Successful Digitalisation Pathways

People Centric Model to Harness User Value

Reflection on Personal Data Spaces in Transformation of Health and Care

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To reap full benefit of ongoing health system transformation, digital health tools and services are urgently needed to equip citizens as patient, informal caregiver or family member. They are the most important, but least supported actors in healthcare, in need of digital health data and services for health management activities at their personal convenience, discretion and control. This will add use-value and assist to attain better health and wellness contributing to more sustainable healthcare. We are proposing a model to drive the discussion of what health managers, policymakers, and society at large can do better to engage citizens.

Key Points

- A people centric model for use-value in personal health data exploration has implications for citizens, healthcare, and policy actors alike.

- For citizens: Ongoing digital transformation of health systems needs adequate digital tools and services that allow for personal use, reuse and control of all health information according to preferences, discretion and convenience while ensuring that no one is left behind due to low digital literacy or inability to access tech.

- For healthcare: Access to, active use and reuse of personally recorded and appropriately curated health data - personal secondary use – is necessary to reap the full benefit of digital transformation.

- For policy actors: The European Digital Health Landscape (including the forthcoming European Health Data Space) needs to include opportunity for personal use and reuse of health data, which include functionality to add and curate, understand and explore, to employ digital tools for healthier lives and successfully coping with disease.

- Hospital managers, and health managers in general, including IT managers who often have to make choices regarding IT projects and digital services for healthcare organisations may benefit from taking the proposed people centric model into account, and this is the essence of a future personal health data space.

Introduction

Across Europe the healthcare systems - hospitals, primary care as well as social care and long term care - are increasingly capitalising on and relying on digital support. Electronic Health Record (EHR) systems are widely implemented across hospitals and other care settings, and more data are available in digital form. Telehealth has transformed patient and citizen interactions with care providers. Deployment of digital health

interventions were boosted by a combination of COVID-19 restrictions, achievements in interoperability standards, and widely available, well established national ePrescription solutions that allow patients the convenience to fill their prescriptions. These initiatives demonstrate the importance of digital health data across settings, health institutions and stakeholder constituencies (Moen 2018).

Consistent with the aims of the EU Digital Single Market Strategy, which highlights the need for digital transformation of health and care innovations to build a healthier society, the recently completed Digital Health Europe (DHE) project highlighted the need to empower citizens and foster health data

sophisticated view of the European digital health landscape, expanding it to include opportunity for personal use and reuse of health data, to employ tech for healthier lives and successfully coping with disease.

Rapid Deployment of Digital Tools and Services Increase Availability of Personal Health Data in Digital Form and Call for Citizen Participation

Without interoperability guarantees, the significant investment in digital solutions cannot build up integrated tailored functionalities to the level that users expect and need. Standards provide the framework for technical interoperability, i.e., agreed

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activism in patients. To reap the full benefit of these initiatives, digital health tools and services are urgently needed to equip the most important, but least supported actors in healthcare - the citizen as the patient, informal caregiver or family member – with digital health data for personal health management activities at personal convenience, discretion and control for personal health and wellness. Digital health services that support and offer a good overview of health data with an understanding of its implications, will, if successfully deployed at scale, come with opportunities and convenience that improve user-experience, engage the person, and transform personal health management (Moen et al. 2022).

This is a demand-side push for a more interoperable digital health ecosystem that can only be realised with the offering of tailored and patient-friendly digital tools.

So, what can we do better to advance digital health and transform how citizens, health professionals, and policy makers engage with tech?

1. For engaging citizens, it is important to recognise that the ongoing digital transformation of health systems needs adequate digital tools and services that allow for personal use, reuse and control of all health information according to preferences, discretion and convenience while ensuring that no one is left behind due to low digital literacy or inability to access tech.

2. Health professionals should be able to have access to, active use and reuse of personally recorded and appropriately curated health data. Such personal secondary use is necessary to reap the full benefit of digital transformation.

3. Policy actors can contribute by advancing a more

upon format for how the data is exchanged, and semantic interoperability, i.e., agreed upon understanding of what the data represents. Currently, the emergence of the HL7 Fast Healthcare Interoperability Resources (FHIR®) standard, allows for data to be electronically exchanged in real-time with both technical, structural and some semantic integrity as well as data security. HL7 FHIR® is rapidly being adopted by large and small technology vendors, regulatory agencies, third party payers and pharmaceutical companies, among many others. Within HL7, several FHIR® accelerator initiatives have been launched. One of them is VULCAN to help healthcare researchers more effectively acquire, exchange and use data in translational and clinical research, and to define a common set of standards using the HL7 FHIR® standard to facilitate data exchange internationally. HL7 FHIR® is moving towards a universally agreed upon interoperability standard, changing the way healthcare data can be exchanged, received and reviewed.

While efforts to create FHIR® resources advance technical interoperability, for meaning to be clear and actionable by humans and algorithms, other challenges in the cross-context identification of diagnosis, clinical status or medicinal and device information must be overcome. For the Identification of Medicinal Products (IDMP), the ISO IDMP standard points to ongoing global consensus processes to describe and identify unambiguously medicines and pharmaceutical products. IDMP standards and accurate medicinal product information can deliver multiple benefits for pharmaceutical companies, regulators, healthcare providers, and especially citizens in all the countries where a medicinal product is prescribed, dispensed and used. ePrescription is widely adopted across Europe and

increasingly available eDispensation services transform how medication is made available within country of residence or in markets across borders. Health data accumulated in silo EHR systems serve documentation purposes. To open up the silos,

understand implications, verify contraindications, risks and in general protect from harm, stimulate coping and obtain best possible health outcomes.

As citizens use digital tools to navigate and use personal

Innovative, digital tools for citizen's active use and engagement include opportunity to share health data at personal discretion, across borders when needed, to support treatment and care

the International Patient Summary (IPS) concept, evolved from the already implemented cross-border EU Patient Summary, provides a summary snapshot and definitions for a curated set of relevant, structured information facilitating continuity and cross-border care (Kay et al. 2020). The ongoing EU funded X-eHealth project seeks to take this a step further by developing three new use cases for the European EHR-exchange Format (EEHRxF) namely laboratory results, imaging reports and hospital discharge letters, on top of revised ePrescription and patient summary guidance and detailed specifications (Bonacina et al. 2021).

Stimulating hospitals and other healthcare organisations to use existing and coming standards and formats for health data sharing, particularly with citizens will create necessary innovation ecosystems in which citizens need also to be allowed to co-create the digital solutions they are to benefit from. For the citizen in its multiple roles, but always as the key actor, these new opportunities call for ethical considerations particularly relevant following the recently proposed European Ethical Principles for Digital Health and new codes of conduct and governance for equity and to take full advantage of emerging opportunities in accessible and understandable services that do not leave people behind.

Situating Citizens and Health Data in the European Digital Health Landscape

A patient's health information remains fragmented and collecting all information about oneself or even access the information to support health and care activity is still quite complicated today. This is largely due to technical and structural obstacles, such as limited availability of or partial access to personal digital health information, interoperability challenges and little opportunity to actively select or use information for relevant, everyday purposes. At the same time, adding health information management to everyday activities can be a challenge. For example, it can be a struggle to read fine print in paper-based medicinal product leaflets and at the same time combine this information with personal health data to

data, also for their health management, the more likely they are to favour its use and reuse held in multiple organisations. Many Europeans support greater transparency or want to guide on how their personal health data is used. We can show a digital certificate of vaccination to enter the bus, an airplane or to go across borders. We can benefit from ePrescription on email/phone or at the pharmacy to dispense a needed medication or we can take advantage of the digital summaries in the maturing patient summary. These examples of cross-border digital health services come with opportunity to read personal health information, most often via tethered patient portals, and expectations for additional services.

To expand service repertoires and maintain trust, integrity and control, active use of personal health information, including collection, processing and use of personal and sensitive personal data requires responsible and ethical conduct in compliance with the European Union General Data Protection Regulation (GDPR). GDPR sets out requirements to be met by service providers who wish to collect and process personal data while providing a service and demands that tool developers ensure that their tools incorporate data protection principles. Furthermore, the European Union Medical Devices Regulation (MDR) and the Revised Directive on Security of Network and Information Systems Directive (NIS2) entered into application May 2021. Prospective citizen centred digital tools should take this complex regulatory framework into account to include security and data protection issues together with national sectoral laws. While ethics in digital health for the most part are not mentioned at EU level, professional and industrial codes of conduct exist and will be taken onboard as well as contributions to digital health ethical reflections (Bonacina et al. 2021). Innovative, digital tools for citizen's active use and engagement include opportunity to share health data at personal discretion, across borders when needed, to support treatment and care, efficient self-management, and EU-mobility grounded in better data to advance research, disease prevention and personalised health care.

Personal Health Data Spaces Adding User Value in Transforming Health and Care Transformations

When citizens are trying to navigate and comprehend their health information, we have observed a plethora of *ad-hoc,* time consuming strategies with limited scalability, little reliable guidance or proper quality control, aggravating the consequences of disconnected, non-centric services. Going beyond opportunity to read personal health data comes with opportunities for active use of collected personal health data, curate and control as well as analysing or visualising personal health data can improve the value of health data to support scenarios for data support in everyday life challenges. This is in essence a future personal health data space, Figure 1 represents a 4 layered pyramid of personal user needs as a simplified people centric model of looking into the health data space and individuals' needs.
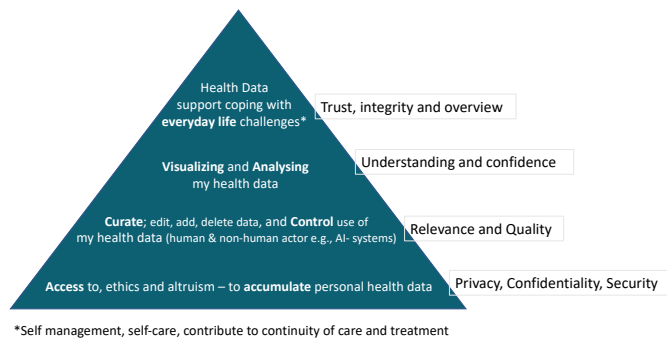

Figure 1: Personal Health Data Space

The pyramid can guide discussion on key features and need for integration of functionality in the personal health data space, and zoom in on necessary steps to nurture personal engagement with personal health information. Personal experience, access to understandable and actionable information, and capacity in terms of digital health literacy are important to fully appreciate the rapid digitalisation in healthcare and take advantage of new digital health information services. Citizens' meaningful engagement with digitally provided information is the way to build up necessary trust and ethical conduct in digital health ecosystems, without which ambitious targets such as a thriving European Health Data Space, health data altruism and advanced secondary use of health data cannot easily be realised. A personal health data space can be seen as a right. We anticipate that citizens needs and motivators to use their health data varies with experiences, and with capacities to leverage functionalities for curation to contribute quality of data for real world visualisations and analytics.

Citizens, Access and Use of Personal Health Data and Prospects of Digital Tools

Engagement in personal health can only be achieved with actionable, understandable, relevant, reliable and evidence-based information that meets the user's (patient or citizen) specific needs, health context, and literacy level. As digital health information becomes more available interoperability of these information resources is very important to offer tools to engage and empower citizens. In addition, there has been increasing recognition of the importance of relevant health information trusted sources, e.g., medicinal product information, health promotion material for wellness or disease specific information in times of crisis. The ongoing transformation comes with opportunities to engage with personally relevant health information, for an increasingly personalised experience. We conceptualise this as *personal health data space*. Here are opportunities for efficient interactions, based on smart, convenient and trusted data-driven contributions solutions. This will allow for participation, engagement and increase awareness and vigilance where our everyday, personal health decisions are rooted in engagement with and capacity to comprehend, understand and engage.

Opportunities – An Example From Gravitate-Health

Over the last years, several important trends and strategic developments in the European Digital Health Landscape can be seen as enablers for developments that leverage from the opportunities that comes in the ongoing development of digital services that transform health and care systems. One example is the IMI funded Gravitate-Health Public-Private Partnership. This project is an example of opportunities to enrich and increasingly focus the health information from trusted sources to the user needs, preferences and context of use. The goal is to equip and empower citizens with digital information tools and make them confident, active, and responsive in their patient journey, specifically encouraging safe use of medicines for better health outcomes and quality of life.

Gravitate-Health is operating in an environment in which there is increasing focus on how to exchange and use health data for multiple purposes to demonstrate that smart delivery of digital health information can improve access, understanding and adherence, leading to better outcomes and a healthier society. In that sense, additional HL7 FHIR® resources and standards come into play to advance quality and provenance of information, while integrating digital health services and so allowing for maximum value to be derived from the increasing availability of health data. Digital tools that support novel and new access to and understanding of personally relevant health information about medicine treatment with ePI content, based on personal health and medicinal product

information are essential. In this context, digitising medicinal product information – in Patient Information Leaflets (PIL), SmPC and labelling – is also taking place. In Europe, Medicinal Product information compendiums are available online (often in collaboration with National Medicines Agencies) and the European Medicines Agency (EMA) launched the ePI set-up project in early 2021, with the publication of a FHIR-based common EU standard for ePI following in 2022. In the US, the Food and Drug Administration (FDA) is working on Structured Product Label (SPL), in Japan work on structured labelling is emerging, and in regions including Asia and Latin America there is growing interest and activity in the area. Starting from digital availability of the regulator-approved medicinal product information included in the package inserts and the label, the future ePI, combined with the specifics of a person's use of medicinal products opens novel opportunities to support the digital transformation of healthcare across the EU, which in turn is anticipated to offer significant public health benefits. From this stance, Gravitate-Health is the catalyst for bringing very important, complementing and different perspectives together to deliver a tool, which we call G-lens® to address the challenge at hand and drive benefit for patients, mobilising public and private stakeholders.

To create and harness the G-lens®, Gravitate-Health offers testbeds which takes the theory and puts it into agile practice, seen as new and deeper insights into how improved access, availability and understanding of health information can translate to higher levels of adherence to treatment, safer use of medication (pharmacovigilance), and when optimised act as effective risk minimisation measures driving better health outcomes and quality of life. The G-lens® (Figure 2) is effectively a tool that operates to focus ePI data according each patient's needs, and when combined with the IPS data, if the patient so wishes, creates the conditions to support the top two layers of needs of our proposed personal health data space model (Figure 1). Over time, we anticipate to illustrate significant contributions that underline the importance of interoperability in action to reap the wider benefits of focusing personally relevant health information from trusted sources.
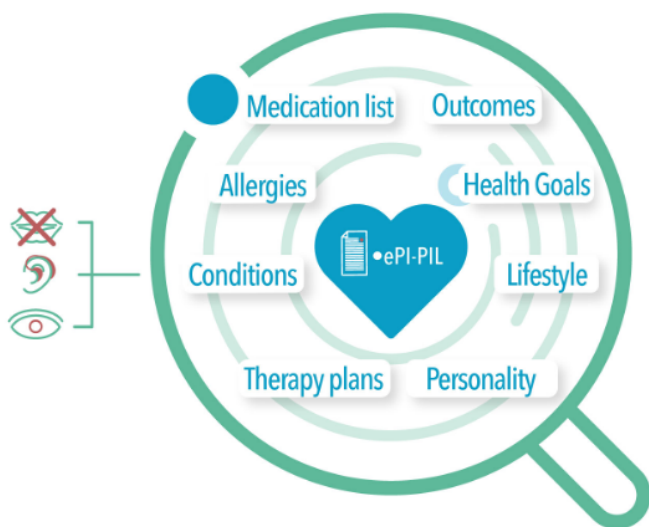
Acknowledgements

Conflict of Interest

None. ■

Figure 2: G-lens®

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