



Expert Panel on Effective Ways of Investing in Health (EXPH)

Opinion on

**Assessing the impact of
digital transformation of health services**

Expert Panel on Effective Ways of Investing in Health



EXPH
provides
independent
non-binding
advice
on effective
ways
of investing
in health

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Acknowledgements



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Terms of reference

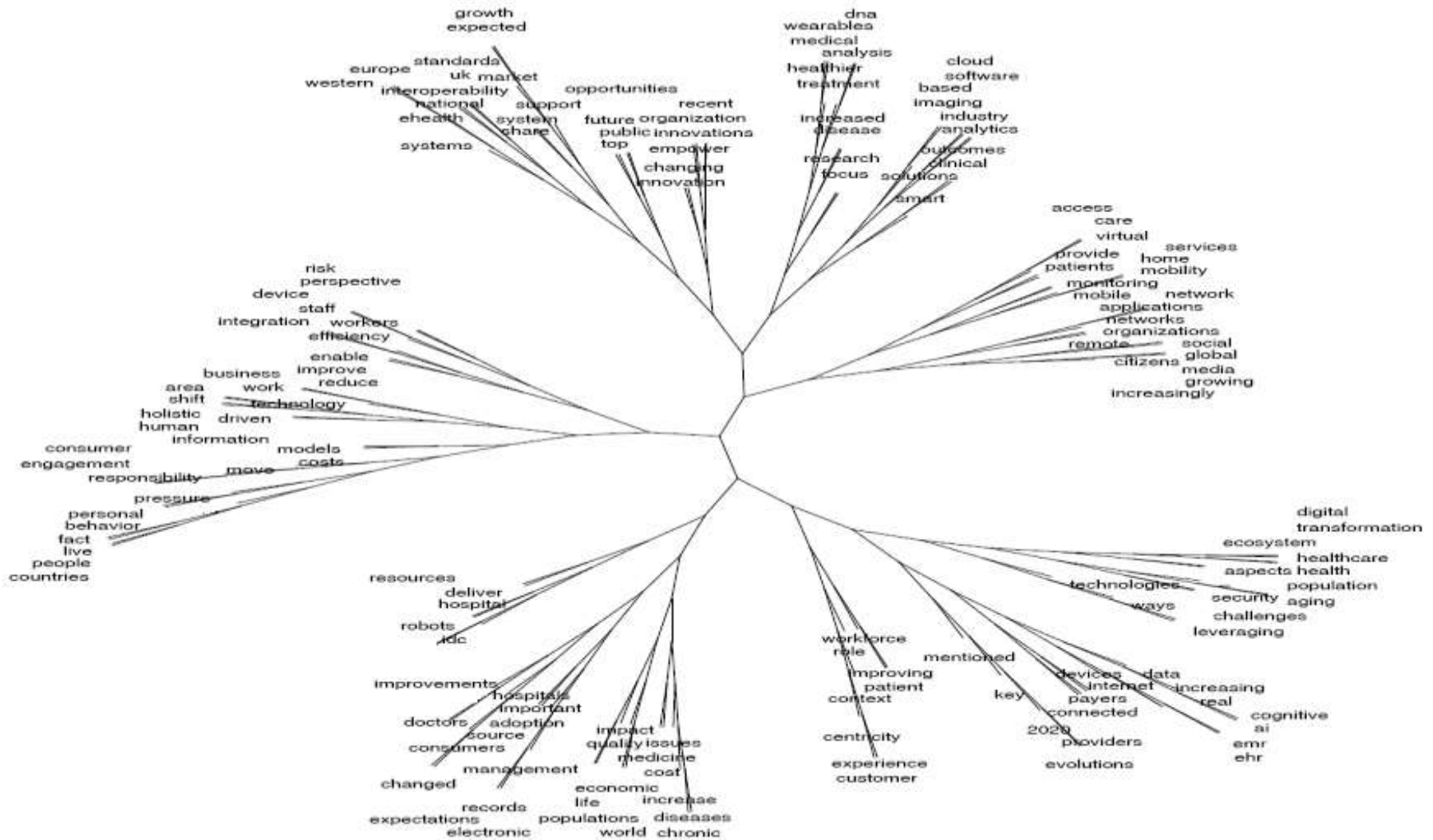


- a) What are the systematic methods available for **assessing the impact of the digital transformation of healthcare** with regard to *health objectives*?
- b) What types of **data** are **available and required** to assess the *value* of digital health services
- c) What **impacts** of digitalisation of health services should be *assessed systematically* and in **which dimensions**?
- d) How could the **impacts on wider fiscal and social policies**, beyond the health sector be assessed?

Setting the scene - the addressed issue is broad & complex

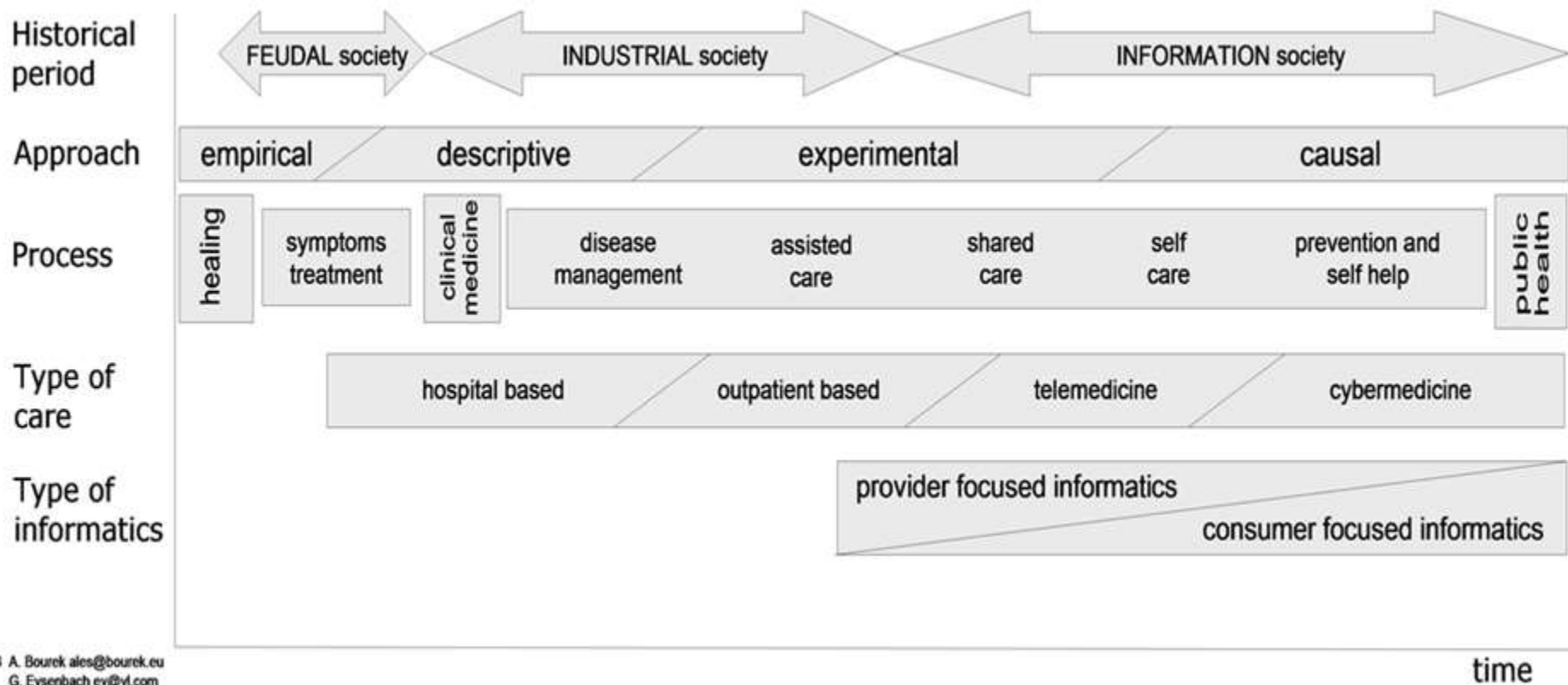


European
Commission



Health

Setting the scene – societal progress & health service



Scale of change - (industrial -> information society)



Progress is a result of the joint interaction of people, processes, power and tools

The “power” has changed only four times in history (manpower, horsepower, steam, electric power). Every new power needed the modification of tools, processes and behaviour of people to improve productivity.

In the last transition from industrial to information society the power has not changed, the only thing that has changed is the *potential* 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 by means of an algorithm, and at a distance by means of the electromagnetic field.

This way of working requires :

- a) **digitisation** - changing the manipulated (data or information) into a digital format
- b) **digitalisation** - use of digital technologies for the production and delivery of a product or service

Digital transformation of health services encompasses the instrumented effort to meaningfully introduce new digital information and communication technologies and corresponding new processes and stakeholder behaviour into the health sector.



NEW ENVIRONMENT - real (natural) versus digital (virtual)



Complexity and interaction of „health“ and „digital“

- in „real / natural World“ issues are evident (seen by eyes, accidents hurt physically – cause & effect observed)
- in „digital / virtual World“ issues are mediated (not so obvious, seen by „the brain“, accidents do not hurt physically, cause & effect not so noticeable)

Interaction of two complex systems will inevitably lead to emergent properties that cannot be anticipated based on the behaviour of each standalone systems (a whole is more than the parts)

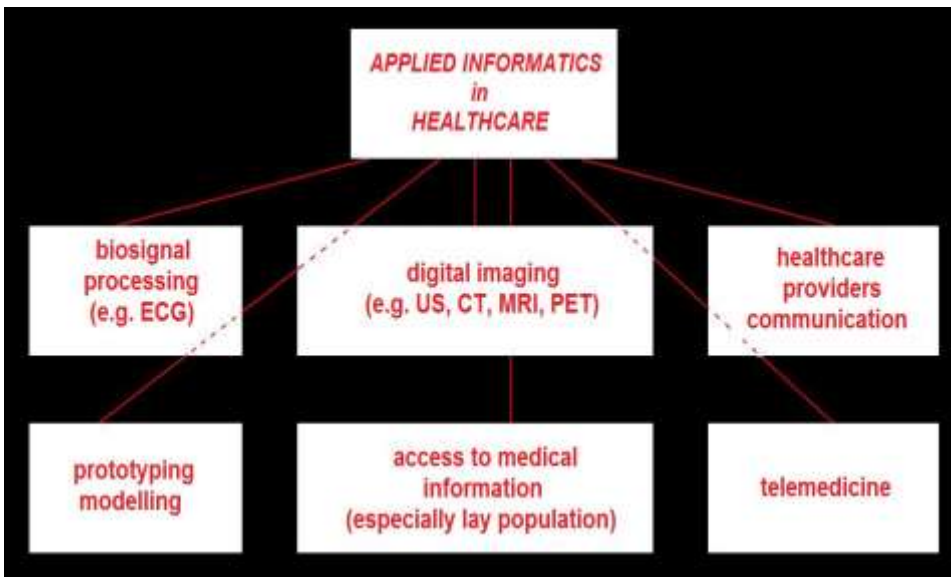
- **Advantages**
 - Adaptable
 - Evolvable
 - Boundless
 - Novelty
- **Disadvantages**
 - Non-controllable
 - Non-predictable
 - Non-understandable
 - Non-immediate

Digital & human dimensions of health service



„**DIGITAL**“ domain (interaction machine-machine, human-machine) – supportive functions

„**ANALOGUE**“ domain (human-to-human interaction) natural communication, reasoning & decision making, wisdom, trust-worthiness, empathy, soft skills



Thinking (fast and slow), Games Theory, Collective Behavior (social dynamics, collective intelligence), Nonlinear Dynamics, Systems Theory...

Specifics of the health service



- The reasoning, decisions and actions have a primary and direct effect on lives / health
- The reliability of the service must be as absolute as possible, safety must be of prime concern „primum non nocere“, errors must be avoided as they lead to loss of trust
- A doctor cannot meet the same „patient-client-service consumer“ twice (either another person, or the same person but at a different time) the situation that has to be addressed is always novel
- The population served is extremely vulnerable and ranges from pre-conception (assisted reproduction and genetics) through the whole life and beyond (pathology autopsy, organ donation) so there will always be the need to serve several generations of sick at the same time
- The correct reasoning, decision-making and collaboration depends vastly on signals and information that is out of the scope of the „digital environment“ (body language, tactile information, emotional information, olfactory information, information processed by mirror-neurons etc.)
- Introduction of new services must be done at a reasonable pace and with sufficient backups

Defining health service scope and goals



- Health service is a helping profession not only helping people **to attain „A state of complete physical, mental and social well-being** and not merely the absence of disease or infirmity“ (WHO 1984) but also
- „The **ability to adapt and self manage**, in the face of social, physical and emotional challenges“ (Huber et al. 2011)
- **Health services** - are seen 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.”*
- (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”

Health systems goals & dimensions (characteristics)



System goals unaltered

Importantly, the digital transformation is not seen as altering the overall goals of health care systems. 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.

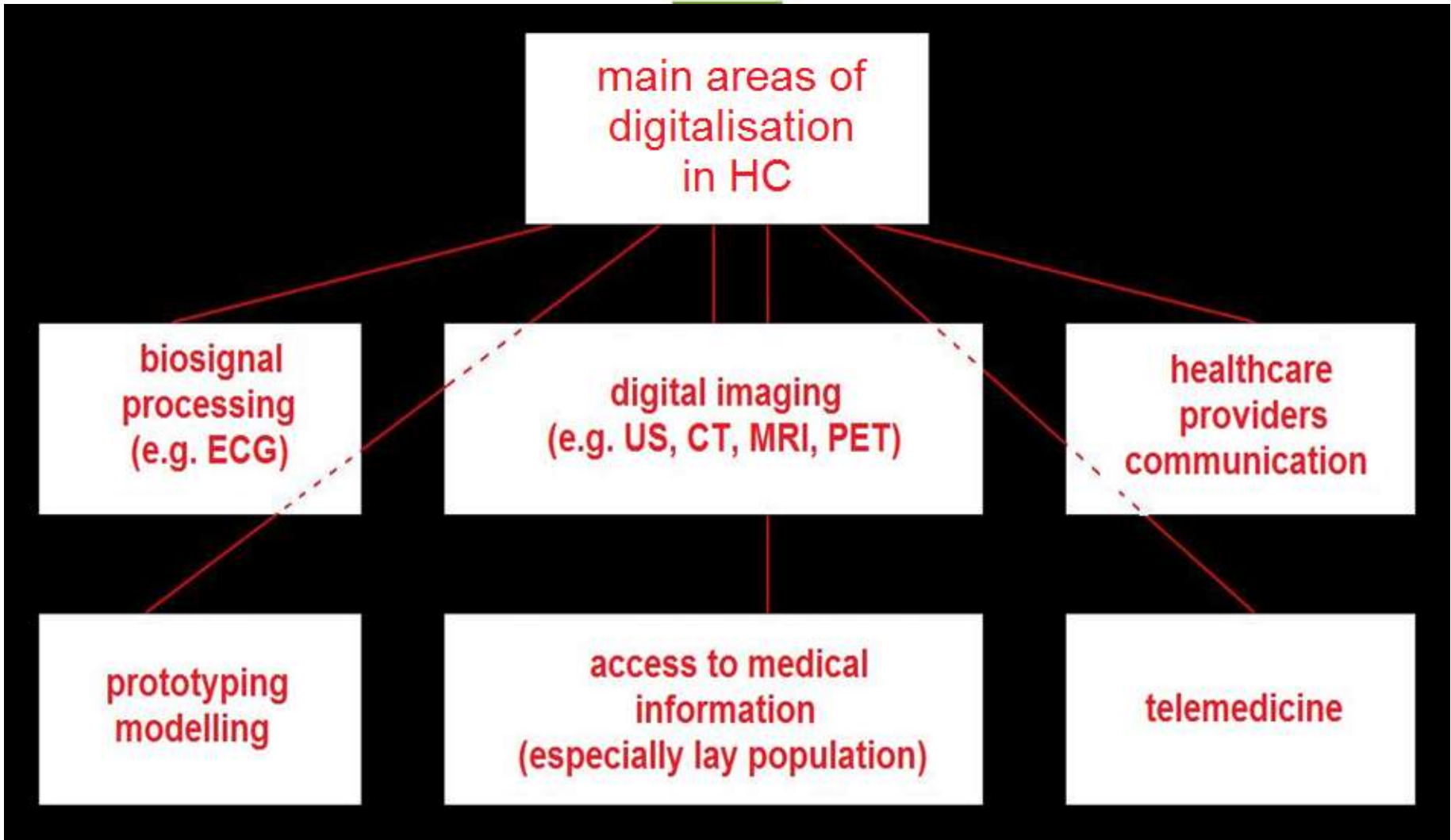
Equitable—providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status

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

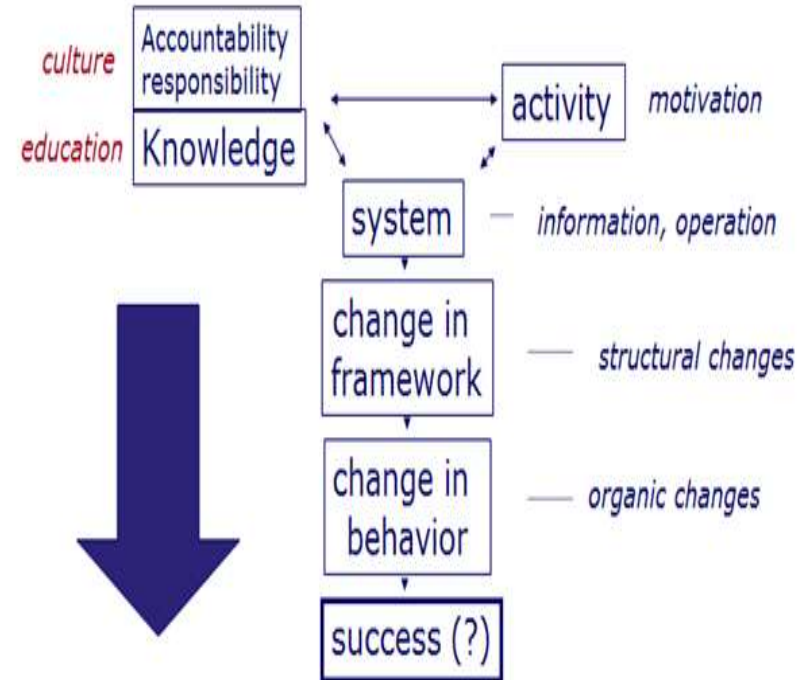
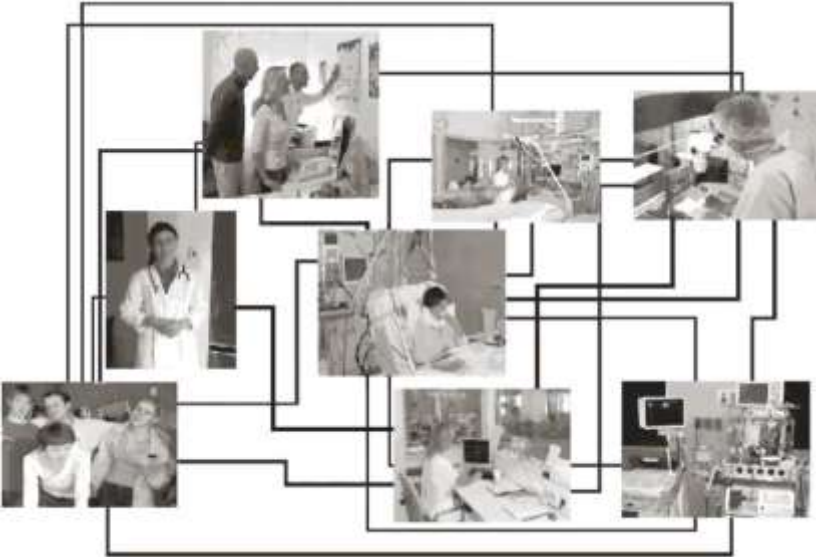
Continuity assured – connectedness between the stages along the patient care pathway

Digitalisation may add new dimensions and meanings to existing goals.

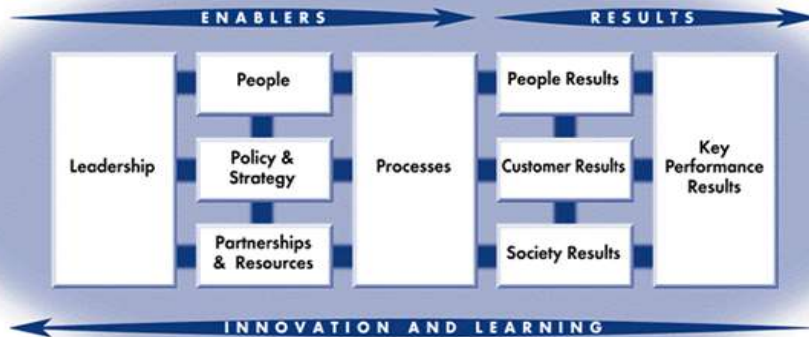
Difficulty of evaluating services in HC



Complex interactions of systems in HC



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



Data, monitoring and evaluation



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)

- **Tailored in such a way that they capture the relevant impacts of an intervention, both those intended and those unintended**

- **Performed to inform the relevant decision maker (at different levels of the health system)**

- **Fit for future use** and „future dimensions“ should be taken into consideration :

- **Predictive**
- **Prospective**
- **Preventive**
- **Participative**
- **Personalized**
- **Goals oriented**



Data sources



- **Evaluation and monitoring requires relevant data.** Much of the effort in evaluations is directed at obtaining such data.
- **Data must be gathered purposely,** be fit to address the questions intended to be answered and „gaming“ should be prevented. Different types of data is needed to address questions at different levels of HC system (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 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.**

Not much out there yet... but some frameworks emerging

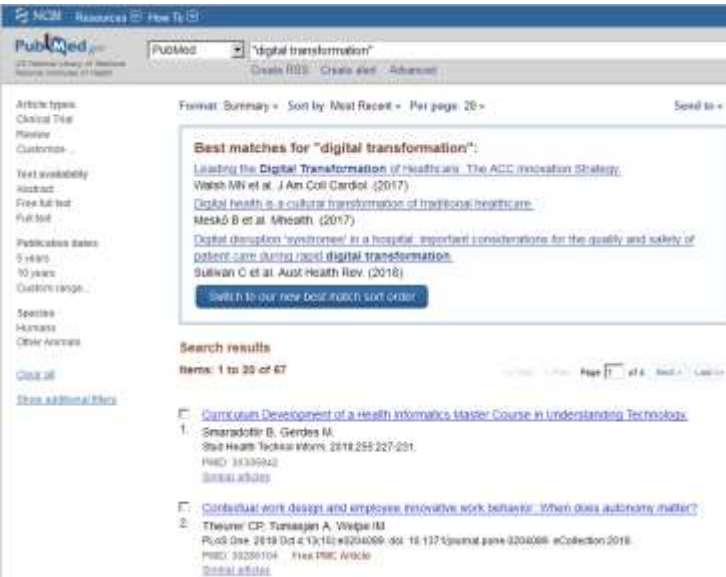
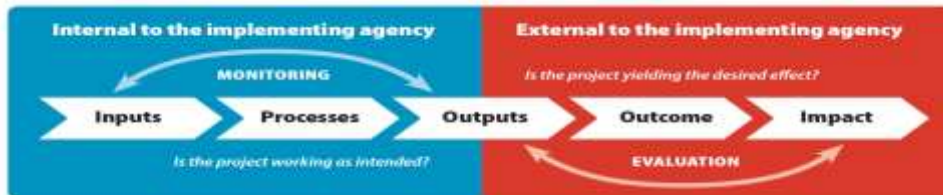
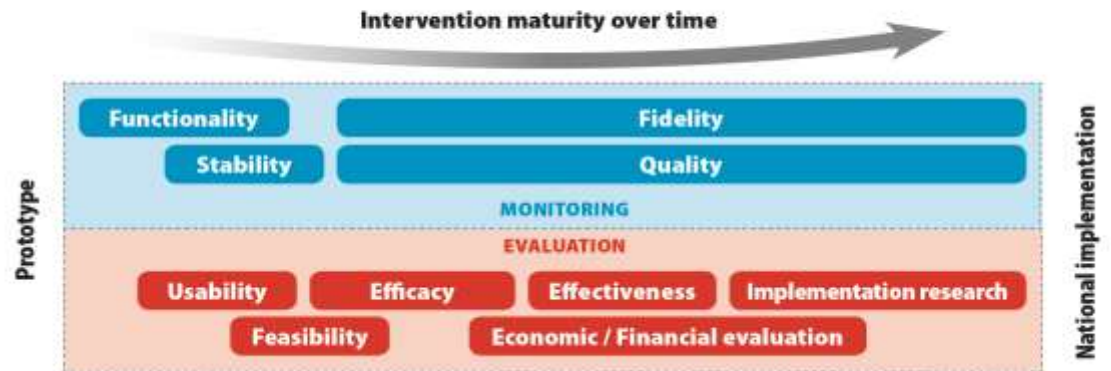


Figure 1.1. Intervention maturity life-cycle schematic, illustrating concurrent monitoring (blue/upper) and evaluation (red/lower) activities that occur as an intervention matures over time (left to right) from a prototype application to national implementation



Leading the Digital Transformation of Healthcare

- _ Healthcare is not entertainment. The healthcare system is complex, ...
- _ The stakes in healthcare are actually high: these are sometimes truly life-or-death decisions...
- _ Many tech companies lack clinical insight...
- _ Electronic health records (EHRs) were a first step in the digital transformation of healthcare, but many consider this a misstep...
- _ Digital health companies have often been fearful of entering the healthcare regulatory process...
- _ Last—although certainly not least—there is the continued issue of nonaligned incentives from a health policy and payment perspective...

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<https://doi.org/10.1016/j.jacc.2017.10.020>



- 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*
 - *for data services*
- It is expected the first two categories will be closest to technologies that are evaluated with common HTA methods more often, for which more specific evaluative frameworks have been developed.

HTA is “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.”
- We distinguish between **decision making**:
 - *centralised* and
 - *decentralised* (we mostly focus on the former)



A Minimum HTA Inspired Framework to Assess the Value of National eHealth Projects

- 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

Methodology



- **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.

STEP 1 - Preceding consideration:

- Purpose of the application?
- Relevant alternatives?
- International/national/regional/local level of assessment?
- Maturity of the application?

STEP 2 - Multidisciplinary assessment (domains):

1. Health problem and characteristics of the application
2. Safety
3. Clinical effectiveness
4. Patient perspectives
5. Economic aspects
6. Organisational aspects
7. Socio-cultural, ethical and legal aspects

STEP 3 - Transferability assessment:

- Cross-border
- Scalability
- Generalizability

Methodologies – tactics / strategies



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 clinical and broader health service 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, organization, or outcome quality of care? (**experimental or quasi-experimental studies**).

Prioritizing monitoring and evaluation



EVALUATION PRIORITIZING 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	+	+/-

Generic evaluation aids - checklists



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?			<p>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?</p> <p>Is there a good plan for the safe transition to the new service for all relevant stakeholders?</p> <p>Is sufficient time provided to all users to adapt to the new service?</p> <p>Was the service piloted sufficiently to avoid failures in further use and implementation (leading to harm, problems, loss of confidence, etc.)?</p> <p>Is there a mechanism in place to prevent the use of the service by people who lack the necessary training, skills or attitude?</p>	
Were all relevant stakeholders involved in designing and evaluating the service?				
Has the introduced service been evaluated from the perspective of assuring equity and minimizing possible inequalities? Has there been sufficient attention for (vulnerable) subgroups?				
Has explicit attention been paid to avoid the effect of “de-humanizing 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 optimize the (use of the) service after implementation?				Is funding for initial training and ongoing support of all involved stakeholders assured?
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?				Will the service require adjustments of training of new professionals (including the integration in the curricula for HC professionals)?
Is there a good plan for the safe transition to the new				



Monitoring

- 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. Such monitoring should not only be performed for evaluated programs 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 of the opinion provides an overview of indicators suggested by the Panel (EXPH, 2014)
- **In principle, where possible, “digital” and “non-digital” services should be benchmarked in all assessed areas**



Combine frameworks

- European repository in which existing frameworks, tools and methods may be collected, but subsequently also combined is strongly encouraged. Evaluation should include “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, cover many aspects discussed in this opinion.

Cover intended and unintended impacts and facts not promises

- Evaluation should cover both intended (positive) outcomes as well as unintended (negative) outcomes (which tend to be under-reported). Evaluation needs to be permanent and best based on using data the systems are producing (data feedback to provide information)

Answering mandate



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

- No. Assessing the value of ‘the digital transformation’ is a highly difficult task (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”. Progress has been made, also reflected in available evaluation frameworks (thanks to EU funded projects in this area), but many questions are still open. We strongly recommend to strengthen the knowledge base through methodological advances, performing evaluations and monitoring, and making these widely available for consultation. A European repository would be helpful as well.

Answering mandate



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, yes. The degree of need for modification largely depends on the degree of similarity between the digital health service and the technologies evaluation methods that are commonly used for in the field of health care (mostly pharmaceuticals), 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.

Answering mandate



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. Data need to be tailored to policy questions and gathered in an experimental design (such as RCT). Real world data 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. For 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 increased access to data leakage, privacy violations, lack of person-centred care etc.).

Answering mandate



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 digitally aided 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.

Answering mandate



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). 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.

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.



- Patient empowerment, shared decision making, goal-oriented care
- Governments should have sufficient knowledge about digitalisation
- Safety
- Respect patient's privacy rights and data protection principles
- Ensure cyber-security and resilience
- Role of professionals
- Capital and labour
- Incentives for innovation and uptake
- Exercise of market power: short term and long term
- Steering development of digital services
- Fiscal and social policies

Measures and actions to take



- Better methods and attention for evaluating the contribution of digital health services to patients, care providers and health systems is of utmost importance.



Financial Times, Sept. 26, 2018

opportunity carries risks . . . and AI is no different,” he says.

Interviewed in his London office at the health department, he says that alongside “the traditional cyber risk” is “the risk to public trust [of] poor behaviour, or indeed, if the security is not done properly”.

For politicians and regulators, the first priority “is to minimise risk and to provide that reassurance. I think of that as the foundation stone, and if you don’t

Ten recommendations



- **Develop a strategy for the digital transformation**
- **Develop a coherent framework for monitoring and evaluating**
- **Invest in robust monitoring and evaluation methodology**
- **Invest in systematic evaluation procedures**
- **Invest in evidence informed policy measures**
- **Invest in decentralised / local level decision making**
- **Invest in aligning literacy with technology development and introduction into practice**
- **Create an environment that wants and can adopt innovations**
- **Set up European repository** for evaluation and monitoring methods, studies and results
- **Be progressive but with caution**



Commission and governmental engagement in steering transformation



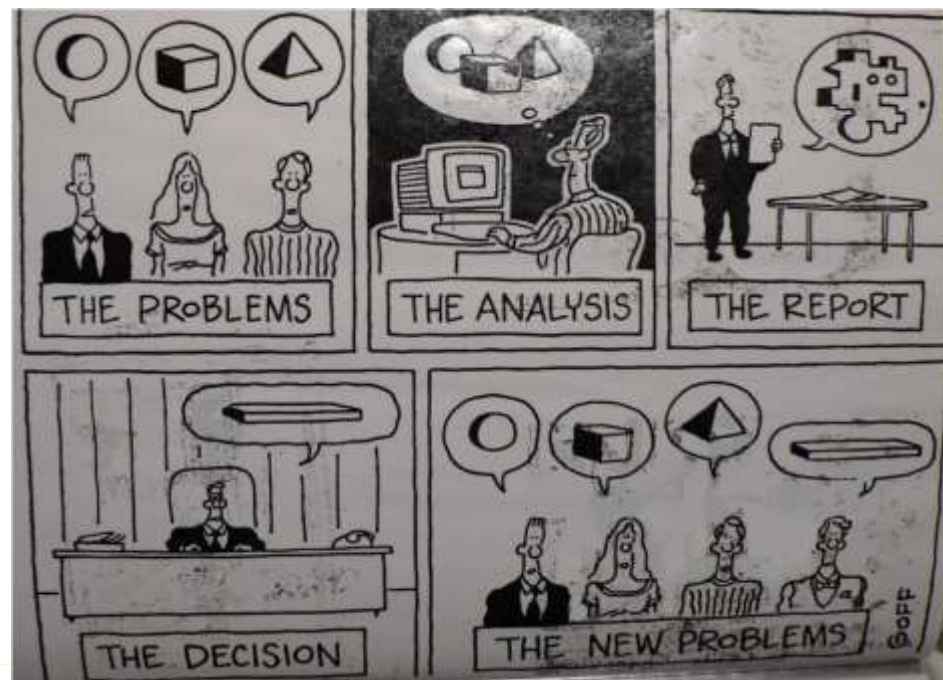
We are managing our work with utmost effort, but if ICT would not be helping us, we would be managing without the need of such extreme effort!

Digitally aided health service transformation should help ordinary people to achieve extraordinary results in providing health services rather than have extraordinary people achieve only ordinary results

Governance, steering – be progressive BUT with caution



NOT creating problems while trying to do the best possible



NOT dehumanizing health services



**Thank you for your attention
and
your dedication to help improve
health service provision
by the
„digital opportunity“**

