Feedback on the EXPH opinion -

Assessing the impact of digital transformation of health services

European Alliance for Vision Research and Ophthalmology (EU EYE)

November 2018

ID in Transparency Register: 221589017973-83

15.11.2018

Executive Summary

The EU EYE welcomes the EXPH's opinion on the need to assess the impact of digital transformation at a time when uncertainties about the evidence base persist: evaluations of telehealth and telecare have showed no evidence of cost-effectiveness[1] and mixed results on patient outcomes. The EU EYE recognises a number of systemic difficulties in the evaluation of the effectiveness of digital systems such as the need for extrapolation when comparing digital health services and their manual predecessors; or incomplete impact assessment when environment factors prevent the digital health service to deliver its maximum potential systemic benefit.

Patients are surrounded by their community, primary care, and secondary care and experience care as a pathway, not an individual service. Impact of the digitalisation of health care on patients should not focus on only one specific point of the care pathway. However given the current political push to invest in the digitalisation of health systems, evaluation frameworks may be forced to focus on the service itself instead of the patient.

The EU EYE highlights that the Directive 2011/24/EU Cross Border Healthcare and governance structure for knowledge sharing and care coordination across the EU such as the European Reference Networks create a unique environment for health care. New dimensions emerge in integrated care, multidisciplinary teams and patient empowerment with implications in competition between producers of digital health services and cross-regional activities in co-training and co-education in healthcare. Any generated improvements must not only be relevant across the patient pathway but also consider the patient as a citizen of the European Union and the greater health policy environment.

The EU EYE therefore calls for a health care-specific evaluation model tailored to the policy environment of the European Union with interoperability, information exchange, care coordination, patient engagement and analytics at its core. Furthermore we ask that the EXPH strengthens the message on the need for a broad and holistic evaluation framework to manage expectations regarding cost-effectiveness. The impact of digitalisation of healthcare must be assessed as a driver of integrated care, improved patient experience and improved coordination across all the care pathway and across all care settings with focus on the overall goal of the health care system - to improve outcomes, efficiency and patience experience. A European evaluation framework which is **patient-centric** (based on a sector-wide patient understanding and allows for **analysis across the entire care**

---

[1] Padraig D, et al Cost-effectiveness of telehealth for patients with depression: evidence from the Healthlines randomised controlled trial BJPsych Open. 2016 Jul; 2(4): 262–269. doi: [10.1192/bjpo.bp.116.002907]

pathway can generate improvements that are relevant across the patient pathway and the policy environment of the European Union.

The EU EYE believes that integrating multi-service or whole systems concepts in existing frameworks - such as digital maturity - will ensure a holistic approach and patient-centricity together with flexibility to adapt to the current European policy environment and any future developments. Particularly important domains are the interoperability and usage of digital systems. Without monitoring the degree of interactions between systems and the taking up digital health service, other indicators at later stages of maturation may become irrelevant. The indicators presented in the opinion paper by the EXPH may not cover sufficiently these areas as they neglect organizational, cultural, policy, and other external factors. Insufficient monitoring has the risk that unintended and unexpected effects will remain hidden with no information as to where and when to introduce changes for cost-effective meaningful improvement.   We see this EXPH opinion paper as an opportunity to draw the attention on the special merits for an evaluation framework that conceptualizes **digital maturity** as a sector-wide, patient-centric measure for objective evaluation of digitalisation as:

- it links the dynamic evolution of services over time to the environment within which such services are to be embedded, the different settings and cross-setting interactions (whether synergies or antagonism prevails) and their usage in real world;

- it provides insights into cost-effectiveness and activates internal benchmarking;

- it contributes to the formation of a robust evidence base regarding patient benefits (care coordination; enhanced information) particularly crucial for perceptions regarding the usefulness of digitalisation.

The EU EYE welcomes in particularly the acknowledgement of the role and position of healthcare workforce in the context of implementation and in maximising efficiency in decision processes and in the development of a workable exchange of information.

The EU EYE believes that the EU has a role to play in:

-initiating the formation of a European repository as a learning platform that informs at macro and micro level e.g. the type and level of investment, policy environment and incentives

- decision processes involving cross border care where decentralised and centralised decision processes of the participating Member States create a new environment and demands for digital health services.

Detailed Feedback on the EXPH opinion -

Assessing the impact of digital transformation of health services

The EU EYE welcomes the EXPH's opinion highlighting the need to assess the impact of digital transformation at a time when uncertainties about the evidence base persist: evaluations of telehealth and telecare have showed no evidence of cost-effectiveness[2] and mixed results on patient outcomes [3].

Systemic issues. The EU EYE recognises a number of systemic difficulties in the evaluation of the effectiveness of digital systems particularly when in comparison to the preceding manual systems. Monitoring 'success' will involve extrapolations from the preceding systems as many errors were not registered if they were ever noticed. For example, the Danish Shared Medication Record (Fælles Medicin Kort)[4] gives access to updated patients current medication in one national database; it is a read-only system for citizens and aims to minimize medication errors caused mainly by loss of information and lack of communication among healthcare professionals. However its impact in comparison to previous manual systems is not realistic. Any errors in the preceding 'manual system' may not have been noted e.g. nurses in home care settings not having updates regarding information prescribing medicines for elderly citizens.

The most crucial issue in impact assessment is restrictions in maximising the impact of a digital health service in the absence of a common standard for collected clinical data in medical fields. For example a plethora of devices and images for ocular imaging (OCT scanners, topographers, perimeters etc) generate rich data which however can only be accessed in their original format through purchasing various platforms. Aside the suboptimal exporting of PDF/image files from each device, the costs make such exercise expensive and hence unrealistic. If however the maximum potential systemic benefit of a digital health service is not achieved, any impact assessment under the current conditions will not be meaningful and interoperability issues will remain hidden.

---

[2] Padraig D, et al Cost-effectiveness of telehealth for patients with depression: evidence from the Healthlines randomised controlled trial BJPsych Open. 2016 Jul; 2(4): 262–269. doi: [10.1192/bjpo.bp.116.002907]

[3] Henderson C, et al Cost-effectiveness of telecare for people with social care needs: the Whole Systems Demonstrator cluster randomised trial. Age Ageing. 2014 Nov;43(6):794-800. doi: 10.1093/ageing/afu067. Epub 2014 Jun 20.

[4] Fælles Medicin Kort", abbreviated "FMK": Kindly provided by Jan Petersen, MedCom, Alice Kristensen MedCom
https://sundhedsdatastyrelsen.dk/da/registre-og-services/om-faelles-medicinkort/fmk-sundhedsprofessionelle
Medicines prescribed for citizens by healthcare professionals are held in a unified server with the information being accessible by patients and healthcare professionals - either online or via a smartphones app.

Investment and evaluation. Political pressure to invest in digital solutions in health comes at a time of unprecedented financial and operational pressures faced by the European healthcare systems. If political motivation behind the digitalisation move remains the expectation for cost savings within a short timeframe, the risk is high that any impact assessment (particularly on cost-effectiveness) may be service-centric focusing on one or two settings of care rather than on the well being of the patient and population health outcomes. Research has shown the importance of quantifying implementation effort when the system is younger, and advancing into usage and then cost metrics only as the system matures[5] . The EU EYE is concerned that existing evaluation frameworks may not be able to withstand the political push to invest in the digitalisation of health systems and it will be easy for the evaluation not to focus on the patient but on the service.

Patient-centricity. Patients are surrounded by their community, primary care, and secondary care and experience care as a pathway, not an individual service. Impact of the digitalisation of health care on patients must not be assessed in only one specific point of the care pathway. There is a need to instill a holistic approach in the evaluation of the digital health systems across all the care pathway and across all care settings. The impact of digitalisation of healthcare must be assessed as a driver of integrated care, improved coordination at all levels and above all improved patient experience. Only an objective and fair evaluation will manage the risk of unrealistically high expectations and prevent confusion regarding cost-effectiveness. The evaluation framework must therefore be flexible with the capacity to disaggregate the components of digital services measuring them individually across different points in time so that failure in one area does not hinder success in another area.

> For example a holistic approach on the evaluation of mHealth (phones/tablets) should include evaluation across the entire care pathway including the home setting for the target population, the community setting and the primary and secondary care levels including readiness in the system for adoption of mHealth (e.g. digital literacy of target population) and cost-effectiveness in using them. Currently evaluation focuses on the functionality of the service, collecting and relaying patient data to different care settings (hospitals, community in real time) but not on how effective such functionality is in achieving better health outcomes.

Evaluation framework within the context of Crossborder Care and the European Citizenship. The Directive 2011/24/EU Cross Border Healthcare and the emerging governance structure for knowledge sharing and care coordination across the EU such as the European Reference Networks (ERNs) create a unique environment for health care.

---

[5] Dixon B, Zafar A, Overhage J. A Framework for evaluating the costs, effort, and value of nationwide health information exchange. J Am Med Inform Assoc 2010;17(3):295-301

Such evolution in health policy demand that any generated improvements must not only be relevant across the patient pathway but also consider the patient as a citizen of the European Union and the greater policy environment.

Cross-border care and in particularly the evolution of the European Reference Networks (ERNs) rely heavily on digitalisation that supports efficiency in information exchange. If ERNs fulfill their potential they will give rise to new dimensions in integrated care, multidisciplinary teams and patient empowerment. It is therefore paramount to have structures that can assess the efficiency in information exchange and its impact on cost-effectiveness within the context of shared decision in cross-border care in addition to multidisciplinary teams; between patients and healthcare professionals; cross-settings. The ability of digital systems for cross-setting communications and information exchanges (interoperability) is central to the range and depth of the impact of digital systems in integrated care particularly with the move from disease- oriented to goal-oriented approach. The EU EYE believes that the context of interoperability is implied but it needs strengthening particularly because:

- it is vital in achieving effectiveness in cross-border care

- it has implications in competition between producers of digital health services.

- it is inexorably connected to other activities supported by the European Commission such as cross-border telemedicine commitments of the European Innovation Partnership on Active and Healthy Ageing

- cross-regional activities in co-training and co-education in healthcare are on the increase.

The EU EYE therefore calls for a health care-specific evaluation model tailored to the specifics of the European Union with interoperability, information exchange, care coordination, patient engagement and analytics at its core. Furthermore we ask that the EXPH considers strengthening the message on the need for a broad and holistic evaluation framework with focus on the overall goal of the health care system - to improve outcomes, efficiency and patience experience. Such framework can generate improvements that are relevant across the patient pathway if:

- it takes into consideration the policy environment of the European Union with its specific needs in cross-border care and the European Reference Networks;

- it is patient-centric (based on a sector-wide patient understanding;

- it allows for **analysis across the entire care pathway**;

- it provides information regarding performance at different service levels;

- it considers all care settings from home and community to secondary care and beyond;

- it allows for longitudinal benchmarking.

Existing frameworks developed in other socioeconomic and political settings may not be sufficient for the purposes of the European Union. For example Canada's evaluation framework for health information systems (mentioned in pp. 56-57 of the EXPH opinion) progresses from serial to iterative stages; although it measures a system across a variety of metrics over a period of maturity, it may not indicate whether the digital system under investigation is compromised by lags in other care settings particularly when such settings are located cross-border or when innovative virtual networks are involved such as the European Reference Networks.

The opinion paper covers extensively both the current methodology and the functionality of digital health services (text box 4 p30) with the core common feature of all groupings being the facilitation of health information exchange whether for clinical practice, research or administrative purposes. The EU EYE calls for caution on evaluation methodologies and frameworks of digital health services which:

- focus on functioning of health services and not impact on improved health outcomes e.g. electronic health records (EHR) bring an evolution in the collection and storage of data but their true cost-effectiveness lies in whether EHR truly improve efficiency in shared decisions (multidiciplinary teams; between patients and health professionals; or cross-settings and systems).

- measure progression and success primarily within the confines of individual services' or care settings' performance.

- lack mechanisms for detecting holes in maturity in other services or care settings that might affect overall maturity of the whole system.

CONCEPTS & INDICATORS

 The EU EYE believes that integrating multi-service or whole systems concepts in existing frameworks - such as digital maturity - will instill a holistic approach and patient-centricity together with flexibility to adapt to the specific environment of the European Union and any evolution in health policies in future. The concept of the digital maturity is implied in many places in the EXPH opinion paper: intervention maturity as a key concept in Figure 2 p36 of WHO in longitudinal evaluations; or the need for an appropriate time horizon (p52) in the

development of digital services; changes in the value of information (p55) with evolution in use, etc.

The EU EYE believes that digital maturity deserves a special mention particularly because studies have shown it to be a key factor when assessing cost-effectiveness of digital interventions for uptaking and upscaling[6].

Digital maturity is a multidimensional concept with four key domains across a patient pathway (resources and ability to use a system; usage measures; interoperability between systems; and impact on the public). The indicators presented in the opinion paper by the EXPH may not therefore cover entirely these areas with the risk that they will be inefficient in uncovering possible unintended and unexpected effects or in indicating where and when to introduce changes for cost-effectiveness and meaningful improvement. It is not enough to just recognise the importance of certain indicators to patients; the discussion must be about how the evaluation accounts for success across entire care pathways. Particularly important in evaluation is the usage and interoperability of digital systems, two key domains of digital maturity.

Interoperability. We have explained above the reasons for the need for interoperability and although interoperability appears in the checklist in p61-63 of the EXPH opinion, it is not clear what indicator if any, will measure its extent and progress.

Usage. Usage pattern analysis in routine use is mentioned in p49 within the WHO guidance and the EXPH document recognises the different groups of users (patients, workforce) and the need for different evaluations. The EU EYE believes that usage needs to be at the forefront of the design of the evaluation framework. Without monitoring the degree of taking up digital health service, other indicators at later stages of maturation may become irrelevant. Some indicators in the EXPH document measure usage but they neglect organizational, cultural, policy, and other external factors. Usage measurements can be more meaningful when differentiated by activity during use. For example usage in health information exchange has 5 classifications: minimal usage, repetitive searching, clinical information, mixed information, and demographic information. These types of usage varied by the user's role. Minimal usage was highest among physicians and clinical information was highest among nurses[7]. An evaluation framework must allow for such differentiation: quantifying how the system is being used and their associations with

---

[6] **A Patient-Centered Framework for Evaluating Digital Maturity of Health Services: A Systematic Review**
K. Flott, R Callahan, A. Darzi, E.Mayer J Med Internet Res 2016;18(4):e75 doi:10.2196/jmir.5047
https://www.jmir.org/2016/4/e75/

[7] Vest JR, Jasperson S. How are health professionals using health information exchange systems? Measuring usage for evaluation and system improvement. J Med Syst 2012 Oct;36(5):3195-3204

specific roles help formulate a target improvement strategy; evaluate where return on investment can be maximized. Increasing the capacity to deliver to those stakeholders to whom changes would be most impactful, strengthens further the take up of digital technologies in the real world.

The EU EYE believes that a number of key issues need to be addressed early in the development of an evaluation framework to facilitate uptake and upscaling of digital health services that serve the patient within the political environment of the European Union. Interoperability and usage are key factors integrated in digital maturity. We see therefore this EXPH opinion paper as an opportunity to draw the attention on the special merits for an evaluation framework that conceptualizes digital maturity as a sector-wide, patient-centric measure, as it will allow for:

- an objective evaluation of digitalisation as it links the dynamic evolution of services over time to the environment within which such services are to be embedded, the different settings and cross-setting interactions (whether synergies or antagonism prevails) and their usage in real world;

- resolution of complaints about digital services: evaluating the maturity of an intervention will show which reports on digitalisation hindering productivity reflect reality or digital immaturity and lack of training e.g. patients waiting in the wrong room when self registered;

- insights into cost-effectiveness and mobilize internal benchmarking;

- the formation of a robust evidence base regarding patient benefits (care coordination; enhanced information) particularly crucial if perceptions regarding the usefulness of digitalisation are to change.

THE ROLE OF THE EU

The EU EYE believes that the EU has a role to play in decision processes involving cross border care where decentralised and centralised decision processes of the participating Member States create a new environment and demands for digital health services. The EXPH acknowledges the link between decentralised decisions and interoperability issues and rightfully calls for governments to undertake a coordination role. New dialogues and new infrastructure (or added functionalities in existing infrastructure) may be required at EU level to improve ability to communicate across service settings and care sectors. The EU EYE welcomes in particularly the following:

Engaging the healthcare workforce at EU level. We applaud the EXPH position that the role and position of healthcare workforce need to be considered in the context of implementation. Digital transformation brings an evolution in health information exchanges with an inevitable impact on the decision process e.g. patient-held records can be a cost effective method of improving shared decisions between patients and health professionals. The engagement of the healthcare workforce is paramount in maximising efficiency in decision processes particularly as interoperability at syntactic and semantic levels[8] will require the development of a workable exchange of information. In particularly semantic interoperability will require the harmonization of clinical terminology across care providers, settings, and systems.

European repository for evaluation and monitoring methods. It will be good to collect the different methodologies used as a first step. However the European repository should be able also to function as a learning platform. This is particularly important as digital technologies are rolled out at different times across the EU, such as the electronic health records. A European repository will assist in the benchmarking of efforts across countries which are 'mature' in their use of some digital technologies. It can also inform at macro and micro level e.g. success factors in implementation; innovation pitfalls to avoid when designing a digital health service e.g. forgetting the user, confirmation bias, viability and sustainability. It will also allow for information on how to assess successfully the environment in which digital health services are embedded. Information on the prerequisites at national and European level for success cases such as the type and level of investment, policy environment and incentives are crucial if national visions on 'go digital' are to be successful.

Additional points

p81: The EXPH has referred in other opinions that spending in health should be seen as investment. In this document the EXPH mentions that cost reductions do not need to imply lowering health budgets: it will be good to strengthen this message by using the word re-invest instead of 'allocating freed budget'.

---

[8] Garde S, Knaup P, Hovenga E, Heard S. Towards semantic interoperability for electronic health records. Methods Inf Med 2007;46(3):332-343.