Expert Panel on Effective Ways of Investing in Health
Hearing on 'Assessing the impact of the digital transformation of health services'

Brussels, 13 November 2018

Background

The Expert Panel on Effective Ways of Investing in Health is currently working on the Opinion/report on 'Assessing the impact of digital transformation of health services' as part of its continued work on innovation in the healthcare sector. Opinions of the Expert Panel are drafted to support the European Commission and interested stakeholders in identifying specific aspects to be considered as well as tangible results that should be achieved to make a real change in terms of reforms to health systems and investments at the EU level. This hearing was held to gather views from a range of key experts on public health and healthcare services from well known institutions and professional bodies, representatives of Member States, non-governmental organisations, academics, EU institutions and relevant stakeholders from health-related areas (industry, research, economy). The hearing will contribute to shaping the Opinion on 'Assessing the impact of digital transformation of health services' and to provide input for reflection on possible actions to be undertaken at the national and European levels.

Four members of the Expert Panel on Health led the discussions:
Professor Jan De Maeseneer
Doctor Aleš Bourek
Professor Lasse Lehtonen
Professor Werner Brouwer

The following is a summary of the key points raised by members of the Expert Panel on Health and the key experts.

The hearing started with **Dr Aleš Bourek** setting out some of the main points in the Opinion.

He explained that we have seen the transition from an industrial to an information society and we witness the impact of this in all areas of human activities. With regard to assessing the impact of the digital transformation of health services, this is a difficult and complex issue as it ranges from the micro to the meso to the macro and from the purely technological aspects to the personal and societal effects such as personal privacy and the technical possibility of digitally scanning people's mental processes. There are also different goals and different scales in relation to these goals, from the personal to the societal level.

There have been dramatic changes (e.g. the move from descriptive medicine to causal medicine) since around 1990 when the industrial society turned into the information society. The shifts included moving from diagnosing and therapy of a disease to the more pro-active, prospective and personalised care of today, from disease management to assisted care and to shared care (i.e. where patients themselves collect a lot of facts and need health professionals to discuss the context and meaning of the facts in order to help make appropriate decisions), from hospital-based care to outpatient-based care and telemedicine. We are also moving into cyber medicine. Today, professionals are faced with a situation where technical and human systems form an integral part (e.g. person with a pacemaker). The transition into the information society resulted in today's way of doing things digitally.

In the last 30 years, society has worked on transforming (where possible) data/information into the digital format in order to assure efficient storage and to minimise errors in the course of message sharing. To benefit from the above issues, it is not enough to just introduce digital technologies, but we have to change the whole process of doing things.

Complexity and the interaction of health and digital

The interaction between the health and the digital domains leads to vast complexity.

In the real world, issues are evident (they can be perceived by vision; accidents hurt physically; cause and effect can be observed) whilst, in the digital world, issues are mediated (they are not so obvious; they can only be "seen by the brain"; accidents do not hurt physically; cause and effect is not so noticeable).

People have not always changed their ways of doing things even in the digital world. For example, in the past, doctors would scan a text with their eyes to find something in a text. Many doctors still use this old habit instead of using 'Ctrl F' or F3 to search for words in a digital document and to find the needed information.

In today's world, people have to switch permanently between behaviour in the real world (e.g. human interaction such as greeting people in the office) and in the digital world (e.g. using templates in a word processor rather than typing documents from scratch every time). This continuous switching between two different environments (the real and the virtual) is taking its toll in terms of increasing problems in the area of mental health. We need to be aware of the issues addressed above when we attempt to assess the impact of digitalisation.

The virtual world offers opportunities and also bears risks. We need to consider both the virtual and real world in evaluations. When it comes to healthcare and the digital society, we should try our best to avoid surprises and the unexpected as we are looking at the results of interaction between two complex systems. Moreover, this interaction has its positives as well as negatives.

Some impacts of the digital world and considerations to take into account

- Digital code can be used effectively for production of "spare parts" for humans (e.g. for hip replacements). Having input the data, it is possible to model the optimal shape and produce the part by sending data to a 3D printer. The turnover rate for producing individualised and optimised replacement parts is higher thanks to digitalisation.
- In the past, health professionals had the knowledge and lay people did not (e.g. because they had no access to professional information resources). Now, anyone digitally literate can get hold of information and for this reason the role of professionals has changed. They are now not there so much to provide the facts as to weigh the options, do the best possible reasoning with the information available on behalf of the patient and arrive at the optimal solution from the point of view of the care receiver. They function more as information brokers and this leads to changes in health service provision (issues such as goal-oriented care).
- It is important to note that there are situations where there is a place for a digital approach and situations where there is a place for an analogue approach (a cancer patient may derive more comfort from being held by the hand then being video-consulted).

- Healthcare professionals and whole systems have to be as errorless as possible and also need to be trustworthy. Errors must be avoided, since they lead to a loss of trust.
- Healthcare services are always facing new and unique situations. It is not so simple to introduce technologies into the healthcare service. Healthcare professionals never encounter the same situation twice. This means that one needs to find new approaches. It is challenging to digitalise such a type of service provision correctly.
- The population served by healthcare professionals is very vulnerable (e.g. ranging from prenatal diagnostics to post mortem services). This makes healthcare very different to other services.
- Some information (tacit, olfactory) is difficult to turn into digital format and a loss of context can result from inappropriate transformation of analogue information into digital.
- The introduction of new digital services must be done at a reasonable pace and with sufficient back-ups.
- We are moving from healthcare defined only as 'state of complete physical, mental and social well-being' to a definition of health as a process 'the ability to adapt and self manage'.
- The goals of healthcare services, whether provided digitally or not, have not changed. What we expect from healthcare services is delivery of goals as defined by IOM (Institute of Medicine) accessibility, safety, effectiveness, equity, efficiency, affordability, responsiveness and appropriateness). Digitalisation may add new dimensions and meanings to existing goals (e.g. in addition to 'safe' meaning 'no harm to the person', in a digital sense, safe also means 'no leaking of data to someone who should not have access to the data').
- Indicators might need to be redefined because of the digital way of providing the services.
- The 'information society' can also easily become 'a disinformation society'. The effects of sharing inappropriate information must be recognised (e.g. the vaccination hoax). It is about knowledge education and culture that has to go hand in hand with technological advances and this dimension also has to be monitored.
- Evaluation in systems needs to assure that the right amount of data goes to the right people.
- We need to set up a system of evaluation that will also be fit for future demands and use.
- Evaluation and monitoring requires relevant data. Data should be gathered for a purpose and fit to address questions that we want to address. If not handled by professionals, data can be "gamed" easily with undesirable effects.
- It is important to prioritise monitoring and evaluation.
- The EXPH has produced a sample checklist for the evaluation of digital healthcare services before and during their introduction and use.
- The EXPH recommends the creation of a European repository of methods to evaluate digital health services because it has not found a systematic and collated effort on evaluation options in literature.
- Where possible, digital and non-digital approaches should be benchmarked to show if and where the introduction of a digital approach has been beneficial.
- Evaluation should cover the positive and unintended/unexpected outcomes. Data collected must be used to modify behaviour and optimise the behaviour of the systems.

The Opinion sets out ten recommendations for policymakers:

Develop a strategy for the digital transformation.
Develop a coherent framework for monitoring and evaluating.

Invest in systematic evaluation procedures.
Invest in evidence informed policy measures.
Invest in robust evaluation methodology.
Invest in monitoring.
Support decentralised/local level decision-making, ensuring, at the same time, interoperability.
Create an environment that can adopt innovations.
Set up a European repository for evaluation and monitoring methods, studies and results.
Be progressive in research and horizon scanning, but cautious when it comes to implementation.

Other key points he made included:

Align literacy with technological development – do not give health professionals technology without supporting them in how to use it properly.
Do not introduce digital things only because they can be introduced.
We should introduce appropriate evaluation in order not to unintentionally create more problems than we had before the introduction of digital services.

Ioanna Psalti, Advisor at the European Alliance for Vision Research and Ophthalmology

Ms Psalti expressed concern about how to integrate cross-border care (in that connection there is a new Opinion on the European Reference Networks). She raised the importance of the interoperability indicator, which, in her view, is not sufficiently in the spotlight in the Opinion.

She would like the Opinion to look at the patient from a longitudinal perspective (the pathway is important and the service in relation to goals). She also mentioned the importance of utility measures (the report mentions that as one of the ways to go). In addition, she drew attention to the digital maturity of interventions as an important concept.

Professor Werner Brouwer

Mr Brouwer agreed that interoperability is an important issue. The Opinion covers it but not in the context of cross-border care. He thinks that this adds value as, in particular circumstances (e.g. the ERNs or border regions) a failure to address the issue of interoperability could potentially hurt patients.

He also agreed that patient pathways are important and that, if there is a change in the pathway, one should look at the effects of that change on the total pathway, rather than only evaluating the actual intervention in an isolated way. The panel will look into whether this is sufficiently clear in the Opinion.

As a health economist, whilst he is fond of utility measures, he does not see them as the answer to all situations. There could be situations where one might prefer patient satisfaction or other types of clinical measures. He agreed that, to his dismay, there is a difference in the availability of utility measures at different levels of our healthcare systems. We talk a lot about the alignment between the different levels in our healthcare systems. And even if we had alignment in terms of the goals that we pursue at the different levels of our healthcare systems but you do not have similar instruments to see whether or not you are on the right track, you could still have differences that might be unwarranted. So we will look into that too.

Dr Aleš Bourek

On interoperability, we have ICD-9, ICD-10 coding. If, with an electronic medical record we do not have information on coding used confusion will arise. We have to assure that we use agreed and common coding/languages.

The whole impact of the digital environment is that, for the first time in human history, we decided to use Transmission Control Protocol/Internet Protocol (TCPIP) and for the first time we have an international code that allows us to collaborate. If we confuse the code, then we can expect the same effect that we saw with the Tower of Babel story. This needs to be prevented.

With regard to digital maturity, a mature person is one who voluntarily adopts a code of conduct. If everyone uses their own code, we will have complete digital anarchy. And if we decide on common languages, then possibly we can find the same voice and we can start collaborating in a much more efficient way. The indicators on interoperability are important and they should be a part of the European repository. These are the basic cornerstones. We have to work on interoperability and that is by setting a common language.

Professor Werner Brouwer

With regard to digital maturity, the maturity of a new intervention is crucial. It relates to optimal timing of your decision. In your decision framework you need to take into account the maturity of an intervention. Optimal timing of an evaluation and decision can be difficult; sometimes you cannot wait any longer, also because different (competing) services may be at different stages of maturity.

In this context, some of the learning effects might be different in different organisational environments. For these types of interventions, it might well be that the environment changes the way in which the digital service works. And that means that it is not only about maturity but also the places in which it is used and the interaction with that environment. That makes this an incredibly complex issue. It is, however, clear that maturity is a crucial issue in this context. That is one of the reasons why we reference the World Health Organisation (WHO) report so strongly in the Opinion.

Professor Lasse Lehtonen

On digital maturity, the panel's opinion was that we do not want to have any other criteria for evaluation of health systems that are already established. So it is difficult to evaluate digital maturity without looking at the overall goals of the health system. For the health system as a whole, he thinks that we need to stick with the general criteria as indicated in the Opinion.

He strongly supported that we should emphasise the interoperability issue more in the evaluation (especially in relation to decentralised decision-making).

Professor Jan De Maeseneer

We need to look carefully at the coding system. In terms of goal-oriented care, the goals of people are very often formulated in terms of functioning. So then you will need, for instance, international classification of functioning if you work interprofessionally. We also have to prepare the future and to

enable that this new kind of approach can in practice be translated into the digital aspect of our service delivery.

Jan De Belie, a Professional Affairs Advisor for the Pharmaceutical Group of the European Union (PGEU)

He thanked the Panel for taking account the roles of the healthcare professionals and important aspects there – co-creation is one that was mentioned - and for taking into account the experiences of healthcare professionals with these products and digital services to ensure that they are fit for practice. He also highlighted the importance of not dehumanising health. He said that the PGEU also embraces the focus on education and training for healthcare professionals when it comes to digital services and when it comes to improving the efficiency (e.g. saving time on logistic/administrative procedures to have more time with patients).

He said that the Opinion could have more on continuity of care (not just cross-border but also within the national system) to come towards a more integrated care model. Electronic and digital services have a very high potential to increase collaboration, to make this more efficient and to improve communication and the sharing of relevant information between healthcare professionals that is needed in every kind of care setting.

Professor Jan De Maeseneer

It is about 24/7 continuity. Especially when it comes to informational continuity, digital services may make a big difference.

Professor Werner Brouwer

We focused to some extent on the problems of achieving continuity of care (this is one of the things listed as an element of quality). If you want to achieve it, you both run into the problems of interoperability, of information sharing and of potential risks in terms of who sees that information, when and why. We might have focused more on that particular element. The ultimate goal is to overcome some of these problems and hopefully overcoming them will ultimately lead to better continuity of care.

Professor Lasse Lehtonen

He raised some of the 'caution issues' in relation to continuity of care. Resilience is critical because if people start to rely on the services that are available 24/7 for remote areas and so on, it is of huge importance that then there is no interference and that there is a back-up system that can work if the systems break down.

Regarding the equity issue, if you make these systems available for the whole population then you start to have groups, such as the visually impaired, who are unable to utilise the digital services if there is no specific equipment.

He drew attention to the conflict between privacy issues and sharing of information which is very difficult to solve. For example, with mental disorders, where you really need good integrated care if you want to have good efficacy for the treatment, the issues are very sensitive for the patient and could be socially problematic if the information is shared with a large group of people. These things have to be balanced and we have to be cautious and look at the unintended effects that these type of systems may have for society.

Dr Aleš Bourek

If we increasingly provide services digitally, then we must assure, that human check-episodes exist (i.e. coming to a healthcare professional to find out if what is being done has the intended effect). In addition, there are many formats as to how this can be done.

If someone gets telemedicine support, then at a certain point they arrive at a point where they do not know if they are doing those things right. In addition, they need a professional today not for providing facts but to give weight to the facts depending on the context. This can be done in a much more orchestrated way.

Finding indicators for this collaboration that goes across all the different providers will be challenging. The Expert Panel would like to see more effort from the Commission in constructing these indicators and following this line of thinking.

Dorota Sienkiewicz, Policy Coordinator at EuroHealthNet (representing public health authorities, also at local and regional level)

She described the Opinion as very interesting and noted its emphasis on the equity dimension, on shifting the focus from curative care more towards preventive care. She expressed support for the continuity of care mentioned and seeing how it fits into the community-based delivery of care.

One of the ten recommendations was to be careful with introducing services in a digital way without any backup. She argued that we do not want to have a two-tiered system of delivery of care where digital services work for certain populations while we not improve healthcare services for underprivileged groups in our society.

In the parts of the Opinion she has read, she missed how digital transformation can help health services, health systems and health professionals in addressing the health inequalities by addressing social determinants of health.

With regard to the real world data that is difficult to obtain, she asked what kind of evidence would need to be sought after by the core health services and the public health community across Europe. She asked about strengthening capacity building of the public health community and the public authorities that would then have to deal with and contribute to appropriate design, evaluation, implementation, evaluation and monitoring of the digital transformation of health services across Europe.

Professor Werner Brouwer

He said that the Expert Panel emphasised equity throughout its Opinions. He referred to two simple goals that a health system has: efficiency (to produce as much health as possible) and equity (that health should be fairly distributed). There is quite some attention to equity in the Opinion, including that digitalisation can solve problems relating to equity by, e.g. increasing the access to healthcare in rural/remote areas by new connections, telemedicine etc. but it can also create new types of inequities. Traditionally, inequities between the 'haves' and the 'have nots' have been noted. Nowadays, in the context of digitalisation you may encounter a new division in terms of the 'cans' and the 'cannots' – i.e. those people who can access and work with digital environments and understand information provided to them via these types of processes and those who cannot. He argued that we need to be careful about overstating and expecting effects of providing information. His view was that we can reduce some inequities through digitalisation but that we can also create new inequities. We need to be as sensitive to the new inequities as we were to the old ones.

In terms of prevention/self-management, a lot of the general tendencies that are part of digitalisation is to move care away from hospitals, from fixed environments/places to other places including to people's homes, including putting people much more in control as to how they manage their own diseases. Health promotion and self-management are important in that context.

The mandate we had was: How would you evaluate such services and related changes? We tried to include the important aspects that should be included in any evaluation of digital health services. We did not write a report to indicate that we felt that digital services would be most appropriate in certain health care contexts or sectors, or that they would be most attributing to, e.g. equity solutions in certain circumstances. This was not part of the mandate. We emphasised that, if you are dealing with evaluating these types of digital services, you need to look at a total pathway. We did not exclude particular areas of health care, like health promotion.

Importantly, in evaluating changes, you cannot just look at effectiveness and efficiency. You also need to look at equity. If you serve new people, are you also leaving other people behind that were served before? That is why we also, e.g., distinguish between complementary health services (that add on to the things we already had) and substitute services (that substitute the thing that you had before). Especially in the latter case, there is a danger that people who were happy with the old service but are now left potentially unattended to in the new service. We wanted to be as balanced as possible in relation to the mandate that we had about these aspects of digitalisation and health equity.

Professor Jan De Maeseneer

He has just returned from a WHO conference on primary healthcare. It was emphasised there that the integration of public health and primary care is a step forward and is the next step to do and it is obvious that we have to shift from an individual diagnosis, where digital services can help a lot, to community diagnosis, which public health is dealing with. The digital transition enables us to do that in a consistent way, which could be a new perspective for the future that could be part of the assessment and that will bring together the concerns of public health with those of primary care.

Tobias Ioachim, Project Manager Professional Relations from Roche Diabetes Care

From an industry perspective, we as a medical device manufacturer are involved in health services and have discussions about HTAs in connection with medical devices and we are open to work transparently and voluntarily with HTA bodies.

The HTA has to be fit for purpose. Originally they were made for pharmaceutical products for medication. We have to find an adaptation of this.

He liked the interoperability aspect because, when you think of chronic diseases, we have to find a common language for it and a common basis for relevant data for stakeholders. This makes it much easier for the specialists for example to decide on a therapy and the general practitioner can continue on this (because we have a lack of specialists on this in all EU countries).

General practitioners have to take over the opportunity and the responsibility to continue with the therapy. The patient is the owner of the data and has to decide what data to present/open to the physicians. Patients have to be aware that there is not necessarily a risk when they open the data for physicians and that there is more a benefit for them.

He liked the reference made by the Expert Panel to 'progress with caution'. You have to risk a bit to be innovative/go forward but without harming people/putting people at risk. We have an EU funded project starting next year where we spread the risk on many shoulders – we will work with the municipality that reimburses a certain service (we provide test drips/software for patients). We take some risk. We say that we can deliver a basic therapy and when the outcome improves we get a bonus. When the outcome decreases, we get less money. The advantage for the payer is that they know exactly how much they will pay for a year for one patient. The patient in the centre has the benefit that everyone is willing to increase the outcome. The doctors are willing to increase the outcome. It is not a one size fits all solution. It is the patient in the centre with an increased outcome.

Dr Aleš Bourek

In terms of the level of collaboration between commerce professionals and communities themselves, he was not aware of any indicators that cover this area but they would be beneficial. It comes under the concept of shared care. Different organisations have different opportunities to collaborate if we can find a common language. We should think about an indicator that could show us that things are moving from traditional ways of collaborating into these more efficient and modern ways of collaborating (e.g. digital collaboration platforms). We will try to see if we can find something to put in the Opinion on that.

Professor Lasse Lehtonen

Based on his experience in the biggest hospital in Finland for the last 20 years and before that in the pharma industry for 10 years, he noted that there are some challenges to the common base for information. In the clinical setting, we always have the difficulty that the patients change. It is very difficult to create reliable databases that can be used in the development of devices and in the clinical setting where the situations change all the time. The other issue is that the patients and doctors do not agree. There is constant discussion, e.g. in relation to all the information on social media. Patients want to add to the patient records that this is information from this or that guru. Then what is the basis for the data? The patient's opinion or the physician's objective assessment of the patient? Therefore, it is very difficult to create this kind of database that would be universal. In the Finnish hospital where he works, the policy is to try to be objective and to rely on the medical profession to create the data (even though it is not that valid but it is the best that we have). The databases could be a new mandate for the Expert Panel.

Dr Aleš Bourek

Nowadays data can be put in the cloud and a server can be used to make something like a "film trailer" from the vast amount of cloud data. This means working on algorithms to select action frames from the whole uploaded "patient or population data films" to help people reason better and possibly make better decisions. This is where we need to collaborate and we need to find indicators to nudge into that way of working. It is not just putting big data somewhere but having a server that is able to work with that data and feed that data back to people that need that data to make the right decisions. It is not constructing databases but being able to pick the right data from the clouds at this point.

Professor Werner Brouwer

He agreed that HTA needs to be fit for purpose. It is dangerous to forget what we designed something for to begin with. HTA was based on the idea that we needed to have a broad look at new health technologies and to assess their costs and benefits in a very broad sense. This Opinion seeks to highlight some of the peculiar aspects of digital health services in that context and to argue that it should indeed be fit for purpose.

There is a lot of work underway in that sense, especially for medical devices. We need a lot more because it is about particular types of outcomes and about methodological challenges like maturity and learning effects. There is a lot going on regarding medical devices that we need to have a close look at and not all the methods that we need for that are already in place. The Opinion indicates that we need to work more on that.

Risk sharing is an important issue and goes along very well with value-based healthcare. We are moving to new models. But value-based healthcare means many different things to many different people and it is often difficult to make it work in practice. What type of outcome measures are you using? How will you collect the data? How will you make the arrangements, including the financial ones? It is important that we move in that direction but that we progress with caution. The Opinion mentions that some of these new elements bring about new information and that information to some extent is power in itself, which can be used commercially and publicly. We have big data but we also have private data. There is a shift towards less product-oriented and more information-oriented suppliers. That generates more business models, which is a positive thing, but also raises new questions as to how as a society we deal with those new types of business models and what type of power is associated with having particular types of knowledge. It is important to experiment and to have a balanced view on what it means for both sides of the table, i.e. producers and buyers, in these types of interactions.

Daniela Negri, Associate Director at Weber Shandwick

She welcomed the fact that the Opinion put the emphasis on the importance of new evaluation frameworks in order to assess the impact of new health interventions also supported by Information Communications Technology (ICT) solutions. It is important that the Opinion is linked to what the Commission considers as best practice. You emphasise the importance of decentralising pilot interventions and you also mention the repository.

A couple of years ago, we conducted a study looking at the 16 best practices (labelled as such by the Commission) in the area of integrative care. We were expecting to see that these integrative care

interventions would be linked to increased health outcomes. However, we could not draw that conclusion because only two out of the 16 best practices had measurement and evaluation frameworks in place and could show that their interventions could be associated with increased health outcomes.

The conclusion of our paper was that there were clear factors that have improved (e.g. healthcare professional satisfaction and patient satisfaction) but we could only say that two out of the 16 had quantifiable data supporting the fact that these interventions led to improved health outcomes.

The Opinion is crucial and comes at the right time (before the elections) and hopefully will lead to put this on the agenda of the future European leadership. In her view, it is essential that what is labelled as best practice and which is set as a best practice for other areas can also bring data to corroborate that they can make a difference and that they should be adapted to other local contexts.

Professor Werner Brouwer

He fully agreed. This report signals two things: you cannot evaluate everything and we do not need to evaluate everything. We need to think about when we want to evaluate or when we leave it to the market or the healthcare professionals or whatever entity is involved in getting this into the market or into the healthcare system.

We do want to evaluate certain things. This requires, as was noted in the Opinion, clear rules and regulations for when you want such an evaluation to be done. There is a strange discrepancy in many healthcare systems as to what type of healthcare services we evaluate and which we do not. That has to do with very practical things as well as with the policy environment. For example, there are environments in which we can have a third party be responsible to give us the evidence (e.g. in the pharmaceutical industry – we 'force' them to give us the evidence), but there are other environments where that is much more difficult.

As policymakers, you need to think about what is the environment in which you want to gather that evidence, who is responsible to initiate the process and what the selection mechanism is. Those types of (very early on) rules and regulations are quite unestablished in many circumstances and jurisdictions. The report tries to increase that awareness and hopefully stimulate the EU Member States or whatever authorities there are responsible for this to make some progress in this area.

If we want to label something as a best practice, this report signals only one thing – if you look at the healthcare system and the goals we have, what you want from all the separate entities in that system is that they contribute to that goal to the best of their ability. If you do not know whether entities are aligned with overall goals, it can be risky to label something as a best practice. Sometimes there can be perfectly good reasons to do so, if you are using the best available evidence because you do not have any better evidence. Nevertheless, if you are responsible also for the evidence gathering and aim for evidence-based policy, ensuring better information collection is pivotal.

Professor Lasse Lehtonen

The conclusion of a previous Expert Panel report was that very often best practices are not transferable and, with digital services, what applies in one hospital and one country is not always what very easily transfers to another environment. That is why we have to have the assessment. We have

to be very evidence-based. As in pharma trials or device trials, you should need at least two independent trials to show that the systems is really working if you want to expand its usage. We emphasise the evaluation and evidence in our report.

Sabrina Montante, Senior Advisor EU Affairs, National Institute of Health of Italy – Brussels Office

She agreed with the report's reference to the need to advance the method to better evaluate the impact of digitalisation on healthcare. The National Institute of Health of Italy is involved in several initiatives and projects focusing on how to improve the cross-national collaboration to advance methods, to advance health system services for research in Europe.

We went through different practices and we found out that there is a lack of evidence-based collection of practices. In addition, we are trying to understand if the transferability of practices in Europe can help.

Her questions: What do you mean by a European repository? How can European cooperation support the advancement of evidence-based policy? How can we support research and policymaker interaction more (maybe in a European environment)?

Dr Aleš Bourek

25 years ago, health systems started talking about quality and we started talking about quality indicators and we started turning evidence-based tools and resources to improve the quality, safety, effectiveness and efficiency of healthcare (e.g. from Agency for Healthcare Research and Quality (ARHQ) impact case studies) into evidence-based medicine. There were several international collaborations in making repositories of validated evidence-based indicators (e.g. the US's ARHQ: https://www.ahrq.gov/).

Even though this has been done for 25 years, it is very difficult to find measures applicable across different healthcare systems. For example, a common denominator that we use in these indicators is the number of deceased people. You would think that this has the same meaning across Europe. We found out that there are people who deceased and had a clinical diagnosis that deceased and had a pathology/an anatomical diagnosis stated. Merging such "data" is complicated, since they have different meanings. Therefore, it is extremely difficult to construct a validated indicator that can be used across systems.

What we mean by making a European repository is trying to construct a database of available validated measures that could be used for digital assessment. In one of the previous Expert Panel Opinions, there was a very long list of indicators used today for monitoring the quality and performance of health systems. They are used by the OECD. The European repository would earmark some of the already used indicators and see if they could be used to evaluate the efficiency and performance of digitalisation and digital processes in healthcare. It is about getting European collaboration on a centralised repository. The indicator would have a name, a description and validity stated by studies that had been done so that people, governments or hospitals who are thinking about implementing a method could go to this shortlist and find out some validated indicators as you find in the AHRQ databases or some of the other repositories.

Professor Lasse Lehtonen

As to how European cooperation could support the development of evidence, this is about having focus areas for research grants etc., focusing on the Horizon programme etc. We need independent academic research for evaluating this and developing the indicators.

Professor Werner Brouwer

On the repository, it should include new methods developed in ongoing European studies and the results of actual studies, so that other countries can learn from these. There are issues of transferability. Therefore, what you find in that database might not be applicable to your situation but knowing what others have done is already a very good starting point in terms of how you want to design a study and how you want to evaluate it.

Regarding European cooperation, it is crucial that we strengthen it. There are good initiatives underway like EUNETHA. When it comes to evaluating, there are two key aspects: 1) the assessment phase, which is just about the figures 2) the appraisal phase, which is much more about culture and values. We can share the assessment phase more easily than the appraisal phase because there are significant differences across Europe on how we view certain things, whether we want to count certain aspects of costs and effects, and what kind of outcome measures we would allow. As long as those differences are there, you need to come to some kind of common core where you at least can have an exchange.

His suggestion: Try to define things that you can share and share them in a way that is transferable between countries. You might even see the link between those two aspects and, in a repository for instance, have quality checks in terms of the studies that are included in such a database so that people also know that this is a study that has been performed in a way that is correct. That would mean that you would need a third party that would be in charge of such a repository.

Ioanna Psalti, Advisor at the European Alliance for Vision Research and Ophthalmology

Can the link between evaluation and investment strategy be brought forward in the Opinion?

With digital therapeutics rising as a new subsection in digital technologies, this also links to your previous Opinion on the innovative models for payments.

Professor Werner Brouwer

He agreed that this is a fair point but this is beyond what we try to do in this report. In this report, we try to see how you can define digital health services and how you can evaluate them. What the questioner referred to is what you subsequently do with the results of such evaluations. We hint at what to do with it in the report, but it is not our main focus.

Conditional reimbursement is an interesting example. If you do not set the rules for the exit strategy at the end of the period of conditional reimbursement, when you have to decide to prolong or end reimbursement, then you may run into trouble in the decision making process. Decisions can be difficult anyway, because you will have to deal with difficult issues like real world data and the resulting decision uncertainty.

It would take a separate mandate to cover these issues.

Professor Lasse Lehtonen

It is an important issue and we discussed about the cost issues and the market power of the big companies in a way.

In practical life we often see the problem of this type of 'sunk cost' effect, meaning that the digital solution is taken in a hospital or in a healthcare setting and it is not digitally mature. If there are problems, you are asked to spend 100 million euro more to make it mature and then it is repeated a couple of times and then you notice that the technology is now obsolete and you have to start all over again. We rarely see digital solutions that have evidence backing them but it is very often the case that you claim to collect evidence as you use it and then we end up having to invest more than intended.

He did not have any solution except that you should have the criteria that you have to utilise before you make the investment decision and, before you invest more, you should monitor the system in terms of whether it is worthwhile investing. The problem is that the development in the digital field is so fast that if you use a system for five to seven years you should be able to develop it in one or two years to get the benefits out of it, especially in the public sector. Moreover, the public sector executives cannot match this kind of pace because our finances are bound to the budget period.

He said he does not have any good solutions for tackling that but we have noticed at least the problem.

Dr Aleš Bourek

We try to address the problem of where and how much to focus on evaluation of the introduction of digital solutions in the prioritisation matrix in the most generic way by classifying the type of digital activity into three categories. 1st. category - Where the digital solution helps you with strength (replaces physical strength), do it, since the chances of a major side effect are minimal. 2nd. Category - Where the digital solution helps you with the senses, do it but with more caution (since you will be making decisions based on "mediated" elements, not your own senses). 3rd. category - Where the digital solution helps you with the intellect be aware that it might be a very risky investment and may even lead to negative effects on the mental capacity and skills of people that use such a solution without having sufficient digital literacy.

Summary

Dr Aleš Bourek came up with the following conclusions at the end of the hearing:

In principle, digitalisation itself does not create anything new. It just enables people to use a better common language and more efficient and precise collaboration.

The "Wiki process" (e.g. Wikipedia, WikiLeaks) has enabled people to collaborate. It is widely used and is a reliable resource even though the product is created by non-professionals. It has been shown repeatedly that errors in Wikipedia are identified and corrected, keeping the level of errors low and comparable with professionally created encyclopaedias. Something like this could possibly be done in the healthcare sector too.

It is important to be progressive but conservative at same time. We can be progressive in terms of looking at what other industries are doing in the digital area and then being conservative when applying it to the people we help with health services as we can produce undesirable and unexpected side effects in the service we are providing. We know based on the 1999 "To Err Is Human: Building a Safer Health System" report by the Institute of Medicine (IOM), that if we make wrong decisions we can kill 44,000 people a year only in hospitals. But we can also bring benefits to vast areas of people through much more efficient collaboration.

For collaboration, we need some effort in unifying the language and in unifying the effort in the right direction. Therefore, digitalisation of health services does need sensitive stewardship and the EU institutions can play a role here.

Next steps

The Expert Panel will reconsider comments at their meeting on 20 November and incorporate them into the final Opinion.