importantly, while implementation research under ideal circumstances may be performed after the aspects like stability, safety, efficacy, effectiveness and cost-effectiveness have been established, this may not always be the case in practice. Indeed, “*many digital health systems may be scaled up from a prototype stage of development, bypassing traditional hurdles of efficacy and effectiveness studies*” (WHO, 2016). In those case hybrid evaluations may be required, combining evaluations of effectiveness and cost-effectiveness with implementation research.

Concluding remarks

Important frameworks and practical guides for the evaluation of digital health services exist. We have highlighted the recent Jasehn and WHO framework. These can serve as a starting point both for practical evaluation studies and for further development of the frameworks. In evaluations, the development phase of the digital health service as well as implementation of it, are crucial elements. Combinations of different evaluation types may be required to provide relevant information to decision makers at different moments. All of these should be (made) fit for purpose in the context of digital health services. Careful selection and justification of applied methods is warranted.

1.6. Evaluating 'the digital transformation'

Looking at both the mandate (which addresses the issue of evaluation of the digital transformation) and the breadth of the health system goals listed in paragraph 3.2, a number of remarks should be made regarding the currently developed frameworks for central decision-making. These comments are not intended as a critique but rather as complements and encouragement for their further development and use, as some of the issues addressed below could also fit into the developed frameworks under different headings.

Central level decisions

It is good to point to the context of the decisions the frameworks intend to inform. Frameworks like that of Jasehn seem especially targeted to (ex-ante) inform allocation decisions at a central level. Even though they may have elements like 'a business case' under the economic considerations, they appear to be especially targeted at and suited for informing public decisions. Decentralised decision-making may be done by actors with own aims and goals, that may or may not align with public goals. When the goal is to assess the broader influence of digitalisation on health system performance (a question that is also posed in the mandate), ex-ante evaluations to inform centralised decisions are important, but not sufficient. The process of decentralised decisions and the potential role of governments in that process should be addressed more fully (see paragraph 3.8). Hence, while frameworks like MAST and that of Jasehn are important, they are designed to inform specific decisions affecting digitalisation, but not the full transformation. Moreover, evaluating separate technologies does not necessarily result in an overall optimal outcome.

Methodological choices

It is important to emphasise that the developed frameworks and guides are relatively general. While this is a benefit as it keeps the frameworks manageable and broadly applicable, it does leave open many questions in the process of using them. For instance, an evaluation is always a comparison of two situations (e.g. the situation with the new eHealth program and the situation without). The choice of comparator is highly influential and needs justification as typically highlighted (Jasehn, 2017; Kidholm et al., 2012; Drummond et al., 2008). Next to this justification, other choices are influential, some of which are less relevant in the context of pharmaceuticals (for which the HTA framework is still most frequently applied). For instance, the fixed nature of the costs related to some digital health services implies that a long run perspective is required, which brings in issues related to how to assess and discount future benefits and costs. It also raises questions about the appropriate time horizon for the evaluation. Another important feature is that

many digital health services may take time to develop (raising the issue of when to evaluate them), may develop in different ways in different contexts and organisations (making them less comparable and drawing conclusions about 'the' health service difficult), and may involve a learning curve for its users. How such learning effects should be dealt with in an evaluation will likely differ from case to case. We also highlight the need to ensure that the evaluation is sufficiently broad in the sense that it captures the effect of an intervention on the full patient pathway, where appropriate. Two examples in this context are the use of a new diagnostic tool that may change the complete course of action for patients. It is then not sufficient, to assess the costs and benefits of the use of this tool to only consider for instance its sensitivity and specificity, but the relevant full patient journey needs to be considered. The second example is when digital health services lead to more integrated care. Again, the full impact of such a change needs to be considered.

The issues raised above emphasise that influential choices, for which no standard solutions exist, need to be made in the context of these evaluations. These are difficult issues, which require investments in HTA methodology to address. Some of the ongoing EU-funded projects will contribute to this. In that context, differences between member states in how to operationalise (economic) evaluations, for instance in terms of perspective, which costs are included and how, how benefits are expressed, etc., are also important to mention, as they add to the complexity.

European repository

A European repository containing evaluation frameworks, methods, tools, completed and ongoing evaluations, would be useful in this context. It would facilitate optimal exchange of knowledge and experience at a European level and could lead to continuous improvement and expansion of the evaluation framework. Such a repository can also offer guidance as to how evaluations could be performed. Such guidance could be modular (to allow different countries to take different perspectives for instance) and be flexible. The latter is even more important because of the unpredictability of new developments and innovations, which may lead to new methodological and informational questions. Guidance should not turn into rigidity, but should lead to methodological rigour in addressing the right questions as best as possible. Platforms to exchange strategies and synergise expertise are encouraged.

HTA methodologies need to be fit for purpose

Much of the HTA methodology was first developed for (often standardised, self-contained) curative interventions, such as pharmaceuticals, typically aimed to produce improved health (both in terms of length and quality of life). The widely used outcome measure Quality-Adjusted Life-Years (QALYs) used in cost-utility analyses, for example, measured

by the well-established and validated EQ-5D instrument (EuroQoL group, 1990) in many instances has been shown to be a valid measure of health gains. However, in some contexts (e.g., in mental health or elderly care) this is not always the case. As digital transformation does and will also take place in these contexts, one may even expect it to have a potentially relatively larger influence in relation to mental health and long term care. Selecting other outcome measures in those circumstances may be challenging, because of a lack of validated and standardised outcome measures, especially in relation to the fact that the decision-making process is aided by standardisation and comparability. New outcome measures like the ICECAP-O (wellbeing measure for older people), ASCOT (wellbeing measure for social care users) and the CarerQoL (care-related quality of life in informal caregivers) may help (Coast et al., 2008; Netten et al., 2012; Brouwer et al., 2006), but do expand the number of outcome measures (and thus reduce comparability and increase decision complexity). In terms of the various types of economic evaluations, we encourage the applications of cost-utility analysis whenever possible and health and wellbeing are central outcomes. In some cases, for instance considering administrative digital solution, conventional cost-benefit analyses may be more appropriate. The WHO report (2016) provides an overview of available methods and suggestions for when their use would be appropriate.

When digital interventions are variable (e.g., because they are adapted in the specific setting they are used) this hampers assessing their impact and as well as generalisations based on results (e.g. in terms of scaling up). Moreover, randomisation may not always be possible, leading to the need to opt for other research designs. This may result in generating lower levels of evidence for decision-making when compared to (systematic reviews of) RCT's. Both researchers and decision makers need to be able to deal with such situations, in which not always the highest level of evidence may be obtainable but *appropriate evidence* may need to be sought.

In that context, the WHO (2016) report gives an overview of different study types, also linking them to the different phases of the evaluation as described in the previous paragraph.

Figure 8: Hierarchy of evidence

Table 4.4. Hierarchy of evidence by stage of evaluation

		Stage of evaluation			
		FEASIBILITY/USABILITY	EFFICACY	EFFECTIVENESS	IMPLEMENTATION SCIENCE
Confidence in the strength of evidence	Excellent	<ul style="list-style-type: none"> ■ Multicentre randomized controlled trials (RCTs) 	<ul style="list-style-type: none"> ■ Multicentre RCTs 	<ul style="list-style-type: none"> ■ Multicentre RCTs 	<ul style="list-style-type: none"> ■ Multicentre/quasi-experimental studies
	Good	<p>1. RCT</p> <p>2. Quasi-experimental studies</p> <ul style="list-style-type: none"> ■ Interrupted time series ■ With control groups and baselines ■ With control groups but no baseline ■ Without control groups <p>3. Observational studies</p> <ul style="list-style-type: none"> ■ Cohort ■ Case-control 	<p>1. RCT</p> <p>2. Quasi-experimental studies</p> <ul style="list-style-type: none"> ■ Interrupted time series ■ With control groups and baselines ■ With control groups but no baseline ■ Without control groups <p>3. Observational studies</p> <ul style="list-style-type: none"> ■ Cohort ■ Case-control 	<p>1. RCT</p> <p>2. Quasi-experimental studies</p> <ul style="list-style-type: none"> ■ Interrupted time series ■ With control groups and baselines ■ With control groups but no baseline ■ Without control groups <p>3. Observational studies</p> <ul style="list-style-type: none"> ■ Cohort ■ Case-control 	<p>1. Quasi-experimental studies</p> <ul style="list-style-type: none"> ■ Interrupted time series ■ With control groups and baselines ■ With control groups but no baseline ■ Without control groups <p>2. Observational studies</p> <ul style="list-style-type: none"> ■ Cohort ■ Case-control
	Fair	<p>Descriptive studies</p> <ul style="list-style-type: none"> ■ Surveillance ■ Cross-sectional studies ■ Ecological studies ■ Case-series report ■ Case studies 	<p>Descriptive studies</p> <ul style="list-style-type: none"> ■ Surveillance ■ Cross-sectional studies ■ Ecological studies ■ Case-series report ■ Case studies 	<p>Descriptive studies</p> <ul style="list-style-type: none"> ■ Surveillance ■ Cross-sectional studies ■ Ecological studies ■ Case-series report ■ Case studies 	<p>Descriptive studies</p> <ul style="list-style-type: none"> ■ Surveillance ■ Cross-sectional studies ■ Ecological studies ■ Case-series report ■ Case studies
	Poor	<ul style="list-style-type: none"> ■ Editorials ■ Expert opinion 	<ul style="list-style-type: none"> ■ Editorials ■ Expert opinion 	<ul style="list-style-type: none"> ■ Editorials ■ Expert opinion 	<ul style="list-style-type: none"> ■ Editorials ■ Expert opinion

Source: WHO, 2016

Also, from other contexts, like that of conditional reimbursement and real world evidence, it appears that determining which level of evidence is feasible and appropriate, also to base policy decisions on, remains an crucial question. If appropriate evidence is not the highest form of evidence, this necessarily implies that the decision uncertainty will increase. Value of information is an important issue in that context (e.g. Claxton, 1999), as well as the political feasibility. If it is expected that the (use of) the digital health service will evolve over time, this dynamic aspect needs to be included in an evaluation as good as possible.

Measure the appropriate outcomes

Given the diversity of health system goals as highlighted in paragraph 3.2, one may wonder whether all health system goals, or aspects of quality, receive sufficient attention in all current frameworks. The elements of safety, effectiveness and efficiency appear to be well covered, generally. However, while aspects like appropriateness, access, equity and relevance may be captured under some of the additional headings (like monitoring or preceding considerations), they may be perceived as being less visible, especially when in the Jasehn report these elements are listed as 'secondary'. Since digital solutions may affect these elements of quality, and improvements in these aspects of quality remain needed (EXPH, 2014), direct attention for these elements in evaluations of digital services is supported and encouraged. For instance, remote access to primary care may be valued beyond possible health gains involved. Patient empowerment, orientation towards the

lifegoals of the patient, and information (e.g., value of knowing specific parameters like blood pressure or risk profile) are aspects of outcomes that may require specific approaches in evaluations as well.

Equity (horizontal and vertical), also in relation to preferences and abilities of different user groups (see Textbox 8), is important to consider in economic evaluations and methods for doing so are developed (e.g. Cookson et al., 2016; Nord, 2005; Van de Wetering et al., 2013; Cookson & Dolan, 2000). However, often such equity considerations pertain to the disease characteristics or beneficiary characteristics. In the context of digital innovations this may take a different form, and it may be necessary to consider the accessibility of digital health services in terms of financial access, digital literacy, internet access, etcetera, in order to avoid a digital divide.

One of the challenges may also relate to differences between age groups in terms of uptake and understanding of the new technologies. We do note that while digitalisation may result in differences in terms of use in different age groups, it may also offer a unique possibility to tailor services to specific characteristics and needs of different (age) groups. It may also be used to target specifically deprived groups, including people in rural areas, without physical access to health care facilities or people with limited health literacy.

Such considerations should be addressed when evaluating technologies, both generally as well as specifically for the technology under investigation.

Textbox 8: Accessibility of digital services for visually impaired



Helsinki University Hospital has utilised check-in machines (see above picture) for the patient registration for some years. When the patient enters the hospital he/she shows the barcode of his/her ID card or driver's license to the reader of the machine. His/her visit is then registered and the check-in machine gives instructions on screen or prints a paper where to go within the hospital premises. The Association for Visually Impaired was, however, not happy with the machines. They claimed that the touch-screen of the machine is unusable for a person with visual problems and that a printed paper map is useless for the blind. The Association also noted that the *EU Directive 2016/2102 on the accessibility of the websites and mobile applications of public sector bodies* requires that public authorities ensure their access to all digital services that the hospital provides.

The directive 2016/2102 applies to websites and mobile applications under the control of bodies governed by public law. Accessibility has become an important issue for people with disabilities due to the rapid growth of online information and interactive services provided on the web and by mobile applications.

Combine frameworks

In that sense, a European repository in which existing frameworks, tools and methods may be collected, but subsequently also combined is strongly encouraged. Here, for example, we highlight the 'proposed benefits evaluation framework for health information systems' in Canada (Lau et al., 2007) as a relevant framework to include. It focuses on benefits but gives a very broad array of potential outcomes to consider in an evaluation of health information systems. It includes "three dimensions of quality (system, information and service), two dimensions of system usage (use and user satisfaction) and three dimensions of net benefits (quality, access and productivity)" and in that way, covers many aspects also discussed in this Opinion. Merging existing frameworks into one larger framework,

offering guidance to practical evaluations, in that sense would be highly beneficial. The framework should still be manageable and not too complex, which could be achieved by, for instance, using flowcharts and making it modular.

The need for further development of methodological guidance and guidelines, is also emphasised in a recent review of economic evidence for mHealth solutions. The authors indicate that while there is a growing body of evidence, many studies in their review “... *did not report all recommended economic outcome items and were lacking in comprehensive analysis. The identified economic evaluations varied by disease or condition focus, economic outcome measurements, perspectives, and were distributed unevenly geographically, limiting formal meta-analysis. ... Following established economic reporting guidelines will improve this body of research.*” (Ibarren et al., 2017)

Cover intended and unintended impacts and facts not promises

As with many innovations, digital health solutions may be promoted with the promise of great benefits and/or reduced costs. While such claims may be true, they need to be checked. Moreover, any evaluation should cover both intended (positive) outcomes as well as unintended (negative) outcomes. For instance, if an app to replace GP care in heart monitoring reduces contact with GPs and as a consequence may lead to health problems, this needs to be signalled and become an integral part of the evaluation. Partial analyses in that sense may be misleading. Moreover, while an app for self-monitoring particular health conditions (e.g., blood pressure) may in theory reduce visits to the GP, in practice fluctuations in blood pressure may lead to an increased numbers of visits – because people start to worry when faced with this information. While additional information may mitigate this problem, such (unexpected) behavioural responses (and potential solutions) need to be part of an evaluation. Textbox 9 highlights the issue of unintended outcomes of digital health services.

Textbox 9: Unintended consequences of health information technology

Since decades, expectations about digital technology in terms of improving healthcare and reducing costs have been high. Health information technology (HIT) is supposed to make the delivery of care safer, more effective and more efficient. Measuring the effects of health information technology implementation is however, difficult, not least because the outcomes of technological interventions may deviate from the functionality expected from the originally designed technology.

These deviations were first described by Ash et al. (2004) as “unintended consequences”.

Unintended consequences usually result from a complex interplay among:

- 1) what the HIT vendor provides as a product;
- 2) the customisations offered by the vendor;
- 3) the role of consultants;
- 4) the local clinical team; and
- 5) the local IT team involved in the implementation process” (Koppel & Chen, 2016).

Unintended consequences of HIT may lead to both adverse effects and beneficial outcomes.

A selection of overview papers related to unintended consequences of health information technology can be found at <https://www.ncbi.nlm.nih.gov/pmc/issues/281525/>

Source: EXPH

It is explicitly noted that, while these examples may sound negative towards digital health services, this is not the message that we wish to convey. Rather, we feel that any evaluation of any type of health service should be as objective and complete as possible.

From evaluation to implementation

The need for paying attention to the implementation of any decision made, based on these evaluations, is emphasised. It is suggested that already in the early phases of an evaluation this issue is addressed. Sometimes preconditions and incentives need to be created to facilitate adoption and materialisation of the benefits of the new technology (EXPH, 2016a). A positive reimbursement decision is not sufficient to guarantee uptake and use. The role and position of health care professionals need to be considered in this context as well.

For central decisions, the timing of a funding decision (especially in the case of irreversibility or high costs of reversion), committing to one specific digital service, needs to be carefully set. It needs to strike a balance between not being ‘too early’ (risking the selection of a non-optimal technology and having to deal with large decision uncertainty) and ‘too late’ (with a non-optimal situation continuing while a decision has not been made and potentially increasing the costs of transforming).

Develop the appropriate policy context

The framework put forward by Jansehn (2017) does not capture fully the elements highlighted by Drummond et al. (2008). This is not surprising given the different contexts

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of both lists. One of the issues addressed in Principles A of the Drummond list is to have a clear system of setting priorities for HTA, which exceeds the context of providing a framework on how to perform HTA in the context of digital health services. Such a system of setting priorities involves aspects like horizon scanning, value of information and determining on which basis technologies should be prioritised for HTA research. This remains important, especially in relation to technologies that have been and are less frequently subject to HTA research, among which many digital technologies. Prioritisation will involve considering the potential (health) impacts and costs of technologies.

It is good to base such prioritisations on a clear set of rules and considerations. It is beyond the scope of this Opinion to provide a framework for setting such priorities, but tools like prioritisation tables, containing important elements to consider, would be useful to develop. We illustrate this point with the below prioritisation matrix (Table 1), with an emphasis on safety of the digital health services and some of the relevant elements to consider.

Table 1: Evaluation prioritisation matrix based on generic descriptions of the type of main service activity

EVALUATION PRIORITISING MATRIX				
IMPORTANCE of assessment to assure SAFETY (prevent "adverse effects" and "surprises")	Activity involved (generic description)	Example of the "digital" version in HC	Ease of introduction into healthcare	Feasibility/ease of assessment
+	Services dominantly based on human physical capabilities	Automated dispensing of medication, Robots for manipulation	++++++	++++
++	Services dominantly based on use of human senses	Digital imaging, Telemetry, Augmented reality	+++	++
++++++	Services based dominantly on the use of human intellect, wisdom, soft skills, experience	Autonomous systems, "Artificial intelligence" – machine learning based systems, Virtual online agents, Decision support systems	+	+-

Checklists like this could be broadened to include issues related to why evaluation is required (prioritisation of evaluations). This could include elements like which risks would occur if the service is not evaluated, the type of intervention to be evaluated, key objectives of the service, key users, its place in health care, whether it can be funded within current financing streams, whether it will substitute or complement existing care, whether legal, financial or other barriers are foreseen, what phase in the development the technology is, whether other evaluations (e.g. in other countries) are ongoing, whether interactions with other services or systems are foreseen (raising issues of interoperability), etc. This can further help in prioritising evaluations, as well as standardise the information included in evaluations.

It is also important in determining which party should be made responsible for gathering the required evidence to make decisions. It may not always be feasible to hold producers responsible, as it is mostly the case in pharmaceuticals (Enzing et al., 2018). Strengthening these elements of evaluating (digital) technologies and the policy context in which this is performed is, therefore, encouraged. We emphasise that the policy context in which evaluations are used, and policy instruments that can be used on the basis of the evaluation (i.e., only a 'yes or no' decision regarding funding, price negotiations or conditional reimbursement) is crucial to consider in this context. For many digital health technologies, this policy environment still seems suboptimal, including the general requirements regarding performing evaluations in a systematic way.

Moreover, in some cases evaluations and decisions need to be tailored in such a way that individual preferences and needs are reflected in the outcomes and decisions. Some digital solutions may fit particular groups very well, but not others. This may relate to preferences, to needs, to patient characteristics or to knowledge and experience in using particular technologies and services. Ideally, evaluations highlight this diversity, enabling decision makers to enable use of one technology in one group and another technology in the other group.

Develop tools

In order to facilitate practical evaluations of digital health services, the development of checklists and other standardised formats to ensure a full consideration of potential issues seems advisable. These could be included in the European repository. We provide a further example of such a checklist below (Table 2). This checklist for the evaluation of digital health services before and during their introduction is again provided only as an illustration. The checklist is certainly not exhaustive, especially in light of the many areas of healthcare in which digital health services may have an impact. The "Criterion" column in the checklists below alludes to a number of issues that have been addressed in this Opinion

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which can have implications for the evaluation of digital health services. It gives an idea of the diverse questions that need to be asked in the context of an evaluation.

Such checklists could be further developed to allow relevant stakeholders, involved in design, funding or implementation of digital health services to perform evaluations at different stages of maturity and development of the service, complementing more comprehensive evaluations. We emphasise the need to assess the maturity of an intervention, both in relation to the question of whether a (specific type of) evaluation is appropriate and also in interpreting the results and considering next steps (e.g. further implementation or scaling up). Using checklists could contribute to the development and use of rational, reasonable, safe and evidence-based services. Note that we use the term service in the broadest sense, including processes, ICT systems, and so on.

Table 2: Illustrative checklist of important evaluation criteria

CHECKLIST FOR EVALUATION OF DIGITAL HEALTH SERVICES BEFORE and DURING THEIR INTRODUCTION			
CRITERION	Yes	No	If yes, provide brief evidence/explanation:
Was the service previously properly evaluated?			
Is the previous evaluation relevant for current context and use of the digital health service?			
Has the new service been evaluated or benchmarked against relevant existing services and on all relevant dimensions?			
Were all relevant stakeholders involved in designing and evaluating the service?			
Has the introduced service been evaluated from the perspective of assuring equity and minimising possible inequalities? Has there been sufficient attention for (vulnerable) subgroups?			
Has explicit attention been paid to avoid the effect of "de-humanising medicine" if relevant (e.g. treating a human as a digital code)?			
Is a system in place for continuous monitoring and periodic evaluation of the service?			
Is attention given to the need for different assessment at different levels of systems (micro, meso and macro) use?			
Was the iterative and incremental approach in the design, implementation and evaluation of digitalisation (ICT processes) used?			
Are feedback loops in place (PDSA cycle) to further optimise the (use of the) service after implementation?			

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Are investigations studying the socio-cultural impact of the service (e.g. changing roles and responsibilities of involved stakeholders, effects on work process and organisation of health care) relevant, available or being performed?			
Is there a good plan for the safe transition to the new service for all relevant stakeholders?			
Is sufficient time provided to all users to adapt to the new service?			
Was the service piloted sufficiently to avoid failures in further use and implementation (leading to harm, problems, loss of confidence, etc.)?			
Is there a mechanism in place to prevent the use of the service by people who lack the necessary training, skills or attitude?			
Is a decreased workload projected for the involved professionals when using the service? Has this effect been demonstrated?			
Is the "ownership" (participation in the creation and continuous improvement) of introduced systems by all involved stakeholders assured?			
Is user-centred design assured and supported?			
Is adequate funding of the new services secured?			
Is a "backup" parallel service available and functional?			
Will a dependency on the new service develop because of loss of old services and skills?			
Will potential dependency also create market power, in the short or longer term, for producers of the service?			
Does the new service lead to new data streams? Has safety of these data streams and storage been secured?			
Is cyber-security meticulously handled and "data protection by design and by default" as requested by General Data Protection Regulation of European Union (EU 2016/679) respected?			
Is interoperability with other systems and services guaranteed? Is a unified language / code with unambiguous and agreed syntax and semantics present before implementation?			
Is there a possibility of commercial use of data acquired through the service? How is this regulated?			
Is attention given to the evaluation of the effect of different speeds and scales and the level of user engagement as well as differences in healthcare structures? (transferability issues)			

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Are only processes and environments assuring a high level of confidentiality for all stakeholders in sharing personal data used?			
Is the service been developed in such a way that it does not burden users with unnecessary tasks related to e.g. secure data handling and sharing?			
Is funding for initial training and ongoing support of all involved stakeholders assured?			
Will the service require adjustments of training of new professionals (including the integration in the curricula for HC professionals)?			

Multi-disciplinary approaches in HTA needed

Multi-disciplinary approaches in HTA appear to be especially relevant in the context of digital health services. Legal issues, in relation to privacy, intellectual property rights, information exchange, cross-border care delivery, may require specific attention. Sufficient knowledge on the technical aspects, including issues like scalability, stability and interoperability is also important in the assessment. This can add complexity to evaluations as well. Two digital health services may be equally good, but if suffering from issues of compatibility, using both would still be suboptimal.

Cultural aspects, including issues regarding the acceptability of a technology for patients or professionals (as well as variation in such acceptability) can also be influential. This is ideally tackled already in the development phase of new digital health services, to ensure an adequate acceptability, uptake and implementation of the technology. Methods for assessing the impact of digital transformation must be also fit for future use. Apart from addressing the existing care services, they must be able to accommodate future paradigm shifts in the goals of health services. A paradigm-shift from "disease-oriented" towards "goal-oriented care" is for instance needed. The goal-oriented care encourages each individual to achieve the highest possible level of health as defined by that individual (De Maeseneer & Boeckxstaens, 2012).

Health

As digital health services are a combination of the 'digital' and 'health' components, evaluation frameworks of digital health services may emphasise the digital aspects of the health services to be evaluated. In that sense, it is important to also highlight some elements intrinsic to health. First, these services can have a direct or indirect effect on life and health of people. Compensating health losses, certainly at an individual level, is often impossible, stressing the need for safety and the adagio "primum non nocere" (first do no

harm). Trust of citizens, patients and professionals in technologies which may affect health is important, because of the special nature and value of health. In that context, using the terminology of digitally supported health services (analogous to for instance the CAD/CAM terminology: computer aided design and computer aided manufacturing), may be considered more appropriate as it keeps the element of health service as central. The IBM Watson Health partnership also understands ICT as supporting element (not replacing humans, but rather being indispensable to professionals in the future).

Indeed, health services may require or be provided with higher quality with regard to the element of human interaction. For instance, while a remote monitoring device efficiently may provide information about one or a few parameters of a patient, observing that patient, allowing a broader set of information to be obtained (including body language, tactile information, emotional responses, etc.) may be important in diagnosis and choice of treatment. Every patient and situation in that sense is unique. Moreover, the populations served in many parts of the health care system are vulnerable. The services encompass the period from pre-conception (e.g. assisted reproduction and genetics) to end of life and even beyond (e.g. pathology autopsy, organ donation). This indicates the need for the health care system to cater to different populations with different needs and from different generations at the same time. Given the importance of health and health care, their requested safety and continuity, introduction of new services must be done at a pace that allows for carefulness, and with sufficient preparatory activities and backups (in whatever form) in place to avoid and mitigate potential problems. Step-wise, controlled and evaluated introduction is necessary, using for instance PDSA plan-do-study-act cycles, RCA root cause analyses, FMEA failure mode and effect analysis etc.

Concluding remarks

When evaluating digital health services many specific aspects need to be considered. Some of those aspects were highlighted in this paragraph. With this, we did not aim to be exhaustive, but to illustrate some of the specificities of evaluation digital health services, including creating a suitable policy context and rules for setting HTA priorities, and aspects like using appropriate outcome measures.

1.7. Monitoring

From evaluation to monitoring

We encourage further development and use of evaluative frameworks for digital health services. It is believed that this will further result in implementation and use of digital health technologies that contribute to the overall system goals. Still, it is not feasible nor desirable to evaluate all existing and new (digital) health services. This emphasises not only the need to select interventions for evaluation in such a way that potential benefits for the system are maximised as highlighted in the previous paragraph. This will involve considering the potential (health) impacts and costs of technologies. We emphasise that while the focus of evaluations typically is on new technologies, it may also be worthwhile selecting existing technologies for evaluations, also for decisions regarding disinvestment.

However, even with a good functioning mechanism to select health services to be evaluated (either new ones to be funded or existing ones to be terminated), more is needed to monitor and evaluate health system performance. In that context, we refer to the EXPH report on Quality of Care (EXPH, 2014) in which indicators for the overall performance of health systems, in line with the elements of quality deemed important, were suggested. (The report specifically on tools and methodologies for assessing the performance of primary care (EXPH, 2017b) is relevant to mention here as well.) Such monitoring should not only be performed for evaluated programmes and technologies, but also more general to monitor the development of quality of health care delivery in a region or country. In this way, monitoring can also help to evaluate how several (smaller) steps of innovation rather than one clear change in care provision might affect the performance of the system. Appendix A provides an overview of indicators suggested by the Panel (EXPH, 2014), some of which may also more directly indicate trends in digitalisation. All means of assessment provided in that report can also be used to assess and evaluate the impact of digital health services. In principle, where possible, “digital” and “non-digital” services should be benchmarked in all assessed areas similarly.

Inequities

The need to not only consider average progress, but also the distribution of health outcomes, health care use and financial burden in the population is emphasised here. This is relevant in a general sense, but especially in the context of digital health services which may require specific skills or resources to operate. Although some digital health services (e.g., those strengthening prevention and health promotion) may have the potential of reducing health inequities in Europe, others may result in further widening the gap in health achievements between different societal groups. As technical and literacy skills vary greatly between socio-economic and socio-demographic groups, the use of digital health services

such as mobile and eHealth technologies could indeed impact negatively and increase social and health inequities. Issues such as online accessibility, affordability, inadequate digital education and lack of digital literacy constitute real barriers to realising the potential of digital health interventions for many communities. Reviews of the literature in this area highlight that the 'digital divide' encompasses a number of dimensions including; unequal access to digital technologies (internet, mobile phones etc.); variations in use due to a lack of sufficient knowledge and confidence on how to use the technology adequately; the health information or digital services provided may not be comprehensible or useful for disadvantaged populations (Latulippe et al 2017; Weiss et al., 2018). The empirical studies show that while individuals of higher socio-economic status are the first to adopt and benefit most from the introduction of innovative technologies in health, thereby creating and widening existing inequities, the digital divide tends to affect the same individuals and population groups who are at risk of social and health inequities (low income, low education, low literacy, ethnic minority groups, socially marginalised and underserved groups etc.). It is, therefore, critically important that evaluation studies assess the extent to which digital health technologies may produce, reduce, or exacerbate inequities in health.

European level

General developments in the performance of health systems particular directions may not easily be traced back to the digital transformation or its separate components. Therefore, Member States should invest in creating incentives and knowledge structures in their health systems that will incentivise the adoption of technologies in line with the overall goals. This includes sharing of information, training, education and financial incentives. At the level of the EU, facilitating and stimulating the gathering of relevant quality indicators, systematically and comparably across member states and systems, remains crucial. It needs noting that monitoring typically indicates trends rather than causal relationships. It may well be that monitoring leads to further investigation and evaluation of particular segments of health care or health technologies, if for instance the costs, health effects or socio-economic differences in a some area would cause to question the desirability of a trend, which may be related to digitalisation.

In this context, some 'indicators' may be developed to recognise some of the issues that may be particularly relevant for digitalisation. To name a few: issues of privacy and patient data, administrative burden for professionals, issues of interoperability limiting rather than enhancing exchange of digital information, digital literacy and access, and information streams informing or misinforming the public regarding treatments (e.g. vaccines – EXPH, 2018a).

1.8. Decentralised decisions

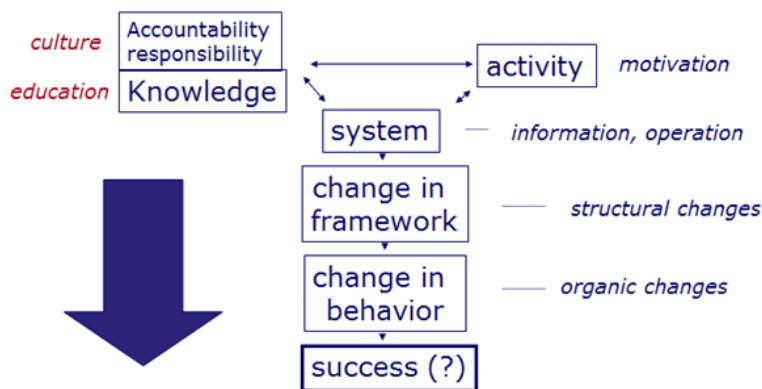
Many investment decisions take place at lower levels in the health system. Importantly, at these levels also the implementation of services that were positively evaluated on a central level need to take place. This emphasises the importance of ensuring that on lower levels the selection and implementation of digital health services is also performed in such a way that they align with overall system goals. Moreover, implementing central decisions requires cooperation and effort at 'lower levels', again underlining the importance of alignment.

Alignment of goals at different levels

Creating and fostering a culture in health care organisations that aim to produce patient and societal value through their actions is imperative, since they form the heart of health systems. This also relates to their selection, uptake and use of digital technologies. As such, governments are believed to also have a role in creating an environment (through statements regarding system goals, education of health professionals and leaders, regulatory and financial schemes, etc.) that attempts to align organisations with health system goals.

As shown in Figure 9, creating changes in behaviour of organisations and professionals, involves aspects like culture and education, creating accountability and responsibility (which may be enforced by formal structures), eventually leading to a 'successful' change.

Figure 9: Change in organisations



Bourek A. 2007: www.med.muni.cz/~bourek

Source: Bourek (2007)

EFQM model

A crucial issue here is the definition of success. In line with what we indicated before, the answer must be found in the contribution to the overall goals of a health care system.

Organisations that excel in performance, therefore, are committed to contribute to these overall goals. Indeed, a well-established European “excellence model” is the EFQM (European Foundation for Quality Management) model.⁹ The EFQM states that “*excellent organisations achieve and sustain outstanding results that meet or exceed the need and expectations of relevant stakeholders within society.*” Its application in the field of health is well documented (e.g. Klazinga, 2000; Moeller, 2001). The model includes aspects like leadership, people, ‘customer results’ and societal results. While both the elements considered part of ‘key performance’ as well as their relative weight may differ between the system level and an organisational level (something that may be influenced), it offers a framework for alignment and excellence. In that sense, it is good to note that the model is not prescriptive in what should be counted as ‘key performance results’, but offers flexibility in that respect.

The benefits of digitalisation for the processes of an organisation may be clear and they may well contribute to the success of an organisation. The benefit of applying digital health services will always depend on understanding (the making of right decisions) by all stakeholders that will be using the digital environment. Successful implementation of digital health services may depend on the exact function and goal. For instance, digitalisation in areas like accounting, logistics, surveillance, digitally aided decision-making may in some ways prove to be easier to successfully implement and operate than digital solutions in processes that require human-human interaction (e.g., situations requesting the management of emotions, passion, compassion and requiring creativity). When digital technologies are complex, their acceptance, implementation and successful use may be difficult. These aspects are context dependent and differ per innovation and digital service. Kelly (1995) already provided an overview of some pros and cons of complex systems, some of which are summarised in Table 3.

Table 3: Pros and cons of complex systems

Benefits	Disadvantages
Adaptable	Nonoptimal
Evolvable	Noncontrollable
Resilient	Nonpredictable
Boundless	Nonunderstandable
Novelty	Nonimmediate

Based on: Kelly (1995)

⁹ <http://www.efqm.org/the-efqm-excellence-model>

It is important to have a better understanding of how and on what basis organisations (and entities within them) select technologies to be adopted, and how such processes could be influenced (e.g. by financing schemes).

The more the key indicators between the organisational level (as in the EFQM model) and system level would be aligned, the greater the likelihood that the evaluation and selection of digital technologies at the level of an organisation will be in line with the system goals. Digital solutions may offer health care organisations possibilities for continuous feedback on performance (e.g. patient health outcomes, goal attainment, or satisfaction), hence enabling a culture of continuous improvement.

Moreover, it is important to learn how organisations use digital health services and new information streams. Portability and interconnectivity were, for instance, identified as two socio-technical features that influence how organisations realise value from big data in practice (Gunther et al., 2017). Some organisations may use digitalisation processes to gain competitive advantages.

Mini HTA

Note that “mini HTA” may offer a bridge between a full HTA as described above and evaluations supporting decisions at a lower level. In a mini HTA a quick and pragmatic HTA is performed on a local level to inform local decision makers about the costs and consequences of a particular technology. In Denmark the use of such mini HTA’s has been encouraged (Kidholm et al., 2009). There, a checklist is used to structure mini HTA’s. The Danish National Board for Health writes: *“Mini-HTA is a management and decision support tool based on the reasoning involved in HTAs. The tool may be used for instance where a hospital is contemplating the introduction of new health technology.”*

The mini HTA is often structured using a checklist or form that contains items and questions about the new technology, the prerequisites for its adoption and use and the expected impact of its use within the organisation. The impacts are described from four different perspectives: the technology, the patient, the organisation and economy. It should be fairly short and inform decisions regarding the introduction of a new health technology, which could be a digital health service. Likewise, it can be used to inform decisions on a broader use of existing technologies. The format should allow the flexibility to inform either a local or a regional decision, which could result in the use of other decision criteria or time horizons. (DACEHTA, 2005)

Kidholm and colleagues write: *"The mini-HTA forms used in Denmark typically include twenty to thirty questions grouped according to the four HTA perspectives: technology, patient, organization, and economy. The purpose of the form is to provide a brief two- to five-page basis for decisions about the introduction of a specific new health technology or a specified change in the indication for the use of existing technology... Mini-HTA is intended to be a flexible and dynamic tool adaptable to local conditions and the current requirements of decision makers, for example, facilitating local and regional budget, planning and priority processes. Where the problem or the application extends beyond a specific local context, however, the mini-HTA cannot replace a full-size HTA..."*

An exploration of increased use of structured mini HTA's, potentially using predefined items in line with overall health system goals, could help to bridge the gap between decentralised and centralised decision-making and create greater alignment. Given that much of the decisions on investments in digital health services are made at lower levels in the health system, this could help to steer the digital transformation in a desired direction. Learning from previous experiences with mini HTA and developing a context in which their use could be encouraged, facilitated or perhaps for some investments even prescribed, is a potential route forward that Member States could explore and the EU could facilitate.

Decentralised decisions, coordination and competition

Even in a situation where goals at different levels of the health care system would be reasonably aligned and all local outcomes could be seen as optimal, overall outcomes need not be optimal.

Take a very simple example. A country has two hospitals and both choose their own electronic health record system, completely aligned with overall system goals. If there are two equally good and expensive systems A and B, both providers may end up with two different systems. While locally optimal and separately in line with overall goals, exchange of information may now be hampered by having two different systems, which may not be compatible. This is not optimal at a central level (information about referred or switched patients is not exchanged) and may require additional costs (building an interface or forcing one of the hospitals (ex post) to switch system, etc.). Hence, there may be a need for coordination for overall optimal solutions to be attained.

This is an important yet complex issue because decentralised decisions may have both positive and negative consequences compared to centralised decisions, some of which are especially important for digital health services. Here we list a few, without attempting to be exhaustive:

Development costs

Without coordination of innovations and their adoption, and without contracts steering their development, several actors may develop (similar) products simultaneously, increasing the development costs. While this may involve private companies, bearing risk, the end result may be (depending on market structure and pricing strategies) that if different products enter the market, the total rewards from the market (repaying development) are higher than under coordination.

Competition

Decentralised decision-making can result in competition between producers of digital health services. This may, under certain conditions, both improve their quality as well as reduce their price. It is difficult to mimic competition through negotiations, especially early on in the development. By letting market forces function under the right conditions, the best product may prevail and then be selected by more providers. The Panel previously elaborated on the issue of competition in health care (EXPH, 2015).

Selection

Relatedly, especially with new and evolving technologies, the optimal timing for a central selection of one preferred (or allowed) provider is difficult. Taking a decision in favour of one producer may facilitate good coordination between health care providers in implementation, increase learning effects, provide economies of scale (if appropriately negotiated), but also gives market power to the selected producer, diminishing possibilities for growth and competition. Early selection or later evaluation, therefore, presents a trade-off that decision makers need to be aware of. General indications of optimal timing cannot be given straightforwardly, but the costs and consequences of both options should ideally be addressed.

Coordination and watchful waiting

A final point made here relates to coordination of decisions. If decentralised decisions lead to issues of interoperability, coordination may be required to overcome this. This may well be a role for the government, either through arranging meetings or, ultimately, forcing coordination through rules and regulations. Coordination could also take place by trying to have providers that will likely be affected by each other's choices jointly choose a preferred technology.

Another issue here is the timing and degree of experimentation. If, for example, a few hospitals are testing some new digital technology, others could just wait to see the results of their evaluation. This has the additional advantage of being able to learn from implementation issues and a more mature technology. Of course, the

possibility of using a strategy of watchful waiting depends on the decision context and (expected) impacts of the new technology compared to current care, but it may be worth creating and stimulating learning networks around the choice, implementation and use of digital health technologies, in which duplications of experiments are avoided and information is effectively shared.

Standards

Some new digital health technologies may also require early guidance from governments regarding standards and appropriate use. This may for instance relate to telemedicine, where new legal regulations may be required, and certain aspects of artificial intelligence in relation to accountability, or standards in terms of privacy and data quality for information streams.

Education and culture

Education and culture are both highly important in the context of the digital transformation. This transformation will not only increase the need for future health care professionals with critical knowledge regarding digital health services and new types of health care professionals (some combining technical and medical knowledge and skills), but also the need to be open to positive changes through new technologies. Contact with patients may change, the role of patients in their own treatment may change (also through e.g. goal-oriented care), developing interprofessional platforms of integrated electronic health records, creating new and more interconnected care pathways (e.g. through prevention, home monitoring, e-contact with professionals, etc.) which may (further) change the care culture. Ensuring health professionals, organisations and systems are able to meet the challenges and opportunities offered by the digital transformation is an important task.

Intervening when needed

If lower level decisions are not sufficiently aligned with overall goals but driven by other factors (e.g., medical professionals wish to adopt a new technology, hospitals want to signal they are modern and state-of-the-art), intervention may be required, for instance, by explicitly excluding certain digital health services from coverage, thus effectively reducing use. Monitoring and signaling may provide governments with indications of where such actions are needed. Having signaling processes and appropriate policy measures in place to act upon undesirable developments, as well as the political will and power to act, are important prerequisites.

Scaling up

An important issue is the feasibility, process and efficiency of scaling up the use of digital health services. This is an important element in the total process of development and adoption of technologies. This includes aspects like the evidence required in order to decide on a scale up, the role of the different stakeholders in the process and the evaluation used (Tomlinson et al., 2013). Tomlinson and colleagues write that: "*Despite hundreds of mHealth pilot studies, there has been insufficient programmatic evidence to inform implementation and scale-up of mHealth.*" They recommend reconsidering current standards of research to provide guidance for when scale-up is appropriate, to use plausible theories of behavioural change in the context of mHealth technologies, exploration of implementation strategies that allow testing several features of a new technology and more co-operation between developers, funders and governments. Involving users and citizens is important as well.

Concluding remarks

Governments could play a more active role in the further optimisation both of the process of decision-making (both at the central and decentral level) and the related outcomes. In doing so, they need to find a balance between centralised and decentralised activity. Monitoring and horizon scanning can help to detect developments that might be helped by early government coordination (in an appropriate form). This is especially the case for disruptive digital technologies, because governments may need to create environments that would allow their optimal use (e.g., new financing schemes or defining clear and feasible pathways from current care to digital health services). Moreover, the broader preparation of the health care system to be able to deal with digitalisation, from education, through financial and regulatory preconditions, to implementation of monitoring systems to monitor its effects on health system performance, remains important.

1.9. Data sources

It is clear that evaluation and monitoring both require relevant data. Much of the effort in evaluations is directed at obtaining such data.

Evaluations

When evaluations are performed for specific digital health care interventions, this entails obtaining the right information in an adequately designed study. Which study design is required was already discussed above and typically depends on the feasibility and appropriateness of performing RCT's in a specific context. Such choices can also relate to ethical considerations or numbers of patients.

Given the choice for appropriate evidence, the relevant design needs to be chosen, including aspects like comparator, outcome measures and cost categories. Then, data are specifically gathered with the aim of evaluating the digital health service. Sometimes, alternative data sources are used, including real world data or real world evidence (which is derived from real world data). The use of such data is receiving increasing attention (also as a consequence of the broader digitalisation trends). Sometimes it takes the form of large registries or of administrative databases. Typically, such data are not obtained from an experimental context and requires assumptions and (complex) analysis to draw conclusions about the specific interventions. This field is developing rapidly. Real world data can be obtained from sources like electronic health records, claims databases, registries (disease or product oriented), etc. Potential problems with such data include that they may be gathered for different purposes and sometimes lack certain information (e.g., contextual information) that would be important for the evaluation and that real-world data tends to be 'noisy', given that specific developments (e.g., combination therapies) and selections (of specific service users) may complicate drawing conclusions.

One point of note is also that differences may exist between the different levels in the health care system in terms of the availability of certain types of data. For instance, utility measures (like the EQ-5D) often used in central decision-making, may not be available or routinely collected on the level of a hospital or GP practice. Such differences can hamper comparability while greater agreement on the collection of data throughout the health system could improve this.

If data are gathered purposely, they need to be fit to address the questions for which they are intended to answer. Different types of data are often needed to address questions at different levels in a health care system, for instance, (treatment versus hospital versus system performance. In many cases, the use of real-world data or big data, leads to new questions regarding analysis, interpretation and subsequent decision-making.

As far as we are aware of, no large scale (European) registries exist for digital health services. Transferability of data is also an issue (for reasons of privacy and generalisation). Methodological guidelines for data gathering and use in the context of digital health services could be useful.

Monitoring

The issue of monitoring was extensively discussed in a previous EXPH report (EXPH, 2014). Appendix A provides an overview of indicators suggested by the Panel (EXPH, 2014), some of which may also more directly indicate trends in digitalisation. All means of assessment provided in that report can also be used to assess and evaluate the impact of digital health services. In principle, where possible, “digital” and “non-digital” services should be benchmarked in all assessed areas similarly.

Member States and European Union have developed information systems capable of offering ample information for institutions, professionals and patients, to monitor health care quality (including OECD Health care quality indicators; European Community health indicators; WHO European Health-for-all database; Eurostat indicators). The Panel has previously indicated that it would be useful to develop a Health System Performance Assessment Framework at the EU level, in order to better identify the dimensions and quality measures required (EXPH, 2014). This could also help to monitor and evaluate developments in European health systems in relation to the digital transformation. Specific indicators (e.g., regarding issues of privacy and continuity of care facilitated by digitalisation) could be included to facilitate this further.

New dimensions requiring attention are likely to emerge and gain importance during the further introduction of digital health services, which will also require monitoring and evaluation. For example, the level of interoperability of systems and services, including standardisation of coding, “using the same agreed language codes and protocols”, etc. Other issues include the level of competence of involved stakeholders in the appropriate and safe use of the introduced digital health services and processes (level of digital health literacy), the level of available safety mechanisms (alert systems) based on processing of data that the digital tools and processes provide, and number of ‘digital incidents’ (privacy issues, data leakage, etc.). In general, the level of threat to dignity, privacy and safety of stakeholders based on pooling and unauthorised processing of, or access to, data across different sectors, potentially in combination with other available health data, will require special attention. Higher degrees of digitalisation may be associated with fewer direct interactions between service providers and care users. “Button-centred” health services instead of person-centered services should clearly be avoided. Broader aspects, such as

the level of cooperation, also in care networks, facilitated by digital health services, are also relevant. In this context, having a set of broad principles that should be followed by sources of data and those who gather data, including similar definitions and modes of obtaining data, would be useful for both current data collection and potential future data collection.

For system analysis and health system research, we also highlight that investigations using random and representative samples from the relevant population can be used to provide data and insights.

Generation of data

Digital health services will also generate data. The use of some data will be limited to only one treatment path, but often data may be used and analysed more broadly. The way in which these data are produced, stored, analysed and used is a key issue in the evaluation process. We also emphasise the importance of data interoperability, also in the context of collecting, sharing and manipulation of data. To increase interoperability, the use and development of international classifications and terminologies, such as ICD, ICPC-2 (International Classification of Primary Care), and ICF should be supported.

Privacy and safety of data are key issues in an era in which more data is gathered and stored, in larger quantities than before. Even though some of the current electronic storage and use in general may be considered safer than some previous 'physical storages' (e.g., in hospital archives), also because of the quantities and quality of data stored, the consequences of data theft may be larger.

Some digital health services will mainly be targeted at producing data. For example, monitoring systems for glucose levels or home monitoring of vulnerable patients. Such services can improve autonomy and empower patients. Digital health services may allow much more frequent (even continuous) measurement and monitoring. Next to issues of safety, issues of reliability of data (streams), the relevance of the gathered data, the timeliness of the data are all factors to consider.

The use of the data, which may become easily available as a result of the digital transformation, also raises questions, like: who will use the data, how, when and for what purpose? Where is the data stored (if at all) and who can access it? These issues require concerted attention, also at a European level.

Finally, data generation can also be stimulated through requirements. A failure to evaluate changes in health care systems at different levels, can result in a lack of understanding whether it actually has been a 'good' or 'bad' change. The will to evaluate changes, including policy changes, and to increase evidence based medicine and evidence-based health policy making, can increase data generation and, through that, improved knowledge.

1.10. Broader considerations

In this section, we present some broader considerations relevant to the evaluation of digital health services and the digital transformation.

Patient empowerment, shared decision-making, goal-oriented care

Digital health services have the potential to strengthen patient empowerment and provide a more equal basis for shared decision-making. Such aspects are valuable assets of a health system. It needs to be further investigated how such aspects can be evaluated. Moreover, relatedly, we believe that a shift in health care, towards goal oriented care is important, especially in view of ageing populations. Digital tools can help in this process (rather than *substituting* contact with for instance GP's) to allow patients to articulate their goals which may involve trade-offs between length and quality of life, as well as between treatment and no treatment. Digital tools can also contribute to improving and measuring user experiences, which can be fed back into organisations / treatment paths in order to further improve them. Payers may use such data to appropriately reward and stimulate further improvement. The World Economic Forum indeed indicated recently that shifts in care would not only entail a shift in place (e.g., hospital to home) but also in responsibility (e.g., from diagnosis and treatment to prevention and managing).

Involvement of patients in the development and implementation of new digital health technologies that have patients as users is important, in order to optimise their form and impact, as well as to maximise the patient value and acceptance. The distinction between different types of digital health services is important again. Patient involvement may be less relevant or take other forms, when dealing with digital health services that do not affect patients directly (like how an electronic health records is coded exactly).

It is important to explicitly note that when new technologies allow more self-care and self-management by patients and health care users, this does not reduce the responsibility of the health care system for these individuals.

Governments should have sufficient knowledge about digitalisation

The digital transformation is ongoing, in some cases at a rapid speed. When having to evaluate digital health services (or purchase or procure them – EXPH, 2016b), but also when monitoring their impact, and preparing (new generations of) health care professionals for the digital transformation, a good knowledge of these technologies is also required within governments. Investment in such knowledge, also in the public domain, is required.

For large national digitalisation projects, elements like optimal timing, risk sharing, procurement conditions etc., may also be relevant, which requires sufficient knowledge to act as a well-informed counterpart in negotiations (EXPH, 2016b). Especially in such cases, evaluating the new technology is not enough, but negotiations may be required regarding both quality and price. Both aspects are not a given, but part of a purchasing process.

Digital evolution / horizon scanning may offer governments and decision-making bodies knowledge about the type of products that will come onto the market in the future, so that preliminary decisions can be made about which to evaluate and how to evaluate them, as highlighted above.

Interoperability

Interoperability has been addressed before in this Opinion, but it deserves even more emphasis as it is of crucial importance. In the context of European public administrations, interoperability has been defined as *“the ability of organisations to interact towards mutually beneficial goals, involving the sharing of information and knowledge between these organisations, through the business processes they support, by means of the exchange of data between their ICT systems”* (EC, 2017). The goal of increasing interoperability is *“the development of a European public services ecosystem in which owners and designers of systems and public services become aware of interoperability requirements, public administrations are ready to collaborate with each other and with businesses and citizens, and information flows seamlessly across borders to support a digital single market in Europe.”* Much of this goal is directly applicable to the health care systems, at different levels. Issues of interoperability can arise within institutions (e.g., when two different wards use two different codes or systems), between professionals and institutions, and even between countries.

Especially in health care, a seamless information flow is the prerequisite for person-centred care and the exchange of quality assured information. This is crucial to ensure continuity of care, avoid repetition of diagnostic procedures, increase efficiency, avoid delays, and to optimise treatment by having knowledge of other treatments and treatment histories. The use of different, non-compatible systems, codes, languages or devices, can lead to difficulties in cooperation at many levels, and hence harm quality of care. With an increase in digitalisation, issues of interoperability become more important. In this context, we also stress the role of cross-border care (in border regions and for instance ERNs (EXPH, 2018b) and the need for European level action. There is a clear analogy between the tension between centralised decisions and decentralised decisions in this context. If countries need

or wish to collaborate, lack of coordination of choices and standards, may lead to problems with interoperability between countries.

National and supra-national authorities should, therefore, collaborate on defining a "common language" to be used in health care, meaning internationally agreed classifications and terminologies such as ICD, ICF, ICPC-2, ATC and SNOMED CT as well as health informatics standards such as DICOM for imaging, the HL7 family of standards, etcetera. Without standardisation, using different languages, codes, and systems, cooperation could be hampered rather than enhanced through digitalisation. Moreover, at least, failing to standardise would reduce the benefits that are to be had from digitalisation. More attention to these issues seems warranted.

Safety

Safety has always been an important evaluation criterion in health care, and rightfully so. Where in other sectors problems with safety may lead to compensationable losses (e.g., of money or goods), in health it may lead to irreversible health losses. This emphasises the need to consider safety, not only for pharmaceuticals and (fortunately) increasingly medical devices but also for digital health services. The principle of '*Primum non nocere*' (first, do no harm) is important to adhere to here as well.

Any evaluation of a medical product should consider safety and in the evaluation of digital health services, the definition of safety needs to be broad enough for the specifics of the service. For instance, when using certain digital devices, the issue of hacking and interfering with the treatment of a patient needs to be considered. For home monitoring systems, hacking and breaching privacy of patients or consumers' needs to be taken into account. Developing standards for these products in this respect, as well as for the evaluation of these products is important.

We also emphasise the relation with more 'traditional' features of interventions, like the security, stability and sensitivity and specificity of digital diagnostics/monitoring and of algorithms to avoid both over- and under-diagnosis and/or -treatment.

Risk assessment and safety research thus may take particular forms in the context of digital services. This includes considering use and storage of data as well as access to data. The issues of privacy, data protection and cybersecurity are further addressed below.

Respect patient's privacy rights and data protection principles

The requirement of patient consent for medical interventions is a well-established rule in medical law (Mason and McCall Smith, 2012). Patient consent is commonly required also when sensitive data are distributed to persons not involved in the actual treatment of the patient (Council of Europe, 1981). Many of the benefits of digitalisation will not be realised if the use of patient data is restricted only for the small medical team directly involved in current treatment. Rather, the data should be utilised by the different players in the health system. Thus, in the digital health system there seems to be a constant confrontation between the privacy protection and the data utilisation interests.

The recent General Data Protection Regulation of European Union (EU 2016/679), "GDPR" tries to create a balance between privacy rights and the development of the digital market. The GDPR aims to give individuals control over their personal data and to simplify the regulatory environment for the digital market. It applies to an enterprise established in the EU or (regardless of its location and the data subjects' citizenship) that is processing the personal data of people inside the EU. Controllers of personal data must put in place appropriate technical and organisational measures to implement the data protection principles listed in Article 5 of the regulation. These principles require that personal data are:

- (a) processed lawfully, fairly and in a transparent manner in relation to the data subject ('lawfulness, fairness and transparency');
- (b) collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes ('purpose limitation');
- (c) adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed ('data minimisation');
- (d) accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay ('accuracy');
- (e) kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research

purposes or statistical purposes in accordance with Article 89(1) subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject ('storage limitation');

- (f) processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures ('integrity and confidentiality').

The GDPR also introduces a new accountability principle to data protection rules in Europe.¹⁰ Organisations themselves must demonstrate that they are compliant with the Regulation. The GDPR also requires "Data protection by design and by default", meaning that all business processes that handle personal data must be designed and built with consideration of the principles and provide safeguards to protect data (and use the highest-possible privacy settings by default, so that the data are not available publicly without explicit, informed consent, and cannot be used to identify a subject without additional information stored separately. No personal data may be processed unless it is done under a lawful basis specified by the regulation or unless the data controller or processor has received an unambiguous and individualised affirmation of consent from the data subject. The data subject has the right to revoke this consent at any time.

The gathering, storage, accessibility, sharing and use of data that are generated with or through digital health services should be an important aspect considered in the process of evaluation. It is an aspect of safety and quality that is different from other previously used technologies. Without sufficient attention to this issue, data may be gathered and used in ways that are unlawful and undesirable. This may for instance lead to problems with privacy, but also to unbeneficial commercial use of information (direct or indirect).

Ensure cybersecurity and resilience

Finally, health care is not only utilising digital solutions but is also becoming dependent on them. This makes the health system susceptible to new kinds of threats. Cybersecurity plays a very important role in ensuring the undisturbed and safe functioning of health care facilities and services. Electronic health records and other core systems are protected with firewalls and user recognition systems. However, they might still be hacked. Unauthorised users may steal sensitive data (like from the Singapore national health records¹¹) or block

¹⁰ (European Data Protection Supervisor, https://edps.europa.eu/data-protection/our-work/subjects/accountability_en)

¹¹ <https://www.bbc.com/news/world-asia-44900507>

the utilisation of patient records (see Textbox 10). Use of own mobile devices by health care personnel, remote patient access to health records, wide utilisation of applications and electronic devices all increase cybersecurity threats and require specialised expertise to ensure appropriate data protection. Adequate attention to these aspects, that may be central to some digital health services and more complementary to others, is indispensable. Health system resilience may be defined as the capacity of health actors, institutions, and populations to prepare for and effectively respond to crises; maintain core functions when a crisis hits; and, informed by lessons learnt during the crisis, reorganise if conditions require it (Kruk ME et al., 2017). Since cybersecurity threats are more or less a part of the daily routine in digitalised health care, a special emphasis has to be put on the resilience of the system, also in relation to these issues. A resilient health system is one which is able to effectively prepare for, withstand the stress of, and respond to the public health consequences of cybersecurity threats. It is advisable to routinely perform checks on the robustness of health facilities and systems, in order to determine their resilience. A periodic stress-test for health services, health care providers and health systems could inform about their resilience or how it could be improved.

Textbox 10: WannaCry virus was used to blackmail NHS hospitals

Attempts to blackmail hospitals with cybersecurity threats unfortunately have become more common. Cyberweapons are developed both by different entities and for different purposes. The increase in cybersecurity threats has resulted in a cyberweapon and counterweapon arms race.

Cyber extortion takes different forms, ranging from ransomware to denial of service. Ransomware attacks involve encrypting data, blocking a healthcare provider from accessing its own data, and threatening to publish or destroy it unless the attackers are paid. Meanwhile, denial of service and distributed denial of service attacks involve continuous assaults on the computer systems of health care providers with emails and other traffic, which results in shutting the system down. Attackers then demand money to stop the attack.

The WannaCry ransomware attack in May 2017 was widely reported in the media. Among the largest agencies struck by the attack were the National Health Service hospitals in England and Scotland. Some 70,000 devices including computers, MRI scanners, blood-storage refrigerators and operation theatre equipment may have been affected. On May 12, 2017 some NHS services had to turn away non-critical emergencies and some ambulances were diverted.

WannaCry ransomware cryptoworm targeted computers running obsolete Microsoft Windows operating systems. While Microsoft had released patches previously to close the exploit, much of WannaCry's spread was from organisations that had not applied these in due time.

(*Millar SA et al. WannaCry: Are Your Security Tools Up to Date? The National Law Review 2017, <https://www.natlawreview.com/article/wannacry-are-your-security-tools-to-date>*)

Role of professionals

Many digital health technologies strongly depend on the uptake and appropriate use by health care professionals. This may lead to new health care professions, as well as to existing health care professionals acquiring new skills and competencies to work with new digital health services. This implies that adequate education and training needs to be in place to enable this. Co-creation in developing new digital health services can be useful to increase acceptability and user friendliness, also in practice. Professionals' experiences with using the technologies are also crucial to monitor and consider in any evaluation. Some systems may be time consuming to (learn how to) operate, placing additional rather than less strain on often already burdened professionals (in the short or even longer run). Some technologies may also be more or less acceptable (in different ways) for professionals and patients, which is a clear prerequisite for successful implementation and regular use.

Digital health technologies may also change the content and type of professions needed. For instance, when virtual coaches supplement human counselling, the responses of the

virtual coaches need to be coded. In some cases, digital solutions may replace human labour. The Panel does not consider this to be desirable or undesirable in itself. For example, freeing nurses from administrative duties to allow them to spend more time with patients can be a positive change. This is emphasised by the current and future shortages of staff. Cost reductions brought about by digital health services also do not need to imply lower health care budgets, but simply the possibility to allocate the freed budget elsewhere.

Capacity building, at all different levels and in all different sectors of the health system, remains important in this context.

Capital and labour

In relation to the previous point, important threats to health care systems include the increase in health care expenditures and the shortage of labour (health care professionals). It is important to highlight that part of the increase of health care expenditures can be related to a difficulty of increasing productivity in the sector, due to the nature of health care (leading to the so-called Baumol effect). Some digital health services may lead to improved productivity and perhaps cost saving, reducing (the growth in) health care expenditures. This is important, also in relation to the potential (and actual) shortage of personnel. If new digital health services can replace some of the functions currently performed by health care professionals, this may relieve some of the pressures due to shortage of personnel. Of course, quality of care needs to be fully considered in this context as well.

Incentives for innovation and uptake

Digital transformation may sometimes lead to new care pathways and services, which may not be a good fit with current organisation of care, care pathways or financial structures. Lack of flexibility in those aspects may lead promising developments not to be used, simply because the organisational prerequisites for their use are not met. The barriers and possibilities for the uptake of 'disruptive' health services have been discussed at length in EXPH (2016a). Here, we refer to that Opinion, and also highlight a few relevant observations with three extracted quotes:

"Some of the most important barriers to keep in mind are: lack of engagement of patients/people; resistance of the health workforce and organisational/institutional structures; inadequate networks and processes; economic and legal factors; lack of political support, lack of coordinated actions across agents, and lack of knowledge and evaluations."

"Payment systems are of particular relevance for the adoption and diffusion of disruptive innovations, since what is not paid for can usually not be done, and payments also send signals to innovators about what types of innovations are profitable to invest in. However, the use of new business/financial models should not be considered only as an element that influences the adoption and diffusion of a disruptive innovation, but also as an important area for the development of disruptive innovations."

"A difficulty in the implementation of disruptive innovations in the European health systems is represented by the significant knowledge gaps (e.g. methods of development, frameworks for designing the necessary system changes, limited experiences in the EU systems)."

These aspects are highly relevant for the digital transformation, even when recognising that not all digital transformation needs to be disruptive. Here, we will not focus on payment systems (see EXPH, 2016a for more details), even though we emphasise that this is an important and potentially complex issue, since the payment systems used in some environments may not be well-suited for some digital health services, or even hinder their adoption (even when beneficial).

Exercise of market power: short term and long term

We stress the importance of considering elements of market structure and power in the evaluation and implementation of specific digital health services. Adoption of some digital health services may result in market power in the short or long run. This can lead to undesirable developments and dependency. Moreover, when digital health services need to be integrated in care paths and potentially other digital systems, compatibility (culturally and technically) and interoperability become issues to consider. This may require specific coordination and policy. Especially for large, national programs these issues should be an integral part of an evaluation and decision.

Any health care product that is sold by a private entity to the health care system, including digital health services, can be associated with market power. This issue is rarely addressed in (economic) evaluations of health technologies. However, especially in certain circumstances, like high entry costs into the market and only one or a few providers of a specific service on the market (perhaps due to a selection process by the government including a full evaluation), producers of specific digital health services may have or gain market power, that is, the ability to set the price for its product well and above its cost of production and delivery in a sustainable way over time. For digital health services that may become essential to the health system, very high prices for such services may create

affordability issues (if part or the whole price is paid by citizens) or create financial sustainability issues to public and private health care payers alike.¹²

This may also be the case when large producers of digital health services do not only supply a service, but may also use the data generated through or collected in that service, hence getting into a situation where they are the only or one of the few providers able to provide some services.

Market power exercised by providers of digital health services can lead to subsequent behaviour that does not contribute to health system goals. Examples include the lowering of quality of the service and/or increasing the price of the service (over time). The nature and causes of market power may be diverse for different types of digital health services and the context in which they are delivered, as well as whether, when and how that power can subsequently be exercised. When evaluating and monitoring either specific services or more generally health system performance, these elements are important to consider. This is especially true in cases where governments select one or a few providers for nation-wide delivery of services. Including checks and balances to counter potential (misuse of) market power, already in the early phases of evaluation and selection, can avoid problems later in time.

In that context, ownership of systems and the data gathered with it is important, as well as the distinction between hardware and software.

Steering development of digital services

Much of the innovation in health care follows a 'bottom up' or non-guided process. In some cases, it may be worthwhile for policy makers to stimulate the development of technologies addressing specific health (care) issues. Compare the current efforts to stimulate the developments of new antibiotics. Through direct and specific incentives digital innovation in particular areas could be stimulated. This means a proactive rather than a reactive approach. For instance, governments could stimulate developments of technologies that reduce the pressure on scarce labour, for instance in the care sector. Or it could stimulate digital health services that empower patients, also stimulating goal orientation of care. This can also be done through commissioning new innovations (EXPH, 2016b).

¹² In the health sector the same dominance of a digital health service provider might emerge as seen in other contexts. Such market power motivated challenges to companies such as Microsoft, Apple, Google, etc.

Fiscal and social policies

The impact of health and health care on the wider society is stressed. These impacts go in both directions. Fiscal sustainability is an important issue. When digital health services increase health care expenditures, this may lead to increased fiscal pressures. The height of health care expenditures, as well as the mechanisms by which health care financing is secured, as well as the distribution of expenditures across the population (e.g., progressive, proportional or regressive in relation to income of citizens) are important aspects. Unless a particular health service has a very large impact on expenditures, such issues are less easily addressed in evaluations of one digital health service. In cases in which the budget impact of funding and implementing a service is very large, this issue should be addressed specifically (Lomas et al., 2018). One of the reasons for this is that if the health care budget is not (sufficiently) flexible, spending more on the new technology means displacing care elsewhere in the system.

Sometimes fiscal measures are used to stimulate the development of particular products. If such measures are used, they should relate to the goals of the system (e.g. stimulating the search for new antibiotics to avoid unnecessary illness and deaths), not to the fact that a health service is digital per se.

We stress the important role of health care for society as a whole. Not only can a healthy population be a more productive population, health is a key parameter of human flourishing. Health is wealth, both in terms of productive possibilities and, especially, in terms of its intrinsic value. A good, fair and accessible health system also contributes to social cohesion. It can contribute to helping deprived groups and to increased inclusion. Such parameters are not easily captured in individual evaluations, but some elements, like increased productivity and the distribution of health gains can be included and made visible. This underlines the importance of taking a societal perspective in evaluations.

1.11. Ten recommendations

Digital transformation will substantially change the future of health systems. Given the importance of this issue and the issues addressed in the previous paragraphs, we have formulated the following recommendations for the EU, EU Parliament, Member States and relevant authorities.

1. **Develop a strategy for the digital transformation of health care.** This strategy should be developed at and for the different relevant levels (European, national, regional and local), entailing how health care should develop and respecting the specifics of health services as well as the mechanisms, including education (of professionals and patients), incentives, and regulation to allow this development. Stimulating shifts of care (hospital to home), substitution (from labour to capital), interoperability, and increased person centeredness (through self-management, orientation towards attainment of life goals, and shared decision-making) are examples of goals. Actively stimulating development and adoption of 'digital solutions' for particular issues (with quality, shortage of personnel, inequities, etc.) can also be part of the strategy.
2. **Develop a coherent framework for monitoring and evaluating** the performance of systems, sectors and services in light of current and future digitalisation developments. Such a framework ideally consists not only of the rules regarding which technologies should be formally evaluated and how the selection, evaluation, decision and implementation process is organised, but also how those and other technologies are monitored. Such a coherent framework will also highlight the interdependencies between centralised and decentralised decisions, avoid potential blind spots, and increase consistency in evaluation and monitoring. It needs to indicate how and when monitoring and evaluation should take place and by whom. Such a framework is especially relevant at the national or regional level and for centralised decision-making. Development of such frameworks could be stimulated and supported at the European level.
3. **Invest in systematic evaluation procedures.** Relevant authorities (ranging from EU level to local levels), should invest in the creation of clear evaluation procedures. At a central level, such procedures include the legal framework for evaluation (what should be evaluated and when), which is underdeveloped for digital health services. Risk assessment (regarding costs, efficiency, quality and safety; including aspects like privacy and cybersecurity) of new and existing technologies would be part of this. The legal framework also includes aspects like who is responsible for providing the relevant decision maker with the required evidence.

4. **Invest in evidence informed policy measures** to follow up on evaluations and monitoring. Evaluations and monitoring inform decision-making at different levels. The policy instruments available to the involved policy makers (price negotiations, commissioning, coverage with evidence development, exclusion from funding, countering market power, etc.) matter in that context, both for what type of evidence is needed and how that evidence should be used.
5. **Invest in robust evaluation methodology.** Performing HTA in the area of digital health services raises a number of specific methodological challenges, including aspects like learning curves, iterative development of innovations, variability between settings (i.e., non-standardised services), determining optimal timing of evaluations in the development process (maturity), and measuring relevant outcomes. Improving and standardising methods will aid researchers and decision makers. In this context we stress that commonly HTA is often less equipped to study aspects like access, equity, patient empowerment or goal-orientation. These are likely to be relevant in the context of digital health services. Methods to systematically consider such aspects need to be developed and included in HTA frameworks. This will lead to more information and perhaps requires multi-criteria decision analysis. Mini HTA may bridge the gap between centralised and decentralised decisions.
6. **Invest in monitoring.** As argued in EXPH (2014), health systems would benefit from systematic monitoring their performance on key parameters. This helps to ascertain that health system performance develops in a desired way and allows for intervening if this is not the case. Elaborate, systematic monitoring schemes, ideally uniform across Europe, would facilitate monitoring, benchmarking and evaluations, create possibilities to detect underperformance, and stimulate early intervention when needed. The digital transformation can assist such systems by allowing efficient gathering and analysis of data, and can also be the subject of monitoring.
7. **Support decentralised/local level decision-making.** Much of the innovations, including digital health services, enter the health system through lower level decision-making. This can have advantages, like competition and diversity, and disadvantages, like simultaneous experiments and problems with interoperability. Setting rules for which digital health services need to be evaluated centrally (as discussed under point 2 and 3) is important, but given that not all interventions can or should be evaluated centrally, strengthening lower level decision-making processes and aligning these with overall health system goals remains important as well. Education, monitoring, incentives and, for instance,

increased use of mini-HTA as a tool, are options. Coordination to improve interoperability should also receive sufficient attention.

8. **Create an environment willing and able to adopt evidence based innovations.** The adoption and implementation of effective and cost-effective new digital health services requires having an environment that allows for this. This relates to the attitudes and training of citizens, patients and professionals, but also to overcoming organisational and financial barriers in adopting new technologies. Removing such barriers and allowing the freedom to (controlled and evaluated) experiment with new technologies is needed. This can also facilitate decentralised innovation, which may contribute to the best services being developed and implemented and to continuous improvement of health services.
9. Set up a **European repository** for evaluation and monitoring methods, studies and results. An open access European repository containing evaluation tools and completed and ongoing evaluations, facilitates optimal exchange of knowledge and experience at a European level. It can contribute to continuous improvement and expansion of the evaluation framework. The repository could be maintained by an independent body to ensure quality. This could also stimulate the quality of separate evaluations, if researchers want to have their evaluations included in the repository. The repository could also contain information from monitoring activities at a European level or by individual Member States. This may further stimulate systematic monitoring activities and knowledge regarding key parameters.
10. **Be progressive but with caution.** The Panel recognises the impact the digital transformation will have on future health care, and the associated positive and negative aspects. We encourage scanning for opportunities but notwithstanding this also emphasise the need for caution in adoption and deployment of new digital health services. This should be done carefully, in view of all relevant costs and benefits, intended and unintended. Avoiding harm, service failure or system failure is crucial. The apparent paradox of being progressive and conservative at the same time, simply implies that adoption of innovations takes place based on evidence, prudently, in a controlled manner, and is continuously evaluated. Regular checks on the robustness of the health care system are advised, to see how the system could deal with loss of digital services and infrastructure in case of breakdowns or calamities.

2. ANSWERING THE MANDATE

In this section, we briefly provide a direct answer to the questions posed in the mandate, which are also a synthesis of the main points discussed above.

1. Are the existing methods best tailored for assessing the value of digital transformation of health services?

No. First of all, assessing the value of 'the digital transformation' is a highly difficult task (and it is also not clear what policy the answer would inform, given the variation in underlying digital health services). The evaluation must focus on the service, not on a more elusive concept like "digital transformation". Second, the current methods for assessing the value of digital health services are largely based on the evaluative framework primarily developed (and used) for pharmaceuticals. Digital health services are often different, in key elements. This involves all phases of an evaluation, the process of (and responsibility for) evidence generation as well as legal frameworks. In terms of the evaluation itself, aspects like diversity of relevant outcomes, gradual development of innovations, issues of interoperability in exchange of information and user friendliness, learning curves in using digital services, and potential difficulties in performing RCT's, are just a few examples of the need to further develop the current framework. Progress has been made, also reflected in available evaluation frameworks (and thanks to EU funded projects in this area), but many questions are still open. We strongly recommend strengthening the knowledge base through methodological advances, performing evaluations and monitoring, and making these widely available for consultation. A European repository would also be helpful in this respect.

2. Is there a need for modification of existing methods or for the development of new ones to assess and evaluate the impact of digital health services?

In general, the answer to this question is yes. The degree of need for modification largely depends on the degree of similarity between the digital health service and the technologies evaluation methods commonly used in the field of health care (mostly pharmaceuticals and devices, less for evaluating processes), in terms of characteristics and goals. We expect modifications to be frequently needed, in relation to the policy questions addressed, the selection of which services to evaluate, who should gather the evidence and when, the design and execution of the evaluation, the included costs and outcomes etc. In many cases, the optimal design and methodology for a study will be context dependent. However, in order to standardise and increase quality and comparability of studies, guidance on modified elements (including measurement and valuation of relevant outcomes) remains needed. This guidance needs to permanently reflect evolution of technologies assessed and methodologies used to perform that assessment. Investing in developing and disseminating methodological knowledge is important.

3. *What types of data are available and required to assess the value of digital health services?*

There is insufficient data readily available to systematically assess the value of digital services. As for evaluations of other health technologies, these normally need to be tailored to the policy question at hand and gathered in an experimental design (such as RCT). Real world data and evidence may help, but often is not available for new technologies, not fit for purpose of evaluation, and not without problems in terms of analysis and interpretation of results.

Even less data will be available regarding the contribution of specific digital health services to broader health system goals, such as access, equity, etc. In terms of monitoring, more systematic gathering of key performance indicators of health care systems is advocated. These could include indicators highlighting the use of digital services and potential consequences (ranging from improved access to services to data leakage and privacy violations).

4. *What impacts of digitalisation of health services should be assessed systematically?*

While we emphasise the impossibility and undesirability of systematically evaluating all separate health technologies, including digital health services, a systematic approach to which to evaluate is important. Ideally, the selection is based on an impact assessment (the risks related to the technology and its potential impact), also in relation to decision uncertainty, prior to carrying out the evaluation.

For those interventions evaluated, the evaluation should focus on the most relevant outcomes (intended and unintended) related to the intervention in relation to the objectives of the health system. This should normally include all relevant costs and benefits, inside and outside the health sector. Inclusion of broad impacts, affecting health care and societal goals, if relevantly affected, is encouraged. The selection of impacts to consider in an evaluation typically needs to be done context specific (i.e. on a case by case basis) and needs to be justified.

For digital health services, information on adoption and implementation, organisational, legal and cultural barriers, as well as financial barriers, need to be considered as well. Whenever digital services are an integral part of a broader health service that is evaluated, the role of the digital components need to be included in the evaluation of the broader health service, which is then evaluated under existing procedures.

5. *Should this impact be considered with regards to health outcomes, health systems, the wider society, or all of these? Or should other dimensions be considered instead or in addition?*

In principle and in theory: all of these (where relevant) should be considered. We advocate taking a societal perspective in evaluations, which implies the inclusion of all relevant costs and benefits, wherever, whenever and on whomever they fall. This includes distributional aspects and the influence of separate decisions on issues like interoperability.

Again, the exact factors to be included in an evaluation need be determined in each specific context, but ensuring that all relevant aspects are included (without double-counting) is crucial. Otherwise, elements of value could be left out of the evaluation and subsequent decision-making, which could lead to suboptimal decisions.

This includes all aspects related to health system goals, including access, equity (including avoiding the risk of a digital divide) and patient empowerment. Adoption of digital health services, which have all relevant effects within a health care organisation, can be evaluated by the relevant provider. This will be the case when the digital health service improves the internal process of the provider only.

6. How could the impacts on wider fiscal and social policies, beyond the health sector, be assessed?

In taking a societal perspective, consequences for the broader economy and society can be included. This may include the fiscal sustainability of systems when new digital services would increase budgets or save costs. Impacts on the broader economy, for instance through productivity gains in healthy citizens, or in time saved being absent from work due to digital communication with health care professionals, etc., can be measured and valued using existing methods. Equity considerations may also entail the consideration of who bears the costs or finances the innovation. Sustainability (financial, political, etc.) of health systems are typically not directly affected by single technologies. However, in monitoring the performance of the full system, such elements may be considered. Monitoring the degree of solidarity (with regard to financing and delivery of care) can be important.

Concluding remarks

The evaluation of digital health services is an important and challenging topic. Given the expected growth in digital health solutions, as well as the impact this will have on future health care delivery, the development of improved methods for evaluating the contribution of digital health services to patients, care providers and health systems is of utmost importance.

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APPENDIX A

We found no literature-based evidence of newly identified dimensions of healthcare services other than those in detail addressed in the previous EXPH Opinion on quality and safety of health services (EXPH, 2014).

Developments that can be observed include the gradual ongoing re-orientation from illness oriented services to goal oriented services, single-provider/entity services to networks-provided (distributed) services and a time-dependent shift from reactive services to proactive and prospective personalised health and healthcare related services.

Because of this, there is no need to define and collect additional service indicators than those already listed in the previous EXPH Opinion paper. For means of appropriate evaluation and as a means of supporting meaningful use of digital health services, the EXPH advocates the use of following list of indicators extracted from the full list of indicators as published in the previous EXPH Opinion.

Intra-institutional and intra-county health care (to a lesser degree intra-national, due to structural and processual differences) systems for self-benchmarking could benefit from the use of these selected indicators to assess the effects (benefits/trade-offs) of digitisation, digitalisation and digital transformation – subsequent comparison of these indicators before introducing the “digital” and in defined periods of time after the introduction and during continuous improvement of digital transformation of health services.

List of selected indicators for assessing of the impact of “digital” on HC services (highlighted with higher relevance – more “digital” specific as chosen by the Panel Experts):

Underlined indicators are those chosen by the Panel Experts.

Process	Appropriateness	Presence of programs guaranteeing the quality of infrastructure and equipment
Process	Appropriateness	Organisation of services guarantees enough time to offer a high quality service
Process	Appropriateness	Proportion of professionals that attend continuing education programmes in a regular base: including patient safety
<u>Process</u>	<u>Appropriateness</u>	<u>Proportion of professional with access to medical Evidence-Based information, and training to benefit from their use</u>
<u>Process</u>	<u>Appropriateness</u>	<u>Proportion of professionals that use appropriate clinical guidelines</u>
Process	Appropriateness	Proportion of professionals that participate in the development of clinical pathways
Process	Appropriateness	Consultation skipped due to costs
Process	Appropriateness	Average time dedicated per specialist consultation
Process	Appropriateness	Average length of stay
<u>Process</u>	<u>Appropriateness</u>	<u>Electronic medical records adequately performed</u>
Process	Appropriateness	Systematic discussion of clinical cases by responsible team
<u>Process</u>	<u>Appropriateness</u>	<u>Proportion of centres/professionals that adhere to appropriate clinical guidelines (up-to-date evidence based)</u>
Process	Appropriateness	Presence of enough well trained and motivated professionals
Process	Appropriateness	Health promotion habits in childhood, coverage of programs (primary care)
Process	Appropriateness	Health problems detection in adults, coverage of programs (primary care)
Process	Appropriateness	Diabetic patients with good control
Process	Appropriateness	Hypertensive patients with good control
<u>Process</u>	<u>Appropriateness</u>	<u>(Regular) doctor spending enough time with patients during the consultation</u>
Process	Appropriateness	Waiting time for planned PC

Assessing the impact of digital transformation of health services

Process	Patient safety	Exchange of knowledge, experience and good practice in patient safety
Process	Patient safety	Guides on education and training of health professionals in patient safety, and on effective setting up and functioning of reporting and learning systems
Process	Patient safety	Projects funded by EU
Process	Patient safety	Compatibility and comparability of information between EU MS
Process	Patient safety	Presence of patient safety education and training programs in health care settings
Process	Patient safety	Establishment and functioning of an adverse events information system
Process	Patient safety	Compatibility and comparability of information within the country
Process	Patient safety	Establishment and functioning of blame-free reporting systems
Process	Patient safety	Opportunities for patients and other caregivers to report their experiences identifying threats to safety
Process	Patient safety	Complain and redress procedures clearly established
Process	Patient safety	Systematic use of the information to prevent/ameliorate safety risks and unjustified events
Process	Patient safety	Misidentification of patients
Process	Patient safety	Doctors dealing with missing clinical information (proportion per patients seen)
Process	Patient safety	Missing of faulty equipment (proportion per operations performed)
Process	Patient safety	Percentage of impatient risk assessment completed and linked to care plan
Process	Patient safety	Patient strategies or programs in place
Process	Patient safety	Presence of competent authorities and bodies designed
Process	Patient safety	Establishment of safety standards on the territory
Process	Patient safety	Application of safety guidelines
Process	Patient safety	Development of specific programs to assess and reduce unjustified variation
Process	Patient safety	Medication error
Process	Patient-Centredness	Patient experiences take into account (captured through feedback system and used as learning and improvement resource)
Process	Patient-Centredness	Presence of effective communications between providers and patients
Process	Patient-Centredness	Proportion of (users/persons...) satisfied with the received information
Process	Patient-Centredness	Access of patients to medical records authorised and free of charge
Process	Patient-Centredness	Evidence that a mechanism to capture patients' and families/carers' feedback is in place and is used as learning and improvement resource
Process	Patient-Centredness	Proportion of Patients' (persons) with acceptable knowledge about quality (including patient safety) standards and guidelines in country of residence and other EU countries
Process	Patient-Centredness	Percentage of patients who feel they were treated with respect in their health care system/ organisation interaction
Process	Patient-Centredness	Information available for every interested person
Process	Patient-Centredness	Care providers guarantee the optimal care when different providers are needed
Process	Patient-Centredness	Presence of means of communication between levels (e-mail, phone, meetings)
Process	Patient-Centredness	Regular use of means of communication between levels
Process	Patient-Centredness	Proportion of patients who declared they were given the right amount of easily understandable information to enable them to participate actively in medical decisions
Process	Patient-Centredness	Proportion of patients and families who are able to comprehend the information and instructions given to them in relation to discharge of transfer to other care institutions

Assessing the impact of digital transformation of health services

Process	Patient-Centredness	Presence of available ways of communication with the patient (e-mail, phone, video)
Process	Patient-Centredness	Regular use of ways of communication with the patient
Process	Patient-Centredness	Presence of protocols for coordination between levels/centres/professionals, and adequate means to do that (including time)
Process	Patient-Centredness	Presence of effective reference systems in place
Process	Patient-Centredness	Electronic medical records compatible between centres/institutions/countries
Process	Patient-Centredness	Presence of experiences of integrated care (primary care, hospital care, social care)
Process	Patient-Centredness	Patients/citizens actively participate in their care
Process	Patient-Centredness	Proportion of patients/families who experience the care process as being "joined up" according to their needs
Process	Patient-Centredness	Meaningful informed consent properly regulated
Process	Patient-Centredness	Presence of education and training programs for patients to help them participate in decisions related to their health/care, and for training patients in self-management of chronic conditions
Process	Patient-Centredness	Proportion of patients/clients with chronic conditions who actively participate in the development of a treatment plan with their health care provider
Process	Patient-Centredness	Presence of training programs for health professionals aimed to involve patients in all decisions about care and treatment
Process	Patient-Centredness	People/patient rational use of service
Process	Patient-Centredness	Possibility of choice between practitioners, centres, etc.
Process	Patient-Centredness	Assessment of availability of professional-led, or peer-led, education/training programmes for patients to enable them participate in decisions relating to their health and care, and to support self-management of chronic conditions
Process	Patient-Centredness	Proportion of children whose parents routinely received all aspects of family centered care
Process	Patient-Centredness	Patient and Patient Organisations meaningful participation in planning, management and regulation of health services
Process	Patient-Centredness	Patients' organisations actively participating in health related policy-making at all levels
Process	Patient-Centredness	Proportion of population considering health services (health system) function well or very well
Process	Patient-Centredness	Proportion of patients considering their care (primary care, hospital, etc.) has been good of very good
Process	Patient-Centredness	Proportion of patients satisfied with each aspect of the services provided
Outcome	Enhancing quality of life for people with long-term conditions	Proportion of patients that feel supported to manage their chronic condition in a national/European patient survey
Outcome	Enhancing quality of life for people with long-term conditions	Employment of people with long-term conditions
Outcome	Enhancing quality of life for people with long-term conditions	Emergency-based hospitalisation for chronic ambulatory care sensitive conditions
Outcome	Enhancing quality of life for people with long-term conditions	Health-related quality of life of carers
Outcome	Enhancing quality of life for people with long-term conditions	A measure of effectiveness of post-diagnosis care in sustaining independence and improving quality of life
Outcome	Ensuring that people have a positive experience of care	Friends and family test (Would you recommend this service to friends and family?)
Outcome	Ensuring that people have a positive experience of care	Patients experience of service/care with FFT

Assessing the impact of digital transformation of health services

Outcome	Ensuring that people have a positive experience of care	Patient experience of hospital care
Outcome	Ensuring that people have a positive experience of care	Patient experience of outpatient services
Outcome	Ensuring that people have a positive experience of care	Patient experience of accident and emergency services
Outcome	Ensuring that people have a positive experience of care	Patient experience of primary care services
Outcome	Ensuring that people have a positive experience of care	Women's experience of maternity services
Outcome	Ensuring that people have a positive experience of care	Bereaved carers' views on the quality of care in the last 3 months of life
Outcome	Ensuring that people have a positive experience of care	Patient experience of community mental health services
Outcome	Ensuring that people have a positive experience of care	Children and young people's experience of outpatient services
Outcome	Ensuring that people have a positive experience of care	Responsiveness to in-patients' personal needs
Outcome	Treating and caring for people in a safe environment and protecting them from avoidable harm	Incidence of harm to children due to 'failure to monitor'
Outcome	Treating and caring for people in a safe environment and protecting them from avoidable harm	Incidence of medication errors causing serious harm
Economics	Macro level	Health care expenditure; per capita; percentage of GDP (€PPP)
Economics	Macro level	Public health care expenditure: per capita, as a percentage of total health spending, as a percentage of public spending, as a percentage of GDP
Economics	Macro level	Private health care expenditure: OOPs as a percentage of total health spending
Economics	Macro level	Private health care expenditure; per capita; percentage of GDP
Economics	Macro level	Pharmaceutical expenditure; per capita; percentage of GDP
Economics	Macro level	Break down per sector/disease
Economics	Macro level	Finance mix
Economics	Macro level	Process: good accounting practice - NHA
Economics	Macro level	Gini-coefficient
Economics	Macro level	Distribution of health financing mechanisms (Kakwani index)
Economics	Macro level	Incidence and distribution of catastrophic and impoverishing OOP payments
Economics	Macro level	Benefit incidence analysis
Economics	Meso level	Degree of integration health, welfare, housing, employment
Economics	Meso level	Performance to link patient-related information across the different levels, sectors, organisations and providers

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