EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Performance of national health systems

Meeting of the Expert Panel on effective ways of investing in health

Minutes

Brussels, 24th April 2018

9th plenary meeting
F101 00/42
Tuesday 24 April 2018, 10:00 – 17:00h CET

1. Approval of the agenda and of the minutes of previous meeting

The agenda was approved without changes.

The previous plenary meeting minutes were adopted without changes.

2. Nature of the meeting

The 9th plenary meeting of the Expert Panel on effective ways of investing in health took place in Brussels on the 24th of April 2018. The meeting, which was a non-public meeting, was chaired by the Chair of the Panel, Prof Jan De Maeseneer. Pedro Pita Barros and Luigi Siciliani attended via a web connection, and Walter Ricciardi sent his apologies.

The Panel members were requested to submit an annual declaration of interests. Concerning declarations of interest on matters related to the agenda topics, one Panel member informed the Panel about his participation in a Horizon 2020 project regarding transformation of technology. No other update on declaration of interested was shared.

3. List of points discussed

Reporting of ongoing work:

Application of the ERN model in European cross-border healthcare cooperation outside the rare or complex diseases area:

The Chair of the panel welcomed the participants and gave the floor to DG SANTE who started by explaining that at the moment the ERNs are in their initial stage of deployment after their launching in March 2017. Many important elements and areas related with their work and success are still under construction like for instance the appropriated referral system for patients to the ERNs at national level. Since November 2017, ERNs have provided advice

to healthcare providers on specific patient cases via virtual panels carried with the Clinical Patient Management System (the IT tool allowing the ERNs members to discuss patient cases). Further developments in many areas like clinical guidelines and knowledge generation, monitoring system, research, registries and data management will be conducted in the future. The priority now is to generalise the use of the Clinical Patient Management System l.

The Panel enquired about the timeline, the effectiveness of ERNs and the added value of this tool. DG SANTE replied that the system builds on networks and that the patients that take part in the ERNs are those that are very serious cases for which there is the need of advice due to their complexity and the lack of experience or resources at national level. ERNs are not having members of all MS due their recent launching. However, DG SANTE highlighted that there are ways to allow that any hospital could refer a case to another hospital forming part of the ERNs to be taken up. The activation of some of these mechanisms like the affiliated partner type of members is ongoing. Member States are accountable for establishing the system for the referral of patients, and this cannot be regulated at EU level.

It would be important for networks to become integrated in the national health care systems. Member states should establish not only clear referral systems but also patient pathways allowing the national system to refer the right patients to the right centres. Therefore, these ERNs will be effective and in the same way inclusive.

The panel members agreed on highlighting various points, e.g. that the burden of the problem relies on the Member States; they have to develop patient pathways, decide who can refer a patient to ERNs and conduct related research. There is also a strong rational for ERNs to work with rare diseases, as they are able to focus on small numbers, rare and complex cases. ERNs can benefit subgroups and there should be a focus in targeting smaller countries.

It was suggested that technology advancements could be used as a rational to use ERNs. However, the more educated and advanced countries will have an advantage over other Member States that maybe have not acquired the technology. DG SANTE reminded the panel that ERNs is a bottom-up structure rather than a top-down by governments. Therefore it is voluntary; the hospitals apply and they are consequently measured by their expertise to be part of the network.

The reason for expansion of the ERNs was discussed. The panel agreed that there would be barriers in doing so with the national integration system, if integrated with the health system in a country. The members reflected on various other options. The knowledge is international but the practices are at national level within the health systems. We have to comprehend where knowledge is incomplete.

Another point was about investigating the factors that enable the ERNs to work and also finding the barriers. One of the barriers seems to be the lack of patient to patient support network so that they can share their experiences. A strong enabler is that it is an innovative network. Another enabler is the integration of ERN peer reviews for the internal validity, and to show how they maintain the high level network.

The Panel determined they had little to none knowledge of how the ERNs worked. They explored ways to gather more information.

Vaccination programmes and health systems in Europe:

DG SANTE presented a mandate for an opinion on vaccinations to the Expert Panel. There have been unacceptable deaths from vaccine preventable diseases, especially in children. The Commission asked the Panel to identify the enablers and obstacles in the organisational factors and looking at good practices in order to have higher vaccination rates.

After the introduction by DG SANTE, a panel member presented a reflection on vaccination programmes and health systems in Europe. The Panel member mentioned that vaccination is one of the most powerful and cost-effective public health measures developed in the 20th century and the main tool for primary prevention of communicable diseases.

Targets for elimination of some of the vaccine preventable diseases were already set up for 2000. However, the EU is facing considerable outbreaks of vaccine preventable diseases and fatal cases of measles and diphtheria have been reported.

As the vaccine preventable diseases are a cross-border health threat, it seems logical that an EU action involving a more coordinated approach is developed. The Commission has taken the initiative to present a proposal for a Council Recommendation to "Strengthen cooperation against vaccine preventable diseases".

There were some concerns from the Panel members of overlapping the work that the Commission is requesting in parallel to the European Observatory. DG SANTE clarified that they are not asking the Panel to do a country by country analysis like the European Observatory, but rather a review of the main factors influencing the outcomes to vaccination uptake (drawing on existing systematic reviews). DG SANTE requests a global opinion from the Panel, not individualised by Member State. The Panel will work in parallel with the European Observatory as the report by them will not come out until July. After that date, the Panel can integrate the results of the European Observatory in the opinion paper if it arrives in time. The Commission mandate requests high level recommendations (as a document to support the political discussion) on how vaccination system should work to improve vaccination coverage, investigating ways to increase the efficiency of vaccination process. The Commission is interested in a summary of what is already available, no new data is needed.

The discussion helped to clarify the scope and the timing of the work. It was agreed that the first step would be a literature review on the main factors influencing the outcomes to vaccination uptake to identify what is available. Problems with the organisation of the vaccination programmes but also possibly socio-cultural differences that lead to resistance to vaccination should also be addressed. However, the Panel should limit to children's vaccination. Some parents think that there is an overloading in vaccinations in children. Influenza vaccination will also be used as an example for adults' vaccination. DG SANTE clarified that the purpose of this opinion is to review information which is relevant for the effectiveness and efficiency of different vaccination programmes in relation to the organization of the health system in general and the organization of the vaccination programmes in particular. The opinion will be conducted to identify and characterize the main factors, enablers and obstacles, influencing the outcomes to vaccination uptake; and to select and assess measures and actions that can be expected to improve vaccination coverage.

A working group was formed and the Chair and rapporteur were appointed. A first draft will be discussed at the next Plenary. The opinion should be approx. 20-25 pages. The deadline for finalising the opinion is the end of September 2018.

Digital Health Working Group:

The discussion started with a question about how the framework to evaluate the digital transformation can be seen; HTA on digitalisation; goal and scope of the evaluation, relevant techniques and even societal perspectives were mentioned. Issues of organizational and legal matters should also be taken into account.

Choosing a definition for digitalization was then discussed. It was mentioned that the question is about technology vs services. The 2014 Paper on quality of healthcare services was mentioned as an existing source of ways of evaluating healthcare services, since appropriate digital transformation of health services should result in improvement of the service provision for all involved stakeholders (patients and their families, health professionals, industry, and society).

Further, the HTA framework was considered as having some limitations, as it might not catch up completely with the costs/benefit framework for evaluating. In this requested framework, services have a broader meaning than simple digital tools and there is a need to assess the transformational impact, not only the traditional questions of effectiveness and efficacy. All evaluation frameworks should have at core same principles, namely, quality, affordability, patient-centeredness, timeliness, equity and sustainability.

Evaluation of digital transformation is not only looking at the framework to assess ICT but also at the health care service provision systems which are impacted and what types of impact can be seen/described/anticipated. It was proposed to look at least at two levels, and suggested to start gathering examples.

The potential for digital transformation should also be looked at. Digital transformation can be seen as an appropriate reshuffle/re-organization of existing elements, either physical or non-physical. However, digital transformation can be evaluated only in situations where such elements (that can be digitally manipulated) exist and are a part of the process. Therefore the argument ended with the panel member saying that they should search for the potential benefits but also limitations and side-effects that may arise.

Specificities of digital transformation have to be identified and characterized. Moreover, examples from industry and people from professionals involved in digital medical processes can be used. Attention was drawn to other specific problems in the context of digitalization, namely areas of health services where information that cannot be digitalized is used (emotional, empathy, haptic etc.). These problems relate to the usability/usefulness by people and privacy, thereafter mentioning the need for specific and relevant rules.

How to target the problem was discussed next. The Chair explained that the evaluation framework must be able to capture the issue of complexity of digital transformation (a complex system is defined as having multiple goals, dynamics in time, lack of transparency), The World Digital Forum work and the grouping of impacts in four categories was mentioned. The Chair mentioned that digitalization normally does not change the goals of the service but the system goals are different. Furthermore, the need for a SWOT analysis for

these changes was brought up; digital transformation opens a wave of opportunities but has also some drawbacks, meaning, mismatches, using medialized, modified not primary/first-hand info, etc. The impact of transformation has to be carefully evaluated; potential implications for various situations have to be taken into account, in for example, the ageing population. Finally, it was suggested that it would be useful to use the expertise of some external advisers for acquiring more inside knowledge on this issue. In conclusion, a draft text will be made available for the next Plenary meeting in June.

4. Conclusion

The meeting ended with the Chair thanking everyone for their presence and the valuable discussion to move forward with the mandates. Further progress will discussed at the next Plenary in June.

5. Next meeting

The next plenary meeting will take place on the 26th of June 2018.

6. List of participants

Members	ANASTASY Christian (CA) BARRY Margaret (MB) BOUREK Aleš (AB) BROUWER Werner (WB) DE MAESENEER Jan (JDM) KRINGOS Dionne (DK) LEHTONEN Lasse (LL) MCKEE Martin (MMK) MURAUSKIENE Liubove (LM) NUTI Sabina (SN) PITA BARROS Pedro (PPB) – (via web connection) RICCIARDI Walter (WR) (apologies) SICILIANI Luigi (LS) – (via web connection) WILD Claudia (CW)
EXTERNAL	BLOOMER Ellen (EB) WALKER Alice (AW)
DG SANTE	CULTRERA Concetta (CC) DE LA MATA Isabel (IDM) DUMITRESCU Constantin-Ovidiu (OD) FRIDELL My (MF) GIRAUD Sylvain (SG) KONTINEN Päivi (PK) MALKIC Sevala (SM) TEROL Enrique (ET) RODRIGUEZ MILLAN Marta (MRM) ROUX Philippe (PR)