



D4.2 - Policy Proposal on People Empowerment

WP4 - Empowering People

26/10/2020

Version 1.0

18th eHealth Network meeting, November 2020

Final, For Adoption

Grant Agreement nº 801558



Co-funded by the European
Union's Health Programme
(2014-2020)

To pave the way for a European policy proposal on people empowerment, this framework proposes an analytical approach to empowering people through digital health, and maps common issues to be addressed at Member State and EU level.

CONTROL PAGE OF DOCUMENT	
Document name	D4.2 - Policy Proposal on People Empowerment
Work Package	WP4 - People Empowerment
Dissemination level	CO
Status	Final
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Beneficiary(ies)	SPMS

Dissemination level:

PU = Public, for wide dissemination (public deliverables shall be of a professional standard in a form suitable for print or electronic publication) or CO = Confidential, limited to project participants and European Commission.

REVISION HISTORY				
Revision	Date	Authors	Organisations	Description
0.1	22/01/2020	Priit Tohver, Elise Peters, Karlijn de Bruin	MoSA, Nictiz	First version of the document to QM
0.1a	24/01/2020	Hugo Agius Muscat, Vivian Brincat	MFH	QM review
0.2	21/02/2020	Priit Tohver, Elise Peters, Karlijn de Bruin	MoSA, Nictiz	Second version of the document to QM
0.2a	24/02/2020	Hugo Agius Muscat	MFH	QM review of version 0.2
0.2b	11/03/2020	Priit Tohver, Elise Peters, Karlijn de Bruin	MoSA, Nictiz	Final draft version of the document for LC and SC
0.3	28/08/2020	Priit Tohver, Elise Peters, Karlijn de Bruin	MoSA, Nictiz	First version for QM
0.3a	06/09/2020	Hugo Agius Muscat	MFH	QM review of v0.3
0.4	23/09/2020	Elise Peters, Karlijn de Bruin	Nictiz	Fourth draft version of the document
0.4a	4/10/20	Hugo Agius Muscat	MFH	QM review of v0.4
0.4b	7/10/20	Elise Peters, Karlijn de Bruin	Nictiz	Final version of the document for LC
0.5	16/10/20	Elise Peters, Karlijn de Bruin	Nictiz	Final version of the document for SC
1.0	26/10/20	Elise Peters, Karlijn de Bruin	Nictiz	Final version of the document for eHN

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Acronyms

Acronym	Description
AAL	Ambient Assisted Living
AMO	Ability, Motivation, Opportunity model
BfArM	Federal Institute for Drugs and Medical Devices (Germany)
CCIO	Chief clinical informatics officers
CEN	Comité Européen de Normalisation
CMIO	Chief medical informatics officer
CNIO	Chief nursing informatics officer
CPO	Chief patient officer
D4.1	Deliverable 4.1 Patient Empowerment Framework
D4.2	Deliverable 4.2 Patient Empowerment Policy Proposal
DHL	Digital Health Literacy
DTS	Draft Technical Specification
eHAction	eHealth Action
eHealth	Electronic Health
EHDS	European Health Data Space
EHII	European Health Information Initiative
EHMA	European Health Management Association
eHN	eHealth Network
eHTM	eHealth Trust model
EHR	Electronic Health Record
EIP AHA	European Innovation Partnership on Active and Healthy Aging
EMSA	European Medical Student Association
EPF	European Patients' Forum
EU	European Union
EUnetHTA	The function of the scientific and technical cooperation of the HTA Network.
GDPR	General Data Protection Regulation
GP	General Practitioner
HBCSSs	Health Behaviour Change Support Systems
HCP	Health Care Provider
HP	Health Professional
HTA	Health Technology Assessment
ISO	International Organization for Standardization
ITU	International Telecommunication Union
IVDR	In Vitro Diagnostic Medical Device Regulation
JAsEHN	Joint Action to support the eHealth Network
LTC	Long-term care
MARS	Mobile App Rating Scale
MDR	Medical Devices Regulation

MedCERTAIN	MedPICS Certification and Rating of Trustworthy Health Information on the Net
mHealth	Mobile Health
MOOCs	Massive Open Online Courses
M-POHL	The WHO Action Network on Measuring Population and Organizational Health Literacy
MWP	Multiannual Work Programme
NHS	National Health Service
PGHD	Patient Generated Health Data
PICS	Platform for Internet Content Selection
RDF	Resource Description Framework
ReEIF	Refined eHealth European Interoperability Framework
SIDA	Swedish International Development Agency
SMEs	Small and medium sized enterprises
UCD	User-centred design
UNDP	United Nations Development Programme
UNICEF	United Nations' Children's Fund
USAID	United States' Agency for International Development
VIPP	Acceleration Programme for Patient and Professional Information Exchange
WHO	World Health Organization
WP	Work Package
WP4	Work Package 4 – People Empowerment
XML	Extensible Markup Language

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Executive summary

The strategic goal of the eHealth Network (eHN) with regard to empowering people is to work towards the implementation of patient-centred eHealth solutions in all Member States and to provide people with the adequate digital tools and skills for people empowerment. Therefore, the purpose of this document is to present a policy proposal with a list of priorities and recommendations for adoption by the eHN in order to improve the empowerment of their citizens. This policy proposal builds upon the Policy Framework on People Empowerment (eHAction Deliverable 4.1), which was delivered and adopted during the 16th eHN meeting in November 2019.

The key gaps highlighted in the D4.1 Policy Framework were developed into nine priority areas for this proposal:

1. Legislation
2. Trust as key
3. Integration & interoperability
4. Quality standards & assessment
5. Users at the centre
6. Digital Health Literacy of people
7. Behavioural change through motivation
8. Awareness/involvement of the social environment
9. Awareness/involvement of health professionals

The indicated priorities for this policy proposal are plotted on one or more elements of the Ability, Motivation, Opportunity (AMO) framework. Each priority area will present a limited number of recommendations taking into account ongoing activities within the European Union in order to target critical unmet needs. The recommendations are presented to a broad list of stakeholders, each of whom should critically assess which policy actions are most needed in their context. The adoption of this policy proposal at the level of the eHealth Network would not in itself entail adopting the recommendations it contains, but it would signal to Member States, stakeholders and the European Commission that the recommendations within this document are important and should be considered for policy action where relevant, in line with national strategies and priorities. The list of recommendations (excluding actors) can be read below:

1. Apply the AMO framework when developing and implementing policy on empowering people.
2. Develop common digital health services guidance (complying with EU Web Accessibility Directive, the key objectives of the user-centred design process and universal design principles) for design and development of user-centric digital health technologies.
3. Involve end-users in all phases of policy from policy-shaping to implementation and evaluation. Ensure a 'whole system in the room' process where patients and health professionals are involved and represented at eHN and within national policy bodies dealing with digital health.

4. Address DHL within existing policies before operationalising such policies by embedding digital health literacy goals into strategies that take a multi-layered and multi-faceted approach to achieving such goals by:
 - Exploring the different target groups and needs with regard to digital health literacy (e.g. low-literate people, blind people) and adapt these findings to the solutions, e.g. by including these different groups in test scenarios.
 - Funding and supporting national, regional or community projects that tackle digital exclusion and prioritise vulnerable groups.
 - Establishing additional supports for patients with chronic conditions that rely on the use of eHealth systems and technologies for the ongoing management of such lifelong conditions.
5. Incorporate digital health literacy into the education system including:
 - Formal and informal digital health literacy education in primary and secondary level school curricula, as per the recommendations of the EU eHealth Task Force 2012 report on Redesigning Health in Europe 2020, which recommended supporting health literacy by teaching it in schools.
6. While developing and deploying tools to increase patients' and health professionals' trust in empowering digital technology follow or use eHTM as a reference model.
7. In accordance with the eHTM, identify or develop reliable ways of measuring trust and trustworthiness and objective third-party system evaluation systems.
8. Establish safe testing and experimentation facilities including functions such as regulatory sandboxes or policy labs for the development of new eHealth applications. A recent EU workshop report indicates for instance that regulatory sandboxes could be an important part of future AI Testing and Experimentation Facilities. One of the priorities set out in the new Commission mandate is the creation of a European Health Data Space (EHDS), which would foster the exchange, and sharing of different kinds of health data, thus supporting the delivery of primary care as well as the development of new treatments, medical devices and services. A policy lab, or similar type of facility, is mainly intended to be used for the evaluation of new methodologies from a legal/regulatory perspective, thereby avoiding the risk for major problems regarding, for example, breaches of personal data, compromising individuals' privacy and similar backlashes that may quickly have a negative impact on people's trust. Consequently, this recommendation of the eHAction, is well aligned with, and supports the development of EHDS.
9. Use the Quality Requirements Conformity Assessments to identify what could be the minimum requirements, preferences and dissatisfiers for people using eHealth and telehealth related solutions and apps. Find, recruit, educate and train healthcare professionals to assist and motivate them to identify and understand patients' non-negotiables (minimal requirements), differentiators (preferred advantages) and dissatisfiers (trade-offs or the facts that could be accepted only if differentiators are provided), in order to enable them to guide and coach potential users of digital health services. Curricula of the training programmes shall also provide sufficient

knowledge and improved skills and competences to use the information that Quality Requirements Conformity Assessments can offer.

Programmes to develop proper curricula and implement recruitment and training activities, are recommended to be financed and funded by local, national and cross-border resources.

10. Develop and sustain tangible services and clear/transparent protocols for satisfying concrete needs to motivate people to use virtual or digital devices, apps or other available solutions for and/or promotion, prevention, treatment and rehabilitation. For improving satisfaction of (unmet) needs, foster and assist citizens, healthcare providers and other key stakeholders (e.g. payers) to identify and share their non-negotiables (minimal requirements), differentiators (preferred advantages) and dissatisfiers (trade-offs or the facts that could be accepted only if differentiators are provided) regarding the use of virtual or digital solutions. To help people to understand who is capable to provide non-negotiables and differentiators assistance is needed to contact them. Find, recruit, educate and train staff to assist and motivate health workforce to identify and understand patients' non-negotiables, differentiators and dissatisfiers.

Also, provide information about state of health, diseases or changes in health status, as well as treatment options, required behaviours, and place it in the patient-provider relations using these digital/gamified solutions.

11. Prioritise online support and digital learning opportunities (instead of face to face) for informal caregivers to receive necessary information about caregiving, share experiences and feel more confident in patient care. Prioritise online support and digital learning opportunities (instead of face to face) for informal caregivers to receive necessary information about caregiving, share experiences and feel more confident in patient care using the following tools:
 - 1) Information and communication tools - disseminating information among caregivers about the possibility of online communication on patient care issues, for example, disseminating information about online support and digital learning opportunities through a family doctor, municipality or mass media (newspapers, news).
 - 2) Knowledge and innovation instruments - provide the necessary training for care professionals jointly increasing their knowledge by engaging in social learning and improving communication skills with informal caregivers, to be able to support, motivate and teach them the necessary skills for patient care. And also provide technical capabilities (online platforms) where care professionals can communicate with informal caregivers.
 - 3) Economic and fiscal instruments - provide an opportunity for care professionals to conduct online support and digital learning, receiving payment for this from the municipality or government, thereby motivating care professionals.
12. Promote the advancement of digital skills for health professionals, giving due attention to digital health for empowerment (including the topics of mHealth, patient access and use of data, digital health literacy and telehealth as a part of patient centric care) through short term trainings, continuing professional development and

inclusion in medical school curricula. This can be facilitated through an online training with a certificate when accomplished.

13. Foster the creation of roles such as chief medical informatics officers (CMIO) and chief nursing informatics officers (CNIO) in HCPs with over 100 employees who can create a bridge between their expertise of being a health professionals and ICT by defining an European standardized profile in order to determine tasks and responsibilities.
Involve CMIO's and CNIO's in co-creating a health system that facilitates the uptake of digital health, e.g. by providing a similar function within ministries.
14. Create a mandatory certification scheme for the industry, MS, etc. for co-creating with HP's when developing digital health solutions. (This is also indicated in the ISO DTS 82304-2:2020 in 5.2.1.6; 'are health professionals involved in the development of the health app?')
15. Collaboration at European level for the harmonisation of national laws and regulatory frameworks for the secure exchange of health data, in accordance to the GDPR, and in relation to the interoperability of Member State electronic record systems and the implementation of the European electronic health record exchange format. Such collaboration could take the form of an expert dialogue or subgroup on implementing legislation focused on the application of patients' rights in cross-border healthcare (Directive 2011/24/EU) with sub-groups focused on specific issues like interoperability. This will create an opportunity to share experience on legal issues in the context of the cross-border directive, taking into account data privacy, data integrity, access, ownership and sharing.
16. Study or adapt existing legal frameworks applicable to patient access, telehealth, mHealth and telemedicine in order to achieve people empowerment building on the work of the MS and EU legislation, to identify "grey" areas that need to be clarified and gaps that need to be closed.
17. Develop a policy proposal to define a uniform regulatory framework for telemedicine as a recommendation to the European Commission for decision making. In particular, the framework should address liability issues, defining telemedicine as a service and distinguishing from any other ICT use in healthcare, and define telemedicine's role in cross-border healthcare.
18. Use proven funding schemes for co-creation (stand-alone twinning scheme) of empowering digital health solutions between vendors and procurers to promote integration and interoperability at the point of development, making sure of the sustainability of the project once the funding runs out.
19. Create a European framework for integration of individual health information (PGHD) in EHR services and functions, able to submit health information by patient and HCP (e.g. MedMij). This needs to be done in a secure way and complying with privacy regulations. This European framework aims to facilitate the collection and use of patient generated health data in clinical care. The objectives are also very clear: improving outcomes, enhancing patient experience, focus on prevention rather than reaction, better use of financial resources.

20. Endorse and implement CEN-ISO/DTS 82304-2 as the common framework for quality and reliability of health apps. This framework has already been referenced in the EU Toolbox for Covid tracing apps. Assess in how far this framework can help harmonisation of national approaches and whether it also helps digital health assessment beyond the area of apps.
21. Establish a dialogue for an open exchange among those responsible for application libraries and assessment frameworks. Let the mHealth hub and involved people on 82304-2 study the minimal requirements for quality assessment on a European and a national level, e.g. starting with COVID-19 apps.
22. Establish follow up funding to enable and facilitate implementation of the common framework. Support and monitor uptake of the common framework and mHealth by healthcare authorities and providers and in efficient public funding (reimbursement), in line with the Digital Single Market communication. Consider role of the European Commission in implementation of the 82304-2 Health App Quality Label in application libraries, to empower citizens who seek to use health apps without a prescription by their provider.

1. Background

This policy proposal is a deliverable of eHAction Work Package 4 (WP4) – Empowering People, led by Estonia (MoSA) and the Netherlands (Nictiz). The four topics of this policy proposal on empowering people are mHealth, telehealth, patient access and use of data, and digital health literacy. This policy proposal builds upon the Policy Framework on People Empowerment (eHAction Deliverable 4.1), which was delivered and adopted during the 16th eHealth Network (eHN) meeting in November 2019.

1.1 Purpose

eHAction is a Joint Action of the Member States supporting the eHealth Network (eHN) and the third Multiannual Work Programme (MWP) 2018-2021¹. People empowerment is one of the four priority areas in this MWP. This policy proposal is aligned with the strategic goal of the eHN to work towards the implementation of patient-centred eHealth solutions in all Member States and to equip people with the adequate digital tools and skills for people empowerment. Therefore, the purpose of this document is to present a policy proposal with a list of priority areas and recommendations for adoption by Member States in order to improve the empowerment of their citizens. These areas have been selected based on key gaps identified in the Policy Framework, taking into account ongoing activities within the European Union in order to target critical unmet needs. The recommendations are presented to a broad list of stakeholders, each of whom should critically assess which policy actions are most needed in their context. The adoption of this proposal document at the level of the eHealth Network would not in itself entail adopting the recommendations it contains, but it would signal to Member States that the recommendations within this document are important and should be considered for policy action where relevant, in line with national strategies and priorities.

Examples of barriers and enablers encountered within the Member States are a lack of reimbursement models, privacy concerns and legal restrictions. However, it is important to address the areas which are of the highest priority. Therefore, a list of priority areas has been created with the help of the Member States and related stakeholders. The list consists of nine priority areas and will be discussed in section 1.3.

1.2 Method

The D4.1 Policy Framework on People Empowerment was used as input for selecting the priority areas. A preliminary list of priority areas was discussed with Member States and stakeholders and divided among the contributors for further analysis. Contributors were asked to gather information about the area, search for existing literature and programmes and eventually formulate recommendations based on this information, highlighting aspects where the Joint Action could add value.

WP leaders consulted with WP4 related stakeholders via a short survey about the priority areas (Appendix 2). The stakeholders involved with the Policy Proposal included the European

1 Multiannual Work Programme 2018-2021. https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20171128_co01_en.pdf

Patients' Forum (EPF), Stichting Ikone, AGE Platform Europe, European Health Management Association (EHMA), European Innovation Partnership on Active and Healthy Aging (EIP AHA), European Medical Student Association (EMSA) and the European mHealth Hub. Feedback from the survey was sent to the contributors of the corresponding priority areas as input for their contribution. The European Commission and other experts on empowerment were likewise consulted and feedback was relayed to the contributors. The results of the analysis of priority areas were discussed during a webinar together with the stakeholders, on 20th January 2020.

1.3 Ability, Motivation, Opportunity (AMO) framework and priority areas

The nine priority areas are:

1. Legislation
2. Trust as key
3. Integration & interoperability
4. Quality standards & assessment
5. Users at the centre
6. Digital health literacy of people
7. Behavioural change through motivation
8. Awareness/involvement of the social environment
9. Awareness/involvement of health professionals

As per the definition used in the Policy Framework, empowering people permits them to gain control of their health and increases their capacity to act on issues they consider important². By introducing the AMO framework³ in the Policy Framework, the underlying elements (AMO) influencing the behaviours of empowered people were explained⁴. The indicated priorities for this policy proposal can be plotted on one or more elements of the AMO framework on empowering people (see figure 1).

² European Patients' Forum <http://www.eu-patient.eu/whatwedo/Policy/patient-empowerment/>

³ eHAction (2019). D4.1 policy framework on empowering people

⁴ Appelbaum, E. Bailey, T. Berg, P. & Kalleberg, A. (2000) Manufacturing advantage: Why high-performance work systems pay off. Ithaca, Cornell University Press



Figure 1. Priorities plotted on the AMO framework on empowering people

1.4 Adapting the Refined eHealth European Interoperability Framework (ReEIF) model to people empowerment

One of the inputs to this policy proposal is the Refined eHealth European Interoperability Framework (ReEIF). As is known, the ReEIF model is used as a model for pursuing interoperability. The ReEIF model describes the interoperability world via a six-level model, with actors and activities on each level, which can be used to accelerate the ongoing transformation process in order to increase eHealth interoperability. However, it can also be useful for organising one's thinking around empowering people, which also needs to account for the different levels of managing change when introducing empowering approaches⁵. Much like in interoperability, empowering (digital) health systems need to apply interventions within the eight domains of the ReEIF model. However, the relevant issues within those domains can diverge significantly when shifting the focus from interoperability to empowerment, as the latter is far broader in scope and must consider as its starting point the need for patients to

⁵ eHealth Network. Refined eHealth European Interoperability Framework. (2015). Retrieved from: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf

take control over their own health. Therefore, this policy proposal considers the ReEIF model when structuring the priorities and recommendations, but it cannot be the main focus of this document due to its specificity.

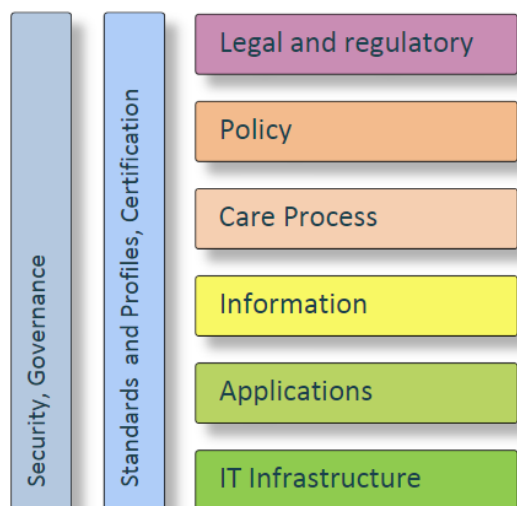


Figure 2. Refined eHealth European Interoperability Framework (ReEIF) model

2. Recommendation focused on the AMO framework

Empowering people permits them to gain control of their health and increases their capacity to act on issues they consider important². Empowered people:

- have the requisite skills to use digital tools for their health, e.g. digital and health literacy (ability);
- have the motivation to take action on and care of their own health, e.g. access and use their health data (motivation);
- have the requisite digital solutions to guide them, e.g. mHealth and telehealth (opportunity)⁶.

People are empowered when all of the above elements are fulfilled, as each of them influence and are dependent upon each other. A framework was created in order to change the behaviour of people: the AMO framework on empowering people. This framework is introduced in our D4.1 Policy framework on empowering people.

The empowering people framework builds further on the AMO framework on changing behaviour, a structure used to link practices to behaviour building on three elements: **ability, motivation and opportunity**⁷. The grounds of the framework lie in the assumption that taking action of your health is a function of capacity to perform (ability), willingness to perform (motivation), and circumstances to perform (opportunity)^{8,9}.

In the D4.1 Policy Framework, we've adapted the AMO framework, specifying it to health and empowerment. The result can be found below:

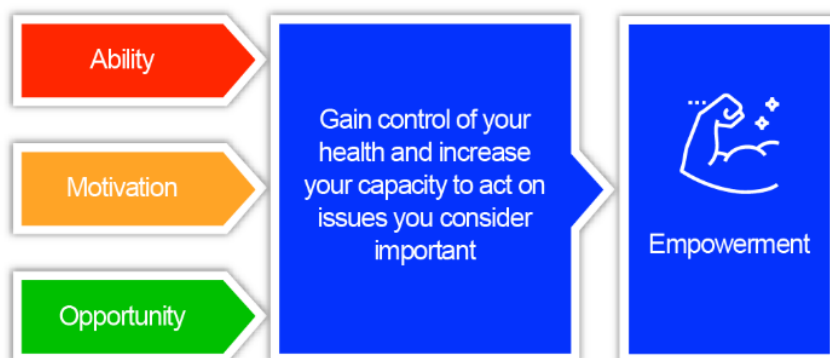


Figure 3 AMO framework on People Empowerment

⁶ D4.1 Policy Framework on People Empowerment

⁷ Juan A. Marin-Garcia¹, Juan Martinez Tomas. (2016). Deconstructing AMO framework: A systematic review. <https://www.intangiblecapital.org/index.php/ic/article/view/838/574>

⁸ Appelbaum, E. Bailey, T. Berg, P. & Kalleberg, A. (2000) Manufacturing advantage: Why high-performance work systems pay off. Ithaca, Cornell University Press

⁹ MacInnis et al. (1991). Enhancing and Measuring Consumers' Motivation, Opportunity, and Ability to Process Brand Information From Ads. Retrieved from: <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.625.7542&rep=rep1&type=pdf>

In November 2019, Member States of the EU eHealth Network unanimously adopted the Policy Framework on Empowering People, espousing the AMO framework as a critical success factor in applying digital health for empowerment. Therefore, when working on one of the recommendations made in this document or any other solution to achieve empowerment, the AMO framework should be used as the basis.

Recommendation

Ref.	Action	Actors
1	Apply the AMO framework when developing and implementing policy on empowering people.	eHN, Member States, national and regional health authorities, health technology companies

3. Recommendations focused on ability

In this chapter, the priority areas with the main focus on the ability element of the AMO framework will be described. These priority areas are 'Users at the centre' and 'Digital health literacy of people'. **Ability** refers to the extent to which people have the necessary competences (e.g. knowledge and skills) in order to engage in their own or others' health¹⁰.

3.1 Users at the centre

Putting users at the centre of digital health innovations

A common barrier to adopting empowering digital health solutions is a lack of focus on users, such as patients¹¹. Successful digital initiatives should be rooted in an understanding of user characteristics, needs and challenges. Mobile applications and other IT solutions need to be produced with adequate consideration of the needs of their intended users so that they are easy to use and perceived as useful¹². In healthcare, already burdened with suboptimal outcomes and excessive costs, premature adoption of untested technologies may limit positive health behaviour change. Digital tools may then ultimately fail to accomplish their objectives and may be ineffective or, at worst, yield adverse outcomes¹³. For instance, IT solutions enabling remote contact with a physician may improve access to care services for those living in rural areas, leading to more equitable access. At the same time, however, new forms of communication may reduce access for those whose digital ability is lower (see Chapter 2.2).

User-centred design starts with getting to know the people you are designing for through conversation, observation, and co-creation. Information gathered through the engagement leads to building, testing, and redesigning tools until they effectively meet user needs. By designing with the users, and not for them, you can build digital tools to better address the specific context, culture, behaviours, and expectations of the people who will directly interact with the technology. Some evidence shows that when the needs of potential users of the digital health technologies are considered from the beginning and found it to be usable and useful, the implementation process of these technologies may be more successful^{14,15}.

Inclusion motivates users

Plotted on the AMO framework, the priority area 'Users at the centre' could be placed at the Ability area because digital technologies should be designed in such a way as to meet the level of patients' digital skills. Patients should have the ability to use digital devices. The Motivation

¹⁰ <https://www.ukessays.com/essays/commerce/the-amo-model-theoretical-framework-commerce-essay.php>

¹¹ Joint Action to Support the eHealth Network (eHAction). Policy Framework on People Empowerment. 2019.

¹² Schnall, Rebecca, et al. "A user-centered model for designing consumer mobile health (mHealth) applications (apps)." *Journal of biomedical informatics* 60 (2016): 243-251.

¹³ Nilsen, Wendy, et al. "Advancing the science of mHealth." *Journal of health communication* 17.sup1 (2012): 5-10.

¹⁴ McCurdie, Tara, et al. "mHealth consumer apps: the case for user-centered design." *Biomedical instrumentation & technology* 46.s2 (2012): 49-56.

¹⁵ McDaniel, J. G. "The user-centered approach in the development of a complex hospital-at-home intervention." *Advances in Information Technology and Communication in Health* 143 (2009): 328.

aspect plays a substantial role in this priority area as well. When the user understands and can make use of a digital initiative, the motivation to do so increases.

Solutions proposed and added value to putting users at the centre in the EU

Early and active involvement of the users should take place at various levels from policy development to product design, development, and evaluation.

Some international documents and standards draw attention to the importance of the user-centric approach and its role in the development of digital health solutions. The World Wide Web Consortium has summarised a user-centred design process (UCD)¹⁶, which considers multiple frameworks and mirrors some elements of the International Organization for Standardization's multi-part standard, ISO 9241-210. The key objectives outlined in this standard are: the solution should be useful in helping users achieve their goals, effective (i.e. producing results with minimal user error), learnable (i.e. easy and intuitive to use), and likeable (i.e. enjoyable to use).

A report from Accenture¹⁷ finds that two-thirds of America's largest hospitals offer mobile apps to their patients, but only 2 per cent of those patients are using them. This points to a continuing concern that developers of health technologies are not figuring sustainability into their strategies and therefore lose patients' interest. Moreover, low user centricity might be one of the key factors leading to low levels of recognition and uptake.

EU Web Accessibility Directive (EU) 2016/2102¹⁸, in force since 22 December 2016, provides people with disabilities with better access to the websites and mobile apps of public services. The Directive is based on the principle that making websites and apps more accessible results in overall better user experience for everyone, not only for users with disabilities. The Directive refers to specific standards to make technologies more accessible; requires the publication of an accessibility statement for each website and mobile app; calls for a feedback mechanism; and expects regular monitoring of public sector websites and apps by the Member States.

Based on the work of a group of 10 experts on universal design, in 1997 the Centre for Universal Design in North Carolina State University published the seven principles of universal design¹⁹. The purpose of these principles is to articulate the concept of universal design in a comprehensive way, and they are intended to be applied to all environments, products, and communications. Application of the seven principles highlights that universal design requires the integration of accessibility and usability features from the onset, removing any stigma and resulting in the social inclusion of the broadest diversity of users. That is, universal design is clearly distinguished from accessible design.

¹⁶ User Centered Design Process [online] Available at: <https://www.w3.org/WAI/redesign/ucd> [Accessed 5 June 2020].

¹⁷ Losing Patience: Why Healthcare Providers Need to Up Their Mobile Game. [online] Available at: https://www.accenture.com/t20151112T042615__w__/us-en/_acnmedia/Accenture/Conversion-Assets/DotCom/Documents/Global/PDF/Dualpub_24/Accenture-Losing-Patience.pdf#zoom=50 [Accessed 5 June 2020].

¹⁸ European Union (2016). Directive (EU) 2016/2102 of the European Parliament and of the Council of 26 October 2016 on the accessibility of the websites and mobile applications of public sector bodies. [online] Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016L2102&from=EN> [Accessed 5 June 2020].

¹⁹ National Disability Authority. (n.d.). The 7 Principles. [online] Available at: <http://universaldesign.ie/What-is-Universal-Design/The-7-Principles/> [Accessed 5 June 2020].

Moreover, end-users are a valuable asset in policy development. The World Health Organization (WHO), together with the International Telecommunication Union (ITU), urges governments, their ministries, departments, and agencies to involve end-users in strategic processes and reflect their needs. The published guidelines present recommendations and encourage active participation among all the stakeholders in the strategy development processes²⁰. Healthcare management changes observed throughout Europe and elsewhere in the world mark the need for patient involvement. In less than a decade, the chief patient officer (CPO) – and similar roles with different titles – has become a key part of the healthcare industry executive team. The role enables patients and industry to become closer and understand what is important to each other.

The greatest challenge is that there are simply too many competing standards. Ultimately, most of them are not widely used in practice. Guidance from the eHN could contribute to better harmonisation of standards used by the Member States, especially as regards the design, implementation and evaluation capacity of digital health solutions, facilitating the recognition by citizens and health professionals, thus making the digital health services more user-centric and increasing their safety and quality. This makes users more able and motivated to use empowering digital technologies.

Recommendations

Ref.	Recommendation	Actors
2	Develop common digital health services guidance (complying with EU Web Accessibility Directive, the key objectives of the user-centred design process and universal design principles) for design and development of user-centric digital health technologies.	European Commission, eHN
3	Involve end-users in all phases of policy from policy-shaping to implementation and evaluation. Ensure a 'whole system in the room' process where patients and health professionals are involved and represented at eHN and within national policy bodies dealing with digital health.	eHN, Member States MoH

3.2 Digital Health Literacy of People²¹

People who are digitally health literate can find, appraise and understand health information from electronic sources, before applying it in their own lives to achieve better health

²⁰ National eHealth Strategy Toolkit (2012). [online] Available at: https://www.itu.int/pub/D-STR-E_HEALTH.05-2012 [Accessed 5 June 2020].

²¹ By digital health literacy of "people" we aim to set the focus on patients and other regular people, and not health professionals. Traditionally this would be called "digital health literacy of patients" but our Work Package posits that "empowerment" is relevant to a broader audience than patients, also including e.g. people who just want to live healthier but are not yet patients.

outcomes²². Improving the level of digital health literacy empowers people to take a more active role in the management of their health and wellbeing.

Digital health literacy can be plotted on two areas of the AMO model:

Ability – People need a level of digital health literacy to be able to access and interpret online health information, use electronic services and devices efficiently and correctly.

Motivation – Being aware of the availability of health apps, data repositories and eHealth services motivates people to acquire the relevant digital health skills.

The WHO Action Network on Measuring Population and Organizational Health Literacy (M-POHL), founded under the umbrella of the European Health Information Initiative (EHII), aims to add value to national efforts in improving health literacy by 'ensuring the availability of high-quality, internationally comparative data to facilitate evidence-informed policymaking'²³. M-POHL are currently conducting a European Health Literacy Population Survey (HLS19) that includes, for the first time, an optional question package on digital health literacy²⁴.

Recognising digital health literacy as an important aspect of health literacy in national and European policy helps decision makers understand the significance of digital health literacy and align appropriate strategies, plans and programmes to achieve better health outcomes. Such strategies must address broad sweeps of the population at one level and particular cohorts of the population at another level, involving all stakeholders that can contribute to improving digital health literacy, i.e. public and private organisations, professional bodies, 'MedTech', 'Pharma', educators, the non-profit sector and more. Here are some examples of the diverse digital health literacy needs to be addressed within a population:

- All people need to be aware of the availability of reliable health information and the application of eHealth services in their country, region or community that can assist them in achieving their health potential.
- Vulnerable sectors of society, the elderly or those from low socio-economic backgrounds are at risk of digital exclusion because of a lack of access to the internet or low digital literacy levels. As health services move online, the health of those digitally excluded citizens may be negatively impacted. Vulnerable sectors need thoughtfully designed non-threatening interventions and support structures to prevent digital exclusion.
- People dealing with chronic conditions require lifelong digital health literacy training and targeted supports that are designed specifically for their situation.
- Young people are comfortable using technology but need appropriate education to develop the critical thinking and media literacy skills in order to be digitally health literate.

²² Levin-Zamir D, Bertschi I. Media Health Literacy, eHealth Literacy, and the Role of the Social Environment in Context. *Int J Environ Res Public Health*. 2018;15(8):1643. Published 2018 Aug 3. doi:10.3390/ijerph15081643

²³ The Vienna Statement on the measurement of population and organizational health literacy in Europe. Vienna: M-POHL (2018). [online] Available at: <https://dory.goeg.at/s/yo6HazJ2HBcnbZn#pdfviewer>

²⁴ Short communication: The Action Network on Measuring Population and Organizational Health Literacy. M-POHL (2019). [online] Available at: http://www.euro.who.int/_data/assets/pdf_file/0010/398341/short-comm-health-literacy-eng.pdf?ua=1

- Finally, health professionals often accompany and support their patients in the appropriate use of digital health technologies and interpretation of digital health data. In these situations, they assume an informal role as digital health literacy coaches, motivating and facilitating patients to engage with digital health technologies and services. Health professionals need support through education or continuous professional development that focus on this new aspect of patient/health professional relationship.

Recommendations

<i>Ref.</i>	<i>Action</i>	<i>Actors</i>
4	<p>Address DHL within existing policies before operationalising such policies by embedding digital health literacy goals into strategies that take a multi-layered and multi-faceted approach to achieving such goals by:</p> <ul style="list-style-type: none"> Exploring the different target groups and needs with regard to digital health literacy (e.g. low-literate people, blind people) and adapt these findings to the solutions, e.g. by including these different groups in test scenarios. Funding and supporting national, regional or community projects that tackle digital exclusion and prioritise vulnerable groups. Establishing additional supports for patients with chronic conditions that rely on the use of eHealth systems and technologies for the ongoing management of such lifelong conditions. 	eHN, Member States, national and regional health authorities, business representative organisations, NGOs, health insurance providers, health technology companies
5	<p>Incorporate digital health literacy into the education system including:</p> <ul style="list-style-type: none"> Formal and informal digital health literacy education in primary and secondary level school curricula, as per the recommendations of the EU eHealth Task Force 2012 report on Redesigning Health in Europe 2020, which recommended supporting health literacy by teaching it in schools²⁵. 	Health and education ministries, education boards and authorities, national and regional health authorities, health professional representative bodies

²⁵ *Redesigning Health in Europe for 2020*. eHealth Task Force Report. eHealth Task Force (2012). [online] Luxembourg: Publications office of the European Union, p.16. Available at: <https://ec.europa.eu/digital-single-market/en/news/eu-task-force-ehealth-redesigning-health-europe-2020>.

4. Recommendations focused on motivation

In this chapter, the priority areas with the main focus on the motivation element of the AMO framework will be described. These priority areas are 'Trust as key', 'Behavioural change through motivation', 'Awareness/ involvement of social environment' and 'Awareness and involvement of health professionals'. In the context of this Work Package, motivation is defined as people's desire or readiness to engage in their own or others' health⁵.

4.1 Trust as key

Trust is the foundation – yet can easily be lost

Trust is a cornerstone and prerequisite for successful health services, including eHealth. Trust, which was listed as a priority in the D4.1 Policy Framework can influence the motivational aspect of the AMO framework. It usually takes time to establish trust, however it can be wasted in seconds. People are motivated to access and use their online data when it is user-friendly and understandable and when trust, security and privacy issues are taken care of. Transparency is a key word in this. Trust is a multifaceted, context-dependent concept, and a term with many meanings. There is no globally agreed definition for it²⁶, but trust is often illustrated as a relationship between one party (a truster) and another (a trustee) with optimistic anticipation that the trustee will fulfil the truster's expectations. This can easily be translated into a patient-healthcare context.

Mitigating risks and uncertainties benefit eHealth and people

Achieving and maintaining trust in eHealth among people improves not only healthcare access, but also the use of digital tools that improve diagnostic procedures, treatment outcomes and patient satisfaction. In terms of digital health technologies, we hypothesise that trust is likely to develop if the risks and uncertainties associated with their use can be minimised²⁷. This priority focuses on minimising potential risk and uncertainties such as privacy, secure communications or data access from the perspective of the end-users. Here end-users are mainly interpreted as citizens and patients, however for optimal implementation of eHealth solutions health professionals (HPs) also constitute an important category of end-users of systems and applications, thereby acting as advocates for eHealth applications.

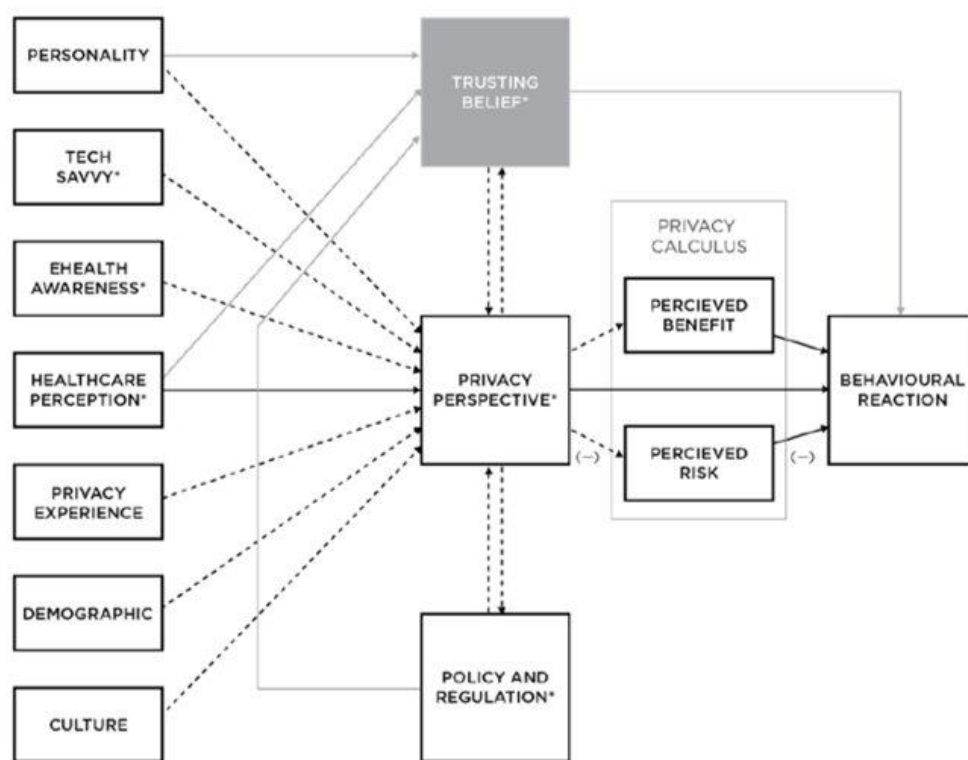
There is a clear difference between digital and health literacy for HPs and patients which is not always understood and taken into consideration while creating policy by Member States. Approach and message usually needs to be tailor-made for the respective target group.

²⁶ Trust Model for Protection of Personal Health Data in a Global Environment. Ruotsalainen P, Blobel B. Stud Health Technol Inform. 2017;245:202-206.

²⁷ Elements of Trust in Digital Health Systems: Scoping Review. Adjekum A, Blasimme A, Vayena E. J Med Internet Res. 2018 Dec 13;20(12):e11254. doi: 10.2196/11254.

A model for eHealth trust

An example of a dedicated governance model for trust is the eHealth Trust Model (eHTM)²⁸ which suggests that a patient's trust for digital health is contextual, informed through their perceptions, experiences, personal dispositions and environment. eHealth trust is the primary determinant in a patient's behavioural reaction to digital health. These reactions can manifest either as the willingness to share personal health information (for primary as well as secondary use), or as the intention to opt out of a "my health data system", or as the intention to use patient-facing health information technology. Behavioural reactions may also be influenced by the trade-offs between the perceived benefit of health information exchange and perceived risk of violating privacy (i.e. privacy calculus)²⁹.



NB: asterix denotes eHealth Trust Model adaption or addition; light grey indicates adaptations from the Web-Trust Model; all arrows indicate positive association unless noted, dotted arrows indicate tenuous relationship between constructs.

Figure 4 The eHealth Trust Model (eHTM)²⁶

eHealth awareness and digital health literacy is crucial

From the above it follows that to achieve trust, personal factors such as eHealth awareness and digital health literacy need to be accounted for, in conjunction with clarifying the benefits and risks associated with digital health. To enable trustworthiness of the use of personal

²⁸ The eHealth Trust Model: A Patient Privacy Research Framework. Nelson Shen, [John Strauss](#), [Michelle Silver](#), [Abigail Carter-Langford](#), David Wilier. *Stud Health Technol Inform*. 2019;257:382-387.

²⁹ Smith, H. J., Dinev, T., & Xu, H. (2011). Information Privacy Research: An Interdisciplinary Review. *MIS Quarterly*, 35(4), 989–1016.

empowering digital health services, there is an urgent need for practical and easy-to-use solutions for trust creation and management, as well as trust measurement, accounting for both the technologies and the users of said technologies. Subsequently priority area four on quality assessment is closely linked to trust, an example being the Medical Devices Regulation (MDR) for contributing to patient safety. Compliance with personal data protection rules, with information of the data subject, data security, and the lawful processing of personal data, including health and medical data, is of course vital for building trust in eHealth and mHealth solutions. The General Data Protection Regulation (GDPR) provides for harmonisation of data protection rules in the EU, increasing trust in eHealth services with a consistent and high level of protection of individuals.

An overarching key to better adoption of digital health for empowerment of the individual is ensuring trust in digital technology among all users, including patients, HPs and regular citizens. This highlights the need to engage these various stakeholder groups throughout the development of digital empowerment programmes, ensuring transparency and user-centricity. Primary tools for this are effective information and educational activities.

Recommendations

<i>Ref.</i>	<i>Action</i>	<i>Actors</i>
6	While developing and deploying tools to increase patients' and health professionals' trust in empowering digital technology follow or use eHTM as a reference model.	eHN, European Commission, citizen and patient associations, professional organisations
7	In accordance with the eHTM, identify or develop reliable ways of measuring trust and trustworthiness and objective third-party system evaluation systems.	eHN, Member States, national or regional health authorities, Governmental bodies
8	Establish safe testing and experimentation facilities including functions such as regulatory sandboxes or policy labs ³⁰ for the development of new eHealth applications. A recent EU workshop report indicates for instance that regulatory sandboxes could be an important part of future AI Testing and Experimentation Facilities ³¹ . One of the priorities set out in the new Commission mandate is the creation of a European Health Data Space (EHDS), which would foster the exchange, and sharing of different kinds of health data, thus supporting the delivery of primary care as well as the development of new treatments, medical devices and services. A	eHN, European Commission and Member States

30 A policy lab can be used to develop a regulatory framework by gathering a group of actors with various competencies and apply a set of user-centric methods and competencies to test, experiment and learn to develop new policy solutions.
<https://www.vinnova.se/en/m/Smart-policy-development/what-is-a-policy-lab/>

31 https://ec.europa.eu/information_society/newsroom/image/document/2020-19/200507_tef_ai_health_-_report_public_506D21A7-F089-C782-07DE5FAF1B2B40C4_66634.pdf

	policy lab, or similar type of facility, is mainly intended to be used for the evaluation of new methodologies from a legal/regulatory perspective, thereby avoiding the risk for major problems regarding, for example, breaches of personal data, compromising individuals' privacy and similar backlashes that may quickly have a negative impact on people's trust. Consequently, this recommendation of the eHAction, is well aligned with, and supports the development of EHDS.	
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4.2 Behavioural change through motivation

Habitual behaviour is often hard to change because of the lack of self-monitoring skills. Digital technologies, however, offer a chance to facilitate self-monitoring by delivering feedback on undesired behaviour. A variety of digital solutions to help us change harmful or habitual behaviour have arrived on the market. Though people empowerment is the key to using them. There is an immense need to change the attitude towards prevention, treatment, rehabilitation and other healthcare services as technology is a new segment of the health professional-patient relationship. Habitual behaviour might not be changed without personalised technological solutions. Patients with different background, lifestyle and knowledge must be considered in order to gain and keep their motivation to share health data and use digitalised services. Methods and tools should be different with respect to diverse target groups.

The digital solutions aim to alter deep-rooted habits by presenting people with behavioural feedback through mobile and interactive devices and applications. When aiming to change their behaviour, people compare their performances to a behavioural goal. When a discrepancy is noted, given enough opportunity, the right abilities and most importantly motivation, people will attempt to reduce this discrepancy¹.

The motivation of the population often falls – after initial interest – because there are not enough newly developed service protocols and structures (organisational, HR, financial) that would provide continuous and sustainable information and responses to new unmet needs adapted to technology. The reason why these methods often fail to work may be because the lack of trust, transparency and knowledge, and the missing support of the health professionals, or because the technological systems are non-user-friendly.

There are common factors which increase motivation: quick access to information (e.g. patient data, medical treatment documentation), control over own health data, and involvement in the healthcare process. People are motivated to access and use their online data when it is user-friendly and understandable (taking into account the different patient groups) and when trust, security and privacy issues are taken care of². Transparency is a key word in this. Personal factors, such as age, vary significantly between people, and influence the motivation and ability to access and use online health data.

It is important to mention that health professionals are the key performers in motivating patients³; they are responsible for providing information and maintaining the (relatively) high patient motivation of using the respective apps⁴. Health professionals are only able to motivate patients if they trust the apps, have enough knowledge about them and also in case they have time to educate their patients.

Mental imagery can increase engagement in planned behaviours, potentially due to its special role in representing emotionally salient experiences. By allowing individuals to pre-experience rewarding and positive aspects of potential future activities, it might act as a motivational amplifier, increasing the motivation to engage in these activities, which can transfer to actual behaviour.⁵ If people can perceive the positive effects of their changed lifestyle, they are likely to keep their resolutions; positive feedback might act as a motivational factor.

Technological solutions like Health Behaviour Change Support Systems (HBCSSs) can contribute to record personal success or barriers. There are common factors which increase motivation: quick access to information (e.g. patient data, medical treatment documentation), control over own health data, and involvement in the healthcare process. People are motivated to access and use their online data when it is user-friendly and understandable (taking into account the different patient groups) and when trust, security and privacy issues are taken care of⁶. However, endurance and sustainability are also essential parts of motivation.

Involvement in co-creation teams and activities related to HBCSSs raises adherence and empowers patients and health professionals. HBCSSs come in many forms, such as wearables, mobile apps or dedicated software. However, recent research suggests that people often do not use HBCSS frequently and over a sustained period of time⁷. Consequently, the desired beneficial health behaviour may not be maintained. The key to keeping users engaged is motivation. People are wired differently, so what motivates one person may not motivate another. This is where most apps go astray — they offer only one type of motivation.⁸

Trying to address this issue, developers of HBCSS frequently employ gamification. Gamification refers to the implementation of game elements in non-game contexts^{9,10}. Although a variety of diet-related games have been reported, the research base is inadequate to ascertain whether putting nutrition education or diet-related behaviour change into a game format consistently results in the desired outcomes, or what aspects of game elements or behaviour change procedures appear to be most effective.¹¹ Future behaviour-change-related game research should use randomised controlled designs to appropriately measure their outcome and impact. They should also examine why the desired beneficial health behaviour may not be maintained, e.g. lack of reward, people got bored, or reached their goals.

Research suggests that individuals can regulate their eating behaviours, and that self-determined motivation, when compared to non-self-determined motivation, propels individuals to adopt healthier eating behaviours when in more advanced stages of change.

However, without the support of health professionals patients will less likely use technological support to change their habits. Support and incentives are essential for behavioural change. Recognising, identifying and managing the incentives in digital healthcare is crucial to motivate people/patients in the long run.

In order to be able to motivate their patients, health professionals must be aware of various technological solutions for given health problems. Informing health professionals about different HBCSSs and their benefits should be part of the education even at the university or within the framework of regular compulsory workshops.

Recommendations

Ref.	Action	Actors
9	Use the Quality Requirements Conformity Assessments to identify what could be the minimum requirements, preferences and dissatisfiers for people using eHealth and telehealth related solutions and apps. Find, recruit, educate and train healthcare professionals to assist and motivate them to identify and understand patients' non-negotiables (minimal requirements), differentiators (preferred advantages) and dissatisfiers (trade-offs or the facts that could be accepted only if differentiators are provided), in order to enable them to guide and coach potential users of digital health services. Curricula of the training programmes shall also provide sufficient knowledge and improved skills and competences to use the information that Quality Requirements Conformity Assessments can offer. Programmes to develop proper curricula and implement recruitment and training activities, are recommended to be financed and funded by local, national and cross-border resources.	Digital application and solution developers, healthcare service providers and professionals, healthcare policymakers (Member States/ countries & eHN), funding bodies (Member States/ countries & European Commission)
10	Develop and sustain tangible services and clear/transparent protocols for satisfying concrete needs to motivate people to use virtual or digital devices, apps or other available solutions for and/or promotion, prevention, treatment and rehabilitation. For improving satisfaction of (unmet) needs, foster and assist citizens, healthcare providers and other key stakeholders (e.g. payers) to identify and share their non-negotiables (minimal requirements), differentiators (preferred advantages) and dissatisfiers (trade-offs or the facts that could be accepted only if differentiators are provided) regarding the use of virtual or digital solutions. To help people to understand who is capable to provide	Digital application and solution developers, healthcare service providers and professionals, healthcare policymakers (Member States/ countries & eHN), funding bodies (Member States/ countries & European Commission)

	non-negotiables and differentiators assistance is needed to contact them. Find, recruit, educate and train staff to assist and motivate health workforce to identify and understand patients' non-negotiables, differentiators and dissatisfiers. Also, provide information about state of health, diseases or changes in health status, as well as treatment options, required behaviours, and place it in the patient-provider relations using these digital/gamified solutions.	
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4.3 Awareness/involvement of social environment

In the majority of countries a supportive policy for informal carers as a part of an overall long-term care policy does not exist. Although some countries now have specific support policies for informal carers, for example, the ACTION service (currently operating in West Sweden) that provides a range of web-based educational caring programmes for carers of older people together with videophone facilities to enable direct peer support with other users and access to a call centre run by professionals in the municipality, together with an in-depth computer training course³². However, there are some guidelines that has focus on specific health issues, for example, 'Guidelines for healthcare professionals on how to support and communicate with informal caregivers of persons with cancer'³³.

Multiple barriers have been identified to increasing awareness within the social environment and the possibility of the social environment to get involved in empowering people. The key inhibiting factor is lack of resources, both internal (such as information and skills) as well as external (such as finances). Other perceived barriers are the living environment, physical state and psychological factors (for example, coping behaviours and caregiver burden). The quality of care provided to the care-recipient is affected by the caregiver's motivation and the meaning one finds in caregiving. In order to keep them motivated, opportunities that mobilise and automate the daily care of caregivers should be provided, thereby to balance their rhythm of life.

In the AMO model, the impact of improvements in the opportunity to perform through greater empowerment is reinforced by steps to enhance the abilities and motivation of the workforce.³⁴ The improvement on the awareness/involvement of social environment is achieved by offering opportunities to facilitate care and letting to feel more confident. The target group of the below-mentioned recommendations is caregivers and patients.

³² Casanova, G G. Lamura & A. Principi (2017). Valuing and Integrating Informal Care as a Core Component of Long-Term Care for Older People: A Comparison of Recent Developments in Italy and Spain, *Journal of Aging & Social Policy*, 29:3, 201-217

³³ Association of European Cancer Leagues Patient Support Working Group, "Guidelines for healthcare professionals on how to support and communicate with informal caregivers of persons with cancer" ECL Support Working Group, 2018.

³⁴ John E. Baur, Anthony R. Wheeler, M. Ronald Buckley, "Research in Personnel and Human Resources Management" Business & Economics, page 10, 2019

Some of the implementations for supporting informal caregivers in patient care are eHealth interventions, such as interactive electronic health records, mobile health communication programs and healthcare system portals that may improve patients' ability to look after themselves. It is observed that web-based interventions may result in reduced depressive symptoms, anxiety, and stress or distress among informal caregivers³⁵ as well as improve patient treatment, care and access of healthcare services³⁶. However, more research is needed to further assess the long-term effects of online interventions on caregiver stress and resilience. There are many eHealth interventions such as mHealth, European Electronic Health Record (EHR) and eHealthMonitor Dementia Portal (eHM-DP).

To make it easier for the patient to interact with the physical environment (for example, to cope with eating, walking and toileting, or to make an emergency call) and be less dependent on the caregiver, one of the solutions proposed is using assistive technologies (AT). Assistive technologies help caregivers by reducing time, levels of assistance and energy put towards caregiving, anxiety and fear, task difficulty and risk for safety, particularly for activities requiring physical assistance, and increase the independence of the users, thereby reducing the burden of the informal caregiver³⁷. There are a few programmes focused on the development of products and services to improve assisted living and involve social and informal caregivers, such as the Innovative Ambient Assisted Living (AAL) products and services, Enhanced Living Environments (ELE), and Elderly-oriented Network-based Services (ENSAFE).

Trainings for informal caregivers (professional training, digital health training, face-to-face or online support) have a beneficial effect on their awareness and involvement. Digital health training helps caregivers feel more confident about the patient care, reduces their perceived stress and enhances their feelings of empathy, understanding and concern³⁸. With regards to outside the caregiving setting, the face-to-face or online support of other caregivers seems to be beneficial for caregivers because they share comparable experiences³⁹. Informal social support, including online, can diminish burden and burnout. Being part of a group is a key element in helping informal caregivers to feel that they are not alone, continue leisure activities, learn from others and sustain participation in organised activities⁴⁰. There are a few programmes that provide education, skills training and support to informal caregivers, for

³⁵ Ploeg J, Markle-Reid M, Valaitis R, McAiney C, Duggleby W, Bartholomew A, Sherifali D "Web-Based Interventions to Improve Mental Health, General Caregiving Outcomes, and General Health for Informal Caregivers of Adults With Chronic Conditions Living in the Community: Rapid Evidence Review" *J Med Internet Res* 2017;19(7):e263. DOI: 10.2196/jmir.7564

³⁶ Schaller S, Marinova-Schmidt V, Setzer M, Kondylakis H, Griebel L, Sedlmayr M, Graessel E, Maler JM, Kirn S, Kolominsky-Rabas PL "Usefulness of a Tailored eHealth Service for Informal Caregivers and Professionals in the Dementia Treatment and Care Setting: The eHealthMonitor Dementia Portal. *JMIR Res Protoc* 2016;5(2):e47. DOI: 10.2196/resprot.4354

³⁷ Keshini Madara Marasinghe "Assistive technologies in reducing caregiver burden among informal caregivers of older adults: a systematic review" Pages 353-360 | Received 11 Jul 2015, Accepted 23 Aug 2015, Published online: 15 Sep 2015 DOI: 10.3109/17483107.2015.1087061

³⁸ Klimova, B., Valis, M., Kuca, K. et al. E-learning as valuable caregivers' support for people with dementia – A systematic review. *BMC Health Serv Res* 19, 781 (2019). DOI:10.1186/s12913-019-4641-9

³⁹ Perkins E. A., Hewitt A. (2016). "Coping with caregiver stress" in *Health care for people with intellectual and developmental disabilities across the lifespan*. eds. Rubin I. L., Merrick J., Greydanus D. E., Patel D. R. (Switzerland: Springer International Publishing;), 2165–2183.

⁴⁰ Matthieu Tixier and Myriam Lewkowicz. 2016. "Counting on the Group": Reconciling Online and Offline Social Support among Older Informal Caregivers. In *Proceedings of the 2016 CHI Conference on Human Factors in Computing Systems (CHI '16)*. Association for Computing Machinery, New York, NY, USA, 3545–3558. DOI: 10.1145/2858036.2858477

example iSupport, understAID and PeerCare. Some EU programmes are focusing on the elderly and on informal carers, such as the AGE Platform Europe, the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA) and Eurocarers.

The proposed solutions will expand the existing work done at the EU level by improving existing opportunities and providing new ones, as well as presenting solutions in countries with no supportive policy for informal caregiving. The recommendations add value to the people empowerment as they increase awareness on involvement of patients and informal caregivers in the healthcare process, improve their skills and knowledge, and provide opportunities to increase patient independence.

Recommendations

<i>Ref.</i>	<i>Action</i>	<i>Actors</i>
11	<p>Prioritise online support and digital learning opportunities (instead of face to face) for informal caregivers to receive necessary information about caregiving, share experiences and feel more confident in patient care using the following tools:</p> <p>1) Information and communication tools - disseminating information among caregivers about the possibility of online communication on patient care issues, for example, disseminating information about online support and digital learning opportunities through a family doctor, municipality or mass media (newspapers, news).</p> <p>2) Knowledge and innovation instruments - provide the necessary training for care professionals jointly increasing their knowledge by engaging in social learning and improving communication skills with informal caregivers, to be able to support, motivate and teach them the necessary skills for patient care. And also provide technical capabilities (online platforms) where care professionals can communicate with informal caregivers.</p> <p>3) Economic and fiscal instruments - provide an opportunity for care professionals to conduct online support and digital learning, receiving payment for this from the municipality or government, thereby motivating care professionals.</p>	eHN, Member States, national and regional health authorities, health technology developers

4.4 Awareness/involvement of health professionals

The Policy Framework on People Empowerment points out the vital role of health professionals to advance the empowerment of people. The key role of HPs was highlighted in achieving higher levels of digital health literacy through coaching, better data access through promotion of EHRs, as well better uptake of digital tools such as mHealth and telehealth through qualified recommendations and the willingness to adopt new models of care.⁴¹ As such, the contribution of HPs can be considered transversal: they have the potential to increase ability, motivation *and* opportunity. As the role of HPs as motivators was stressed on numerous occasions in the Policy Framework, this priority area has been classified under Motivation.

However, the Policy Framework also points out that HPs can be a barrier to empowerment, which is why it is key to understand how to involve physicians in using digital health for empowerment. Digital skills have been seen as one solution, as research has pointed out that HPs with digital skills are associated with a higher uptake and success rate of digital solutions⁴². Insofar as the ability to use and understand digital health translates into the motivation to do so, it is worth noting that clinicians receiving any training in digital health have found these solutions not difficult to use, highlighting the importance of education for overcoming “technology-related anxiety”⁴³. Within the Digital Europe Programme, the European Commission seeks to advance the digital skills of health and care professionals via short-term trainings⁴⁴. Additionally, an EU Thematic Network titled “Digital Doc” was launched in 2020⁴⁵, to bring digital skills into medical curricula. Further, each EU Member State has the opportunity to advance the digital skills of its HPs through EU Structural Funds. It is important that these initiatives are seized upon to introduce not just aspects of digital skills to HPs training but specifically the topic of digital health for empowerment (e.g. digital health literacy, mHealth, patient access and use of data, and telehealth). In doing so, work done by HPs can be leveraged, such as the guidance documents produced by ENS4Care⁴⁶.

Foremost among digitally skilled HPs are the chief clinical informatics officers (CCIO), such as the CMIO (chief medical informatics officer) and CNIO (chief nursing informatics officer). These roles are increasingly seen as essential for addressing clinician reluctance and resistance in the adoption of digital health^{47,48}. Given their dual expertise, these professionals are well placed to ensure digital health adds value to healthcare service delivery while encouraging their peers to accept new solutions. In light of their task, not just digital skills but also leadership,

⁴¹ eHAction. D4.1 Policy Framework on People Empowerment. 2019.

⁴² Ingebrigtsen T, Georgiou A, Clay-williams R, et al. The impact of clinical leadership on health information technology adoption: systematic review. *Int J Med Inform.* 2014;83(6):393-405.

⁴³ European Commission. Chain of Trust. 2013. Understanding patients’ and health professionals’ perspective on telehealth and building confidence and acceptance. <http://www.eu-patient.eu/globalassets/projects/chainoftrust/epf-report-web.pdf>

⁴⁴ European Commission. Digital Europe. Draft Orientations for the preparation of the work programme(s) 2021-2022. 2019.

⁴⁵ <http://www.inhwe.org/news/european-health-policy-platform-2020-thematic-networks>

⁴⁶ ENS4Care. Evidence Based Guidelines for Nursing and Social Care on eHealth Services. Prevention. 2015.

⁴⁷ Kannry J, Sengstack P, Thyvalikakath TP, et al. The Chief Clinical Informatics Officer (CCIO): AMIA Task Force Report on CCIO Knowledge, Education, and Skillset Requirements. *Appl Clin Inform.* 2016;7(1):143-76.

⁴⁸ Registered Nurses’ Association of Ontario. *Adopting ehealth solutions : implementation strategies*. Toronto, Ontario, 2017. Print.

interpersonal and communication skills are stressed to ensure change management, and an awareness of new technologies such as patient portals and telehealth for empowerment.⁴⁹

Some studies also suggest that co-creation of digital solutions with HPs can lead to more involvement of physicians in their successful rollout to patients⁵⁰, and some frameworks already consider co-creation an important quality measure for certifying digital technologies⁵¹. This is also closely linked to the 'Users at the Centre' priority area.

Other interventions that are likely to lead to more physician engagement with digital health for empowerment are ensuring trust, user-centricity, integration and interoperability of digital health solutions, clear legislation around matters such as liability, and high quality and safety standards^{52,53} – issues that are explored further under our other priority areas.

Recommendations

Ref.	Action	Actors
12	Promote the advancement of digital skills for health professionals, giving due attention to digital health for empowerment (including the topics of mHealth, patient access and use of data, digital health literacy and telehealth as a part of patient centric care). This can be facilitated through an online training with a certificate when accomplished.	Health and education ministries, medical schools, national and regional health authorities, hospitals, health insurance providers, clinical networks
13	Foster the creation of roles such as chief medical informatics officers (CMIO) and chief nursing informatics officers (CNIO) in HCPs with over 100 employees who can create a bridge between their expertise of being a health professionals and ICT by defining an European standardized profile in order to determine tasks and responsibilities. Involve CMIO's and CNIO's in co-creating a health system that facilitates the uptake of digital health, e.g. by providing a similar function within ministries.	MS policy level, national and regional health authorities, hospitals, health insurance providers

⁴⁹ Kannry J, Sengstack P, Thyvalikakath TP, et al. The Chief Clinical Informatics Officer (CCIO): AMIA Task Force Report on CCIO Knowledge, Education, and Skillset Requirements. Appl Clin Inform. 2016;7(1):143-76.

⁵⁰ Ziefle M., Klack L., Wilkowska W. & Holzinger A. 2013. Acceptance of telemedical treatments – A medical professional point of view. Berlin. Int. conference on human interface and the management of information 21–26, 325–334.

⁵¹ NICE. Evidence Standards Framework for Digital Health Technologies. 2019. p 14 ("Credibility with UK health and social care professionals")

⁵² European Commission. Chain of Trust. 2013. Understanding patients' and health professionals' perspective on telehealth and building confidence and acceptance. <http://www.eu-patient.eu/globalassets/projects/chainoftrust/epf-report-web.pdf>

⁵³ European Commission. Green Paper on Mobile Health (mHealth). 2014. COM(2014) 219

14	Create a mandatory certification scheme for the industry, MS, etc. for co-creating with HP's when developing digital health solutions. (This is also indicated in the ISO DTS 82304-2:2020 in 5.2.1.6; 'are health professionals involved in the development of the health app?')	MoH, national and regional health authorities, technology vendors
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5. Recommendations based on opportunity

Opportunity reflects the extent to which a situation is conducive to achieving a desired outcome. In this context it refers to the availability and accessibility of empowering solutions, as well as the involvement of people in the process⁵⁵. In this chapter, the priority areas with the main focus on the opportunity element of the AMO framework will be described. These priority areas are 'Legislation', 'Integration and interoperability' and 'Quality standards and assessment'. These are linked to the ReEIF model. Legislation is linked to the legal and regulatory level of the model, integration and interoperability is naturally linked to a variety of levels, including the level of application and IT infrastructure. Finally, quality standards and assessment are related to either the application level or the cross-cutting level of standards and profiles, and certification.

5.1 Legislation

Ideally, empowered people, (i) would have the requisite skills to use digital tools for their health (**A**bility, *digital health literacy*), (ii) would be motivated to take action and care of their own health (**M**otivation, *access and use of data*), and (iii) would be offered the requisite digital solutions to guide them (**O**ppportunity, *mHealth and telehealth*). Legal challenges can hinder the use of empowering digital health solutions because the benefits of eHealth are based on the overall acceptance of users. Legislation, therefore, needs to focus on issues such as privacy, confidentiality, data quality, integrity, access, ownership and sharing so that patients are aware and confident about the use and role of their data in care⁵⁴.

Patient access and use of data

A recent study⁵⁵ suggests as an important obstacle for cross-border patient mobility the lack of an established, systematic and secure framework for data exchange among healthcare organisations across EU. The major outcomes regarding legislation barriers include: (i) unaligned national and European laws, that are hard to be interpreted and applied, (ii) liability issues regarding data sharing that are not sufficiently clarified, and (iii) ambiguities regarding data ownership. Moreover, as technology evolves, new scenarios of data usage and transfer are emerging, causing legal gaps, as legislation cannot keep pace with fast evolving IT. The study recommends aligning legislation among EU Member States to provide the context of an IT solution facilitating secure cross-border data exchange and processing.

Similar findings regarding patient mobility have been reported in the Report on the implementation of the Cross-Border Healthcare Directive⁵⁶. The Commission has identified four areas which have the greatest potential to act as barriers to patients if left unaddressed: systems of reimbursement, use of prior authorisation, administrative requirements and charging of incoming patients.

⁵⁴ From Innovation to Implementation, eHealth in the WHO European Region.

⁵⁵ P. Natsiavas et.al, Identification of Barriers and Facilitators for eHealth Acceptance: The KONFIDO Study (2017).

⁵⁶ Report on the implementation of the Cross-Border Healthcare Directive, 2019.
https://www.europarl.europa.eu/doceo/document/A-8-2019-0046_EN.html#title6

mHealth and telehealth ^(57, 58)

In the framework of European law, telemedicine is, simultaneously, a *health service* and an *information service*. In what concerns healthcare and the practice of medicine the most relevant achievement to regulate this domain is Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. In what regards information and telecommunications, relevant acts include Directive 2000/31/EC on the information society services, Regulation 2017/745/EU on medical devices and Regulation 2016/679/EU on data protection. However, many issues still lack uniform regulation, like the determination of potential liability⁵⁹, e.g. in the case of an incorrect diagnosis by a cross-border health professional, with a negative impact on the treatment decision by the health professional in the patient's country of residence. A study about "Telemedicine in daily practice" suggests that an adequate regulatory framework for telemedicine is required to overcome the inconsistencies of adapting the currently available rules to remote-care delivery. Although the responsibility of creating and delivering telemedicine services falls on Member States, the European Commission has the important role of supporting and coordinating policy initiatives to support convergence towards common solutions.

The ultimate goal is patient empowerment. The proposed solutions aim to overcome the aforementioned legal barriers, by means of alignment and harmonisation of national legislation, in the context of cross-border healthcare, to increase confidence and availability of empowering digital health solutions. As a step forward, we suggest addressing first the barriers with the highest potential impact on patient empowerment: secure exchange of health data, systems of reimbursement and liability issues.

The solutions proposed will add value by: (a) improving the availability of cross-border healthcare services across EU, contributing to patient's awareness, confidence and access to these services, and: (b) overcoming the inconsistencies of adapting the currently available regulations to remote-care delivery (telemedicine), contributing to patient protection and the promotion of a deeper engagement in the control of their own health conditions.

Recommendations

Ref.	Action	Actors
15	Collaboration at European level for the harmonisation of national laws and regulatory frameworks for the secure exchange of health data, in accordance to the GDPR, and in relation to the interoperability of Member State electronic record systems and the implementation of the European electronic health record exchange	European Commission, eHN

⁵⁷ Vera Lúcia Raposo, Telemedicine: The legal framework (or the lack of it) in Europe, 2016.

⁵⁸ Carlo Botrugno, Telemedicine in daily practice: Addressing legal challenges while waiting for an EU regulatory framework, 2018.

⁵⁹ REPORT on EU state of play on telemedicine services and uptake recommendations, JAseHN, 2017.

	format. Such collaboration could take the form of an expert dialogue or subgroup on implementing legislation focused on the application of patients' rights in cross-border healthcare (Directive 2011/24/EU) with sub-groups focused on specific issues like interoperability. This will create an opportunity to share experience on legal issues in the context of the cross-border directive, taking into account data privacy, data integrity, access, ownership and sharing.	
16	Study or adapt existing legal frameworks applicable to patient access, telehealth, mHealth and telemedicine in order to achieve people empowerment building on the work of the MS and EU legislation, to identify "grey" areas that need to be clarified and gaps that need to be closed.	eHN
17	Develop a policy proposal to define a uniform regulatory framework for telemedicine as a recommendation to the European Commission for decision making. In particular, the framework should address liability issues, defining telemedicine as a service and distinguishing from any other ICT use in healthcare, and define telemedicine's role in cross-border healthcare.	eHN

5.2 Integration & interoperability

Problems addressed and relation to people empowerment and the AMO model

In the healthcare industry, integration means the organisation and management of health services in such a way that people get the care they need, when they need it, in ways that are user-friendly, achieve the desired results and provide value for money⁶⁰. Interoperability is the ability of different information systems and software applications to communicate and exchange data and use the information exchanged. The use of standards and data exchange models enable this information to be shared between e.g. HCPs, HPs, patients and hospitals, regardless of the application being used⁶¹. In this way, interoperability is a driver of integration.

A commonly stated issue regarding using digital health for empowerment is that of existing solutions not being integrated into the care process of patients and the lack of interoperability

⁶⁰ Norman, C.D. & Skinner, H.A.(2006). eHealth Literacy: Essential Skills for Consumer Health in a Networked World. Retrieved from: <https://www.jmir.org/2006/2/e9/?xml>

⁶¹ <http://www.eu-patient.eu/News/News/epf-position-paper-on-access-from-the-patients-perspective/>

between the different systems. This causes a strain on the opportunity and ability elements of the AMO framework, and functions as a disincentive to use potentially empowering solutions, as it adds undue complexity to the process and undercuts their potential. Another common issue is the lack of sustainable funding schemes to promote interoperability between vendors and small and medium sized enterprises (SMEs).

Following the Refined eHealth European Interoperability Framework⁶², which has been developed to support telehealth solutions in achieving full interoperability, interoperability encompasses six layers which have to be addressed: IT Infrastructure, Applications, Information, Care Process, Policy, Legal and Regulatory (L&R). With respect to addressing interoperability on all levels of the ReEIF, major gaps pertain to care process (alignment of care process), policy (establishment of collaboration agreements) and legal and regulatory (definition and enactment of L&R constraints) aspects between participating actors of a telehealth solution on regional, national and international levels⁶³.

Health professionals often don't have real-time access to all available health data about a patient's life outside the clinical setting. This limits the potential for a holistic perspective of their patients' health and care. The use and sharing of PGHD (patient generated health data) for clinical care and research are not yet in widespread practice, in part due to several barriers across the health ecosystem.⁶⁴ Nevertheless, beyond PGHD, cross-sectoral health data and even clinical data between hospitals can be challenging as well.

Connected solutions substantially impact the patient and health professional relationship in the context of healthcare provision. Patients highly value the ability to monitor, track and influence their own health status. They feel better educated and actively engage and share their experiences with peer-patients or professional moderators⁶⁵. However, health professionals perceive connected solutions as an additional service, disrupting their existing workflows and increasing their workload due to necessary data review and timely response^{66,67}.

Solutions proposed and added value to empowering people in the EU

The use of PGHD offers the potential to empower patients to actively participate in their healthcare and better manage their health outcomes. For clinicians, the use of PGHD may provide a holistic view of patients' changing health status over time. For researchers, the use of PGHD may provide access to a more expansive and diverse dataset.⁶⁸

⁶² https://jasehn.eu/wordpress/wp-content/uploads/2016/03/ev_20151123_co03_en.pdf

⁶³ Raposo VL. Telemedicine: The legal framework (or the lack of it) in Europe. GMS Health Technol Assess. 2016 Aug;12

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⁶⁵ Nissen L, Lindhardt T. A qualitative study of COPD-patients' experience of a telemedicine intervention. Int J Med Inform. November 2017;107:11–7

⁶⁶ Kuijpers W, Groen WG, Aaronson NK, van Harten WH. A Systematic Review of Web-Based Interventions for Patient Empowerment and Physical Activity in Chronic Diseases: Relevance for Cancer Survivors. Journal of Medical Internet Research. 20. Februar 2013;15(2):e37

⁶⁷ Davis SW, Oakley-Girvan I. Achieving value in mobile health applications for cancer survivors. Journal of Cancer Survivorship. August 2017;11(4):498–504

⁶⁸ https://www.healthit.gov/sites/default/files/onc_pghd_practical_guide.pdf

What's more, on the one hand, connected solutions must be seamlessly integrated to existing care processes and even embedded along with new care models, and on the other hand, the legal and regulatory basis for employing connected solutions in healthcare has to be established in order to address health professionals' concerns pertaining to changes in roles and responsibilities.

Recommendations

Ref.	Recommendation	Actors
18	Use proven funding schemes for co-creation (stand-alone twinning scheme) of empowering digital health solutions between vendors and procurers to promote integration and interoperability at the point of development, making sure of the sustainability of the project once the funding runs out.	Member States, national and regional health authorities, hospitals, health insurance providers and health technology developers
19	Create a European framework for integration of individual health information (PGHD) in EHR services and functions, able to submit health information by patient and HCP (e.g. MedMij). This needs to be done in a secure way and complying with privacy regulations. This European framework aims to facilitate the collection and use of patient generated health data in clinical care. The objectives are also very clear: improving outcomes, enhancing patient experience, focus on prevention rather than reaction, better use of financial resources.	eHN, Member States, national health authorities, European Patients' Forum, national patient organisations, hospitals, health insurance providers and health technology developers

5.3 Quality standards & assessment

Assessing digital health

The assessment of digital health interventions, in the broadest sense, can focus on the quality, safety and usability of this technology, ethical and legal requirements, clinical and cost effectiveness, as well as long-term societal impact. Some of these dimensions are represented in existing assessment regimes, e.g. at market approval stage (such as providing data on patient safety in the course of medical device conformity assessment) or when it comes to reimbursement decision-making (see, for instance, the dimensions of the EUnetHTA model, including ethical, legal issues and social aspects). Others, like privacy, usability and societal impact, are underrepresented so far. Ongoing changes in the way healthcare is delivered

suggest that this underrepresentation is a problem, particularly when looking at digital health from a patient empowerment perspective. Patients/users access and consume medical technology more directly (less mediated by health professionals) than before, bringing along novel interfaces and more reliance on codified data. These new human-technology interfaces and available data offer opportunities for people empowerment, if designed and evaluated properly.

Opportunities for people empowerment

In order to provide opportunities for people empowerment, mHealth and telehealth solutions have to be assessed appropriately, considering aspects like privacy and usability, but also patient access or digital health literacy. Patient access and health literacy are thus important assessment dimensions for digital health interventions. If the intervention itself is a solution designed to address data access or a digital health literacy initiative, these can and should be evaluated against their effect in terms of people empowerment.

For the area of health apps, a quality and reliability assessment framework is in the process of CEN-ISO-certification; the ISO DTS 82304-2:2020 document⁶⁹. This document provides a Quality Requirements Conformity Assessment and standardised label as a way for App Manufacturers and App Assessment Organisations to communicate the quality and reliability of health apps. This framework can give guidance on a European level and can help the harmonisation of national assessment approaches⁷⁰.

As highlighted under priority area 'Trust as key', the likelihood of deriving benefit from digital health interventions correlates with the perceived benefits and risks associated with said solutions. Assessment is a key tool for intervention design, for enabling informed decision-making on the interventions, and for engaging with perceptions on benefits and risks in different audiences.

Requirements for people empowerment

As stated in eHAction D4.1, instituting quality standards and assessment frameworks can help meet the need for evidence for market approval, while also paving the way for better and more informed reimbursement policies.

As to market access, the mHealth and telehealth space has been largely unregulated. A growing body of norms pushes developers to comply with software development standards, risk assessment and product validation procedures. As apps and telemedicine solutions have mostly been outside of the scope of the EU Medical Device Regulation (MDR), there is currently little regulation beyond harmonised norms. MDR will change this, for instance by imposing stricter regulatory frameworks on those types of software that are considered a

69 Health Software — Part 2 Health and wellness apps - Quality and reliability. EN-ISO DTS 82304-2:2020. CEN TC 251-ISO TC 251/WG 2.

70 Report on the mHealth Assessment Framework. World Health Organization. May 2018. <https://ec.europa.eu/digital-single-market/en/news/report-working-group-mhealth-assessment-guidelines>

medical device. Stricter rules for market access, however, only partially clarify the paths towards reimbursement. This concerns both the mHealth and the telehealth space. Currently only a few examples of systematic assessment of novel digital health solutions exist, indicating a gap to be overcome.

While decision-makers need reliable evidence before implementing or granting reimbursement for digital solutions, problems have been highlighted around providing such evidence. Thus, solutions discussed in the health technology assessment (HTA) context could provide a way to overcome this gap: rapid assessments; early dialogue HTA or, even earlier, prospective HTA; use of routine and real-world data; etc. There will likely also be a need for different assessment institutions. While reimbursement decisions are national or subnational, there might be added value for Member State bodies as well as EU-level evidence gathering and assessment activities. Likewise, testing and reference sites could be important catalysts supporting developers in meeting evidence requirements and public authorities in assessing for reimbursement.

Specific to digital health, users (citizens, patients, professionals) might benefit from additional guidance going beyond market approval, such as official app libraries. This is because not all approved solutions are useful; not all solutions that are useful and used are reimbursed.

Quality standards and appropriate assessment can provide opportunities for empowering solutions. There are three problems to be considered in relation to digital health assessment and people empowerment:

- **Suitability** of general assessment tools for digital health interventions: some dimensions relevant for people empowerment with regard to digital health (e.g. accessibility and equity issues, user experiences, societal impact) might not be covered by existing assessment frameworks (e.g. in national reimbursement decision-making).
- **Availability and harmonisation** of digital health assessment tools: digital health-specific assessment frameworks (MAST, MARS, ORCHA, Tic Salut Social, Bertelsmann/Fraunhofer, NHS and NICE standards, etc.) are used in project contexts or nationally. There is exchange through initiatives like the European mHealth Hub (e.g. on the analysis of assessment frameworks), the eHealth Network or the Global Digital Health Partnership, but further efforts are required and stakeholders are missing from these discussions.
- **Design** of assessment processes: it might not be enough to assess just for market approval and reimbursement, but additional steps would be necessary to empower users.

The proposed recommendations will add value by ensuring that the right digital health solutions are available and that citizens, patients and professionals are empowered to make use of them. The proposed activities link to and expand existing work done at EU level within the eHealth Network or projects like the European mHealth Hub. In addition, they will help by

linking communities that might otherwise tackle the issue separately (e.g. the European-level HTA discussions, market approval stakeholders, funders at national level, etc.).

Recommendations

Ref.	Action	Actors
20	Endorse and implement CEN-ISO/DTS 82304-2 as the common framework for quality and reliability of health apps. This framework has already been referenced in the EU Toolbox for Covid tracing apps. Assess in how far this framework can help harmonisation of national approaches and whether it also helps digital health assessment beyond the area of apps.	eHN, also coordinating with ISO/TC 215 (ISO/AWI TS 82304-2)
21	Establish a dialogue for an open exchange among those responsible for application libraries and assessment frameworks. Let the mHealth hub and involved people on 82304-2 study the minimal requirements for quality assessment on a European and a national level, e.g. starting with COVID-19 apps.	European mHealth Hub and people involved on 82304-2, eHN, Member States and their relevant agencies, MDR notified bodies.
22	Establish follow up funding to enable and facilitate implementation of the common framework. Support and monitor uptake of the common framework and mHealth by healthcare authorities and providers and in efficient public funding (reimbursement), in line with the Digital Single Market communication. Consider role of the European Commission in implementation of the 82304-2 Health App Quality Label in application libraries, to empower citizens who seek to use health apps without a prescription by their provider.	European Commission, eHN, Member states and their relevant agencies, people involved on 82304-2 study, application libraries, assessment framework owners, mHealth developers

6. Follow-up

This document provides a menu of policy options that Member States and supranational bodies can adopt and work towards to enhance the empowerment of people through digital health. While all the recommendations have the potential to positively impact the empowerment of people, readers are welcome to pick and choose the recommendations that are most relevant to their context, as different measures are likely to be most effective in different settings. The adoption of this document by the eHealth Network does not therefore mean that all countries are expected to implement all recommendations, it merely signals an endorsement of these measures as areas worth further exploration by all interested in empowering their respective stakeholders.

The authors of this document, including its contributors and participating stakeholders, would like to emphasise, however, that the work towards empowering people should not stop with this document. It is vital that the priorities enlisted here do get carried forward in one way or another, and in this, readers of all backgrounds – from member states to regulatory bodies and non-state actors – have a role to play.

During the final workshop for preparing this deliverable, much was discussed about how and by whom should these recommendations be carried forward, and some key themes emerged.

Everybody has a role

This document has been produced by the Joint Action supporting the eHealth Network, which is an EU level consortium. In order for these recommendations to come to life, they must make it also to the local level, and to other supranational groups. This can be achieved if all parties contribute effort to communicate this deliverable to their respective networks, including the National Digital Health Networks of Member States.

The key role of the eHN

Readers will have noted that the eHealth Network has been mentioned multiple times throughout this document as one of the key stakeholders to carry forward the recommendation. As a leading body for eHealth in the European Union, the eHealth Network does indeed have a key role in carrying forward the eHealth agenda and setting its priorities. Although the eHN can definitely not be expected to carry out all the activities, it should definitely act according to its mandate in prioritising which recommendations are worth allocating resources to moving forward. These decisions can then cascade onwards into funding decisions, communication campaigns and much needed work being commissioned. In its role as a convenor of Member States and non-state actors, the eHN can also play a key role in many of the activities requiring dialogue and harmonisation among a broad range of actors.

The need for further granularity

We recognise that many of the recommendations presented are rather ambitious in scope, which is why it is important to break them down into immediately actionable subcomponents. For example, in educating health professionals on empowering digital health, one key activity would be to assess current educational models for HPs on their suitability for the purposes of empowering people. This work of turning the broader goal into tangible actions can take place in the form of an “implementation guide” addendum for this document, or can be done for a smaller subset of recommendations considered to be of high priority within the eHealth Network, within, for example, a dedicated subgroup.

The need for general metrics

While it is not too difficult to think of metrics for success within the individual recommendations and priority areas – and indeed many have been suggested by our contributors – the need for general metrics on empowerment is apparent. While we may be successful in creating new educational materials on increasing trust in digital health, the key question we are seeking to answer is whether the implementation of such measures is actually leading to more empowerment. Within the Policy Framework for People Empowerment, we did explore some metrics on empowerment, but agreeing on a unified set for Member States deserves to be its own dedicated workstream. These metrics are vital for keeping track of how our recommendations are actually progressing the empowerment agenda.

The need for continued dialogue

Although it is not revolutionary, many of us agree that one of the best ways to keep track of our progress and troubleshoot the problems emerging from implementing these recommendations is a continued dialogue between Member States and stakeholders. Such dialogue could take place, for example, at the level of the eHealth Network, where Member States can report on their progress towards empowering digital health.

Appendix 1. Definitions

When describing people empowerment, the scope was limited to the original four tasks described in the Policy Framework: mHealth, telehealth, patient access and use of data, and digital health literacy.

People empowerment is a process that helps people gain control over their own lives and increases their capacity to act on issues that they themselves define as important⁷¹. Patients are, by definition, already considered 'ill'. Gaining control over decisions and actions affecting health is important for many more people than just patients. With a patient also comes a healthcare worker, a caregiver, family and many other roles that are not included within the term 'patients'. Furthermore, the 'healthy' part of the population should be able to express needs and concerns regarding their health as well. In this way their health can be maintained. It is therefore important to include all the roles of the population involved with either health or illness. Therefore, the terms 'people' and 'people empowerment' are used throughout this document.

mHealth includes the use of mobile communication devices in health and well-being services covering various technological solutions, which support self-management and measure vital signs such as heart rate, blood glucose level, blood pressure, body temperature and brain activity. The World Health Organization (WHO) defines mHealth as 'medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices'⁷².

Telehealth encompasses the delivery of healthcare services by HPs using ICT to provide clinical and non-clinical services: preventive, promotive and curative healthcare services, research and evaluation, health administration services⁷³.

Patient access and the use of data. The European Patients' Forum (EPF) provides a detailed definition of patient access by basing it on 5 A's: Adequate, Accessible, Affordable, Appropriate and Available. In this report, patient access and use of data refers to people having access to their own online health data from e.g. electronic health records. The 5 A's are prerequisites to give patients access to their online data. In the policy framework at hand patient access and use of data is seen as a follow-up action; once accessing their health data online, they can use their data by for example changing, modifying, improving, deleting it⁷⁴. Accessing and using health data is not limited to patients. People with good health should be able to access and use their data as well.

Digital health literacy (DHL). For Task 4.3 digital literacy has been defined as the ability of people to seek, find and access online data and information. Health literacy has been defined as the ability of people to understand and appraise online data and information once found, and the ability to translate the online data and information into actions to improve a person's

71 European Patients' Forum <http://www.eu-patient.eu/whatwedo/Policy/patient-empowerment/>

72 WHO https://www.who.int/goe/publications/goe_mhealth_web.pdf (mHealth)

73 European Commission. Chain of Trust. 2013. Understanding patients' and health professionals' perspective on telehealth and building confidence and acceptance. <http://www.eu-patient.eu/globalassets/projects/chainoftrust/epf-report-web.pdf> (Telehealth)

74 <http://www.eu-patient.eu/News/News/epf-position-paper-on-access-from-the-patients-perspective/>

health. The combined definition of digital health literacy refers to the ability of people to understand and appraise online health information. It can also be interpreted as the ability to use electronic services and devices to manage one's own health⁷⁵.

Ability refers to the extent to which people have the necessary competences (e.g. knowledge and skills) in order to achieve a certain outcome. It represents the capacity to perform, and it is dependent upon variables such as age, knowledge and intelligence. In this context it is the ability of people to engage in their own or others' health. A lack of ability implies that knowledge structures necessary to perform more complex operations either do not exist or cannot be accessed. If, for example, the ability to access and use information is low, patient data is uninterpretable⁵.

Motivation is the desire or the action of people to gain and retain control over their own health and/or the ones they care for. Motivation incorporates readiness, willingness, interest and desire to engage. In the context of this policy framework, motivation is defined as people's desire or readiness to engage in their own or others' health⁵.

Opportunity reflects the extent to which a situation is conducive to achieving a desired outcome. In this context it refers to the availability and accessibility of solutions provided, as well as the involvement of people in the process. A lack of opportunity can for example arise when the right digital tools to gain control over one's own health do not exist or are inaccessible to those who need them, because of a lack of connection availability⁵.

⁷⁵ Norman, C.D. & Skinner, H.A.(2006). eHealth Literacy: Essential Skills for Consumer Health in a Networked World. Retrieved from: <https://www.jmir.org/2006/2/e9/?xml>

Appendix 2. Survey to Stakeholders

All stakeholders were presented with a basic description of the nine priority areas. For each priority area, some key questions were highlighted. Based on a description of these priority areas, the stakeholders were asked:

1. Are there other priority areas you think we should explore?
2. Are there other questions you consider relevant for the priority areas? If so, which questions and under what priority area(s)?
3. Is there existing work done under the priority areas that we should look into? Please provide links or other references.
4. Are there any questions that you would particularly like to emphasise?

Appendix 3. Good practices (or brilliant failures)

Users at the centre

1. The Principles for Digital Development first created in consultation with internationally recognised organisations including – but presumably not limited to – Swedish International Development Agency (SIDA), the UN's Children's Fund (UNICEF), UN Development Programme (UNDP), the World Bank, and the U.S. Agency for International Development (USAID), and the World Health Organization (WHO) are nine living guidelines that are designed to help integrate best practices into technology-enabled programmes and are intended to be updated and refined over time. They include guidance for every phase of the project life cycle, and they are part of an ongoing effort among development practitioners to share knowledge and support continuous learning. The first principle focuses on the design with the user and provides detailed recommendations how to engage users from analysis to monitoring phases⁷⁶.
2. The UK Service Standard (originally 'Digital Service Standard') has contributed to the growth in digital maturity across government, to the extent that the best government services are now among the simplest, most accessible services around. The Service Standard⁷⁷ is a set of criteria to help government create and run good services, including digital services. Among these standards a great emphasis is given to user involvement and putting user needs first.
3. UNICEF Global Innovation Centre in partnership with the UNICEF Health Section has developed 'A Human-Centred Guide to Digital Health Deployments' to help others apply human-centred design approaches, informed by emerging insights from the behavioural sciences, to challenges that benefit from digital, technological, or data-based solutions⁷⁸.
4. Smart4Health is the EU's Horizon 2020 funded project that provides an easy-to-use, secure, constantly accessible and portable health data and services prototype within the EU and beyond. It focuses on the citizen as the end user and enables managing own and own-generated health data in the EU and beyond, secure, seamless communication of health-related data through clarity and oversight. Citizens are consulted throughout the process of design and development of Smart4Health.
5. The World Wide Web Consortium has summarised a user-centred design process (UCD)⁷⁹, which considers multiple frameworks and mirrors some elements of the International Organization for Standardization's multi-part standard, ISO 9241-210:2019⁸⁰. The key objectives outlined in this standard are applicable to the evaluation of digital health applications: the solution should be useful in helping users

⁷⁶ Retrieved from: <https://digitalprinciples.org/>

⁷⁷ <https://www.gov.uk/service-manual/service-standard>

⁷⁸ Retrieved from:

<https://www.unicef.org/innovation/media/511/file/Designing%20Digital%20Interventions%20for%20Lasting%20Impact.pdf>

⁷⁹ <https://www.w3.org/WAI/redesign/ucd#sent>

⁸⁰ <https://www.iso.org/standard/52075.html>

achieve their goals, effective (i.e. producing results with minimal user error), learnable (i.e. easy and intuitive to use), and likeable (i.e. enjoyable to use).

Digital health literacy of people

6. As the national centre of expertise on health disparities in the Netherlands, Pharos is involved in the Acceleration Programme for Patient and Professional Information Exchange (VIPPP). Collaborating with hospitals, rehabilitation centres and similar institutions, this programme facilitates development of online portals that enable patients to access their own medical data. Additionally, Pharos has also developed comprehensible and easy-to-use digital tools that allows local partners in prevention and care to implement digital tools within local infrastructures through the '4 steps to eHealth4All' working model.
7. Norway Health Directorate promotes health literacy among young people through digital information and help services as part of the Norwegian Youth Health Strategy. This leads to the creation of a project known as DIGI-UNG21 that coordinates and develops digital services for young adult between the ages of 13 and 20, focusing on healthcare and school health services⁸¹.
8. In July 2013, Tinder Foundation and NHS England launched the Widening Digital Participation programme, aiming to help millions of people across the UK to improve their digital health skills. This programme developed various projects to tackle digital exclusion, including sharing of digital health skills between health professionals and patients, raising awareness of online health resources and integrating digital health training into the existing programme⁸².
9. IC Health was a Horizon 2020 project with an aim to boost digital health literacy skills among European citizens through the testing of a new model of digital health literacy intervention development. The project aimed to improve EU citizens' ability to search, understand and appraise online health information. The project developed a set of Massive Open Online Courses (MOOCs) in eight different languages for various population cohorts (children, adolescents, pregnant women, elderly, citizens affected or susceptible to be affected by diabetes). The final conference to showcase results took place in October 2018⁸³ but the MOOCs continue to be available at www.ichealth-moocs.eu.

Awareness/involvement of health professionals

10. ENS4Care – The project has developed five guidelines for European nurses and social workers on how to use eHealth for promoting a healthy lifestyle and prevention,

⁸¹ Norwegian Directorate of Health, "Ungdomshelse i en digital verden - DIGI-UNG Innsiktsarbeid (del 1)," Norwegian Directorate of Health, Oslo, 2018.

⁸² Tinder Foundation, "An evaluation of the Widening Digital Participation programme," Tinder Foundation, England, 2016.

⁸³ IC Health, "Improving Digital Health Literacy in Europe IC Health Final Conference" Brussels, 2018. Available at: https://ichealth.eu/wp-content/uploads/2018/10/ICH-FC_Final-Presentation_allDay.pdf

clinical practice, skills development for advanced roles, integrated care and nurse ePrescribing.

11. PICASO – The project is developing an ICT platform to support coordination of care plans for people diagnosed with co-occurring chronic diseases. The goal of this Europe-wide Continuum of Care service platform is to:

- a. Improve cooperation and exchange of knowledge between caregivers in health, rehabilitation and social care domains and actively include patients and their relatives;
- b. Bring about improvements in health outcomes, daily activities, and quality of life by personalising care management programmes to the patients' profiles and support adherence to care plans;
- c. Reinforce medical knowledge and create new care models for management and treatment of patients with multi-morbidity conditions;
- d. Allow more cost-effective care management through increased skills and collaboration of care professionals and more automated and efficient workflows, which leads to better health outcomes and less hospital admissions, and thus contributing to the sustainability of health and social care systems in Europe.

12. An EU Thematic Network on 'future-proof doctors' called 'Digital Doc' has been launched to discuss the necessary (minimum) changes and requirements in medical education to better include digital healthcare.

Trust as key

13. Quality management, certification and rating of health information on the Net with MedCERTAIN. MedCERTAIN (MedPICS Certification and Rating of Trustworthy Health Information on the Net) is a recently launched international project funded under the EU's 'Action Plan for safer use of the Internet'. It provides a technical infrastructure and a conceptual basis for an international system of 'quality seals', ratings and self-labelling of Internet health information, with the final aim to establish a global 'trustmark' for networked health information. Digital 'quality seals' are evaluative metadata (using standards such as PICS (Platform for Internet Content Selection), now being replaced by Resource Description Framework (RDF) or Extensible Markup Language (XML) assigned by trusted third-party raters. The project also enables and encourages self-labelling with descriptive meta-information by web authors. This will help consumers as well as professionals to identify high-quality information on the Internet⁸⁴.

⁸⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2244104/>

Behavioural change through motivation

14. The validation of the Healthy and Unhealthy Eating Behaviour Scale (HUEBS): Examining the interplay between stages of change and motivation and their association with healthy and unhealthy eating behaviours and physical health. The purpose of the present research was to examine how self-determined and non-self-determined motivation for eating was related to healthy and unhealthy eating behaviours at different stages of change. The conclusion of the research suggests that individuals can regulate their eating behaviours for different reasons and that self-determined motivation, when compared to non-self-determined motivation, propels individuals to adopt healthier eating behaviours when in more advanced stages of change⁸⁵.

Awareness/involvement of social environment

15. Homes4Life certification scheme – The project that is run by a multidisciplinary group of nine partners from five EU countries under the coordination of TECNALIA (Spain) started in December 2018 and will last for 24 months. The scheme is based on an inspirational and realistic long-term vision of people's needs and requirements in a holistic life-course approach and help develop better living environments integrating construction and digital solutions where this is beneficial⁸⁶.
16. PICASO – The project provides an integration platform for the cross-organisational exchange of electronic health records and care plans to facilitate the closer integration of formal and informal carers and a personalised concordance of care services. PICASO enables the collaboration of carers across sectors encompassing the entire care continuum from the clinical setting to a patients private home. It further provides a method for sharing patient information across all relevant formal and informal care providers using a unique, trust federated solution to the problem of data privacy in cloud based health systems⁸⁷.
17. ACTIVAGE – The project aims at promoting IoT (Internet of Things)-based solutions for Active and Healthy ageing. The main objective is to build the first European IoT ecosystem across nine Deployment Sites in seven European countries, reusing and scaling up underlying open and proprietary IoT platforms, technologies and standards, and integrating new interfaces needed to provide interoperability across these heterogeneous platforms, that will enable the deployment and operation at large scale of Active & Healthy Ageing IoT based solutions and services, supporting and extending

⁸⁵ Guertin, C., Pelletier, L., & Pope, P. (2020). The validation of the Healthy and Unhealthy Eating Behavior Scale (HUEBS): Examining the interplay between stages of change and motivation and their association with healthy and unhealthy eating behaviors and physical health. *Appetite*, 144, 104487.

⁸⁶ Retrieved from: <http://www.homes4life.eu/>

⁸⁷ Retrieved from: <https://www.picaso-project.eu/>

the independent living of older adults in their living environments, and responding to real needs of caregivers, service providers and public authorities⁸⁸.

Legislation

18. The recently commissioned EU regulatory gaps study, launched at the beginning of 2020, which is looking into, among other things, issues around mHealth, telemedicine and use of data.
19. The European Privacy Code of Conduct on mobile health apps⁸⁹, which is currently being updated for the GDPR era.

Integration and interoperability

20. Smart4Health is the EU's Horizon 2020 funded project that provides an easy-to-use, secure, constantly accessible and portable health data and services prototype within the EU and beyond. It focuses on the citizen as the end user and enables managing own and own-generated health data in the EU and beyond through secure, seamless communication of health-related data through clarity and oversight.
21. ACTIVAGE is a project aimed to prolong and support independent living of older adults in their living environments and responding to real needs of caregivers, service providers and public authorities. The project is deploying innovative and user-led large-scale pilots across nine sites in seven European countries based on Internet of Things (IoT) technologies. This way, ACTIVAGE will build the first European interoperable and open IoT ecosystem, reusing and scaling up underlying open and proprietary IoT platforms, technologies and standards, that will enable the deployment and operation at large scale of Active & Healthy Ageing IoT based solutions and services.
22. PROGRESSIVE was a project that provided a dynamic and sustainable framework for standards and standardisation around ICT for active and healthy ageing. It established parameters by which good practice in standards and the standardisation process can be identified.

Quality standards and assessment

23. In 2016, the WHO published a framework on the monitoring and evaluation of digital health interventions. The so-called mERA checklist⁹⁰, encompassing 16 items, was developed to ensure reporting on digital health interventions would be done in a way that allows for the assessment of effectiveness. It can be applied to digital health interventions at various stages of development (prototype to scaling).
24. In the wake of its efforts in digital health as well as the GDPR, the European Commission facilitated a Privacy Code of Conduct on mHealth directed towards app

⁸⁸ Retrieved from: <https://www.activageproject.eu/>

⁸⁹ <https://ec.europa.eu/digital-single-market/en/privacy-code-conduct-mobile-health-apps>

⁹⁰ <https://www.who.int/reproductivehealth/topics/mhealth/mERA-checklist/en/>

- developers. It addresses issues such as user consent, data retention, data minimisation, etc., but does not address features of quality or effectiveness.
25. The EU-funded Horizon 2020 project 'European mHealth Hub', jointly carried out by International Telecommunication Union (ITU), WHO, the Andalusian Health System in Spain and more than 15 partners, currently also works on the issue of mHealth assessment frameworks. There are no published results so far, they are expected for summer 2020.
 26. An example of a public authority assessment framework tied to reimbursement can be found, for example, in Germany, where the Federal Institute for Drugs and Medical Devices (BfArM)⁹¹ is mandated to establish a directory of digital health applications. Developers can apply for registration, upon which BfArM performs a first check of product safety and quality. Evidence on effectiveness can be provided up to a year after registration. Registration goes along with acceptance for reimbursement in the German health insurance system.
 27. In some EU countries there are official health app libraries that provide guidance to users based on quality standards. The NHS Apps Library⁹² is one example. It relies on an assessment process combining self-reporting through a survey with systematic reviews of the reports.
 28. Numerous private bodies across Europe have also published guidance either in the form of checklists for consumers or developers, or criteria catalogues for evaluators. One example is the patient checklist for health apps of the three major German-speaking patient safety platforms.
 29. There are also tools for professional users (digital health evaluators, etc.) that have been developed in public and/or private research projects: most notably the Mobile App Rating Scale⁹³, the Model for the Assessment of Telemedicine⁹⁴, going back to the European Commission-funded MethoTelemed project), which builds on the EUnetHTA core model, and the Bertelsmann/Fraunhofer AppQ app quality indicators. The EU-funded TeleSCoPE project developed the International Code of Practice for Telehealth Services, which the International Society for Telemedicine & eHealth is looking to develop into a good practice guideline or a basis of certification.
 30. Private organisations like ORCHA⁹⁵ or HealthOn⁹⁶ also provide app assessment and/or directories, including for public app libraries.

⁹¹ https://www.bfarm.de/EN/Home/home_node.html

⁹² <https://www.nhs.uk/apps-library/>

⁹³ Stoyanov, S. R., Hides, L., Kavanagh, D. J., Zelenko, O., Tjondronegoro, D., & Mani, M. (2015). Mobile app rating scale: a new tool for assessing the quality of health mobile apps. *JMIR mHealth and uHealth*, 3(1), e27. doi:10.2196/mhealth.3422

⁹⁴ Kidholm, Kristian & Ekeland, Anne & Jensen, Lise & Rasmussen, Janne & Pedersen, Claus & Bowes, Alison & Flottorp, Signe & Bech, Mickael. (2012). A Model for Assessment of Telemedicine applications: MAST. *International journal of technology assessment in health care*. 28. 44-51. 10.1017/S0266462311000638.

⁹⁵ <https://www.orchac.co.uk/>

⁹⁶ <https://www.healthon.de/>