Digital Health Uptake

Executive Digest

Digital tools for the self-management of chronic diseases: Mode of action and conditions of market success

Topic: Digital tools for the self-management of chronic diseases: mode of action and conditions of market success

Relevance of this topic to Digital Health

Digital medical devices (digital health applications) facilitating the self-management of chronic diseases are expected to help ensure **sustainable care** in the face of aging societies, an epidemic of chronic diseases, a shortage of skilled workers and economic uncertainties. This value proposition is based on the unique potential of digital medical devices to **personalize disease management** through iterative cycles of individualized therapy adaption, thereby narrowing the gap between the efficacy of treatments seen in well controlled clinical trials and their effectiveness in real-world healthcare where real-world treatment effect modifiers are operative. Specifically, digital medical devices can continuously collect and (optionally supported by AI-powered algorithm) process health data that reflect each patient's individual health status and therapeutic needs. Automated insulin delivery systems based on the processing of continuous glucose measurement (CGM) data represent an advanced paradigm example from diabetology where people living with type 1 diabetes get relieved from the burden of multiple daily finger pricking and insulin injections. Another example is the individualization of nutritional therapy in persons with type 2 diabetes not on insulin, based on the AI-powered processing of CGM profiles. Iterative cycles of treatment individualization have been proposed in the integrated personalized diabetes management (iPDM) scheme and adopted in the guidelines for the management of hyperglycemia jointly published by the American Diabetes Association and the European Association for the Study of Diabetes.

It is widely accepted that **digital medical devices** (digital health applications) **should be positioned alongside drug therapies**, which is reflected in reimbursement policies established e.g. in Germany (DiGA fast-track), France (PECAN) and Belgium (mHealth pyramid). Evidence-based market success strategies should take into account the perspectives of various stakeholders on value propositions and its evidence at an early stage. Manufacturers should take advantage of various **co-creation** and **clinical trial formats** to address the needs and requirements of patients, health insurers, healthcare providers and regulators. **Clinical trials** should proof for medical efficacy, safety and tolerability and in addition measure patient-reported outcomes and experiences. **Randomized controlled trials** (RCTs) that incorporate measures to minimize bias are considered the gold standard for credible evidence of medical benefits, positioning digital health applications alongside drug therapies. The integration of remote decentralized, virtual or hybrid design elements may increase the external validity of RCTs. The benefit to patients can be ensured through co-creation with them, collaboration with do-it-yourself initiatives, and measurement of patient-reported outcomes and experiences in clinical trials. Digital tools should integrate into and **improve existing care pathways and platforms** while reducing workload of healthcare professionals. There is a trend towards the recognition of sustainability criteria. Digital health applications are prone to fulfil such criteria e.g. by solving cross-indication issues such as polypharmacy, frailty & disability, and cognitive impairment.

The integrated use of digital medical devices in chronic disease management opens doors for the conclusion of innovative, dynamic reimbursement agreements (“precision reimbursement“) involving manufacturers, healthcare providers, health insurers, and patients - based on the continued proof of real-world evidence (RWE) from the (AI-powered) analysis of constantly collected real-world data (RWD).

By lowering the risk of complications and reducing hospital visits for ambulatory care-sensitive conditions through a highly personalized self-management, digital health technologies contribute to more cost-effective healthcare, benefiting both patients and entire healthcare systems. If healthcare providers manage to assess the level of digital health literacy of the person living with chronic conditions, **personalized tools can be advised** to them, which would help to tailor the disease management and the treatment to the needs and requirements of the individual patient. This personalization could include **patients receiving different models of care in their local community** – instead of automatically defaulting to medication, healthcare providers could “in theory” prescribe technology solutions in return for patient’s sharing their data or prescribing services in their local community (e.g. gym memberships, health cooking classes, etc...). Combining “precision reimbursement” with smart forms of incentivisation for various stakeholders could create a new sense of collaboration, responsibility and effectiveness in healthcare.

Keywords

Empowerment, data collection, personalized management, continuous monitoring, informed decision-making

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

the European Parliament and the Council reached a political agreement on **European Health Data Space** (EHDS) in April 2024. According to EHDS, all data collected from different sources, including the electronic health records, health data from apps, from digital health applications, other devices, but also data which are available in health data registries shall be used primarily for improving the treatment of patients. These data shall be used to enable an earlier diagnosis and a more personalized therapy of persons with chronic disease, following the goal to increase healthcare effectiveness. In addition, there is also a secondary use of this data possible by different stakeholders, including public research organizations, but also pharmaceutical and medtech industries in order to conduct further research to design policies for healthcare provision, but also to develop more treatments, drugs and medical devices addressing the individual patient's needs and requirements.

The **European Medical Device Regulation** (MDR) came into force on 26 May 2021. MDR governs the development, production and distribution of medical devices in Europe. Compliance with this regulation is mandatory for medical device companies (that want to market or sell their products in the European Economic Area, therefore MDR ensures the security and compliance of devices for the benefit of patients and HCP). The MDR takes a differentiated, risk-based approach to whether medical device manufacturers are required to implement clinical investigation as part of their mandatory pre- and post-market clinical evaluation.

Implications for digital health uptake

Developers

- By implementing a participative approach involving stakeholders (co-creation) in the digital tool/device development, including persons living with chronic disease, healthcare providers, and payers, the acceptance of digital health applications is likely to increase. Compliance with regulations and the quality of the evidence generation are key determinants for market acceptance of digital medical devices.
- It is equally important to achieve a cultural shift regarding the perception of the ethical obligation to share health and treatment data and create new solutions facilitating the responsible integration and use of data for the common good.

Enablers

- Providing clear, evidence-based insights on the benefits and outcomes of digital solutions at the levels of each individual patient and each stakeholder in chronic care.
- Provision of intuitive and actionable information rather than mere data collection.

Payers and procurers

- Changing the narrative around "healthcare spend" or "technology spend" into "investment" as the benefit will be seen by healthcare providers further down the line with reduced expense per patient. Models for risk sharing between different stakeholders should be developed.
- With their reimbursement policies, health insurance companies play a decisive role when it comes to incentivising the uptake of digital tools. Health insurers should be involved at an early stage to achieve a good market fit.

Users

- Empowering users to enable them to take control of their long-term medical conditions. Citizens living with disease need confidence to take informed decisions around their personal health and care.
- Persons living with chronic conditions are the owners of their health data. They should be incentivised to share their data with different audiences. Citizens could be incentivised in return for access to technology solutions or services. They could even be "prescribed" technology in return for access to their data**.**

Remaining gaps and issues

New digital solutions are created every day for all sorts of challenges but instead perhaps the **already existing "off the shelf' platforms"** which meet global standard and are used extensively should be **better integrated** first. These solutions are more likely to be trusted to share data.

Persons living with chronic conditions are not well aware that it is their decision to **share their health data** and/or they are not sufficiently incentivised to share their data for further research which could improve their and many of their peer citizens' life. **Cybersecurity** is also an obstacle to data sharing. Trusted systems and institutions are needed for data storage and processing to increase confidence and willingness of the data owners.

Data collected via digital tools for patients **cannot be integrated with clinical data** and healthcare providers will also be reluctant to do so if they cannot interpret the data or it increases their workload. Tools for clinical data collection and patient or wellness tools are often not interoperable. Patient tools should also have a parallel tool of high usability for HCPs so that they can understand and analyse the data. This would allow HCPs to have access to data from the "grey areas" of everyday life such as nutrition, sleep, physical activity, etc.

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Legislative, regulatory, policy or standardisation instrument, or good practice
Title
Transforming diabetes care through innovation (Report)
Instrument status
Published
Publisher or source
Transforming Diabetes Care through Innovation is a project undertaken by the Digital Health and Care Innovation Centre (DHI) on behalf of the Scottish Health and Industry Partnership (SHIP) and the Scottish Diabetes Innovation Technology Group.
URL or reference
https://www.dhi-scotland.com/learning/resources/transforming-diabetes-care-through-innovation/
Summary of the instrument
The project aimed to map the current diabetes innovation landscape, gathering an overview of innovation projects undertaken in Scotland with the potential to impact the experiences of people living with diabetes in the next five years. Through engagement with people living with diabetes and relevant health, care and third sector professionals, it sought to understand unmet needs and identify gaps in the diabetes innovation landscape. This will inform future innovation funding calls for diabetes that are centred on the needs and aspirations of people living with diabetes and the professionals who support them.

Legislative, regulatory, policy or standardisation instrument, or good practice
Title
User Requirements for Co-Managed Digital Health and Care (Whitepaper)
Instrument status
Published
Publisher or source
Digital Health & Care Innovation Centre
URL or reference
https://www.dhi-scotland.com/learning/resources/user-requirements-for-co-managed-digital-health-and-care/
Summary of the instrument
This whitepaper is produced by the Digital Health & Care Innovation Centre and summarises a peer-reviewed journal article, published in the Journal of Medical Internet Research, that presents a set of recurring user requirements and themes for co-managed digital health and care services from a body of co-design projects within a digital health and care programme. The paper aims to support knowledge sharing to enable people and organisations to re-orient their health and care transformation from a system-led and condition-specific approach to a more person-centric, whole-of-life model.

Legislative, regulatory, policy or standardisation instrument, or good practice
Title
Integrated personalised diabetes management goes Europe (iPDM-GO)
Instrument status
EU innovation project co-funded by EIT Health. Project has finished.
Publisher or source
Jones, A, et al., Integrated personalized diabetes management goes Europe: A multi-disciplinary approach to innovating type 2 diabetes care in Europe. https://pubmed.ncbi.nlm.nih.gov/33184011/
URL or reference
https://eithealth.eu/product-service/ipdm-go/
Summary of the instrument
Despite a plethora of therapeutic approaches many people with diabetes fail to reach their treatment goals. Integrated personalized diabetes management (iPDM) has been shown to improve clinical outcomes, treatment satisfaction and adherence, and developed tools for implementing value-based healthcare in diabetes management.
Implication for digital health stakeholders
Digitally supported personalized diabetes management with a data-based centering around the individual patient.

Legislative, regulatory, policy or standardisation instrument, or good practice
Title
CLOSE (Automated glucose control at home for people with chronic disease)
Instrument status
Innovation project co-funded by EIT Health. Project has finished.
Publisher or source
Schliess, F. et al., Artificial Pancreas Systems for People With Type 2 Diabetes: Conception and Design of the European CLOSE Project. https://pubmed.ncbi.nlm.nih.gov/30241444/ Reznik, Y. et al., Should people with type 2 diabetes treated by multiple daily insulin injections with home health care support be switched to hybrid closed-loop? The CLOSE AP+ randomized controlled trial. https://pubmed.ncbi.nlm.nih.gov/37921083/
URL or reference
https://eithealth.eu/product-service/close-project/
Summary of the instrument
CLOSE develops and deploys an integrated package centered on closed loop metabolic control for severely ill patients with T2DM. CLOSE will boost homecare service provision, improve quality of life of patients and their families, and increase the sustainability of health care systems.
Implication for digital health stakeholders
Paradigm example for the co-development of a digital medical device.

Legislative, regulatory, policy or standardisation instrument, or good practice
Title
RealWorld4Clinic (Real-World Cardio-Respiratory Health Monitoring for Clinical Contract Research & Telecardiology)
Instrument status
Pan-European innovation project co-funded by EIT Health. Project has finished.
Publisher or source
Schliess, F. et al., The German Fast Track Toward Reimbursement of Digital Health Applications: Opportunities and Challenges for Manufacturers, Healthcare Providers, and People With Diabetes. https://pubmed.ncbi.nlm.nih.gov/36059268/
URL or reference
https://eithealth.eu/product-service/realworld4clinic/
Summary of the instrument

RealWorld4Clinic has been designed to launch a medical device for collecting and processing health data in tele-cardiology and clinical contract research
Implication for digital health stakeholders
Opportunities in tele-cardiology and for the design of Remote Decentralized Clinical Trials.

Legislative, regulatory, policy or standardisation instrument, or good practice
Title
Fast Forward – Next Level Healthcare
Instrument status
Implemented for the first time in 2024. The application phase for participation in the programme ran from 18 June 2024 to 30 July 2024, after which the participants are now being selected, and the collaboration will begin.
Publisher or source
GWQ ServicePlus AG
URL or reference
https://www.gwq-serviceplus.de/veranstaltungen/fast-forward-next-level-healthcare/das-programm
Summary of the instrument
This format aims to promote promising cooperation opportunities between providers of digital healthcare solutions and statutory health insurance (SHI) companies. The aim is to initiate collaboration at an early stage in order to jointly develop, validate, and promptly implement innovative ideas for improving healthcare. Mixed team constellations, consisting of employees from the providers of digital healthcare solutions and the health insurance environment, promote mutual learning and enable access to additional know-how and the expertise of the respective partners. Interested providers of digital healthcare solutions apply with their co-creation idea and describe the expected added value of the collaboration. After the application, an expert jury will select the most promising ideas for the co-creation phase and teams will be put together. This is followed by an 8-week work phase to develop and validate the idea, which ends with a results pitch in front of the jury. The aim is to realise the validated concepts together as soon as possible.
Implication for digital health stakeholders
Providers of digital healthcare solutions and statutory health insurance (SHI) companies work together in the early stages of an idea to develop and validate it. In this way, health insurers can actively co-develop innovative ideas for healthcare and ensure that they comply with the regulatory and legal framework conditions of the SHI market. As a result, the ideas of providers of digital healthcare solutions are more likely to be accepted by the market, which improves the financing of their projects. This ultimately enables faster implementation and wider acceptance of innovative ideas in the SHI market.

Legislative, regulatory, policy or standardisation instrument, or good practice
Title
Healthy Hub
Instrument status
Started in 2017; 5 competitions held to date
Publisher or source
Healthy Hub
URL or reference
https://www.healthy-hub.de/home.html#start
Summary of the instrument
The Healthy Hub is a consortium of four statutory health insurance funds in Germany. They organise competitions for providers of digital healthcare solutions in order to jointly develop selective contractual reimbursement models and to use the solutions in pilot projects under real market conditions in healthcare practice. This makes the Healthy Hub a springboard for market entry into the primary healthcare market.
Implication for digital health stakeholders
Patients of the participating health insurance companies benefit from innovative healthcare solutions at an early stage.

Executive Digest

Start-ups and providers of digital healthcare solutions learn how the SHI market works and how their ideas are received there. Together, care structures are created that make it easier for digital health start-ups to enter the SHI market and expand.

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