Digital Health Uptake

Executive Digest

Implementation strategies for successful uptake of Digital Health Solutions

Topic: Implementation strategies for successful uptake of Digital Health Solutions [1]

Relevance of this topic to Digital Health

There is a profound paradigm shift in the provision of health care supported by the proposed European Health Data Space (EHDS) Regulation, placing patients in the driver's seat of their health. Digital health innovators are challenged to deliver tools that empower the citizen/patient, ensure the right to portability and support shared decision making of patient and care team. This calls more than ever for engaging patients in the whole development cycle of solutions from the design phase all the way to collecting feed-back and acting upon it in improvement cycles. Early engagement with patients and patient representatives is necessary. Co-creation activities should start from the beginning making sure that patients have a say in what they need and expect out of your innovation.

The use of co-creation tools and methods for digital innovation has demonstrated feasibility and value with patients and physicians even within the most challenging target groups such as older people with multiple comorbidities. The same applies for the need to co-create new solutions with health authorities, payers, and health care providers and for supporting a paradigm shift away from technology-push approaches, towards digital health tools that empower patients to actively participate in their care, and the use of technology to solve well defined and prioritised user problems.

Design of patient-physician collaboration tools should keep the care ecosystem in mind and focus on efficiency for work in environments challenged by high workload and low time availability. Integration with existing EHR systems needs to be achieved to avoid duplication of efforts and ensure a unified and comprehensive view of patient information for physicians. User interfaces of digital health solutions must be intuitive and user-friendly, catering to individuals with varying levels of digital literacy. Health care professionals should be also involved from the very beginning to warrant real world utility of digital tools.

Delivering standards based and open technologies will allow for pulling of resources to advance and maintain solutions in a dynamic health care landscape. Examples of solutions that address outstanding pain points are incorporating tools that are able to interpret free text in order to exploit a lot more uncoded information that is currently not exploitable and considering automation of processes whenever possible, keeping the human intervention in the loop when it is most needed. Establishing mechanisms for continuous feedback from both healthcare providers and patients is essential to iteratively improve digital health solutions based on real-world usage and evolving needs.

Keywords

Co-creation, patient driven design, Interoperability, DH standards, European Health Data Space, labelling

Current focus of policy, legislation, standards, emerging practices in this landscape

The implementation of Digital health tools must be always based on standards. The use of domain standards and specifications in addition to technical standards will ensure that research, care workers and patients speak the same language. Implementation support is provided by guidelines and tools, such as the WHO Smart Guidelines, the HL7 Computable Care Guidelines and the PRSB Information Standards.

The use of interoperability and security standards will also facilitate seamless integration with other health technologies and systems, promoting a holistic approach to patient care and streamlining integration with existing EHR systems. The ISO International Patient Summary and the European Electronic Health Record Exchange Format (EEHRxF) are important foundation standards[2]. It is also necessary to implement robust security measures to safeguard patient data, and clearly communicate the privacy features to build and maintain trust among users.

These requirements are an essential part of the proposal for an EHDS Regulation, which makes it obligatory for providers of EHR systems to draw up a declaration of conformity, stating that the manufacturer has demonstrated that the essential requirements laid down in Annex II of the proposed Regulation have been fulfilled. There are also provisions for labelling of digital health applications to declare their ability to exchange data with compliant EHR systems.

[1] Learnings from the DigitalHealthUptake Catalyst session organised within the "Building Trust in Health Data" 2023 Conference

[2] See also The interoperability of EHR systems and health apps in the European Health Data Space

Beyond interoperability, building quality and reliability of digital health solutions will secure their faster and informed uptake by the ecosystem. Establishing context for defining intended use, and ensuring effectiveness (across Apps, MedTech, Medicines, Healthcare Services) is a critical first step. Additional tools have proven to be the use of Personae, Scenarios, Activities/events, Processes, Data, Decisions, and Metrics-data definitions in context.

EU harmonization of criteria, certification and labeling schemes stand to address the outstanding problem of market fragmentation creating an EU wide unified market for DH solution providers. It is anticipated that professional medical associations will be then likely to prioritize labelled Apps into their recommendations for inclusion into clinical guidelines. In turn, healthcare authorities and digital health assessment bodies stimulate awarding models to fast-track quality labelled products towards adoption and reimbursement[3].

The TS 82304-2 is the standard defining the App Quality Label which shall be recognized across Member States and internationally. As such, it can be a valuable resource at the design and implementation phase of digital health innovations.

Remaining gaps and issues

The EEHRxF is being promoted as an EHR representation but is, in practice, limited to a Patient Summary and continuity of care Clinical Documents. Digital health solutions may benefit from the ability to receive interoperable Patient Summary data, but the real impact of interoperability for digital health is likely to be greater when the EEHRxF is extended to include specifications supporting a wide range of clinically relevant use cases.

Decision makers will need to plan for and make investment provision for the wider use of digital health when its data is interoperable.

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Legislative, regulatory, policy or standardisation instrument, or good practice

Title

The EHDS (draft) Regulation requirements for interoperability

Instrument status

Draft EU Regulation, currently under review and revision by the European Parliament. It is expected to be adopted and enter into force in the first half of 2024.

Publisher or source

The European Commission

URL or reference

https://health.ec.europa.eu/publications/proposal-regulation-european-health-data-space_en

Summary of the instrument

The European Health Data Space (EHDS) Regulation is an ambitious legislative proposal, backed with a substantial multi-billion budget, to establish two infrastructures and corresponding data ecosystems. They are briefly summarised below, with an emphasis on those aspects relevant to this Digest.

a) A *primary use* network that expands the existing eHealth Digital Services Infrastructure which provides the basis for implementing MyHealth@EU. This targets enabling all European citizens to be able to access their own health record and to authorise any cross-border healthcare provider to access this information in order to deliver safe and effective care in a country other than the country in which the patient usually receives care (i.e. cross-border care). The provisions for MyHealth@EU include the required participation of all Member States and the requirement to utilise the EEHRxF. Compliant EHR systems must be self-certified by their manufacturers against

[3] See also The Certification of Health Apps Executive Digest

essential requirements specified in the Regulation (to be further detailed in secondary legislation), and must be able to import/export using the EEHRxF. Data quality must be checked for completeness and accuracy. Digital health applications exchanging data with other systems must also conform to the EEHRxF. As provided for in the GDPR, citizens will have the right to access their EHR consolidated at Member State level, which must be portable. Persons may limit access to the EHR and know who has accessed it.

b) A *secondary use* network named Healthdata@EU is to be implemented across the Member States, to enable researchers, innovators, policy-makers and regulators at EU and Member State level to access relevant electronic health data to promote better diagnosis, treatment and well-being of natural persons, and lead to better and well- informed policies.

The EEHRxF content covers the following types of electronic clinical document:

- European Patient Summary
- Electronic prescriptions
- Electronic dispensations
- Medical images and image reports
- Laboratory results

Discharge reports

Implication for digital health stakeholders

The proposed EHDS Regulation enforces the role of, and compliance with, the EEHRxF. This includes EHR systems, and wellness applications claiming interoperability with them and it is therefore becoming an important requirement for digital health developers to include and procurers to insist on.

Legislative, regulatory, policy or standardisation instrument, or good practice

Title

ADLIFE

Instrument status

A European Commission project, H2020-875209, running from 2020 to 2024

Publisher or source

The ADLIFE project

URL or reference

https://adlifeproject.com/

Summary of the instrument

ADLIFE is an EU-funded project aiming to improve the quality of life and independence of elderly patients with advanced chronic diseases **such as Chronic Obstructive Pulmonary Disease, and/or Chronic Heart Failure** through digitally supported interventions enabled via **digital health solutions**. Our innovative and intelligent ADLIFE toolbox strives to leverage integrated and personalised care, based on multidisciplinary collaboration and patient empowerment.

The ADLIFE integrated care solution provides two complementary software platforms for the use of healthcare professionals and patients: (1) A Personalized Care Plan Management Platform (PCPMP) supported by clinical decision support services, which acts as a chronic disease management platform served to multidisciplinary care team members (specifically GPs and Nurses), and (2) A Patient Empowerment Platform (PEP) used by the patients and their informal care givers, enabling them to be informed, educated, and guided about their active care plan and to be active participants of their care plan activities.

The PCPMP serves the multi-disciplinary care team members and facilitates the creation of personalized care plans for patients. It retrieves important parameters from the Electronic Health Records (EHR), and invokes Clinical Decision Support Services (CDSS), to recommend personalized suggestions about care plan goals and activities. The suggestions of the CDSS are produced by automatized evidence-based clinical guidelines, that support healthcare professionals in creating a care plan for the patient.

As part of the care plan, roles and responsibilities of the patient in the management of his chronic condition are clearly defined. Once the care plan is finalized, this care plan is then shared with the multidisciplinary care team members via PCPMP, and with the patient and his/her informal caregivers via PEP. In this way, the care plan and all its components can be accessed by the patients.

Successful long-term management of patients with chronic conditions requires active patient self-management and a proactive involvement of patients in their healthcare and treatment. This calls for a patient-provider partnership within an integrated system of collaborative care, supporting self-management, shared-decision making, collection of patient reported outcome measures, education, and follow-up. Hence, a**s a part of this integrated care solution, ADLIFE delivers a patient empowerment platform** (PEP) **supporting Patient Reported Outcome Measures (PROMs) and Shared Decision-Making (SDM) to support the patients in their daily lives for the management of their chronic conditions.**

In order to be effective, patient empowerment tools need to be well-integrated with the chronic disease management and care planning tools used at the clinical sites. Continuous two-way information exchange is essential to convey the care plan in clear terms to the patients and their informal care givers, to encourage them to adhere to their care plan, be in constant communication with the patient to collect and process preferences, feedback, symptoms and patient recorded data. This introduces an interoperability challenge, and results in development of custom patient empowerment tools that are tightly integrated with the chronic disease management systems mostly via proprietary interfaces, which diminishes re-usability across sites. ADLIFE utilized HL7 FHIR to design and implement an interoperable digital health ecosystem where chronic disease management systems, patient empowerment tools and Electronic Health Record (EHR) systems can be seamlessly integrated. We have positioned a standard based HL7 FHIR Repository (onFHIR.io) as the common data repository that enables seamless data exchange between local EHRs, chronic disease management platforms such as PCPMP and the PEP.

The technical development of the ADLIFE Toolbox has been done in close collaboration with target end users, i.e., patients and healthcare professionals. This is to ensure that the requirements of end users are correctly elicited and taken into account and for any remaining issues to be resolved before the deployment of the platform for use during the ADLIFE clinical pilot study. Between April and June 2022, a usability study was conducted to gather feedback and to subsequently prioritize updates to the ADLIFE toolbox before the clinical pilots are initiated at each site for the clinical pilot study. The initial usability study indicates a positive overall user satisfaction regarding the ADLIFE PEP platform, which has been well received by participants. By involving a clinical reference group composed of GPs, specialists and nurses who are working closely with patients in the development process, we have ensured that the ADLIFE PEP platform addresses the needs and preferences of our end users. This approach aligns with existing knowledge highlighting the importance of user involvement in ensuring a successful adoption of new healthcare technologies in clinical settings.

The project will use and evaluate these technology innovations in six healthcare environments across Spain, UK (two sites), Germany, Denmark, and Israel as a part of large-scale clinical pilot study that will be completed in 2024.

Implication for digital health stakeholders

- This project may be a valuable source of practical tools for care planning, patient empowerment and guidance on designing tools for physician patient collaboration.
- This project may be a valuable source as a standard based implementation guideline for addressing interoperability challenges.

Legislative, regulatory, policy or standardisation instrument, or good practice

Title

Label2Enable

Instrument status

European Commission funded project, running from 2022 to 2024

A certification scheme for CEN-ISO/TS 82304-2

Publisher or source

The Label2Enable project

URL or reference

https://label2enable.eu

Summary of the instrument

By the end of the first quarter 2024 the project is going to deliver a tested and validated CEN-ISO/TS 82304-2 certification scheme (conforming to the ISO/IEC 17065 standard for certification schemes). This scheme specifies how a European ecosystem of assessment bodies and certification bodies can enable the wide scale formal assessment and certification of health and wellness apps conforming to CEN-ISO/TS 82304-2. It

effectively transforms the content of the TS into a process and governance framework for independent app assessment and labelling that ensures consistency of the assessments across Europe.

This will be accomplished through a process of accrediting assessment organisations to implement this scheme, and the delivery of a handbook for such organisations to ensure the consistency of their assessments. The project is also establishing an oversight framework, and a process for monitoring uptake. This includes a process for identifying improvements and new areas of requirement that are needed, maintaining the scheme and handbook, and a method for feeding this into CEN and ISO to inform future updates of the TS.

The project is also engaging with health professionals and patient organisations to co-create educational communication on the label, to explore the potential of 82304-2 for uptake of (quality requirements for specific types of) apps in clinical guidelines, and how the availability of an app quality label could support clinical decision making. This includes finding out what healthcare professionals need in the detailed health app quality report to be able to recommend health apps for use by their patients and how developers should display their label effectively in app stores, app libraries and trusted sources. It will explore with health insurers and health technology assessment bodies how the Label2Enable assessment framework can help in their decision-making on reimbursement of health apps.

The project is also undertaking extensive communication and promotion about the importance of quality labelling health and wellness apps.

Implication for digital health stakeholders

- The forthcoming introduction of an app certification scheme will allow developers a route to formally demonstrate the quality of their apps to approval bodies such as HTA and to purchasers such as health systems.
- App developers also need to take on board that they will need to demonstrate the quality of their products, through certification and the label, as this will become an increasing and competitive expectation in the market, for approval bodies and purchasers.

Legislative, regulatory, policy or standardisation instrument, or good practice

Title

The XpanDH Project

Instrument status

A European Commission project

Publisher or source

The XpanDH project

URL or reference

https://xpandh-project.iscte-iul.pt

Summary of the instrument

XpanDH has the overall objective of preparing, supporting and empowering individuals and organisations to be ready and adopt the European EHR exchange format (EEHRxF) through the establishment of a network of networks and a vibrant ecosystem. The XpanDH project aims at preparing and building capacity in individuals and organisations to be ready to use the European Electronic Health Records Exchange format (EEHRxF), by establishing a pan-European effort through a Network of Networks approach, that will ensure that the involved and multiple digital health actors are motivated, inspired and supported to advance to concrete adoption of the EEHRxF by guidance and real examples organised as an aggregation of interoperability assets - the X-bundle -, around the EEHRxF. The XpanDH project pursues the main goal of maturing and accelerating a sustainable and scalable interoperability environment in Europe for digital health innovations based on the EEHRxF, involving both the supply and demand aspects. The consortium is composed of several associations with the common goal to mature and accelerate a sustainable and scalable interoperability environment for EEHRxF-based digital health innovation among EU Member States.

XpanDH will develop and publish interoperability resource bundles for particular “adoption domains” using the EEHRxF, which may be used by future implementers needing to be interoperable to this format. This will be complemented by training materials, and support communities for different stakeholder groups.

Implication for digital health stakeholders

This project may be a valuable source of practical specifications and guidance on how to adopt the EEHRxF