Digital Health

Today's Agenda

What is digital health?

Telehealth

eHealth

Digital transformations

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Class exercise

Digital Health and Care

TRANSFORMATION OF HEALTH AND CARE IN THE DIGITAL SINGLE MARKET - Hamessing the potential of data to empower citizens and build a healthier society

European health challenges

- Ageing population and chronic diseases putting 88 pressure on health budgets
- Unequal quality and access to healthcare services
- Shortage of health professionals

Potential of digital applications and data to improve health

- Efficient and integrated healthcare systems 1
- Personalised health research, diagnosis and treatment
- Prevention and citizen-centred health services 1

What EU citizens expect...

90% agree

To access their own health data (requiring interoperable and quality health data)

80%



To share their health data

80%

To provide feedback on quality of treatments

Support European Commission:





Citizens securely access their health data and health providers (doctors, pharmacies...) can exchange them across the EU.

Ambition.

- eHealth Digital Service Infrastructure will deliver initial cross-border services (patient summaries and ePrescriptions) and cooperation between participating countries will be strengthened. - Proposals to extend scope of eHealth cross-border services to additional cases, e.g. full electronic health records. - Recommended exchange format for interoperability of existing electronic health records in Europe.



Health data pooled for research and personalised medicine

Actions:

Ambition: Shared health resources (data, infrastructure, expertise...) allowing targeted and faster research, diagnosis and treatment.

- Voluntary collaboration mechanisms for health research and clinical practice (starting with "one million genomes by 2022" target). - Specifications for secure access and exchange of health data. - Pilot actions on rare diseases, infectious diseases and impact data.

3

Digital tools and data for citizen empowerment and person-centred healthcare

Ambition:

Citizens can monitor their health, adapt their lifestyle and interact with their doctors and carers (receiving and providing feedback).



- Facilitate supply of innovative digital-based solutions for health, also by SMEs, with common principles and certification. - Support demand uptake of innovative digital-based solutions for health. notably by healthcare authorities and providers, with exchange of practices and technical assistance. - Mobilise more efficiently public funding for innovative digital-based solutions for health, including EU funding.



How are these priorities managed in your country?

The EU Communication on the digital transformation of health and care identifies 3 priorities:

- 1. citizens' secure access to their health data, including across borders, enabling citizens to access their health data across the EU;
- personalised medicine through shared European data infrastructure, allowing researchers and other professionals to pool resources (data, expertise, computing processing and storage capacities) across the EU;
- 3. citizen empowerment with digital tools for user feedback and person-centred care using digital tools to empower people to look after their health, stimulate prevention and enable feedback and interaction between users and healthcare providers.



Active Assisted Living Technologies

- Broad term to describe products and services designed to improve quality of life for older people
- Receives significant investment from EU programmes and private sector



Analysis

Examples

COGNIVITRA overall concept and technology







1-16 of 55 results for Alexa Skills : "The Elderly"



New Arrivals

Last 7 Days Last 30 Days Last 90 Days

Grant a few

birthday

wishes

Shop gift cards •

*



Senior Moments

★★★☆☆~8

FREE Available instantly on your connected Alexa device.



All About Caring For The Elderly

FREE



• Private sector

• AAL

technologies an extendend functionality of the ecosystem

 Goal: Add more users to the ecosystem and multiply the network effect

- Basic research (EU)
 - Create IT extension to the healthcare infrastructure
 - Goal: Make healthcare system more efficient and save money

Informational safety and security issues

What should we put the emphasis on?

"Take home" hardware

- "Medical device" or "hobby device"
- •Should we allow regulation shopping
- Sensor based or vision based

Ecosystem

- •Liability of a service provider (alexa, apple watch)
- ·Liability of a healthcare provider (telemetry cardiology)

Safety/Security concern

- •Leak of (personal) information
- ·Compromised functionality of the device

Liability of

- Manufacturer
- Service provider
- Healthcare provider

Regulation

General data protection regulation

- Directly applicable to all scenarios
- Chapters 2-4

The directive on medical devices (EU) 2017/745

- Applicable only if the device meets the definition (treats disease, disability)
- Annex II bullet point 17 devices that incorporate electronic programmable systems

Patient privillege, medical privacy,

- · Rules of private law under national law
- Applicable to hardware supplied by healthcare provider

Health records

- · Rules of administrative law
- · Applicable to hardware supplied by healthcare provider

Medical devices regulation

- 14. Construction of devices and interaction with their environment
- 14.1. If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices.
- 14.2. Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:

(b) risks connected with reasonably foreseeable external influences or environmental conditions,

Medical devices regulation

• 17. Electronic programmable systems

- 17.1. Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.
- 17.2. For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.
- 17.3. Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).
- 17.4. Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

Liability – what if something does not work

IT only ecosystem

- Personal data
 - GDPR and fractional national regulation
- Civil
 - Consumer liability

Healthcare ecosystem

- Personal data
- Healthcare records
- Medical device certification
 - Adverse events
- Medical malpractice
- Civil liability
 - Consumer liability
 - Personal injury

Telemedicine

Ease of · Ease of Use for the patient Use · Ease of Use for the HCP · Evidence of improved cost-effectiveness of care · Evidence of improved quality and continuity of care Evidence · Evidence of patient benefit · Evaluation and monitoring of quality of care **Technological** Interoperability and technical standards · Availability of connected digital ecosystem (e.g. Infrastructure EHR, e-prescription, online appointment) · Sustained funding Clear reimbursement mechanisms Funding and · Coherent governance Policies National strategy for telemedicine · Specific legislation on telemedicine (e.g. liability, GDPR compliance)

HEALT

Figure. Foundations for Building a Successful Telemedicine Ecosystem



Figure. Conceptualising digital transformations of health (Lancet, 2021)



Figure. Conceptualising the interface between digital technologies and the determinants of health (Lancet, 2021)

Health information systems in LMICs- DHIS2



Imperial college research

- Giving a certain disruptive technology alone to a patient has not improved health outcomes. digital health represents this transformation but most medical studies dedicated to the issue have focused on the technological instead of the human component. For instance, studies that aimed at incorporating health sensors to drive behavior change for patients, did not take into consideration the importance of providing coaching with the technology.
- There have been studies focusing on whether a web-based intervention or monitoring service could help manage medical conditions better, like the measuring of quantified parameters such as hemoglobin A1c levels or blood pressure. **There were no significant improvements in those parameters when patients received access to a web portal without prior training** (22-24); or when participants had trouble with the registration process and using tools designed to allow them to track their health and self-report health information indicating that complex portal interfaces may present a barrier to use (25).
- However, where coaching was an equal element to the use of technologies in the study design, the use of disruptive technologies such as VR devices led to quantifiable, significant changes. Patients who could experience VR worlds for up to 20 minutes through wearing a headset and chose to travel to Iceland, participated in the work of an art studio or swam with whales in the ocean described the experience as pleasant and capable of reducing pain and anxiety (<u>26</u>).

Another big problem

 misinterpreted information obtained from digital health devices and unreliable online resources can lead to medical decisions that do not involve medical professionals and endanger the lives of patients - Fahy E, Hardikar R, Fox A, et al. Quality of patient health information on the internet: Reviewing a complex and evolving landscape. *Australas Med J* 2014;7:24-8.

Health literacy

- The European health literacy survey (HLS-EU) found that every second person possesses limited health literacy (<u>39</u>). Also, patients with lower health literacy rates are more unlikely to use the possibilities of eHealth (<u>40</u>).
- We are standing before an enormous challenge: will technological transformation improve health literacy levels, or the contrary: will digital health deepen the already existing digital divide?
- Using digital health is a teamwork, thus the era of lonely doctor heroes will end.

- 60 percent of world population will have mobile internet by 2025
- Globally-
 - Inhabitnats of fural areas and women are less likely to own a smartphone
- Digital health interventions targets only part of population in public health

Enablers (Imperial college london)

- A supportive regulatory environment
- A culture of innovation
- Leadership commitment to clinical quality and public health
- Data governance
- Public support

FAILURES

- 1. Forgetting patients and diversity
- 2. Not taking into account care providers
- 3. Difficulties in creating clinical value
- 4. No scientific validation
- 5. Overclaiming what technologies can do
- 6. Forgetting to go where users are
- 7. Not cost-effective enough
- 8. Not being easily implemented by healthcare practitioners or patients
- 9. Not matching the relatively slow pace of healthcare change
- 10. Being too early or too late

Example – succes or failure



EU Digital COVID Certificate	
Certifikát EU COVID-19	
P	Surname(s) and forename(s) Jméno a příjmeni ŘEHOŘ ŘEPNÝ Date of birth Datum norozeni 1979-07-19 Unique certificate identifier Unikátní identifikátor certifikátu aahc3bpapřenbastár272/ScR4umngf62 VACCINATION CERTIFICATE
MEMBER STATE PLACEHOLDER	Certifikát o provedené vakcinaci
	Disease or agent Targeted Cilenó nemoc nebo ogens SIRS-CoV-2 (ICO 11 XNL09, SNOMED CT 840533007) Vaccine/prophylaxis Vacina/profytore mRNA vakcina proti onemocnění COVID-19 COVID-19 mRNA Vaccine, Severa autor respiratory syndrome coronavirus 2 mRNA only vaccine product(SNOMED CT 1119349007) Vaccine medicinal product Vaccine medicinal product SloVitech Manufacturing GMB Number in a series of vaccinations/doses and the overall number of doses in the series
This certificate is not a travel document. The scientific evidence on COVID-19 vaccination, testing and recovery continues to evolve, also in view of new variants of concern of the virus. Before traveling, please check the applicable public health measures and related restrictions applied at the point of destination. Relevant information can be found here: <u>https://reopen.europa.eu/en</u>	ause in une series Prodově čilo dávy / počet dávek 2/2 Date of vacination Datum vskcinace 2021-02-09 Member State of vaccination: čenský rdt C2 Certificate issuer Vydovatel certifikátu
Relevant information can be found here: https://reopen.europa.eu/en	CE Certificate issuer Vydavate/ certifikátu Ministry of Health of the Czech Republic / Ministerstvo zdravotnictví České republikv

CLASS EXERCISE

Class exercise

- Case Studies of Digital Health Governance
- What to do:
 - form into 8 groups
 - \circ read the case presented
 - Suggest Solutions using the provided space
 - Time: 15 minutes
- Each group selects 1 person to present for 2 minutes their answers in class

TEAM 1: BRNO



TEAM 2: BRNO



TEAM 3: BRNO



ZOOM groups 4-8

Key Topics: Training the health workforce; Inequality; Equity

Source Type: Global governance (G7) recommendation Focus: Worldwide

Case Made:

The Minister's Statement specifically focused on the necessity of developing trust to realize the full potential of AI. In relation to the SDGs, the Statement detailed that for trust to be developed within AI it is important that there is equitable representation of perspectives.

Solutions Suggested...?:

TEAM 1: BRNO

Key Topics: Digital health technology; Climate Change and Warming; Environment

Source Type: Digital health intervention Focus: M/HICs; Older demographics

Case Made:

Heat waves cause deaths amongst those with comorbidities and older populations.



Key Topics: Data governance; LMICs; Governance tools; National strategies

Source Type: WHO Report Focus: Worldwide

Case Made:

Compared to HICs, LMICs often have less legislation surrounding eHealth data because they do not have capacity to engage in the legislative process alongside the implementation of eHealth interventions.

Solutions Suggested...?:

TEAM 3: BRNO

Key Topics: Environment; Addressing the climate harms of digital health; ICT

Source Type: Lancet policy review and recommendations Focus: Worldwide

Case Made:

While many highlight the benefits that come from digital health, few have addressed how digital can increase greenhouse gas emissions and further the environmental determinants of health. Specifically, these determinants are strengthened through digital health due to increased energy usage and data storage.



Key Topics: Urban Environments, Digital Infrastructures, and COVID-19.

Source Type: Panel event hosted by Geneva Global Cities Hub Focus: Cities Worldwide

Case Made:

The event discussed how cities have managed the COVID-19 pandemic while maintaining mental health.



Key Topics: ICT; Funding; Coordination; Human resources

Source Type: Regional strategy Focus: Regional

Case Made:

The African Union says that there are three main challenges for the digital transformation of health in Africa including: i) "Weak infrastructure and device access, including reliable electricity and affordable high-speed broadband connectivity, especially in rural areas." ii) "A lack of sufficient and consistent funding for digital health programs" iii) "Limited human resource capacity and digital skills"

TEAM 6:

ZOOM

Key Topics: Youth; Inclusion.

Source Type: WHO Report Focus: Worldwide

Case Made:

Despite youth being the most competent and most impacted by digital health in the present and the future, there is little engagement of youth in digital health care governance. This report lays guidelines on how youth engagement can take place. Further, the report highlights how it is important to be more proactive in this process noting that the history of youth engagement in health care began with the HIV/AIDS crisis.

ZOOM

Key Topics: Development funding; Basic digital infrastructure; Funding gaps

Source Type: Interview Focus: Uganda

Case Made:

For this interviewee, the largest barriers for bridging the digital and health divide comes from basic infrastructural challenges. These often occur because of funding gaps between international organization (IO) programs as well as infrastructural gaps thought to be beyond health care. IOs do not see it as their responsibility to fund basic infrastructures such as roads, laying of fiber, etc.

Solutions Suggested...?:

TEAM 8: ZOOM