D5.1 Policy Framework

Document contributing to the Policy Framework for EU on Cross-Border Adoption and Assessment of Innovation

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Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

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List of abbreviations

ACSA	Agencia de Calidad Sanitaria de Andalucía (Andalusian Agency for Healthcare Quality)
AI	Artificial Intelligence
API	Application Programming Interface
App	Application
ASVS	Application Security Verification Standard
CEF	Connecting Europe Facility
CHF	Chronic Heart Failure
cMHAFF	Consumer Mobile Health Application Functional Framework
COPD	Chronic Obstructive Pulmonary Disease
COPD	Chronic obstructive pulmonary disease
DHT	Digital Health Technology
DHTS	Digital Health Technology Standard
e-	Electronic-
EC	European Commission
EDIFACT	Eletronic Data Interchange for Administration, Commerce and Transport
EESZT	Elektronikus Egészségügyi Szolgáltatási Tér (Electronic Health Services Space)
eHDSI	eHealth Digital Service Infrastructure
eHealth	Electronic Health
EHDS	European Health Data Space
eHR	Electronic Health Record
eIDAS	Electronic IDentification, Authentication and trust Services
EPR	Electronic Patient Record
ESI	European Structural and Investment
ESIF	European Structural and Investment Fund
EU	European Union
FAQ	Frequently Asked Questions
FHIR	Fast Healthcare Interoperability Resources
GDPR	General Data Protection Regulation

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HCIM	Health and Care information models
HL7	Health Level Seven
HNRC	Haapsalu Neurological Rehabilitation Centre
ICD	International Statistical Classification of Diseases and Related Health Problems
ICO	Information Commissioner's Office
ICT	Information and Communications Technology
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
IHE	Integrating the Healthcare Enterprise
InEen	Organiseert de eerste lijn (organizes primary care)
IROP	Integrated Regional Operational Programme
ISDB	International Society of Drug Bulletins
ISN	Information standards notice
ISO	International Organization for Standardization
IT	Information Technology
ITU	International Telecommunication Union
JIP/KAAS	Jednotný identitní proctor / Katalog autentizačních a autorizačních služeb (Unified identity proctor / Catalog of authentication and authorization services)
KNMP	Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie (Royal Dutch Pharmacists Association)
LDEP	Federal Law on the EPR
LHV	Landelijke Huisartsen Vereniging (Rural Doctors Association)
LSP	Landelijk Schakelpunt (National Switch Point)
m-	Mobile-
mHealth	Mobile Health
MHD	Mobile-Access-to-Health-Documents
MoH	Ministry of Health
mSSPA	mobility in the Public Health System of Andalusia
mXDE	Cross-Enterprise Document Data Element Extraction
NICE	National Institute for Health and Care Excellence

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NGO	Non-Government Organization
NHS	National Health System
NIA	National Identification Authorities
NRHCP	National Register of Healthcare Providers
NRHP	National Register of Health Professionals
NSC	National Steering Committee
NSEH	National Strategy for eHealth
NPS	Narcotic and Psychotropic Substance
NVZ	Nederlandse Vereniging van Ziekenhuizen (Dutch Hospital Association)
ORF	Order & Referral Form
OWASP	Open Web Application Security Project
PCD	Patient Care Device
PGO or PHE	Personal Health Environment
PHD	Personal Health Data
PRSB	Professional Record Standards Body
R&D	Research & Development
SAS	Andalusian Health Service
SLA	Service Level Agreement
SME	Small and Medium Enterprise
SMS	Short Message Service
SSPA	Sistema Sanitario Público de Andalucía
T2DM	Type 2 Diabetes Mellitus
TVS	AccessVerleningService
UK	United Kingdom
USA	United States of America
VIPP	Acceleration program Information Exchange Patient
VZVZ	Association of Healthcare Providers for Healthcare Communication
WCAG	Web Content Accessibility Guidelines
WHO	World Health Organization

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WP	Work Package
XDS	Cross-Enterprise Document Sharing

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Executive Summary

The **European Innovation and Knowledge mHealth Hub** (Hub) (https://mhealth-hub.org) is a project established by the International Telecommunication Union (ITU), in partnership with the World Health Organization (WHO) and the Regional Ministry of Health of Andalusia (Spain) to support the integration of mHealth programmes and services into the national health systems of European countries.

The Hub project is funded by the European Commission under the Horizon 2020 program and is underpinned by a consortium of 17 public and private partners from 12 European countries led by the Andalusian Public Health System.

The **Work Package 5 – Policy Framework** aims to contribute towards developing a policy framework for EU on cross-border adoption and assessment of innovation in mHealth to help pave the way for moving towards a "Single Healthcare Digital Market" in Europe. Moreover, the Policy Framework described in this report aims to contribute to the development of a Common Policy Framework for mHealth in Europe, by sharing lessons learnt and recommendations, with the goal of promoting harmonization.

The Policy Framework targets primarily **policy makers** and **implementers**. Even so, app developers, industries, academia, research institutions and end-users (citizens and healthcare professionals) are seen as key actors for the Policy Framework development, and their role should be highlighted.

This final report describes the work developed to achieve such a Policy Framework, regarding methodology, results, conclusions, and recommendations for the target audience.

The **methodology** followed by the European mHealth Hub research team comprised several steps:

a. **Definition** of the mHealth Hub Strategic Policy Areas;
b. **In-depth desk research** to identify relevant mHealth (eHealth)-related policies on several policy areas;
c. **In-depth analysis** of such policies, extracting the most relevant information for policy recommendations and guidance;
d. **Interview** process with relevant stakeholders in the realm of policy making and some experts on developing and deploying policies related to mHealth;
e. **Concrete set of procedures, measures and actions** that constitute the Policy Framework and provide information on how to develop and advance mHealth policies and strategies.

The analysis of the policy landscape had an important footing in desk research activities, with the focus in what important and relevant common areas would be useful to address. After gathering 17 different important areas, it was needed further simplicity for the areas to tackle without discarding depth and relevance. The analysis paved the way to the definition of the **8 mHealth strategic policy areas** that comprehend the shared expertise, experience, and knowledge of the European mHealth Hub:

1. **mHealth strategies, governance models and change management**
2. **Integration mechanisms with EHR and interoperability**
3. **Ethical and regulatory issues. Secondary use of data and data security**
4. **Business models, innovation funds and reimbursement**
5. **Human centred design and patient safety. Patient empowerment, health literacy and digital skills**
6. **Assessing the impact of innovations**
7. **ICT infrastructure and backend technical infrastructure**
8. **Policy for addressing countries health policies in times of emergency**

These policy areas and their respective importance for the mHealth ecosystem were discussed in **Policy Ecosystem**. mHealth policy is a complex ecosystem, and mHealth integration requires multiple policy and regulatory issues: strong governance

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structures that are able to define clear mHealth strategies, policies and regulations along several dimensions: patient centredness, efficient healthcare systems and innovations perspective, and to consider all ethical issues that may arise. Not only change management processes should be adapted, but the integration and rolling out of all policies and regulations should also be supported to achieve mHealth integration from both national and cross-borders perspectives.

The **integration of health applications** and wearable health technology within eHealth and establishing seamless communication between the patient's Electronic Health Record (EHR) and the wearable devices / apps has the potential to transform patient care. However, to achieve a seamless integration and communication of health applications and EHRs, several aspects need to be addressed, such as interoperability of EHR systems, the provision of common standards and specifications to enable seamless communication between the EHR and health applications, as well as data transfer security.

While there is a high potential to improve and increase the efficiency of healthcare systems and ensure a better continuity of care, the **secondary use of data and data security** raises several ethical and policy issues concerning the sensitive nature of health data. There is a clear need to define under which circumstances and conditions the data can be reused, as well as to guarantee the compliance with GDPR and protection measurements against the growing risks of data misuse.

One of the barriers to the deployment of mHealth solutions are the inadequate **reimbursement models** and the direct costs to users. Therefore, a key factor to ensure the sustainability of mHealth adoption is through feasible business models and reimbursement plans, as well as encouraging innovation for development of efficient tools, which should be considered in mHealth policies.

MHealth policies can also support countries in the promotion of user **autonomy, empowerment, and digital health literacy**. Furthermore, users and healthcare professionals should be involved in applications development process and legislation should address topics that enable the wider use of electronic communications in healthcare.

While mHealth apps have the potential to add value to clinical practice and, implicitly, to patients' and citizens' health and wellbeing, there is a need for the mHealth apps to be properly assessed through comprehensive and well-established assessment frameworks. Therefore, to support scaling-up innovations, is fundamental that policies address **assessment innovation impact** of mobile health solutions on healthcare. For instance, it should consider the cost benefits, cost effectiveness and other mHealth-related aspects, as well as reliable processes for measuring mHealth intervention impact.

Regarding **ICT infrastructure and backend technical infrastructure**, most Member States indicated that the necessary infrastructure, including wireless and mobile communication networks coverage, is already in place. However, to fully integrate mHealth, policies and regulations must be defined in relations to semantic and technical interoperability, as well as organisational and legal matters.

In **times of emergency**, policy for addressing countries health priorities are essential in order to enable them to act efficiently and in a timely manner to be able to deal effectively with a crisis situation, as it was clearly demonstrated by the emergency of the COVID-19 pandemic. For instance, countries developed contact tracing apps to support the fight against the virus. MHealth apps could also provide benefits in other types of medical emergencies, such as the use of health apps and wearable devices for monitoring patient's vital signs (e.g., to ensure continuity of care to chronic patients).

These Policy Areas were used to analyse selected policies, which lead to the identification of the main elements for each of these Policy Areas that are recommended to be addressed to implement any policies in a specific area. For instance, the design and approach for implementation and creation of a mHealth policy:

a. should be coordinated and involve several ministries / organizations
b. leverage the use of applications for healthy people use,
c. focus on prevention rather than cure,
d. create a concept of data quality,
e. promote more involvement of private companies to work together with established health systems in creating the APIs for integration of health data,

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f. create real incentives and concrete interoperability strategy to embrace a cascade of mHealth apps that are created every day, and
g. use mHealth certification / assessment frameworks as a way to evaluate apps worthy of integration into health systems.

Some valuable views on these topics were also gathered through **interviews** (**National /** Regional Approaches to mHealth) with relevant stakeholders, whose perspective was fundamental to understand essential building blocks, good practices already established, and constraints that need to be addressed when implementing a mHealth policy and strategy. The stakeholder involvement was also turned to other projects and initiatives that, in a way, have a deep understanding and a view to promote mHealth into the policy landscape across Europe.

Interviews		
• Belgium	• Estonia	• Ireland
• Croatia	• Finland	• Portugal
• Czech Republic	• France	• Region of Catalonia, Spain
• Germany		

Most countries do **not have a specific mHealth policy**, but rather have an **eHealth policy where aspects of mHealth are addressed**. In Europe, the exception is the Region of Catalonia, Spain, that has a specific mHealth policy. The strategy of having a mHealth policy incorporated in the main eHealth strategy has the advantage of combining components that are mutual and synergistic to each other, such as the baseline ICT infrastructure, which in turn can leverage the efforts already made. In the case of Catalonia, initially it was identified the need to start with a specific mHealth strategy, since there was not yet a plan for mHealth. This stand-alone strategy allowed to design and plan specific actions and projects in this direction to address the identified needs at that time. Noteworthy, during the interview with this region, it was mentioned that for the development of the new policy, mHealth will most likely be incorporated in a more global eHealth plan, since it can be connected to the other eHealth-related projects and plans, and thus uptake the existing knowledge to the overall regional strategy.

In mHealth trends and opportunities, different **trends and opportunities for mHealth** were also explored, which were initially collected from the audience during the HubTalk focused on mHealth policies (28th April, 2021), which was then complemented with desk-research when needed. The several trends and opportunities identified by the audience are deeply connected with the above-mentioned 8 main strategic policy areas. Policies related with Artificial Intelligence were also discussed in Annex IV – Policies Considerations for Artificial Intelligence.

Different **use cases** related to the 8 main Strategic Policy Areas were collected from across Europe. This use cases are presented in **Annex II – Policy areas research**, which were organized according to the main policy area that it is addressed, even though some use cases also address aspects of the other policy areas.

The use cases were analysed in terms of main enablers and disablers, and for each policy area, main findings, gaps and trends were highlighted, along with the presentation of key recommendations that are targeted to policy makers and implementers.

Policy Area	Use cases
Policy Area 1 – mHealth strategies, governance models and change management	• Estonian eHealth Strategic Development 2020 (Estonia) • Action Plan for National eHealth Strategy (NSEH) 2016-2020 (Czech Republic) • Mobility Master Plan (mHealth.Cat) strategy and action plan (Region of Catalonia, Spain) • National indications for the provision of services in Telemedicine (Italy) • TrentinoSalute4.0 (Italy) • Swiss eHealth Strategy 2.0 (Switzerland)

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Policy Area 2 – Integration Mechanisms with EHR and Interoperability	• mSSPA (Andalucia, Spain) • The Netherlands MedMij Framework (The Netherlands) • VIPP (The Netherlands) • ProEmpower (Europe) • ELGA Electronic Health Record (Austria)
Policy Area 3 – Ethical and regulatory issues. Secondary use of data and data security: privacy, confidentiality, integrity, and availability	• Isaacus – Digital Health Hub in Finland (Finland) • Medical Informatics Initiative (Germany)
Policy Area 4 – Business models, innovation funds and reimbursement.	• The German Digital health apps reimbursement case (Germany) • mHealthBelgium initiative (Belgium)
Policy Area 5 – Human centred design and patient safety. Patient empowerment, health literacy and digital skills.	• Living Labs (Europe) • Human-centred approach to develop a digital environment for the management of Type 2 Diabetes Mellitus: The PROEMPOWER experience (Europe)
Policy Area 6 – Assessing the impact of the innovations	• Evidence standards framework for digital health technologies. Behaviour change: digital and mobile health interventions. NICE (England).
Policy Area 7 – ICT Infrastructure nd Backend Technical Infrastructure	• NHS Digital Health Technology Standard (United Kingdom) • e-Health and patient data exchange landscape in the Netherlands (The Netherlands) • eHealthSuisse – mHealth (Switzerland) • National eHealth Infrastructure (EESZT) (Hungary)
Policy Area 8 – Policy For Addressing Countries Health Priorities In Times Of Emergency	• Focus on mHealth in Italy (Italy)

This collective knowledge and analysis were used to design the **mHealth Hub Policy Framework** (mHealth Policy Framework).

The core of the Policy Framework is powered by the main **8 mHealth Strategic Policy Areas**, and is based on **the 4 Policy Phase**s: i) Formulation, ii) Adoption, iii) Implementation, and iv) Monitoring & evaluation.

Having the policy cycle phases and main areas in mind, the Policy Framework presents relevant and important **processes** and valuable insights into streams of action and direction to take, represented by the **procedures**. **Examples** from relevant use cases are provided with key **recommendations**. The examples can be further analysed within **Results from the interviews** and **Annex II – Policy areas research**.

The policy framework is primarily aimed at policy makers and implementers, and offers a **dynamic approach** that can be customized to a country / region's individual needs and expectations. The framework does not need to be comprehensively employed or provides all the information that a certain country / region requires. Despite this, the policy framework offers key recommendations, processes and procedures that take into account the various phases of development. This framework can be a useful resource to build a mHealth strategy, regardless of the current state of development.

A common recommendation found across the framework is the need to **involve all stakeholders** of the mHealth ecosystem since the beginning to implementation, and during the evaluation of a new version. This will aid in the development of a **more comprehensive approach** and increase the **likelihood of adoption** in the latter phases. Furthermore, **promoting**

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synergies between existing strategies (including those outside of the Health sector, such as digitalization and administrative sectors) was shown to yield positive outcomes, particularly when combined with **international cross-border activities**.

Close cooperation across countries was deemed necessary to advance global mHealth and make it accessible across countries. Harmonization across Europe requires **common interoperability standards** and many efforts are already underway. All essential stakeholders from the mHealth ecosystem should be involved in this process, and guidance on how to lead this effort should be provided.

This model has the potential to build connections with the countries and it is expected to guide policy makers and implementers in the development of a **collaborative and inclusive mHealth policy** that ultimately benefits end users and healthcare systems in the long run.

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1 Introduction

The **European Innovation and Knowledge mHealth Hub** (Hub) has its work separated into Work Packages (WP), of which for this document the focus is on **WP5 – Policy Framework**, and more specifically **Deliverable 5.1** – Developing a policy framework for EU on cross-border adoption and assessment of innovation in mHealth.

In order to align the reader with the intent of the project itself, some key definitions need to be described. The first and most important term is **Policy** which stands for a deliberate system of principles to guide decisions and achieve rational outcomes. A policy is a statement of intent and is implemented as a procedure or protocol. Not to be confused with **Regulation**, which indicates a set of techniques or actions that when applied to an organization or process allow to achieve a determined state or goal. Both of the above-mentioned definitions have distinct but complimentary purposes to **Laws**, which refers to a system of rules created and enforced through social or governmental institutions to regulate behaviour.

With these definitions in mind, WP5 will develop the role of the Hub in facilitating innovation adoption, promoting the progress from market innovations to implementation stage and with special focus on **mHealth policies**.

The WP5 aims to contribute towards developing a **policy framework** for EU on cross-border adoption and assessment of innovation in mHealth to help pave the way for moving towards a "Single Healthcare Digital Market" in Europe. Moreover, the Policy Framework aims to contribute to the development of a Common Policy Framework for mHealth in Europe, by sharing lessons learnt and recommendations, with the goal of promoting harmonization.

The Policy Framework targets primarily **policy makers** and **implementers**. Nonetheless, app developers, industries, academia, research institutions and end-users (citizens and healthcare professionals) are seen as key actors for the Policy Framework development, and their role should be highlighted.

Moreover, this document will describe what roles digital innovation can play in enabling clinicians and other healthcare professionals to adopt mobile solutions for different diseases management, and in preparing the public and private healthcare provider market and relevant stakeholders, such as industry, policy makers and NGOs, to embrace and recognise the value of these novel ways of prevention, treatment, or follow-up.

WP5 expects to produce a model has the potential to build connections with the countries and it is expected to guide policy makers and implementers to develop a collaborative and inclusive mHealth policy that ultimately benefits end users and healthcare systems.

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2 Objectives

This document describes the work developed in the context of WP5 and explores several mHealth-related policies across Europe. The main objectives of this document are:

- To contribute to the development of a Common **Policy Framework** for mHealth apps in Europe.
- To capture the various Policy Areas a country is advised to consider in order to create an **enabling environment for mHealth** solutions and to allow the cross-border flow of innovations in mHealth / digital health.
- To develop a **policy adoption model** that would allow an institution, a national or regional government to replicate or adapt according to their own environment and needs.
- To provide guidance / recommendations for **countries / regions** to follow when implementing and adopting Policies for mHealth.

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3 Methodology

3.1 Overview

The methodology (Figure 1 – D5.1 Policy Framework Methodology) followed by the **European mHealth Innovation and Knowledge Hub** research team comprises several steps, which include:

- an **in-depth desk research** to identify relevant mHealth-related policies on several policy areas;
- an **in-depth analysis** of such policies, extracting the most relevant information for policy recommendations and guidance;
- an **interview process** with relevant stakeholders in the realm of policy making and some experts on developing and deploying policies related to mHealth;
- **validation initiatives** where communication on the relevant discoveries and information gathered is made through webinars, roundtables, workshops, etc.

Finally, a **concrete set of procedures, measures and actions** will be discussed and worked on to provide policy makers and relevant stakeholders information on how to develop and advance mHealth policies and strategies.

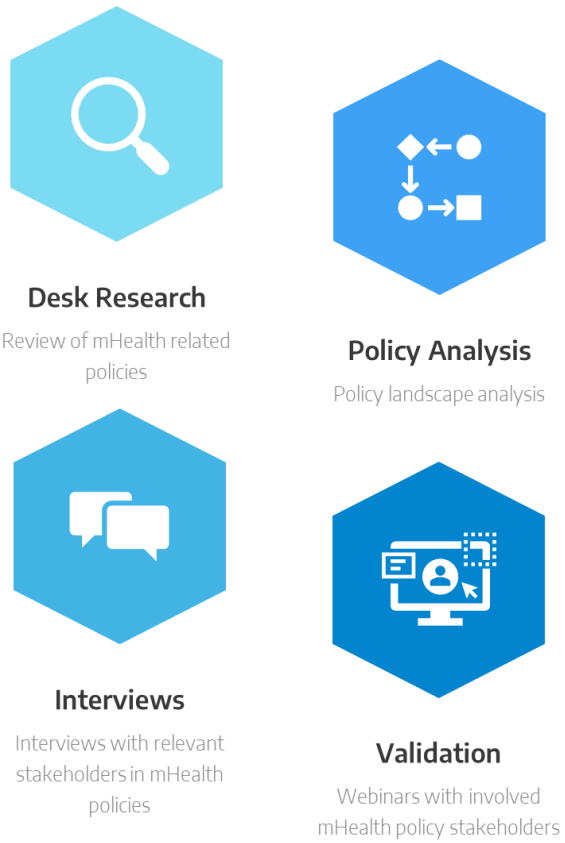

Figure 1 – D5.1 Policy Framework Methodology

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3.2 Desk Research

The overall approach consisted of identifying documents, webpages, papers, etc. that focused their efforts in developing mHealth policies.

The analysis of the policies includes the main contents; the adoption criteria; the enabling factors and barriers; the implementation strategies; the legal constraints; the impact of choices, implementations and constraints, according to the available information.

All these steps will then be the baseline to identify the main findings, the gaps and trends of such policies, and finally to be able to transfer meaningful recommendations to countries and regions that want to create / implement an mHealth strategy / policy.

3.3 Policy analysis

Digital health plays an essential role in reforming and modernising European healthcare systems. The shortage of medical professionals along with rising costs due to the growing ageing population and increase of chronic illnesses add to the challenges faced by the global healthcare ecosystem. Public expenditure on health and long-term care is expected to increase in the next years[1].

The fast growth of mobile technologies and applications creates new opportunities for mHealth. There is a high potential for mHealth to become an important part of the healthcare ecosystem, as it has the unique capacity to reduce the costs of healthcare services, while at the same time improving healthcare quality. A systematic adoption and integration of mHealth across EU would reduce the costs of total annual healthcare expenditure by €99 billion, extend the professional lives of more than 11 million persons with chronic conditions, and increase the European GDP by €93 billion[2].

mHealth can enable essential aspects such as patient self-care and empowerment, better care coordination and remote patient monitoring. Yet adoption and integration of mHealth into healthcare systems require well-defined strategies that need to address several policy and regulatory issues, as multiple and, often complex aspects need to be considered.

Governance models are essential for ensuring oversight, accountability, and the execution of the strategic plans. For health applications to be properly used and **empower patients**, important features such as **human-centred design, health literacy and digital skills** need to be addressed in patient empowerment policies. Due to the sensitive nature of health data and the protection of users, issues such as **data privacy and secondary use** of data in health applications need to be addressed. A proper **ICT infrastructure** needs to be in place for a full mHealth deployment. Promotion and adoption of mHealth requires proper frameworks, in which **health applications that are fully integrated** into the healthcare system can be **reimbursed** and innovation funds are available for further development. At the same time, if mHealth applications are to work seamlessly in the ecosystem and exchange information with systems such as Electronic Health Records (EHRs), **common interoperability** standards and approaches must be used. To speed up mHealth adoption, the effectiveness of health applications must be evaluated through recognised **impact assessment** methods and tools. And lastly, **change management** processes must be defined to ensure that all necessary changes brought about by new mHealth solutions are implemented at all organisational levels, as digital transformation requires also the mind shift of health organisations in embracing changes, not only technological solutions.

[1]OECD (2015). The future of health and long-term care spending [pdf] Available at: https://www.oecd.org/economy/growth/The-future-of-health-and-long-term-care-spending-OECD-Journal-Economic-Studies-2014.pdf

[2] PwC (2013). Socio-economic impact of mHealth: An assessment report for the European Union. Delhi, PWC [pdf] Available at: www.gsma.com/connectedliving/wp-content/uploads/2013/06/Socio-economic_impact-of-mHealth_EU_14062013V2.pdf

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The first approach for the **mHealth-related policy analysis** was to collect information about the policy landscape on mHealth strategies across Europe. Collecting information highlighted some common areas that were deemed important and relevant to assess and explore. Below are the identified relevant policy areas to mHealth:

1. Enable integration mechanisms towards EHR (connecting mHealth solutions / programs to health systems). Interoperability.
2. Stimulate innovations: Engage with the private sector; public-private partnerships (e.g. Open Innovation policies; Pre-commercial and procurement initiatives). Return on investment.
3. Existence of overall mHealth strategies and Governance models for large scale implementation.
4. Secondary use of data for innovation purposes.
5. Business models to ensure sustainability.
6. Change management: How to raise awareness, build capacity of all different stakeholders, from the end users to the professionals to the providers.
7. Policies addressing assessing the impact of innovations.
8. Secure and safeguard these innovations, so these innovations are not creating harm. Patient safety.
9. Ethical issues; Data security: privacy, confidentiality, integrity, and availability.
10. Users centricity, Well-being, and patient empowerment.
11. Digital literacy policies (health workforce / citizens).
12. Reimbursement policies: how you reimburse, how you make innovations part of reimbursement schemes.
13. Setting up innovation funds.
14. ICT infrastructure. Backend technical infrastructure. Cybersecurity.
15. Policy and Regulatory settings.
16. Other related technologies –AI, voices interface.
17. Response to emergencies and national health priorities.

In order to reduce the number of areas to tackle and complexity of the analysis, while maintaining a comprehensive overview, the previously mentioned areas have been grouped into the following eight areas:

1. **mHealth strategies, governance models and change management**
2. **Integration mechanisms with EHR and interoperability**
3. **Ethical and regulatory issues. Secondary use of data and data security**
4. **Business models, innovation funds and reimbursement**
5. **Human centred design and patient safety. Patient empowerment, health literacy and digital skills**
6. **Assessing the impact of innovations**
7. **ICT infrastructure and backend technical infrastructure**
8. **Policy for addressing countries health policies in times of emergency**

Desk research activities then followed with a systematic way to retrieve information on a templated structure. This template can be seen in Annex I – Template structure for desk research. The use cases identified during this activity can be found in Annex II – Policy areas research, which were analysed in terms of main enablers and disablers, and for each policy area, main findings, gaps and trends were highlighted, along with the presentation of key recommendations.

3.4 Interviews

Few interviews were conducted according to a guide (Annex III – Country Interview Guideline) that is structured according to the policy cycle (formulation, adoption, implementation, and monitoring & evaluation); the 8 selected policy areas are embedded in the policy cycle. With this activity it was possible to survey Member States on upscaling challenges and development of regulatory and policy frameworks for digital services including health.

The semi-structured interview based on the mHealth Policy Framework and prioritised mHealth policy areas is meant to provide inputs for the formulating of questions for primary research under each of the 8 policy areas.

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Four sections structure makes the policy cycle that underpins the interview guideline.

1. **Formulation**: definition, discussion, acceptation, or rejection of feasible courses of action. Definition of the structure, goals, and cost of the policy.
2. **Adoption**: this phase focuses on the governance, regulatory and legal actions put in place to guarantee the adoption of the policy.
3. **Implementation**: identification of the actors involved in the implementation plan and overall implementation governance structure. Operational integration with health and mHealth objectives and policies, availability of resources dedicated and referential.

4. **Monitoring and evaluation**: focused on tracking and assessing the results of implementing a certain policy. A Monitoring and Evaluation framework assigns accountability (who) and determines the approach (how) and timing (when) for measuring the results.

There are several resources that propose the policy cycle with 5 phases: Problem Definition, Formulation, Adoption, Implementation and Monitoring & evaluation. Since the common problem for this framework is cross-border adoption and assessment of mHealth innovations that pave the way for moving towards a Single Healthcare Digital Market in Europe, we have condensed the policy cycle into the four main phases mentioned above.

Preliminary Interviews

The pilot interviews were chosen to be a groundwork for more in-depth information gathering throughout Europe and beyond. The participants in this phase of the interviews were individuals with deep knowledge of the policy situation and landscape in their country. Selecting these candidates hopefully improves chances of receiving important information for the consortium tasks and provides a first feedback from the structure of the interviews.

In these interviews selected interviewees were from North Macedonia, France, Estonia, Kazakhstan, and Ireland, which lead to a good heterogeneity and spectrum of mHealth policy related experiences.

When selecting the countries for interview, we took into consideration the following elements:

- Comprehensiveness: selected countries should have all the priority policy domains considered.
- Representativeness: selected countries must have very different characteristics in terms of health systems, size, eHealth history, governance and market.
- Privileging countries on which few information was available (some important countries for mHealth had already been investigated either through desk research or activities in other WPs)
- The interviews performed at the time of the review are only a part of the work performed. Other interviews have been done since then. The idea with this first batch of interview was first of all to develop the approach (policy framework) and make sure that the interviews conducted would be able to express key messages.

The preparation of the pilot interviews was done by several steps, in which some lessons were learned for the future of the interview process of the European mHealth Hub project's activities.

<u>Interviewee selection:</u>

The identification of the suitable person / organisation requires some preliminary investment and desk research to identify the person / public body which would be the most suitable for the interview.

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Interview preparation:

It was necessary to conduct a minimum of desk research before the interview in order to seek the needed confirmations, adapt the questions accordingly and conduct the interview in such a way that the interviewer is capable to reflect on aspects not directly mentioned by the interviewee. The desk search should be oriented towards:

- Reading of last available eHealth and mHealth roadmaps
- Identification of existing frameworks
- Blogs or articles on frequently used mHealth Apps in the country (success stories)

Interview implementation:

Interviewees had no objection to the recording of the interview (at the conditions described in the template). However, in some countries this may have led to the avoidance of politically sensitive observations.

The presence of two interviewers can be very beneficial with one interviewer formally in charge of the interview (making thus sure to follow the template) and the second one in the role of the "challenger".

If there is some mHealth components to discuss, 60 minutes was found of being too short as usually a good 10 minutes is needed to (re)introduce people, project etc. This activity led us to plan rather 90 minutes.

The template which follows the several steps of the policy cycle is adequate for the countries which have already a well dedicated policy, or at least some mHealth related public initiative; but for the others − even for countries which have a public eHealth policy but no real dedicated mHealth component − more flexibility is needed, and it is then needed to reformulate the questions to try to see why some key mHealth related aspects have not yet been taken into consideration and to better exploit some elements unveiled through the desk research (such as, the popular use of an mHealth app). For instance, it does not make much sense to ask about business model if there is hardly any element of policy formulation.

Making sure to ask for all needed references during the interview is an important step to take into consideration and if the reference cannot be found immediately, a reminder is sent after the interview.

It is necessary to take the time to reformulate the answers provided, especially when the answer is long, and challenge the interviewee with elements identified through the preliminary desk research.

Interview transcription:

Interview transcription can be very time consuming. This is mainly related to the fact that the interviewee often refers to concepts, documents or decisions which need to be consulted after the interview to be correctly transcript. Even in 90 minutes, there is no time to explore many aspects in detail. It may also happen that the consultation of those mentioned documents unveils interesting information not necessarily mentioned during the interview.

Interview validation:

It is important to ask for feedback with a short delay (one week is reasonable) and to send a reminder shortly after the expiration of the delay.

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Interviews

After validation of the preliminary interview guide, a set of countries within the European Union was selected based on the current state of eHealth / mHealth policy implementation. The criteria for countries selection was designed to capture different phases / levels of implementation, as well as geographical distribution. However, due to the second wave of COVID-19 pandemic, it was not always possible to schedule an interview with the selected countries, which led to a reducer number of interviews than initially predicted. Nonetheless, the number of interviews conducted were able to reflect important elements associated with mHealth policy, which are aligned with the objective of this deliverable.

For selection purposes, the goal was to achieve several types of countries and their maturity in terms of development of:

- Quantitative metrics and
- Qualitative metrics

For quantitative metrics, we targeted different population sizes, country population density, and GDP per capita. This selection allowed us to see examples of big and small populations, high density and low-density countries, and comparable wealthier and less wealthier countries.

	Population	**Population density [/km2]**	**GDP per capita [Int$]**
High	≥11M	≥110	≥41000
low	<11M	<110	<41000

On qualitative metrics, we targeted countries that have mHealth or digital health strategies present in some way, and that have the existence of infrastructure for mHealth (Mobile broadband, Mobile networks).

Different countries in Europe were interviewed using the guide in Annex III. The main objective of these interviews was to capture the policy development related directly or indirectly with mHealth.

The interviews were transcribed into a document that was used to analyse important elements associated with mHealth and to that particular country context. A set of key messages was drawn as main conclusions, which as are displayed in section 5.

3.5 Stakeholder Interaction and Hub Interdependencies

European Innovation and Knowledge mHealth Hub is a project that aims to deeply interact with relevant stakeholders. Further on the way, results from desk research, interviews, and this policy framework document itself, will subjected to stakeholder validation and discussion. For this purpose, and due to current restrictions related to COVID-19, several on-line events will be preferred.

Contributions are also given from the mHealth Hub project. Contributions were made to projects such as eHealth Action, specifically to People Empowerment tasks and deliverables that aim at developing policy framework and policy proposal.[3]

[3] eHAction. D4.1 – Policy Framework on People Empowerment. WP4 – Empowering People. V1.0 (2019). [pdf] Available at: http://ehaction.eu/wp-content/uploads/2021/01/eHAction_D4.1_Policy-Framework-People-Empowerment_Final.pdf

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Engagement was done with decision makers in European countries to learn and compile experiences and insights from Member States about policy, business and technology challenges and policy measures to address them.

D5.1 also provided important key strategic elements that feed the loop for the several activities of the Hub project. For instance:

- **WP4**: D5.1 is currently being used to provide key recommendations for the Country Assistance activity of WP4. In this regard, in the workshop *Hungary Scoping Workshop ICT technology & infrastructure* held on 11th November 2021, a policy perspective was provided when presenting *The mHealth Landscape to support patients living with diabetes – analysis and recommendations*. Moreover, on the 20th January 2022, D5.1 will be used to develop a tailored presentation for the on-going activities to support Czech Republic. This work will be published within WP4.
- **WP2:** An ongoing dialogue and feedback loop was promoted between WP2 and D5.1 working groups. These working groups had shared elements which allowed an overview of the activities that were taking place in the different WPs. Thus, on the one hand, D5.1 provided a policy perspective for WP2 activities; and, on the other hand, WP2 assisted in analysing the policy ecosystem, and in identifying case studies for Annex II.
- In addition, all activities were coordinated with the **communication and dissemination** working group for its proper management and dissemination.

Webinar on mHealth and policy

A webinar was also promoted within the mHealth Hub project to address the subject of mHealth and policy. This webinar took place on 28th of April of 2021 and counted with the participation of three guest speakers, experts in the subject, like Carme Pratdepàdua (Catalan Department of Health), Mariana Meira (SPMS, Portugal) and Erik Vertommen (Belgian Federal Public Service), which presented different topics related to mHealth policies / strategies and led to an insightful discussion at the end between the three main speakers.[4]

3.6 Constrains and limitations

Some policies on mHealth are closely intertwined with eHealth strategies. eHealth is more generalist and most strategies do not have a specific mHealth strategy, but some strategies are applied that have a great contribution from mHealth.

There are some articles that highlight the same issue as above. Some research on the matter of mHealth end up being attached to some product rather than some policy. This means that sometimes policy needs to follow from a product, or service, demand.

There are some relevant mHealth-related strategies that are only available in their native language, other than English. This may cause translation issues. Even with a consortium that comprises members from different countries, this aspect still may affect the comprehensiveness of studies identified and respective analysis.

Different cases studies and interviews were used to build the policy framework, however not all information is publicly disclosed, limiting the access to information that could be useful for the framework.

Individual countries and regions have different national policies, contexts, needs and constraints that are not static and influence the understanding of specifics needs at a point-in-time. Thus, the policy framework approach tried to provide a dynamic approach that can be tailored to a country / region specific needs and expectations. However, the framework does not need to be comprehensively employed or provides all the necessary details for a specific country / region needs. Nonetheless, the policy framework provides key recommendations, processes and procedures considering the different

[4] mHealth Hub Talk on mHealth policies is available on the following link: https://www.youtube.com/watch?v=c6OcgfiyiRc&t=4141s

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phases of development, being a useful resource that can be leveraged for the development of a mHealth strategy, whatever the current level of advancement.

Importantly, as for any policy, especially those focused on technology, there is a continuous need to refresh, update and promote dynamic processes while maintain continuous engagement and communication with essential stakeholders. This is essential to keep the policy relevant and able to address the mHealth-related needs of the region / country.

Another relevant constraint was the impact of the COVID-19 pandemic on the availability of relevant stakeholders for the interview process, which has limited the number of interviews that were possible to achieved during the timeframe of this report. Most of the relevant stakeholders are key elements that work on the management of the COVID-19 pandemic, and thus, this was their primary priority (some interview that were already scheduled were postponed for COVID-19 related tasks).

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4 Policy Ecosystem

MHealth policy ecosystem comprises several policy and regulatory issues, as well as multiple and complex aspects that need to be considered. Based on the policy analysis (Section 3.3), **eight main strategic policy areas** (Figure 2 – mHealth integration requires multiple policy and regulatory issues: strong governance structures that are able to define clear mHealth strategies, policies and regulations along several dimensions: patient centredness, efficient healthcare systems and to consider all ethical issues that may arise. Change management processes should be adapted and support integration and rolling out of all policies and regulations to achieve mHealth integration from both national and cross-borders perspectives.) were defined, which will be explored in the next subsections.

Figure 2 – mHealth integration requires multiple policy and regulatory issues: strong governance structures that are able to define clear mHealth strategies, policies and regulations along several dimensions: patient centredness, efficient healthcare systems and to consider all ethical issues that may arise. Change management processes should be adapted and support integration and rolling out of all policies and regulations to achieve mHealth integration from both national and cross-borders perspectives.

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4.1 mHealth Strategies, governance models and change management

mHealth Strategies

Member States and regions are responsible for defining national and regional strategies that specify their visions and drive the implementation activities needed to ensure citizens' access to services (eHealth and mHealth specific in this case). While the organisation, financing of health care systems and carrying out of the national strategies belongs to Member States, the EU focuses on support and coordination of the cross-border eHealth aspects.

The **European Commission eHealth Action Plan 2012–2020**[5] sought to provide a roadmap for implementation of smarter, safer and patient-centred health services, by including a special focus on mHealth. However, a horizontal look across Member States' national eHealth strategies reveals a complex situation, where some of the strategies do not treat mHealth as a separate topic but rather include it in the general framework of eHealth or telehealth.

A broad analysis of European mHealth strategies is covered by 2016 WHO[6] (referred further to as the 2016 WHO Report) and European Commission survey[7] (referred further to as the 2016 EC Report on mHealth). After the referred effort in 2016, this report is the first attempt to fill in the identified gaps. The EC Report on national mHealth strategies included information about EU and national policy actions, strategic approaches and other horizontal domains related to mHealth, and performed an in-depth analysis related to existing and prospective mHealth activities.

Along with an analysis on policies and strategies guiding mHealth programmes, the 2016 WHO Report included information related to regulatory oversights, incentives and guidance, types, and operating level of mHealth programmes, and the role or function of health authorities in developing and adopting mHealth.

Both documents concluded that mHealth is usually considered by broader strategic documents, such as eHealth strategies and are sometimes covered by the national telehealth plan or other strategies. Few countries do not have any type of specific policy or strategy in place regarding mHealth. From a global perspective, the review of mHealth policies is as difficult as characterising the European landscape, with important policies and regulations being captured in other wider planning strategy documents[8]. At European level, a special case is constituted by the Catalan Master Plan, which is the only one that provides a specific mHealth strategy, albeit applicable only to the region of Catalonia (Spain). Most of the eHealth strategies consider broad areas of mHealth, such as patient-orientation, market development, quality, security, and increase of mobility.

The same applies to specific legislation, where most countries do not have an mHealth specific legislation implemented and rely on a wider legislation framework for regulating the mHealth domain. In terms of stakeholder responsibilities, in the European region health authorities have been identified to be responsible for promoting standards, interoperability, development and mHealth adoption, and providing guidance for privacy and security, oversight, and enforcement of data ownership. A number of countries have a national entity in place that is responsible for regulatory oversight of mHealth apps for quality, safety, and reliability.

The implementation of mHealth applications in public programmes, primary care and hospitals is also highly heterogenous among Member States. In implementing mHealth, several restrains have been identified. Issues such as ambiguous

[5] European Commission (2012). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. eHealth Action Plan 2012-2020 – Innovative healthcare for the 21st century [online] Available at: https://ec.europa.eu/digital-single-market/en/news/ehealth-action-plan-2012-2020-innovative-healthcare-21st-century

[6] WHO (2016). From Innovation to Implementation. eHealth in the WHO European Region [online] Available at: https://www.euro.who.int/__data/assets/pdf_file/0012/302331/From-Innovation-to-Implementation-eHealth-Report-EU.pdf?ua=1

[7] European Commission (2016). mHealth sub-group. Report on national mHealth strategies [online] Available at: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co22_en.pdf

[8] Malvey, D. M., & Slovensky, D. J. (2017). Global mHealth policy arena: status check and future directions. mHealth, 3, 41. https://doi.org/10.21037/mhealth.2017.09.03.

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regulatory requirements, reimbursement challenges and inconsistent evidence of effectiveness slow down the adoption of mHealth innovations.

Governance models

Governance can be understood as "a set of management or leadership processes used by people structures to take decisions, grant power to make decisions happen and monitor results and performance, where these structures can have different forms of socio-political or economical government, in the broader sense of this term"[9]. Based on values such as transparency, accountability, participation, integrity, and policy capacity[10], the main aim of governance structures is to ensure a seamless flow and enable outcomes according to the adopted decisions.

In the EU framework, both national and European eHealth governance structures exist. eHealth and mHealth governance functions include directing and coordinating eHealth development, reaching agreements on policies, protecting both individuals and groups, and ensuring oversight and accountability in various aspects involving the use of information and communication technologies (ICT) for health[6].

The **Joint Action supporting the eHealth Network (eHAction)** recently reported on the European landscape of eHealth governance bodies, their main responsibilities and the eHealth initiative types that are being carried out[11]. Most Member States have eHealth administrative structures on several levels: national, federal / regional, and local, with each assuming different roles and responsibilities. National bodies are in charge of defining, monitoring, and implementing national eHealth and mHealth strategies, while regional and local administrative structures usually have responsibilities limited to strategy execution and coordination. Regarding the responsibilities of governance structures across Member States, eHAction reports that in most of the countries national bodies are responsible for: strategy design and control, strategy execution, funding, and coordination of eHealth policy. Administrative structures like Ministries of health, insurance funds bodies, regional health agencies and medical councils have been found in most Member States to play an essential role in carrying out all the mentioned responsibilities.

While national governance bodies are responsible for establishing and implementing the Member States' national eHealth strategies, European governance structures oversee the cross-border interoperability of electronic health systems at EU level and wider use of eHealth. This is currently being carried out through **the eHealth Digital Service Infrastructure (eHDSI)** under the **Connecting Europe Facility Programme**. The eHDSI governance model consists of bodies dealing with policy governance, IT governance, secretariat functions and stakeholder liaison[12], with the eHealth Network, as set up by Directive 2011/24/EU, representing the main eHealth Policy Owner.

A successful eHealth implementation demands attention to the dynamics of governance, in particular to the balance between centralised and decentralised structures that can bring together and synergise all partners involved in the deployment of eHealth[13]. Specifically, eHAction reports on countries with a decentralised health system structure (including also regional and local governance structures) being more likely to support a larger number of eHealth initiatives and have a higher engagement level of eHealth stakeholders.

[9] Beratarbide, E. & Kelsey; T. (2011). eHealth Governance, A Key Factor for Better Health Care: Implementation of IT Governance to Ensure Better care through Better eHealth. In S. Brown, & M. Brown (Ed.), Ethical Issues and Security Monitoring Trends in Global Healthcare: Technological Advancements (pp. 72-92). IGI Global. http://doi:10.4018/978-1-60960-174-4.ch006.

[10] Greer. L.S et al (2019). TAPIC: A governance framework to strengthen decision making and implementation. Health systems and Policy analysis [online] Available at: https://www.euro.who.int/__data/assets/pdf_file/0012/416100/PolicyBrief_PB33_TAPIC.pdf?ua=1

[11] eHAction (2019). D8.1 – Report on National eHealth strategies, November 2019. [pdf] Available at: http://ehaction.eu//wp-content/uploads/2020/05/13.1_D8.1-Integration-in-national-policies-and-sustainability_eHAction_16th-eHN_ANNEX.pdf

[12] eHealth Network (2016). Governance model for the eHealth Digital Service Infrastructure during the CEF funding [online] Available at: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co06_en.pdf

[13] Kierkegaard P. (2015). Governance structures impact on eHealth. Health Policy and Technology, http://dx.doi.org/10.1016/j.hlpt.2014.10.016

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Change management

Fully transitioning to eHealth does not imply only technological solutions, but also change processes for all involved stakeholders. Many eHealth initiatives fail to become sustainable on the long term even in developed countries, due to insufficient consideration of the human factors involved in these projects[14] and of the divergent interests of the various stakeholder groups. Change management involves a systematic approach to advance an organisation from its current state to a desired future state. The processes are concerned with strategical changes in organisational structures, systems, processes, and behavioural patterns, as well as creating readiness and willingness for the specific changes within the organisation[15]. eHealth change management processes are needed for all ICT systems implementations and require engagement and training of users, as well as continuous functional and technical support.

The uptake of eHealth and mHealth applications and integrations into healthcare systems and clinical workflows is highly dependent on the change management strategic processes defined by the Member States, but also important for improving cross-border coordination at European level between the countries. For EU cross-border eHealth services, change management processes aim to ensure that Member States use standardised methods and procedures for the efficient administration of all changes in organisational, technical, and other dimensions. It is also recommended for each Member States to document the processes for implementation of changes, where the change process should include proper planning and ensure that sufficient information has been disseminated to other Member States[16].

Change management policies need to address topics that deal with the identification and provision of the required resources, as well as supporting individuals and organisations to adopt change in order to drive organizational success and outcomes. As foreseen for example in Ireland's eHealth strategy, change management processes need to proactively engage both public and private organisations to minimise the disruption of eHealth deployments on organisations, as well as promoting proactive involvement from public and delivery groups in national eHealth deployments[17].

A recent publication on an international comparison of digital strategies[18] suggests that the implementation of digital health strategies in certain countries has been delayed or even impaired due to insufficient change management support (i.e. support for digital literacy and human-resources development) and it represents one of the most neglected success factors for the implementation of eHealth strategies. Digital literacy and professional change-management functions will play an essential role in facilitating transitions between different digital health environments.

4.2 Integration mechanisms with EHR and interoperability

One of the innovations offered by healthcare systems is represented by the integration of health applications and wearable health technology within eHealth and establishing seamless communication between the patient's EHR and the wearable devices / apps. This aspect has the potential to transform patient care, as sharing patient-generated health data can improve medical interventions and treatments. It also enables healthcare professionals to remotely monitor the patient's health and the vast amounts of generated data could potentially be used for further research, allowing for novel insights into disease development and treatment effectiveness. For the healthcare professionals to have access to the data, it must be transferred

[14] D. Wijethilake et al. (2010). HealthChange: A change management model for an eHealth solution in developing countries. IST-AFRICA, Durban, 2010, pp. 1-8.

[15] Fritzenschaft, T. (2013). Critical success factors of change management: An empirical research in German small and medium-sized enterprises. Springer Science & Business Media.

[16] eHealth Network. Guideline on the electronic exchange of health data under cross-border directive 2011/24/EU Release 2. General guidelines.

[17] eHealth strategy for Ireland, 2013-2019. [online] Available at: https://www.ehealthireland.ie/knowledge-information-plan/ehealth-strategy-for-ireland.pdf

[18] Thiel, R., (2019). #SmartHealthSystems: international comparison of digital strategies. Gütersloh: Bertelsmann-Stiftung. [online]. Available at: https://www.bertelsmann-stiftung.de/en/publications/publication/did/smarthealthsystems-1

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to the patient's electronic health record in a secure and reliable manner. The applications destined for monitoring purposes must be subjected to stricter rules in multiple areas: privacy, security, safety, robustness, and accuracy[19].

The 2016 EC Report on mHealth[7] emphasised that by 2016 few EU countries already had linked patient generated data to EHR systems. **Finland** and **Portugal** focused on the interoperability between mHealth applications and personal / electronic health records, and **Denmark** had in plan to initiate a mobile strategy, together with a proof-of-concept project regarding the use of mobile apps for prescription purposes. However, very little up-to-date information is available regarding the situation of mHealth integration with EHR in other Member States. For a seamless integration and communication of health applications and EHRs, several aspects need to be addressed: interoperability of EHR systems, the provision of uniform standards and specifications to enable seamless communication between the EHR and the health applications, as well as data transfer security.

Few countries have achieved full EHR interoperability at a national level. Regarding the situation of national laws on electronic health records[20], "there are major disparities between countries on the deployment of electronic health records part of an interoperable infrastructure that allows different healthcare providers to access and update health data in order to ensure the continuity of care of the patient." The situation becomes even more complex when thinking from a cross-border service provision perspective. Most Member States adopt national standards according to their internal needs, without considering interoperability at EU level, which renders a high variety of semantic standards in use and a low alignment between Member States[21]. To enable cross-border interoperability of electronic health records, EC has released a Recommendation on a European Electronic Health Record exchange format and eHealth Network proposed a **Common Semantic Strategy for Health[21]** in the European Union, which led to the establishment of the eHealth Network subgroup on semantics.

Another issue is that healthcare providers cannot directly transfer the patient health-generated data received from sensors or applications to an EHR. Core standards and specifications need to be provided for enabling the communication between EHR and health applications. In USA, APIs are used to transfer the patient generated health-data to the EHR systems. **HealthKit** is a common framework developed by Apple capable of sharing patient data through apps, services, and providers. It uses, among others, FHIR as a standard. In Europe, the situation is known for very few cases. One detailed case is of the Portuguese eHealth system, where the Portuguese National Strategy on mHealth interoperability is mainly focused on developing a set of APIs to support the utilization of mobile medical electronic prescription and other mHealth services.

When adopting specific policies, countries need to consider several aspects, such as security and privacy issues, the challenge of patient data overload and interoperability issues.

4.3 Ethical and regulatory issues. Secondary use of data and data security: privacy, confidentiality, integrity, and availability

Secondary use of data

The secondary use of data is concerned with the use of clinical data for other purposes than the main one it was collected for. As digital health is becoming more pervasive, the storage and retrieval of health data becomes easier and faster. This creates novel opportunities for health data to be reused in healthcare research. There is a high potential to improve and increase the efficiency of healthcare systems and ensure a better continuity of care. With the aid of big data tools there is a high potential of the health data to be used for a better understanding of diseases, as well as the development of personalised medicine. MHealth has the unique opportunity to collect patient data in real-time. However, due to the

[19] Marceglia, S., Pozzi, G., & Rossi, E. (2018). Integrating Hospital Records and Home Monitoring by mHealth Apps. In Theories to Inform Superior Health Informatics Research and Practice (pp. 415-426). Springer, Cham. https://doi.org/10.1007/978-3-319-72287-0_26

[20] Time.lex (2014). Overview of the national laws on electronic health records in the EU Member States and their interaction with the provision of cross-border eHealth services. Final report and recommendations. [pdf] Available at: https://ec.europa.eu/health/sites/health/files/ehealth/docs/laws_report_recommendations_en.pdf

[21] eHAction (2019). D8.2.2 Common Semantic Strategy for Health in the European Union. [online] Available at: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20190611_co242_en.pdf

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sensitive nature of health data, several ethical and policy issues arise as policy makers must define under which circumstances and conditions the data can be reused.

Several Member States have national or regional legislative frameworks that allow for comprehensive and privacy-protective secondary use of health data. Countries like Finland, Denmark, Estonia, Italy, Netherlands, and Austria do have such frameworks in place[18]. In the case of Finland, the Act on the Secondary Use of Health and Social Data[22] aims to facilitate efficient and secure processing of health data for different purposes, as well as to guarantee citizen's rights, freedoms and legitimate expectations regarding the processing of personal data.

The European Union expressed its interest in the secondary use of data in the EC's 2018 Communication of the Digital Transformation of HealthCare, where "Better Data to Promote Research, Disease Prevention and Personalised Health and Care" was defined as a top priority. The Communication states that "*a critical mass of usable data will support vital knowledge generation and help improve prevention, diagnosis and treatment of patients*". EC offers policy support by providing infrastructure for prevention and research, as well as facilitating voluntary coordination of various stakeholders for data sharing. EU plans to develop and promote the use of standards and technical specifications for secure access and cross-border exchange of health data sects across Member States.

The creation of a **European Health Data Space (EHDS)** is another step in this direction and one of the priorities of the **Commission 2019-2025**. The creation of a common EHDS has the potential to promote better exchange and access to different types of health data to support not only healthcare delivery (primary use of data), but also for health research and health policy making purposes (secondary use of data)[23]. The eHealth Multiannual Work Programme[24] has defined several expected outcomes and achievements, such as: Strengthen the awareness of the possibilities and potentially beneficial impact of big data in health by identifying best practices; Develop frameworks and common principles for realising the added value of big data in health; Support the creation of good governance principles, practices and methods in handling use of health data, including big data.

Data security

The provision of cross-border healthcare services renders an exceeding amount of exchange and transfer of personal data and health data. This creates the need for a harmonization of personal data protection across Member States and consideration of new protection measurements against the growing risks of data misuse.

One of the top priorities of the European Union concerns "citizens' secure access to and sharing of health data across borders", as described in the EC 2018 Communication. Furthermore, the topic of personal data has been addressed in the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, Regulation that repeals the previous Directive 95/46/EC (General Data Protection Regulation). The regulation is concerned with key principles of personal data protection, rights of the data subject, controller and processor of personal data and their obligations, transfers of personal data to third countries or international organisations and independent supervisory authorities[25].

The GDPR came into force in 2018. It allows individuals to control their personal data and understand how their personal data will be used, and intends to protect EU citizens against privacy and data breaches. Processing health data is deemed sensitive under the GDPR (Art.9), and it concerns also mHealth and self-tracking technologies. However, harmonisation issues

[22] Ministry of Health and Social Affairs Finland. Secondary use of health and social data. [online] Available at: https://stm.fi/en/secondary-use-of-health-and-social-data

[23] Digital health data and services – the European health data space. EC [online]. Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-Digital-health-data-and-services-the-European-health-data-space_en

[24] eHealth Network. eHealth multiannual work programme 2018-2021 [online]. Available at: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20171128_co01_en.pdf

[25] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). OJEU L119/1. Available at: https://eur-lex.europa.eu/eli/reg/2016/679/oj

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of data protection in Europe do exist, as the rules of GDPR contains references to national legislations[26]. eHAction reports that across Member States there is a huge difference in financial and organisational levels of universal healthcare services, as well as in industry regulatory affairs, all of which implies differences in the implementation of the GDPR both in national legislation and in the general practice of personal data processing.

4.4 Business models, innovation funds and reimbursement

The mHealth ecosystem comprises a variety of stakeholders. Actors such as healthcare professionals, policy makers, health ministries and regional or local authorities need to coordinate to ensure integration of mHealth in the healthcare systems. The speed of adoption and implementation is determined by the stakeholder's engagement and interaction. For a continuous mHealth support, a key factor is to ensure its sustainability through feasible business models and reimbursement plans, as well as encouraging innovation for development of efficient tools.

One of the barriers to the deployment of mHealth solutions are the inadequate reimbursement models and the direct costs of the users (2016 WHO Report[6]). Topics such as financial flows for mHealth service provision, difficulties in applying for funding (time-consuming and inconvenient process) and lack of knowledge to develop smart financing models represent some of the barriers regarding mHealth adoption by healthcare professionals[27]. Furthermore, health apps that are approved and integrated in the healthcare system and have reimbursement models are more likely to be prescribed by healthcare professionals and trusted by users. While users can promote mHealth adoption with financial incentives for use, reimbursement models are typically an issue for the majority of countries, regardless of development stage[8].

EU supports innovation in the field of eHealth for issues such as health data security, big data and patient empowerment, through Horizon 2020[28] and the new **Horizon Europe 2021-2027**[29], the **biggest EU Research and Innovation programmes**. Several European mHealth projects have been funded through Horizon 2020. Across Member States, few countries have reimbursement schemes for digital applications. Denmark and Finland reimburse mHealth in the framework of general health financing (2016 EC Report on mHealth). Germany has also developed mHealth-specific reimbursement scheme, which is made possible through the German Digital Healthcare Act 2019 *(Digitale Versorgung-Gesetz)*[30].

When considering policies, countries need to take into account clearer guidance and legislation on mHealth and define transparent reimbursement models.

4.5 Human centred design and patient safety. Patient empowerment, health literacy and digital skills

Patient empowerment has been defined as "a multi-dimensional process that helps people gain control over their own lives and increases their capacity to act on issues that they themselves define as important"[31]. The process of empowering patients is concerned with providing tools or frameworks that can facilitate their independence. Elements such as human centred design, health literacy and digital skills are essential for enabling patient empowerment. While human centred design takes into account the user's needs, desires and environment before and throughout the product development, digital health

[26] The futures of eHealth. Social, Ethical and Legal Challenges. Edited by Thomas Christian Bächle and Alina Wenick. Alexander von Humboldt Institute (July 2019). [online] Available at: https://www.hiig.de/wp-content/uploads/2019/07/Ehealth2040_web-1.pdf

[27] Bally, E., & Cesuroglu, T. (2020). Toward Integration of mHealth in Primary Care in the Netherlands: A Qualitative Analysis of Stakeholder Perspectives. Frontiers in public health, 7, 407. https://doi.org/10.3389/fpubh.2019.00407

[28] https://ec.europa.eu Horizon 2020 [online] Available at: https://ec.europa.eu/programmes/horizon2020/en

[29] https://ec.europa.eu Horizon Europe. [online] Available at https://ec.europa.eu/info/research-and-innovation/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe_en

[30] https://bundesgesundheitsministerium.de Digital HealthCare Act (DVG) [online] Available at: https://www.bundesgesundheitsministerium.de/digital-healthcare-act.html

[31] Adapted from work by the European Union Network for Patient Safety and Quality of Care [PASQ]. 8online] Available at https://psnet.ahrq.gov/issue/european-union-network-patient-safety-and-quality-care

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literacy is understood as the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or managing a health condition[32].

MHealth has the potential to empower patients with chronic diseases by allowing self-monitoring, taking educated decisions regarding their treatment and generally better self-manage their conditions by developing healthy habits in an engaging and efficient way. MHealth applications can also address public health issues in humanitarian emergencies, allowing for remote healthcare assistance and enabling self-care when providing care in person by health professionals is not possible.

EU considers empowering citizens through eHealth as a top priority and it has been defined in the **2018 Communication** as one of the three priorities under "digital tools for citizen empowerment and person-centred care". One of its aims is to promote the use of digital tools to empower people to look after their health, stimulate prevention and enable feedback and interaction between users and healthcare providers. Patient empowerment and digital literacy levels were addressed in several EU projects[33]. People empowerment is also one of the four priority areas in the **eHealth Multiannual Work Programme 2018-2021**; and more recently, EC has also published the Communication **"Digital Compass: The European Way for Digital Decade"**[34] were it has been set the goal to reach over the next decade "a digitally skilled population and highly skilled digital professionals".

In this regard, actions are also taking place at national level, with most Member States addressing in their national policies patient empowerment through eHealth. However, the implementation of the policies varies greatly between the Member States[35].

To drive mHealth adoption, countries should develop policies that promote user autonomy and empowerment. Users and healthcare professionals should be involved in applications development process and legislation should address topics that enable the wider use of electronic communications in healthcare.

4.6 Assessing the impact of the innovations

MHealth apps have the potential to add value to the clinical practice and, implicitly, to patients' and citizens' health and wellbeing, when assessed and implemented properly. A high therapy adherence aided by apps could reduce the costs of treatments and hospitalisations in many chronic conditions. Areas in which mhealth applications have been proven to be effective are few, but show promising results[36]:

- Interactive symptoms checkers might be helpful for emergency triage in areas with limited healthcare resources.
- Reducing BMI for obese patients and glycated haemoglobin for mild diabetes case.
- Supporting medication adherence in chronic diseases.
- Improving compliance and clinical outcomes from perioperative care programs.
- Facilitating access to psychotherapists or techniques for management of insomnia and other symptoms with comparable outcomes demonstrated with traditional service provision.
- Delivering disease-related education to improve communication and better patient decision making.

WHO reported that one of the top barriers to mHealth adoption is represented by the lack of evidence on effectiveness of mHealth programs (2016 WHO Report[6]). Despite the enormous potential, little scientific evidence is available in the form of study results. The needed period of investigation is usually long compared to the high development dynamics of the apps to

[32] WHO definition 2015. [online] Available at: https://www.who.int/global-coordination-mechanism/working-groups/digital_hl.pdf

[33] PALANTE, SUSTAINS, EU Digital Scoreboard and Digital Skills Indicators

[34] Shaping Europe's digital future. Europe's Digital Decade. EC [online] Available at: https://digital-strategy.ec.europa.eu/en/policies/europes-digital-decade

[35] European Commission (2017) JAseHN7.5.1: REPORT on EU State of Play of Patient Access to eHealth Data. https://www.ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5bafe5a7d&appId=PPGMS

[36] Rowland, S. P., Fitzgerald, J. E., Holme, T., Powell, J., & McGregor, A. (2020). What is the clinical value of mHealth for patients? NPJ Digital Medicine, 3(1), 1-6. DOI: 10.1038/s41746-019-0206-x

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be evaluated and mobile devices[37]. A further issue is the lack of requisite measurement tools for evaluating efficiency of mHealth interventions. Yet the evaluation of the impact of mHealth is essential, as decisions to adopt, use or reimburse this type of digital services should ideally have an evidence-based background regarding their performance and capacity to improve health and well-being.

To support scaling-up innovations in healthcare, several assessment tools exist, such as the **Maturity Model**, **ASSIST** (Assessment and evaluation tools for e-service deployment in health, care and ageing), **MAFEIP** (Monitoring and Assessment Framework for the EIP on Active and Healthy Ageing), and **MAST** (Model of Assessment of Telemedicine). They have been developed to assess early-stage and mature applications with a community focus, taking into account different dimensions of integrated care or impact of innovation in terms of healthcare outcomes and used resources[38]. Regarding mHealth impact assessment, a recent systematic review comments on the limited evidence for efficacy of mHealth interventions and the low quality of the general methodological approach of the studies that have been carried out[39]. Policies that address assessment innovation impact should consider the cost benefits, cost effectiveness and other related aspects of mHealth, as well as reliable processes for measuring mHealth intervention impact.

4.7 ICT infrastructure and backend technical infrastructure

The electronic health data exchange is only possible if it is based on a core infrastructure that allows the information to be shared between different stakeholders. ICT infrastructure refers to the information and communication technology of a system (including software, hardware, networks, etc.) that are in use.

The **EU Digital Agenda strategy 2010**[40] includes a focus on ICT capacity to reduce energy consumption, support ageing citizens' lives, revolutionise health services and deliver better public services. More recently, the Communication "**Digital Compass: The European Way for the Digital Decade**"[34] highlights the need to increase the percentage of the workforce employed as ICT specialists "who are able to develop, operate, and maintain information and communications technology systems in digitally accessible way, respecting EU values." Moreover, it is also stated that EU should also foster open and interoperable solutions at the infrastructure level.[41]

While Member States must secure a proper ICT infrastructure for national, regional and local eHealth deployment, the European ICT infrastructure represented by the **eHealth Digital Service Infrastructure (eHDSI)** ensures cross-border exchange of eHealth data.

For mHealth to be integrated and supported by the eHealth ICT infrastructure, it should be ensured sufficient cellular coverage, internet connectivity and regular power supply. Most Member States indicated that the necessary infrastructure, including wireless and mobile communication networks coverage, is already in place[3]. Yet for a full integration of mHealth, policies and regulations must be defined in relations to semantic and technical interoperability, as well as organisational and legal matters. The rolling plan for **ICT Standardisation 2020** by the European Commission outlines the importance of European and international standards as a way to further enhance the interoperability of ICT solutions and takes stock of

[37] Chances and Risks of Mobile Health Apps (CHARISMHA). Hannover Medical School,2016. [pdf] Available at: https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/A/App-Studie/charismha_abr_v.01.1e-20160606.pdf

[38] Scale-AHA (2015). Study on support to scaling up of innovations in Active and Healthy Ageing. https://digital-strategy.ec.europa.eu/en/funding/study-support-scaling-innovations-active-and-healthy-ageing-smart-20150039

[39] Marcolino, M. S., Oliveira, J. A. Q., D'Agostino, M., Ribeiro, A. L., Alkmim, M. B. M., & Novillo-Ortiz, D. (2018). The impact of mHealth interventions: systematic review of systematic reviews. *JMIR mHealth and uHealth*, *6*(1), e23. DOI: 10.2196/mhealth.8873

[40] EU Digital Agenda strategy. EC, 2010 [online]. Available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:0245:FIN:EN:PDF

[41] EC. Commission Staff Working Document. Proposal for a Decision of the European parliament and of the Council establishing the 2030 Policy Programme "Path to the Digital Decade". COM (2021) 574 final. Available at: https://digital-strategy.ec.europa.eu/en/library/staff-working-document-policy-programme-path-digital-decade

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detailed specifications, which could contribute to the technical and semantic levels of the eHealth Interoperability Framework[42].

4.8 Policy for addressing countries health priorities in times of emergency

All Member States need policies to address health priorities in cases of emergencies that are concerned with establishing of priorities in disaster responses, how to act efficient and fast in emergencies and disasters, and how to train healthcare staff to be able to deal with crisis situations.

At EU level, the EC issued a Communication on Guidelines on EU Emergency Assistance in Cross-Border Cooperation in Healthcare related to the COVID-19 crisis[43]. National, regional and local health authorities are called to use existing structures and mechanisms and available healthcare staff to alleviate overstretched healthcare facilities in the Member States in need. At the same time, the EC commits to assist the health authorities on important matters such as intensive care places, emergency transport, reimbursement, arrangements for patient mobility across borders, and qualified medical personnel.

As healthcare systems were being overburdened by the increasing number of cases created by the current pandemic, mHealth interventions prove to be essential in contact tracing and warning, support the functioning of healthcare institutions and ensure remote continuous support and monitoring of patients with noncommunicable diseases. Several EU countries have launched contact tracing apps to support the fight against the virus. These apps can be voluntarily installed and most of them rely on Bluetooth proximity technology to preserve the privacy of people's locations. When a person has been in the proximity of an infected person for a certain amount of time, they receive an alert message that allows them to be aware of the situation and take actions for their own and other people's protection[44], such as self-isolation and rapid testing. A recent study suggests that, for the approach to be highly effective, the apps need to be deployed on a large-scale[45], involving 60% of the population.

Contact tracing apps usage in EU countries give rise to key issues related to cybersecurity, privacy, cross-border interoperability, accessibility and data sharing, issues that need regulations both at national and European level. With the support of the European Commission, the EU Member States adopted an EU toolbox[46] to use mobile applications for privacy-preserving contact tracing and warning in response to the coronavirus pandemic, as well as interoperability guidelines[47] for approved contact tracing mobile applications in the EU. One important principle is that citizens should rely on a single app across the European Union, based on the interoperability between these apps and between the countries.

Currently, technical groups of the eHealth Network are defining and developing interoperability specifications and roadmaps for cross-border interoperability implementations, from pilot testing to large-scale deployment[48]. The most recent release

[42] European Commission (2020). Rolling Plan for ICT standardisation. [pdf] Available at: https://joinup.ec.europa.eu/collection/rolling-plan-ict-standardisation/rolling-plan-2020

[43] European Commission (2020). Communication from the Commission on Guidelines on EU Emergency Assistance in Cross-Border Cooperation in Healthcare related to the COVID-19 crisis. OJ C 111I, 3.4.2020, p. 1–5 [online] Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AJOC_2020_111_I_0001

[44] European Commission (2020). eHealth and COVID-19. [online] Available at: https://ec.europa.eu/health/ehealth/covid-19_en

[45] Feretti et al. (2020). Quantifying SARS-CoV-2 transmission suggests epidemic control with digital contact tracing. Science magazine. [pdf] Available at: https://science.sciencemag.org/content/early/2020/03/30/science.abb6936.full

[46] eHealth Network (2020). Mobile applications to support contact tracing in the EU's fight against COVID-19. Common EU Toolbox for Member States. Version 1.0. [pdf] Available at: https://ec.europa.eu/health/sites/health/files/ehealth/docs/covid-19_apps_en.pdf

[47] eHealth Network (2020). Interoperability guidelines for approved contact tracing mobile applications in the EU. [pdf] Available at: https://ec.europa.eu/health/sites/health/files/ehealth/docs/contacttracing_mobileapps_guidelines_en.pdf

[48] eHealth Network (2020). Summary report. 17th eHealth Network meeting (teleconference) [pdf] Available at: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20200603_sr_en.pdf

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of the eHealth Network concerns the European Interoperability Certificate governance, that aims to serve as a security architecture for contact tracing and warning apps[49].

Regarding national legislation, a recent survey conducted by the European Commission[50] reported on the status of specific legislation for the release of contact tracing apps across Member States. The survey showed that only two Member States reported the adoption of specific legislation for the launch of the mobile applications (Italy, Norway). On 29 April, the Italian Government issued a law decree setting out inter alia the rules to govern tracing apps adoption (Law Decree no. 28 of 30 April 2020, the Decree). The Decree describes the principles according to which the app can process necessary data to allow the warning of users that have been in contact with infected users. The app does not require the creation of an account, the users are only required to declare their region and that they are at least 14 years old. The Decree also addresses concerns regarding ownership and localisation, describing that data controller is the Ministry of Health and how data will be stored[51].

Denmark and France were in the process of adopting specific legislation regarding the release of contact tracing apps. In France, a decree (Decree No. 2020-650 of May 29, 2020 relating to data processing known as "StopCovid") was published on May 29, 2020, setting the definitive legal framework for the implementation of the app[52]. Some Member States were considering the adoption (Slovakia, Malta) or amending existing legislation (Estonia, Finland). Several Member States do not have a specific legislation for the launch of the mobile applications and some of them consider specific legislation to be necessary because the app is based on the consent of individuals fulfilling the GDPR requirements (Germany, Ireland, Lithuania), while others indicate that existing national legislation is sufficient for app deployment (Croatia, Poland, Portugal). Member States consider that the adoption of specific legislation is needed to clarify and provide a legal basis for data processing in the mobile apps, as well as to allow public authorities to release mobile apps.

Health apps could also provide benefits for other types of medical emergencies. The use of mhealth apps and wearable devices for monitoring a patient's vital signs could be essential in identifying risk patients and providing medical interventions when necessary.

Having this set of policy areas defined, it was possible to organize and develop the desk research work around these topics.

Further development of these policy areas can be seen in the Annex II – Policy areas research, where the importance of each policy area is highlighted with examples collected from the desk research activities. The use cases were also analysed in terms of main enablers and disablers, and for each policy area, main findings, gaps and trends were highlighted, together with the presentation of main recommendations targeted to policy makers and implementers.

[49] eHealth Network (2020). European Interoperability Certificate Governance [online] Available at: https://ec.europa.eu/health/sites/health/files/ehealth/docs/mobileapps_interop_certificate_governance_en.pdf

[50] https://ec.europa.eu (2020) Mobile applications to support contact tracing in the EU's fight against COVID-19. Progress reporting June 2020. [online] Available at: https://ec.europa.eu/health/sites/health/files/ehealth/docs/mobileapps_202006progressreport_en.pdf

[51] Norton Rose Fulbright (2020). Contact tracing apps in Italy [online] Available at: https://www.nortonrosefulbright.com/-/media/files/nrf/nrfweb/contact-tracing/italy-contact-tracing.pdf?revision=3801f769-ce57-4780-b4a8-fda5982a6e36&la=en-it

[52] Norton Rose Fulbright (2020). Contact tracing apps in France [online] Available at: https://www.nortonrosefulbright.com/-/media/files/nrf/nrfweb/contact-tracing/france-contact-tracing.pdf?revision=19d5ca2c-552b-416b-b4eb-2d5da18159cd&la=en-it

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5 National / Regional Approaches to mHealth

5.1 Progress of mHealth in EU

Many studies and reports were developed in the past years regarding the status and approaches of EU countries to mHealth. The studies collect experiences on approaches in dealing with mobile health apps, to identify common challenges and recommend possibilities for future collaboration among Member States.

One of such works was developed by the mHealth subgroup formed by the eHealth Network in 2016[53] and is based on the responses received to the survey conducted among the sub-group members to have an overview on the status of existing strategies, activities and perspectives on mHealth in the Member States. The report yielded important messages that will be used as a basis of comparison. These messages show that "*mHealth is considered a strategic area in most of the participating countries / regions*" and "*usually, mHealth is covered by broader strategic documents, mainly eHealth strategies*." Also "*The implementation of mHealth applications in public health programmes, primary care and hospitals varies greatly between the countries / regions. In countries where mHealth is utilized it is either for prevention and informational services, or for assisting health professionals*". Nevertheless, at the time of this report, it was clear for almost all the Member States that for the 3 years ahead there were plans "*to conduct mHealth related activities, including development of strategic and action plans), composing guidelines, focusing on compatibility between mHealth applications and personal / electronic health records, and conducting specific projects.*"

To complement the information above, the 2016 WHO report[6] went further in the European Region to understand, among other eHealth related technologies, the status of mHealth in the WHO European Region. This report examined the results of the 2015 WHO global survey on eHealth, which aimed at providing insights on how it is being used, as well as major areas of development, perceived barriers to adoption and potential areas of progress. According to this survey, 49% of respondents (22 countries) in the European Region report having government-sponsored mHealth programmes, with 49% reporting no such programmes, and with the EU having a higher percentage of mHealth programmes established. It was also reported that mHealth programmes in 59% (13 countries) are guided by eHealth policy or strategies, whereas 18% (4 countries) report that mHealth is guided by the national telehealth strategy, and 27% (6 countries) report that no specific policy or strategy guides mHealth. Regarding the barriers to mHealth adoption, funding was identified as the most important barrier to mHealth adoption, which was followed by legal issues, lack of evidence on cost–effectiveness, competing health system priorities, lack of legislation or regulations on mHealth and lack of evidence on effectiveness of mHealth programmes. The WHO report went further to collect some lessons and comments from Member States, to highlight the following:

- **Leadership and coordination** are regarded as some of the most important and understated aspects of successful mHealth implementation.
- There is a need for a **single national institution or coordinating body** to lead the development and integration of mHealth apps; national governments are best positioned to provide the necessary platforms for integration and interoperability.
- **Poor coordination** of mHealth initiatives at the national level is often seen, and there are difficulties in linking public and private parties with each other for mHealth service delivery.
- Making the **distinction between eHealth and mHealth** can, in some environments, make matters unnecessarily complicated.

Considering this information from these reports as a starting point, it is possible to draw some similarities and try to understand where progress has been made in the past few years, how and if the identified barriers have been addressed and identify best cases / policy examples that address those barriers. The next sub-chapter presents concrete messages and important information based on the interviews conducted with specific countries.

[53] mHealth sub-group. Report on national mHealth strategies. Presented to the 10th eHN meeting (2016). [pdf] Available at: https://ec.europa.eu/health/sites/default/files/ehealth/docs/ev_20161121_co22_en.pdf

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5.2 Results from the interviews

One important message taken from the interviews is the absence of an effective dedicated mHealth policy in many Member States. Nonetheless, mobility is considered and encompassed as part of a global eHealth policy. This is also a "moving target" in countries where such a policy has been developed with mobility now being considered as a basic requirement for most of the key solutions and services developed in Europe. Thus, this is an important input which needs to be considered when formulating recommendations.

Representatives from **ten countries / regions** (Belgium, Catalonia (Region of Spain), Czech Republic, Croatia, Estonia, Finland, France, Germany, Ireland, and Portugal) agreed to be interviewed. The main highlights from the interviews were extracted and are presented in Table 1 to 4, which have been organized by policy phase (Table 1 − Main messages extracted from the interviews related to the Policy Phase I – Formulation., Table 2 − Main messages extracted from the interviews related to the Policy Phase II – Adoption., Table 3 − Main messages extracted from the interviews related to the Policy Phase III – Implementation., and Table 4 − Main messages extracted from the interviews related to the Policy Phase IV – Monitoring & Evaluation.).

As mentioned previously, most countries do not have a specific mHealth policy, but rather have an eHealth policy where aspects of mHealth are addressed. In Europe, the exception is the region of Catalonia, Spain, that has a specific mHealth policy. The strategy of having a mHealth policy incorporated in the main eHealth strategy has the advantage of combining components that are mutual and synergistic to each other, such as the baseline ICT infrastructure, which in turn can facilitate leveraging the efforts already made. In the case of Catalonia, initially it was identified the need to start with a specific mHealth strategy since there was not yet a plan for mHealth. This stand-alone strategy allowed to design and plan specific actions and projects in this direction to address the identified needs at that time. Noteworthy, during the interview with this region, it was mentioned that for the development of the new policy, mHealth will most likely be incorporated in a more global eHealth plan, since it can be connected to the other eHealth-related projects and plans, and thus uptake the existing knowledge to the overall regional strategy.

Table 1 − Main messages extracted from the interviews related to the Policy Phase I – Formulation.

Phase I – Formulation	
Country / Region	**Key messages**
Belgium	• Financed pilot projects for good and proven ideas on mHealth. This provided important lessons, but few apps were produced at the end of the pilot. • Based on these lessons, a 3-level pyramid scheme was developed (please see Annex II for more information). • This scheme was developed as a strategy to promote the development of new apps by developers that were less willing to take such a risk due the uncertainty of having investment return (e.g., reimbursement). • This scheme helps to regulate the entrance of new mHealth technology, while ensuring data security, privacy, and even clinical and socio-economic benefit, for M3-level apps. • Government role is to define the rules to access the different levels of classification, and the private sector develops and manages the platform.

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	• Private sector was involved from the start and the government supported the initiative, with the benefit of lowering the risk for the developers, and the costs for the government.
Region of Catalonia, Spain	• Catalonia has a specific mHealth strategy. • The strategy was planned for the 2015-2020 period. • In Catalonia there is a feedback loop from professionals that allowed the governance bodies to know that citizens were using mHealth solutions and were keen on having their data on the health system. • On the inception of the mHealth strategy, the main governance bodies and health professionals' groups were the involved stakeholders. • Although important, citizens involvement in defining the strategy is time and resource consuming.
Czech Republic	• Landscape for mHealth is still in its inception, and the definition of mHealth needs to be clearly addressed. • There is a need to involve a multitude of stakeholders (government – the Ministry and its relevant departments, health insurance institutions, drug control institution, healthcare providers, medical and professionals' societies and chambers, as well as patients´ organizations) and promote discussion as early as possible. • A model for integration of mHealth applications into the national health system including reimbursement and an assessment framework are key points to be addressed to promote the adoption of mHealth solutions. • While there are others successful models in other countries, the Czech Republic needs to create a policy framework that is compatible with its reality. • The technology sector (manufactures) of mHealth apps are still rare but the area steadily grows, and it is therefore important to strengthen the need for a mHealth policy.
Croatia	• There is a need for a more systematic process for mHealth certification. • Croatia have been working for the last year to systematically organize their project initiatives and offer decision makers possible directions for future developments of eHealth and mHealth. In fact, for the development of the eHealth strategic framework, they have been running a one-year project supported by SRSS1, DG reform. • Stakeholders necessary for eHealth framework: Ministry of Health as the main government body in partnership with all 5 Croatian national institutes and funds (emergency medicine, transfusion medicine, medicine and medical devices, public health and Croatian health insurance fund). In addition, interviews and workshops with consultants' group, vendors, patients' organizations, and the main hospitals were conducted.

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Estonia	• Estonia does not have a dedicated mHealth strategy as it is considered as part of the general eHealth strategy largely supported by a wider eGovernment strategy.

Finland	• Finland has two main strategies:
	  ○ **health sector growth strategy** – to make Finland a great place for research, innovation and development activities in the field of social and health care; includes different activities (e.g., new treatments and medicines for the Finnish citizens, new business opportunities inside Finland, export possibilities); and
	  ○ **ICT strategy for the health and social care sector**. The different digital services and systems that should exist in Finland in order to have good services for the Finnish citizens, but also to source on healthcare professionals and other stakeholders in this respect. How these develop the ICT infrastructure, Architecture.
	• The ICT strategy has been implemented about 5 years ago, and Finland is now thinking about updating this strategy. Finland is drafting the basic components for that strategy.
	• Citizens could not be involved in the stakeholder group despite the broad involvement of as many organizations as possible.
	• The citizens' perspective was gathered through primarily pooling citizens opinions on organization that represent several patient groups and communities.
	• Considering different organisations: there was participation from the Social and healthcare system, the major cities and communities in Finland, and other authorities both local and national, and academia and research institutions, as well as some company involvement. Some private sector companies themselves, but mainly through the organisations that are representing that company sector, for example pharma and health tech sectors.
	• Digital literacy / inclusion was not considered in the first ICT strategy, nonetheless, it was included in different policies afterwards, and is being included it into every aspect of the development.

France	• In collaboration with the industry, all involved public bodies created a dedicated working group (28) in order to "create the conditions for a virtuous development of connected objects and mobile health applications". • All categories of stakeholders have been involved in order to agree on the diagnostics and setup the basis of the new policy formulation. • Public bodies and agencies, regional health agencies, patient representatives, all healthcare professions, all hospital associations; all industry segments representative have been consulted prior to the adoption of the "My Health 2020" strategy. • The established governance has also set up an "all stakeholders" body, the CNS (Conseil Numérique en Santé- Digital Health Council) which meets every six months.

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Germany	• Germany focused primarily in guaranteeing quality, transparency, and connectivity to the existing system. • One of the major challenges is to define the criteria for accepting mobile solutions into the system. • Germany consulted a wide range of stakeholders for the policy definition, even creating a stakeholder working group. • A very strong political backing is important.
Ireland	• Mobile health is currently not an explicit priority of the Irish eHealth strategy although some components that are under development could be considered useful for that strategy. • The COVID-19 response has created a new momentum with the first wide deployment of an app funded with public resources and could be a trigger for the development of future mHealth policies.
Portugal	• Portugal has a strategic eHealth plan, ENESIS[54], a 2020 and 2022 version. The latest stayed in formulation phase. • The governance model was defined having in the mind the lessons learned from the previous strategy, and included three levels: strategic, tactical and operational level • The main objective of the first ENESIS was to define common paths for the various NHS entities; the second ENESIS also included the private sector. • Having a high-level sponsoring is important, since the health sector include heterogeneous entities, with independent management and legal autonomy. • The analysis of the Health and eHealth state of play at the national and international levels led to the creation of a structured document "Pensar eSaúde" (Think eHealth) where it was reported trends, reference practices and challenges; this document help to guide the stakeholder engagement (e.g., interviews). • Involvement and engagement of the multitude of players was essential to capture current needs and challenges, having entities with different dimensions and maturity levels. In addition, it was possible to create forums where relevant stakeholders could discuss important topics related to the strategies. • Having structured and scripted interview guides is important to allow capturing ideas in a structured-way to identify patterns for the definition of action areas and strategic axes. • The contributions from the interviews and forums led to the creation of the framework for ENESIS that answered four questions: who, why, how and when.

[54] More information regarding ENESIS can be found on the short technical paper "Case Study: Overview of mHealth Policies in Portugal" published within WP5 of the European mHealth Hub: https://mhealth-hub.org/download/wp5-policy-and-innovation-short-technical-paper-case-study-overview-of-mhealth-policies-in-portugal

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	• Having a proactive attitude during the public consultation is important to raise awareness of these topics, especially with professionals that sometimes only notice these strategies when they are already in operation. • Parallel and as an integral part of the strategy, a financial strategy was also developed. Therefore, when initiatives are proposed it should be considered three important components: 1) Time, 2) the expected results and 3) the costs. This is important to provide information for decision makers to decide which initiatives should be approved.

Table 2 – Main messages extracted from the interviews related to the Policy Phase II – Adoption.

Phase II –Adoption	
Country / Region	**Key messages**
Region of Catalonia, Spain	• The adoption process starts in the creation of the broad strategy by a health system commission, the strategy is refined after approval from the public insurer and finally goes to the Ministry of Health for approval, to allow implementation.
Croatia	• There is a Health Data and Information Act adopted in 2019 by the Croatian Parliament that allowed them to push forward the already mentioned initiatives. • The legal frameworks that are currently being developed will allow the definition of the direction to continue working on eHealth, where mHealth will also be included. • Digital Health Literacy is not a major issue for adoption of new technologies, as demonstrated for example by nation-wide adoption of ePrescription. However, it is important for organizations to have clear instructions on the legal framework and awareness of benefits to promote the adoption. • There is an assessment framework for eHealth: the health insurance fund has a dedicated unit or service that tests the connectivity and interoperability to verify if the IT solution conforms with the functional and non-functional requirements, security and performance to become certified. This assessment framework will serve as a learning experience for the definition of a mHealth assessment framework. • The Health Insurance fund adopted the existing process of medical devices reimbursement to evaluate a particular mHealth solution for diabetes.
Finland	• Evaluated the need for legislation changes, which in some cases can be altered during the implementation phase (e.g. ICT strategy), or during the formulation (e.g., the Health sector growth strategy includes legislation changes on the roadmap). • Initially the ministry defined the different strategic areas, which were then drafted. The final version of the document was then delivered back to the ministry for approval, after which the report was exposed to Finland leading to a large discussion within Finland.

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France	• Creation of a dedicated "Espace Numérique en Santé (ENS) – Health Digital Space" which aims at "allowing each citizen, actor of the health system, to choose and access digital services in a secured and user-friendly environment". • The ENS will reference the services and mHealth Apps approved by the relevant public bodies.
Germany	• The existent medical device regulation is important to have a starting point to define the criteria for accepting mHealth solutions into the Health system (for now the procedure allows only for risk class until IIa).
Ireland	• A dynamic mobile health industry is present in Ireland, but has up to now not yet found its way to public health policies. MHealth is first of all seen as a major contributor to innovation, economy and jobs.
Portugal	• After having a validated document by the tutelage, the document is submitted for approval by Resolution of the Council of Ministers. Then if approved, it is operationalized by the proper legal tools.

Table 3 – Main messages extracted from the interviews related to the Policy Phase III – Implementation.

Phase III – Implementation	
Country / Region	**Key messages**
Region of Catalonia, Spain	• To integrate the healthcare system, solution producers need to comply to standards, such as HL7 and SNOMED CT. • Digital health literacy is not addressed in the mHealth strategy, but it is addressed in a different separated project. • The strategy resulted in creating a dedicated platform that intends to be connected to the regional healthcare system, that will allow for integration of patient data to the EHR.
Croatia	• The Ministry of Health governs the national strategy of Health development and ensures that the strategies are being implemented throughout the years. In the operational sense, the forementioned institutes and the Health insurance fund are some of the main actors in the eHealth platform in Croatia.
Czech Republic	• The Czech Republic is developing a pilot project in a microregion to start implementing and evaluating the acceptance of mHealth apps focused on public health.

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Estonia	• Health care services contracted by the Estonian Health Insurance Fund are integrated and connected to X-Road – the backbone of eEstonia – and differentiated from third-party digital health apps. • All data collection is regulated by national legislation on health services and data protection, cybersecurity and GDPR. • It does not exist a formal certification framework and process for mHealth apps as Estonia is a too small market to have an independent certifying body. • The Ministry of Social Affairs is responsible for eHealth implementation, eHealth standardisation of documents (HL7 CDA) and semantic interoperability.
Finland	• The strategy was built in the Department of Digital Services and Data Management (DDSDM), which are responsible for its implementation and monitoring. The strategy has been implemented into the work and actions plans of DDSDM. • The ideas of the ICT strategy have been further studied and planned into the national system or as a National framework Architecture (roadmaps of that Architecture work). • Mobile access is available for citizens to access MyKanta EHR and data exchange services. • In addition to these national basic services, Finland is now developing different eServices (ehealth services), such as self-evaluation, information about patient's own conditions and how to proceed to maintain their health, as well as communication between the citizens and professionals. Most of these services provide a traditional user interface, but also the mobile interface for the communication. The main idea is that there should be many different user interfaces for the same services. • The infrastructure / services have been built considering interoperability and international standards. • Dissemination: the stakeholders such as the organisations that are participating in development, as well as healthcare and social care professionals, they are to be kept as close as possible, having constantly these discussions, for example, on workshops and seminars. This helps to clarify the aims and actions that are going on. The role of management is extremely important when implementing everything. • Dissemination: Not every decision is disseminated, but rather there is a focus on certain developments (e.g., if there is something major new happening with the National eServices then it is communicated). If a new legislation is coming concerning the biobanking, it is explained what is happening, and how everything is dealt with the biobank samples. • The mobile interface is seen very often mandatory for these services. While it is important to provide this interface, at the same time, it is just one way of providing these services among other user interfaces.

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France	• After the official policy adoption, a "Tour de France" of several months has been organized in the 17 French regions in order to raise awareness and foster the engagement of all the stakeholders. • Continuous stakeholders' involvement in the policy implementation is also guaranteed through an open online participation mechanism to collect inputs and remarks on topics related to the creation of a doctrine, legal or interoperability issues. • The synthesis of the concertation is made publicly available. • In the context of the COVID-19 and to support healthcare professionals, the Ministry of Solidarity and Health maintains a list of digital tools that can be used in telehealth on its website. For each tool, the guaranteed level of security and the features offered are entered.
Ireland	• The private and associative sectors have developed numerous mHealth-related initiatives and have made further progress in defining mHealth policies, frameworks and code of conducts to deal with the fast-paced market forces on mHealth.

Table 4 – Main messages extracted from the interviews related to the Policy Phase IV – Monitoring & Evaluation.

Phase IV – Monitoring & Evaluation	
Country / Region	**Key messages**
Belgium	• Growing number of apps that have been submitted and granted classification. • Not all of the applicants have interest in M3 level certification; some applicants are only interested in applying for M1 to receive recognition for quality. • A steering committee meets twice a year, in which the status of the framework is discussed. Moreover, the private sector, such as AGORIA and beMedTech, and the government have planned meetings to discuss subjects such as eHealth in general but also mHealth. These meetings are important to measure the evolution of what is being done and to evaluate if changes are needed.
Croatia	• They are evaluating the secondary use of health data, as well as the possibility of integration of data in the EHR.
Finland	• There has not been a consistent and organised way or mechanism to monitor the strategy and its realisation. This aspect has been lacking in the implementation and it will be improved in the new versions.

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France	• Under the guidance of the ANS, a global governance for the monitoring of all actions related KPIs has been established. However, each project has also its own governance and monitoring process. • In April 2019, France proceeded to a global reanalysis of its eHealth strategy and concluded that a more systemic approach was needed.
Germany	• Accessing the reimbursement system of apps for 1 year based on first assessment, prior to providing further evidence, accelerates innovation. • Adaptation is key to the constant and continuous monitoring of the policy implementation.
Ireland	• It has been developed an evaluation and reporting framework. Reporting is planned to be done on a bi-annual basis. All projects supported by the Sláintecare Integration Fund will be publicised, as well as the progress and evaluation reports. • A programme for promoting good practices so that successful projects can be recognised and scaled up will also be established. • Aside from this, evaluation remains usually at a project level.
Portugal	• Analysis of existing models at national and international level to define a monitoring plan / platform. • Monitoring plan divided mainly at two levels: i) entity level (similar to a monitoring of a project, whether or not it is being implemented, what is the execution, what funding is being used; execution indicators) and ii) national level (a coordination strategy, with health indicators, indicators of benefit, or impact of the strategy).

Table 5 – mHealth policy status of the countries / regions that were interviewed, as well as the respective policy phase.

Country / Region	eHealth	mHealth stand alone	Policy Phase[a)]
Belgium	✓	×	III & IV
Catalonia, Spain	✓	✓	III & IV
Croatia	✓	×	III & IV
Czech Republic	✓	×	I
Estonia	✓	×	III
Finland	✓	×	III
France	✓	×	III & IV

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Germany	✓	×	III & IV
Ireland	✓	×	III & IV
Portugal	✓	×	I[b)]

Note: Policy phases correspond to the following policy cycle phases, I – Formulation; II – Adoption; III – Implementation; IV – Monitoring & evaluation; Symbols mean the following: ✓ - Available. × - Not available. [a)] Current phase of the policy according to the moment when the interview was conducted. [b)] Phase of development of the new ENESIS version; both versions were discussed during the interview.

From the results of the interviews is possible to see that some barriers from the 2016 reports are addressed by some countries; and that evidence is present in Member States that, in turn, can help mHealth be a part of a national strategy, or as integral part of an eHealth strategy. To this end, the European mHealth Hub proposes a Policy Framework that helps to connect the dots and aid countries with lessons and examples from other countries. More details are available in mHealth Policy Framework.

5.3 mHealth trends and opportunities

During the **mHealth Hub Talk on mHealth policies** (28th April, 2021, Stakeholder Interaction), an online interactive tool was used to collect information about the audience views on trends and opportunities for mHealth (Figure 3).

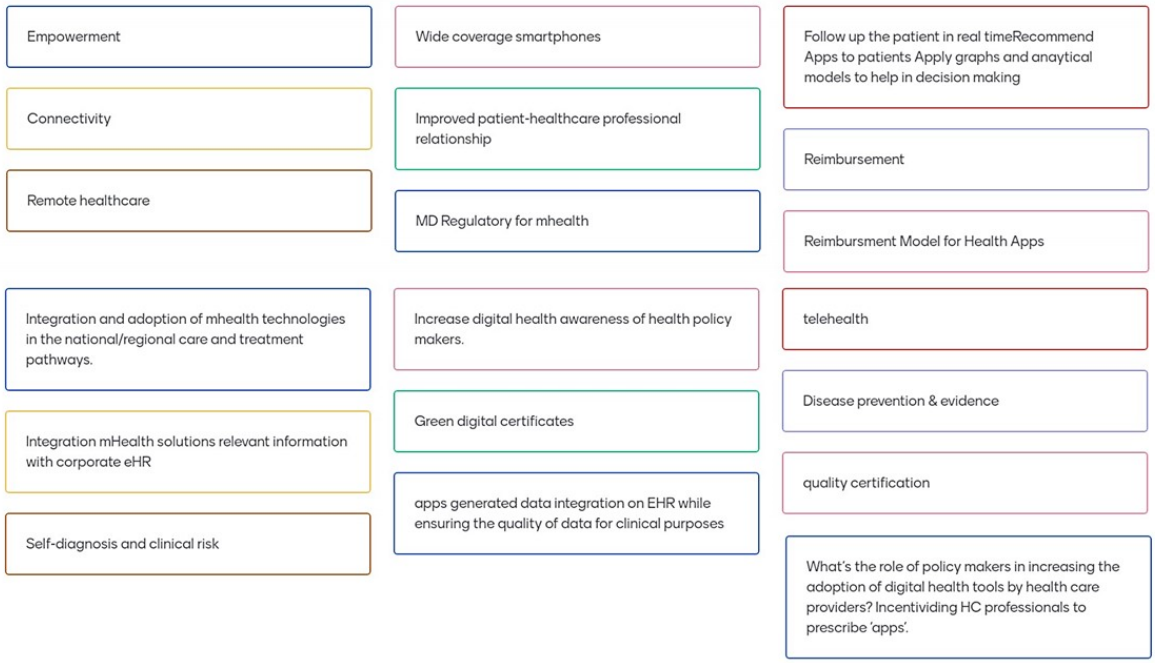

Figure 3 – Results obtained during the Hub Talk on mHealth policies (28th April 2021), using the tool Mentimeter to capture the audience views on mHealth trends and opportunities.

As it can be observed, several of the trends and opportunities highlighted by the audience are addressed in the main 8 strategic policy areas of the mHealth Hub (Section 4).

Reimbursement models for mHealth are among the identified points and is currently of interest in different countries. For instance, Czech Republic is evaluating, in collaboration with WP4, a possible assessment and reimbursement model for mHealth solutions. Recently, it was announced that France is adopting a similar model as the German for the reimbursement

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of Digital health apps[55]. One of the invited speakers represented Belgium, which together with Germany, have already defined specific reimbursement models for mHealth (Annex II – Policy areas research). As mentioned in the last point of the results (Figure 3), policy makers through policies can promote the adoption of mHealth by healthcare providers through incentivising mHealth prescription. It is here that the reimbursement will play a fundamental role.

Integration of mHealth solutions at the national / regional care and treatment pathways, as well as with EHR was also highlighted by the audience. This integration may benefit patients and providers by being fully interoperable allowing significant and seamless communication between these data sources. However, many challenges still exist in the evaluation and selection of such solutions, in its adoption by the relevant stakeholders, and in the integration with existing care pathways. As mHealth market continues to growth[56], policies addressing mHealth integration with EHR will be important to address issues such as security, privacy, and interoperability, and challenges related to patient data overload, which in turn, will be essential to promote trust and adoption by healthcare providers, patients, hospitals, and insurance institutions, among others. Furthermore, there will also be an opportunity to promote transparent data sharing regulations and patient education on data sharing and access.

While the **wide coverage of smartphones and connectivity is an opportunity** and a driving force for the advancement of mHealth solutions, this is only one part of the story. For instance, the lack of interoperability, reimbursement / incentivize models and user training still poses challenges. Therefore, policies are important to build the necessary ecosystem and regulatory environment to allow such development.

Empowerment and awareness can also be viewed as opportunities for mHealth solutions, as they can function as tools to increase not only patient empowerment, but also awareness of their own role as the main player in the management of their own disease.

In addition to telehealth, remote monitoring, disease prevention, evidence and quality certification indicated by the audience, **Big Data Analytics and AI** usage on mHealth solutions are another opportunity to leverage the potential of mHealth solutions. The combination of these technologies' innovations can have the potential for personalized analysis of user data that can contribute to the delivery of tailored recommendations, and support of decision-making[57]. Thus, this can contribute to a more patient-centric healthcare value chain, where the patient (citizen) is put at the centre rather than on the periphery. **Annex IV – Policies Considerations** for Artificial Intelligence provides an overview of AI-related policies and recommendations that ultimately affect mHealth.

As mHealth market continues to evolve and expand, more focus on **clinical outcomes, value, quality of care, and evidence** will be fundamental to get more traction and promote more investment and reimbursement schemes. For instance, in a trends infographic published by HIMSS[58], the performance of long-term studies on the viability of behavioural health technologies for certain care needs was identify as an opportunity, which will be important to further advance new mHealth programmes in this field. Moreover, in the above-mentioned resource, health equity and community-centric innovations can also be extrapolated as an opportunity for mHealth programmes, since mHealth solutions can improve patient's access to quality care, especially for populations with limited resources.

Public-private partnerships are also an important opportunity for mHealth strategies, as a mean to help build more sustainable and stronger solutions considering the regional / country context. For instance, mHealthBelgium is an initiative

[55] HIMSS TV. France adopting Germany's approach to digital health apps. Mobile health news, 2021 [online]. Available at: https://www.mobihealthnews.com/video/emea/france-adopting-germanys-approach-digital-health-apps

[56] According to a research report, the Europe mHealth market size is expected to growth and reach USD 38.42 Billion by 2026. Information retrieved from Market Data Forecast. Europe mHealth Market Research Report - Segmented By Application, Services, Connected Devices & Country (United Kingdom, France, Spain, Germany, Italy, Russia, Sweden, Denmark, Switzerland, Netherlands and Rest of Europe) - Industry Analysis, Size, Share, Growth, Trends, And Forecasts (2021 to 2026). [online] Available at: https://www.marketdataforecast.com/market-reports/europe-mobile-health-market

[57] Khan, Z. F (2020). Applications of Artificial Intelligence and Big Data Analytics in m-Health: A Healthcare System Perspective. J Healthc Eng, 2020, 8894694, https://doi.org/10.1155/2020/8894694

[58] HIMSS. Digital health – Top Healthcare Trends Infographic. HIMSS, 2021. [online] Available at: https://www.himss.org/resources/top-healthcare-trends-infographic

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of the Belgian Federal Government but the platform is managed by beMedTech (sector federation for industry of medical technologies) and Agoria (sector federation of technological industry), in close cooperation with three national authorities (Section 5.2 and Annex II). This public-private partnership had the advantage of not only lowering the risks for the developers, but also reducing the costs for the government.

Whilst the pandemic continues to pose different challenges, mHealth opportunities and trends will continue to emerge. At the time of the webinar, digital COVID certificates were mentioned, which are now a reality[59]. mHealth solutions have the potential to be important tools to prevent and manage future public health emergencies. In addition, the legislative changes introduced during the pandemic to overcome clinical, administrative, and financial barriers, can still be leveraged to facilitate a regulatory enabling environment for mHealth solutions, considering their significant role in helping healthcare systems.

[59] EC. EU Digital COVID Certificate. [online] Available at: https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/eu-digital-covid-certificate_en

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6 mHealth Policy Framework

To accelerate adoption of mobile health services and to ensure that they fulfil their promise, it is important to put in place supportive policies and regulations. Doing so will require collaboration between regulators and policy makers in both healthcare and mobile communications industries.[60] A good example of strides made in that direction in communication and cooperation is the 2012 National eHealth Strategy Toolkit[61] by WHO and ITU. These two organizations have a long history of working together, and this publication represents one of their most substantial and significant collaborations. It fully reflects the importance of governing bodies of the two organizations connected for the development of national eHealth strategies, which in turn can be regarded as a good example to apply to mHealth as well.

Policy is a set of **processes, measures, and actions** to be taken by the government / authorities to endorse certain areas of mHealth. Policies are important to provide a roadmap for consistent and efficient implementation of mHealth strategies. Moreover, considering the rapid technological evolution, these policies should be flexible, appropriate, and regularly updated, so that mHealth frameworks can achieve optimal outcomes and sustainable strategies.

6.1 mHealth Hub Policy Framework

The collective knowledge gathered (Figure 4 – Framework modelling and methodology.) in this report was used to design the **mHealth Hub Policy Framework** that aims at contributing towards the development of a Common Policy Framework for mHealth in Europe. The Policy Framework was built to provide recommendations and lessons learnt, highlighting what worked and alerting what does not, with the goal of promoting harmonization.

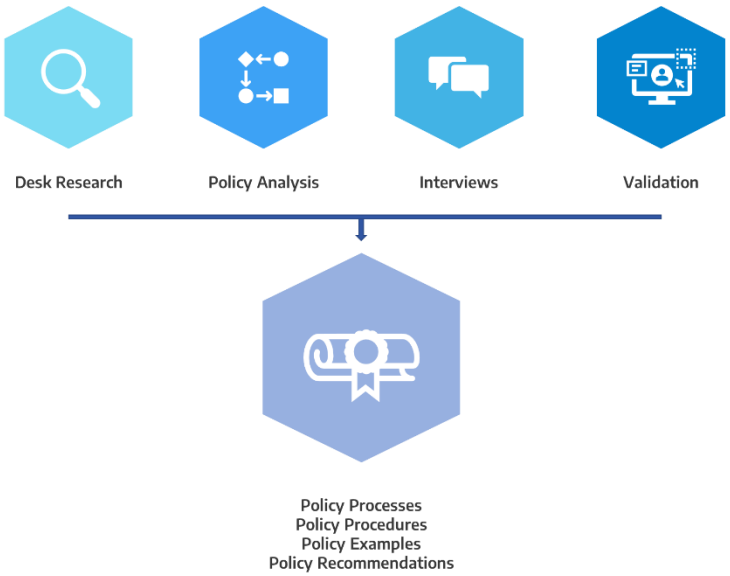

Figure 4 – Framework modelling and methodology.

[60]GSMA (2012). Policy and regulation for innovation in mobile health. [pdf] Available at: https://www.gsma.com/mobilefordevelopment/wp-content/uploads/2012/04/policyandregulationforinnovationinmobilehealth.pdf

[61] WHO and ITU (2012). National eHealth Strategy Toolkit Overview. [online] Available at: https://www.who.int/ehealth/publications/overview.pdf?ua=1

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The policy framework developed in this document combines the resulting efforts of desk research activities, policy analysis, results from the interviews and of the stakeholder involvement in the Hub activities (Figure 4 − Framework modelling and methodology.).

The Policy Framework targets primarily **policy makers** and **implementers**. However, app developers, industries, academia, research institutions and end-users (citizens and healthcare professionals) are seen as key actors for the Policy Framework development, and their role should be highlighted.

The core of the Policy Framework (Figure 5 − mHealth Hub policy framework) is powered by the main **8 mHealth Strategic Policy Areas** (described in Policy Ecosystem), and is organized according to the **4 Policy Phase**s (described in Interviews): i) Formulation, ii) Adoption, iii) Implementation, and iv) Monitoring & evaluation.

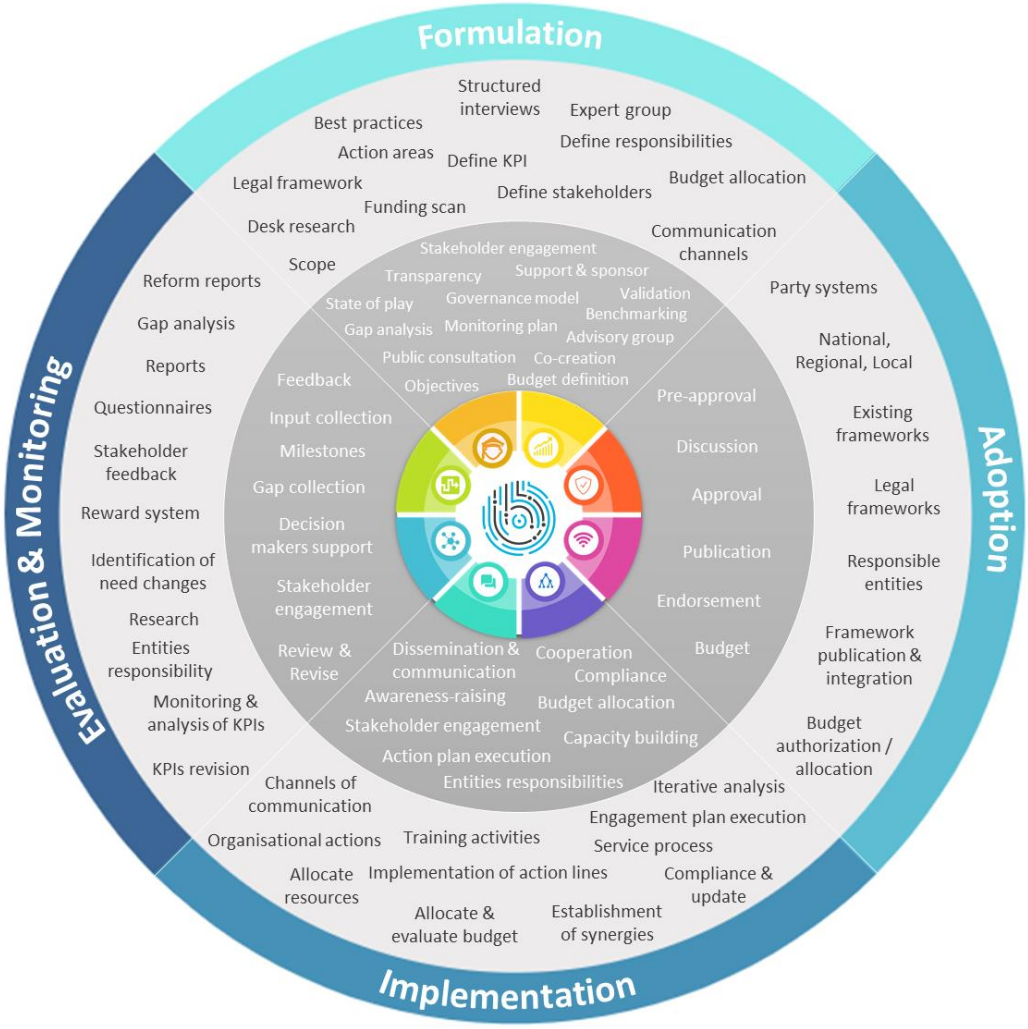

Figure 5 − mHealth Hub policy framework

Having the policy cycle phases and main areas in mind, the Policy Framework presents relevant and important **processes** (**¡Error! No se encuentra el origen de la referencia.**, inner circle, dark grey) and valuable insights into streams of action and direction to take, represented by the **procedures** (**¡Error! No se encuentra el origen de la referencia.**, outer circle, light grey). **Examples** from relevant use cases are provided with key **recommendations**. The examples can be further analysed within Results from the interviews and Annex II – Policy areas research.

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A **process** is a series or set of activities that interact to produce a result; it may occur once-only or be recurrent or periodic.[62] In the sense of the policy this envisions a set of activities that contribute to each phase of the policy cycle to develop. The **procedures** are "a set of actions that is the official or accepted way of doing something"[63] needed to materialize the processes to achieve the necessary outputs.

The policy framework offers a **dynamic approach** that can be tailored to a country / region specific needs and expectations and as mentioned, primarily targets policy makers and implementers. The framework does not need to be comprehensively employed or provides all the necessary details for a specific country / region needs. Nonetheless, the policy framework provides key recommendations, processes and procedures considering the different phases of development. This framework can be a useful resource that can be leveraged for the development of a mHealth strategy, whatever the current level of advancement.

As mentioned above, the processes and procedures represented in **¡Error! No se encuentra el origen de la referencia.** were obtained based on the overall work conducted in this document (e.g., desk research, interviews, etc). These can be used as essential guiding tools to support the development of a mHealth policy from its inception to its evaluation. **Summary of Recommendations summarizes** the set of processes and procedures per Policy Area with the main elements identified as essential steps that should be addressed in that specific area. This set of recommendations could be used as a supporting tool to not only implement a mHealth policy framework, but also to focus this policy to each country, region or organization's context and needs.

A common recommendation found across the framework is the need to **involve all stakeholders** of the mHealth ecosystem since the inception to implementation, and during the evaluation. This will help to achieve a **more comprehensive approach** and **likelihood of adoption** in the latter phases. In addition, **promoting synergies** between existing strategies (even outside of the Health sector, such as digitalization and administrative sectors) was also found to produce positive outcomes, especially when combined with **international cross-border efforts**.

Close collaboration between countries was considered essential to advance global mHealth and make it accessible across countries. **Common interoperability standards** are essential to achieve harmonization across Europe and different efforts are already in place. This should include all relevant stakeholders from the mHealth ecosystem, and guidance should be provided to lead this effort.

This model has the potential to build connections with the countries and it is expected to guide policy makers and implementers to develop a **collaborative and inclusive mHealth policy** that ultimately benefits end users and healthcare systems.

6.2 Summary of Recommendations

In the context of mHealth policy creation and implementation, the activities undertaken in this WP lead to an extensive policy examples list. This chapter represents a summary per Policy Area with the main elements identified for each of these Policy Areas comprising different processes and procedures that were considered relevant for the mHealth / eHealth strategy in question.

This analysis allowed for an extraction of different recommendations and suggestions that can be used to guide and support policy implementers and decision makers that wish to develop or advance a mHealth policy. As mentioned previously, mHealth is in most cases addressed as part an eHealth policy, and thus, certain recommendations are applicable to both cases.

The summary of recommendations has been organized by policy area, each of which is then divided per policy phase. Table 6 and Table 7 list the main use cases that were used to extract the recommendations for this subsection, and help the reader

[62] Process (definition). [online] Available at: https://en.wikipedia.org/wiki/Process

[63] Procedure (definition). [online] Available at: https://dictionary.cambridge.org/pt/dicionario/ingles/procedure

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to locate the analysis of such cases in this document. Moreover, some information was obtained directly through the internal experts of the European mHealth Hub.

Table 6 – Use cases analysed to capture the processes, procedures, examples and recommendations. The use cases can be found in Annex II – Policy areas research.

Policy Area	Examples
Policy Area 1 – mHealth strategies, governance models and change management	• Estonian eHealth Strategic Development 2020 (Estonia) • Action Plan for National eHealth Strategy (NSEH) 2016-2020 (Czech Republic) • Mobility Master Plan (mHealth.Cat) strategy and action plan (Region of Catalonia, Spain) • National indications for the provision of services in Telemedicine (Italy) • TrentinoSalute4.0 (Italy) • Swiss eHealth Strategy 2.0 (Switzerland)
Policy Area 2 – Integration Mechanisms with EHR and Interoperability	• mSSPA (Region of Andalucia, Spain) • The Netherlands MedMij Framework (The Netherlands) • VIPP (The Netherlands) • ProEmpower (Europe) • ELGA Electronic Health Record (Austria)
Policy Area 3 – Ethical and regulatory issues. S econdary use of data and data security: privacy, confidentiality, integrity, and availability	• Isaacus – Digital Health Hub (Finland) • Medical Informatics Initiative (Germany)
Policy Area 4 – Business models, innovation funds and reimbursement.	• The German Digital health apps reimbursement case (Germany) • mHealthBelgium initiative (Belgium)
Policy Area 5 – Human centred design and patient safety. Patient empowerment, health literacy and digital skills.	• Living Labs (Europe) • Human-centred approach to develop a digital environment for the management of Type 2 Diabetes Mellitus: The PROEMPOWER experience (Europe)
Policy Area 6 – Assessing the impact of the innovations	• Evidence standards framework for digital health technologies. Behaviour change: digital and mobile health interventions. NICE (England)
Policy Area 7 – ICT Infrastructure nd Backend Technical Infrastructure	• NHS Digital Health Technology Standard (United Kingdom) • e-Health and patient data exchange landscape in the Netherlands (The Netherlands) • eHealthSuisse – mHealth (Switzerland) • National eHealth Infrastructure (EESZT) (Hungary)
Policy Area 8 – Policy For Addressing Countries Health Priorities In Times Of Emergency	• Focus on mHealth (Italy)

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Table 7 – List of countries interviewed regarding their eHealth / mHealth policy, divided by policy phase.

Policy Phase	Interviews		Location in this report
Formulation	• Belgium • Czech Republic • Croatia • Estonia • Finland • France	• Germany • Ireland • Portugal • Region of Catalonia, Spain	Table 1
Adoption	• Croatia • Finland • France • Germany	• Ireland • Portugal • Region of Catalonia, Spain	Table 2Table 3
Implementation	• Croatia • Czech Republic • Estonia • Finland	• France • Ireland • Region of Catalonia, Spain	Table 3
Monitoring & Evaluation	• Belgium • Croatia • Finland • France	• Germany • Ireland • Portugal	Table 4

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Policy Phase I – Formulation			
Process	**Procedure**	**Example**	**Recommendation**
• **Stakeholder engagement** • **Analysis of previous existing plans**	• Definition of responsibilities • Working groups • Meetings • Participation in conferences and use of posters	***mHealth Catalonia 2015, Region of Catalonia, Spain:*** Health Plan 2016-2020, Catalonia (digital health is addressed in this plan in Line 10):[64] A meeting was promoted with nine working groups that analysed the previous plan (Health Plan 2011-2015) and debated upon the changes that should be addressed in the new plan. The members of these groups included: - healthcare administration; - healthcare providers; - scientific societies; - professionals associations; - industry; - patient associations; - other ministries of the Government of Catalonia; - universities; - the local area. Parallel to these activities, the experiences of posters presented at congresses were also analysed.	Develop the strategic and action plan in a participatory mode. In the example, there was the involvement of an international institution (Mobile World Capital) as a partner. The involvement of stakeholders allows to link objectives to everyday professional activity and define priorities that matters for the future.
• **State of play**	• Alignment with existing legal basis, strategies, and on-going activities • Desk research • Identification of relevant stakeholders	***Swiss eHealth Strategy 2.0*** The new eHealth Strategy replaces the previous CyberHealth (eHealth) strategy and continues the work to support the dissemination of EHR (Federal Law on electronic patient record). Different activities at the national and canton level were evaluated.	Align new the strategy with previous strategies and existing legal and on-going activities. The previous strategy can be used as a basis to analyse gaps, success projects / implementations and draw new action points for the new strategy. In addition, having government support is fundamental. The strategy should be aligned with the existing legal framework (EHR), and other complementary strategies (e.g., health and digitalisation sectors). The regional activities should also be analysed as they can work as reference practices that can be further scaled to other regions. In addition, eHealth and mHealth are intrinsically intertwined, and thus both strategies should be coordinated (even if mHealth is a stand-alone strategy).
• **State of play**	• Desk research • Cooperation	***ENESIS 2020 and new strategy, Portugal:*** Analysis of the state of play at the national and international level to capture existing best practices and challenges. In addition, at the European level, it was possible to obtain from other Member States information regarding their eHealth strategies. Other entities such as WHO also have documents that can work as toolkits. This analysis led to a structured document where it was described some line of thoughts on the future perspective. This work allowed to prepare the next steps of the formulation.	Analyse the state of play and current eHealth (mHealth) strategies to allow identifying current trends, opportunities, challenges, and good practices. This allows to gain sensitivity to the different areas that are at stake and, therefore, prepare the following steps, such as the "listening" phase with the relevant stakeholders.

[64] Government of Catalonia. Catalan Ministry of Health (2016). Health Plan for Catalonia 2016-2020 – A person-centred system: public, universal and fair. [online] Available at: https://salutweb.gencat.cat/web/.content/_departament/pla-de-salut/Pla-de-salut-2016-2020/documents/health-plan-catalonia_2016_2020.pdf

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• **Risk plan**	• Identification of potential risks • Benchmark and lessons learnt • Definition of responsibility	***Swiss eHealth Strategy 2.0*** It is necessary to assess potential risks and to take appropriate measures to avoid these risks. The international experiences can be taken into account during the implementation, as well as nationally recognized and international standards. Moreover, the potential and risks of digitization, as well as the repercussions of digital transformation in the healthcare system are systematically taken into account by the Confederation and the cantons. This is also relevant during the development and implementation of the policy strategy, during the creation of execution procedures, as well as for works on the preliminary design of new legislative projects and for revisions of laws and ordinances.	Identify and analyse potential risks that might happen during the implementation phase. This is also important for the awareness raising efforts. International experience can be leveraged to better understand possible risks, as well as any national initiatives. Risks can happen in different phases, such as during the creation and execution of procedures. However, a preliminary work on the design of new legislative projects, and revision of existing laws and ordinances can avoid / mitigate the identified risks. At this phase, also define responsibilities.
• **Action areas**	• Definition of main areas of action • Alignment with existing strategies • Desk research • Meetings	***Swiss eHealth Strategy 2.0, Mobile Health – Recommendations I*** Article 8 “Access options for patients” of the Swiss Federal Electronic Patient Record Act entails “patients are permitted to access their data” and “they may enter their own data themselves”. Considering this point, eHealth Suisse prepared a document for “mobile health – recommendations I”, where 5 main areas of action were defined: - Certification; - Data protection, data security; - Pricing; - Interoperability; - Capacity building for users. This document aimed to increase the transparency without additional regulation. The new eHealth Strategy 2.0 sets a measure to ensure the implementation of the "mHealth Recommendations I", as well as the evaluation of which measures still to be implemented are relevant and help to achieve the target objectives.	Define action areas according to strategy scope and on-going work. mHealth involves different aspects and this needs to be carefully analysed. It is important to not only define the strategy itself but clear recommendations for the key players in the mHealth sector. In the Swiss example, certification, data protection, data security, pricing, interoperability, and capacity building for users were considered. Change management is another important aspect to allow the conditions for the implementation of a mHealth programme. Coordination is another key aspect to be considered in order to ensure that the digitalization within health systems is carried out in a coordinated manner to allow data flow and secondary use of data considering the infrastructure in place. This can be an advantage to improve the efficiency within health systems.
• **mHealth vectors**	• Analysis of social and economic, regulatory, clinical & care, and technological aspects	***Mobility Master Plan (mHealth.cat) strategy and action plan, Region of Catalonia, Spain*** The strategic plan, that defines the vision, included the analysis of main vectors for mHealth adoption and difficulties to overcome. The following aspects were analysed: - social and economic; - regulatory; - clinical and care; -technological. mHealth is located in the intersection between management and provision of services, health and social welfare, and the management and provision of services with mobile technology. This analysis allows to identify opportunities and difficulties for the development phase.	Analyse the impact of mHealth on different domains, such as social and economic, regulatory, clinical and care, and technological, to identify opportunities and challenges for mHealth. For example, pressure on public resources can be interpreted as an opportunity, and lack of accreditation as a difficulty to be overcome.
• **Expected benefits**	• Definition of the expected benefits for the Healthcare System	***Swiss eHealth Strategy 2.0*** Digitalization should bring the following benefits for the health system: 1. Improvement of quality of care – regardless of location, relevant information to a person’s treatment is available which contributes to the quality of treatment.	Define the benefits that the policy will bring to the healthcare system and citizens and professionals in general. Specify how mHealth can be a key player in bringing these benefits. This will be important for the approval and adoption phase (a value proposition).

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		Moreover, rapid exchange of relevant data is beneficial for chronic ill patients. 2. Improvement of patient's safety - relevant information available at all time at all healthcare institutions / healthcare professionals helps to prevent errors, incidents, and even deaths. 3. Increase efficiency - digital data entry and networking help efficiency, as it improves procedures and interfaces, and eliminate duplicates, among others. 4. Coordination of care and interprofessional. 5.Improvement of competence in healthcare.	mHealth can bring benefits to the management of chronic patients, digitalization of health data and administrative tasks, and enhance efficiency and safety, among others. This should be present in value form – clearly define what value means (it is also important to understand the value for the citizen, which tends to be more challenging to measure).
• **Strategy horizon**	• Timeframe definition • Alignment with existing activities	***Swiss eHealth Strategy 2.0*** The duration of the strategy (2018 to 2022) considered the deadlines in the Federal law on electronic patient records, so that this strategy could be in alignment with developments at the institutional level.	Define a strategy horizon that considers the current timeframes of complementary strategies, so that the developments are aligned, and to increase the overall efficiency.
• **Criteria specification**	• Working group definition and discussion • Definition of criteria for the baseline action areas	***Mobile Health – Recommendations I, Switzerland*** For each main action area, it was defined important criteria that needed to be taken into account: - Data protection: legal opinion; - Certification: list of criteria for advisory services; - Interoperability: technical standards recommendation document; - Certification: guidelines for developers; - Capability: list of criteria for apps and information on secure data management. For this, different drafts were prepared, which were analysed through working group meetings.	Establish a working group to identify and define important criteria for each main action areas. Regarding mHealth, aspects such as data protection, certification, interoperability, and capability should be considered. While defining this, have all relevant stakeholders in mind (users, developers, organizations, infrastructures, etc).
• **Working group**	• Definition of the representatives	***Swiss eHealth Strategy 2.0*** A working group was developed with representatives of the federal services and cantonal administrations, as well as Swiss Conference of Cantonal Directors of the Health (CDS) and eHealth Suisse. The concerns expressed in the parliamentary interventions at federal level regarding eHealth or digitalization within the health system were also considered.	Establish a working group that includes key members at the national and region level. For instance, in the Swiss example the administrations and CDS (cantonal level) were included, as well as the eHealth Suisse. Moreover, as the draft of the strategy evolves, it is important to uptake new developments at the government (federal) level that are directly or indirectly related to eHealth (mHealth).
• **Political support**	• Implementation by official order • High-level sponsoring	***ENESIS 2020 and new strategy, Portugal*** ENESIS was the first national strategy for the health information ecosystem. The 1st Resolution of the Council of Ministers (RCM) in September 2016 approved a common strategy with common objectives and areas of action for information systems at the national level. This strategy, which was approved in RCM, was later implemented by an official order (April 2017). ***TrentinoSalute4.0, Region of Trentino, Italy*** The Autonomous Province of Trento identifies digital healthcare as an important mean for innovating healthcare processes. Since 2010, research and innovation in eHealth was included in the health protection law of Trentino Region – Provincial Law from 23 July 2010, number 16.	Obtain governmental support as this is essential for the development of new strategies / policies. For instance, ENESIS strategy was approved by the government, and then, published as an official order, and only after that was it possible to initiate ENESIS. Promote and obtain high-level sponsoring. Different entities have their own autonomy, and thus this will be fundamental to facilitate the establishment of measures and rules, as well as their respective successful implementation in latter phases of development by the respective entities.

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• **Governance model**	• Definition of governance model and levels	***ENESIS 2020 and new strategy, Portugal*** The strategy defined a governance model that has three levels (strategic, tactical and operational). The previous strategy allowed to draw a set of lessons learned that helped designing the governance model. ***Mobility Master Plan (mHealth.Cat) strategy and action plan, Region of Catalonia, Spain*** The responsible actors within the governance model were defined as: - Strategy and leadership: the Health Department, Social Welfare and Family Department, and Presidency Department. From this leadership, the institutional link should be created with other territories, administrations, and organisations, at the international, regional and local level. - Coordination and execution of the Master Plan of Mobility: TicSalut Foundation is the driving body, but with contributions and support from the different actors involved in the Plan. - Co-execution with global vision: Mobile World Capital Foundation is in charge of dynamizing, exporting and importing experiences, companies and international standards. - Definition, coordination, and report on the evolution of the Plan: Steering Committee will be defined.	Define a governance model and its levels for the policy during the formulation phase. This is essential to ensure a balanced and improved implementation. Previous policies can be analysed to collected gaps and recommendations for this governance model.
• **Methodology**	• Definition of methodology plan • Definition of priorities for the policy	***ENESIS 2020 and new strategy, Portugal*** To develop the strategy, they developed a methodology that would help to achieve the objectives and a final concise document for validation. The methodology included several steps, such as: 1. Analysis of the Health and eHealth context; 2. Stakeholder involvement; 3. Definition of necessary components and measurements; 4. Strategy validation; 5. Value offer; 6. Public dissemination.	Defining a proper methodology is defining the right path. Choose a suitable and sound method that is right for the development of the intended strategy as this will give the tools to achieve the final goal with success. A methodology is important to provide the guidelines to make the strategy manageable, effortless, and effective.
• **Training and accreditation**	• Alignment of existing efforts • Basic training and its continuity: management and governance plan	***Swiss eHealth Strategy 2.0*** In the development of eHealth and mHealth strategies is important to consider training and accreditation. The eHealth Suisse had in consideration the existing efforts for Training and Accreditation. Those responsible for basic and continuing training for health professionals and for management training in the health sector receive help to integrate “Electronic Patient Record” and “eHealth” into training programs. The guide “E-health: key themes for health professionals” has been written for this purpose.	Align training and accreditation efforts for the development of a mHealth / eHealth strategy. The basic training of healthcare professionals, and its continuity, needs to be ensured. For that is important to define the management and governance of such effort.
• **Support plan**	• Definition of framework for development, funding, and advice	***eHealth Suisse 2.0, Switzerland*** The eHealth Suisse has taken the task of supporting reference communities in the framework of common development of funding models, information and advice to patients in regard to the EHR. This involves for example the development of approaches	Include relevant stakeholders in the plan definition, but also provide them guidance to better understand how they can be integrated in the information, and development plan & execution.

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		to how patient organizations can be integrated in information and advice.	
• **Stakeholders**	• Stakeholder matrix • Maturity and dimension mapping (entities analysis)	***ENESIS 2020 and new strategy, Portugal*** This strategy involved different stakeholders from different sectors and dimensions. Therefore, firstly, they started by defining the relevant stakeholder clusters, and afterwards they separated them until reaching the intended key persons. After this, they defined a group of experts from the different areas.	Clearly define the stakeholders as this is critical especially if the strategy involves multiple sectors, such as a national strategy. This will allow to capture an overview of the needs and challenges across sectors to develop a more comprehensive and inclusive framework.
• **Advisory board**	• Identification and creation of an advisory board	***ENESIS 2020 and new strategy, Portugal*** This strategy had an Advisory Board made up of professional orders and associations, and patients' associations that help validating the document.	Consider creating an independent advisory board. An independent advisory board can be helpful to provide / exchange insights and ideas for the day-to-day operations. In addition, it also supports the exploration of new strategies / ideas and helps to review / validate tasks for the framework development.
• **Stakeholder consultation**	• Scripted and structured interview guides	***ENESIS 2020 and new strategy, Portugal*** Several interviews were conducted based on a structured script. These interviews aimed at identifying the current state, problems, and the challenges that lie ahead. The results from these interviews also allowed to verify if the initial document from the context analysis was able to identify goals and critical success factors that corresponded to the national reality.	Focus the initial interviews as this is essential to guarantee the success to define a good framework, since asking objective common questions across interviews and not allowing interviews to be different from each other, is critical to detect and create patterns for the strategy. Including entities with different dimensions and maturity levels is also important to identify the challenges and their different impacts (including public and private sectors).
• **Stakeholder engagement**	• Discussion forum	***ENESIS 2020 and new strategy, Portugal*** For the development of this strategy, they managed to promote forums with representatives from all the relevant entities of the NHS, where they discussed different elements (strategy, service management, plan of business continuity, contingency plan, common architecture for information systems, vision for hospital systems, etc)	Promote discussion forums with all entities to foster an environment where relevant parties can discuss important elements to define the policy. This can also serve as a tool promote awareness and knowledge among the relevant stakeholders.
• **Components and measurements**	• Definition of necessary components and measurements • Analysis / methodology definition • Definition of action areas • Definition of objectives, indicators, source and activity period	***ENESIS 2020 and new strategy, Portugal*** After gathering the contributions, these were analysed and broke down into components. These components were aggregate by areas to identify transversal and vertical areas. This led to the formulation of the framework. ***Health Plan 2016-2020, Region of Catalonia, Spain*** For each objective, different indicators, milestones and Key Performance Indicators (KPIs) were defined, as well as the responsible entities and timeline for the activity period.	Formulate a concise framework that considers the vertical and transversal areas, and it is able to answer the following question: i) to who it applies, ii) how it will be implemented (set of measures), iii) the why, and iv) when (time horizon of the framework). This allows to have the vision, ambitious, areas of action and the time frame.
• **Strategy validation**	• Validation • Revision if needed • Approval	***ENESIS 2020 and new strategy, Portugal*** The step of strategy validation is done by the competent authorities / board of directors. In this phase, the final proposal is discussed before submitting it to the government entities, which will also analyse it (consider what measures should be followed) and approved accordingly.	Promote and establish a high-level engagement with the competent authorities to ensure a successful adoption. This will allow to build a framework that is aligned with the overall goals.

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• **Value offer**	• Public consultation • Active sessions to capture contributions • Website platform to collect comments / suggestions of changes • Stakeholder engagement • Meetings	***ENESIS 2020 and new strategy, Portugal*** After the first validation, the document was placed in public consultation to collect contributions. During this time, they also held sessions with some entities in different parts of the country. The idea was to proactively stimulate criticism, suggestions, and capture more contributions besides the public consultation. The public consultation and sessions were able to provide input on the priorities of the initiatives, to capture not only their opinions about the strategic axes, but also additional proposals and technological areas that should be considered. ***Health Plan 2016-2020, Region of Catalonia, Spain*** After defining the initial version of strategic lines and projects, this worked was presented at a plenary meeting (attended by 600 people), which was followed by a period for comments and suggestions of changes via a specific website.	Encourage a pro-active attitude towards public consultation, to raise awareness of this topic. Not all relevant stakeholders will proactively participate in the public consultation. For example, sessions with healthcare and IT professionals can be promoted to help them realize that, despite being technological, is something that will impact their daily life if taken forward. So, raising awareness of these strategic issues is important. Promote an open discussion of the draft plan through different means, such as meetings and websites, in order to capture possible suggestions and comments that can improve the quality of the final document.
• **Budget**	• Financial analysis • Indicators • Budget allocation • Stakeholder engagement	***ENESIS 2020 and new strategy, Portugal*** Attached to this strategy, they also developed a financial strategy having in mind three important components: 1) Time - the beginning and end of that initiative, 2) the results, what is expected, and 3) the costs; This information is fundamental for politicians to decide which initiatives should be proceeded.	For decision and approval, clearly define a financial strategy with the costs, time and expected results. This will allow to evaluate whether a measure is justified or not; e.g., measures that, due to costs, are probably not opportune because the industry is probably not mature enough to produce at competitive prices; or it already exists and it is an easy matter to implement and results are obtained very easily. In addition, it is important to involve the relevant entities in defining the budget.
• **Funding opportunities**	• Funding scan (international and national)	***Action Plan for National eHealth Strategy 2016-2020, Czech Republic*** Primary sources of funding should be assessed to ensure and support the implementation. European funding opportunities, such as European Structural and Investment Funds, European Social Funds, CEF, etc, could be uptake for this strategy. Other funds such as WHO, Norwegian Funds are also considered.	Assess funding opportunities at the national and international landscape. EC has different opportunities for digital health and digitalization of services, and this could be uptake as an opportunity. For instance, European Structural and Investment Funds (ESIF) could be used to implement projects (although implementation via projects financed in this way will bring a certain level of administrative burden, but it can represent a significant level of savings).
• **Monitoring and evaluation plan**	• Definition of the monitoring and evaluation plan • Definition of Indicators	***ENESIS 2020 and new strategy, Portugal*** Analysis of existing models at national and international level to define a monitoring plan / platform. For this strategy, there were 2 levels of monitoring: i) at entity level (similar to a monitoring of a project, whether or not it is being implemented, what is the execution, what funding is being used; execution indicators), and ii) national level (a coordination strategy, with health indicators, indicators of benefit, and impact of the strategy). ***Action Plan for National eHealth Strategy, Czech Republic***	Define a monitoring and evaluation plan since this is critical for the latter phases. This will allow to evaluate if the strategy is being applied successfully, and simultaneously capture data to review the strategy and update / develop a new policy framework. In addition, define a platform to capture the indicators at the local and national level. Design and define a management model for the monitoring, where the organizations / entities responsible for managing, promoting, monitoring and evaluating the different elements are clearly identified (responsibility attribution).

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		To evaluate the fulfilment of indicators predicted in the implementation phase the following was consider: - the fulfilment of targets values is determined by the applicant in the application for support; - the date is specified in the legal act and is binding for the recipient; - the recipient is obliged to maintain the achieved values of the indicators and to preserve the results of the project for a period of five years from the start of the sustainability period; - If the recipient fails to meet the determined deadline for achieving a target value or for sustaining it during the sustainability period, they will be penalised in accordance with the Conditions.	
• **Government plan alignment**	• Revision	***Health Plan 2016-2020, Region of Catalonia, Spain*** When the new legislative period started while developing this plan, the proposal was reviewed considering the new priorities of the current Government plan. In this case, led to the reinforcement of specific line of actions.	Align the proposal with the changes that might happen in the government plan during the development of the policy. This alignment is fundamental in order to evaluate if new lines of action are needed to be incorporated / reinforced. This will increase the chance of the policy being adopted in the subsequent phase.
Policy Phase II – Adoption			
Process	**Procedure**	**Example**	**Recommendation**
• **Discussion** • **Approval**	• Responsible entities • Legal framework • Existing national and regional frameworks	***mHealth Catalonia 2015, and Health Plan 2016-2020, Region of Catalonia, Spain*** "provided for by Decree 201/2015 of September 15, the organs of community participation in the public health system of Catalonia, amended by the LOSC, the Health Plan was validated by the territorial participation boards and the Ministry of Health. It was ultimately submitted for approval by the Executive Council of the Government of Catalonia and was referred to the Health Commission of the Parliament of Catalonia"[65]. ***ENESIS 2020 and new strategy, Portugal*** After having a validate document by the tutelage, the document is submitted for approval by Resolution of the Council of Ministers. Then if approved it is operationalized by the proper legal tools.	Involve multiple government actors. After being approved, it needs to be dispatched by order to be operationalised in the health ecosystem; or according to the country / region respective procedures.
• **Discussion** • **Approval**	• Responsible entities • Legal framework • Existing national and regional frameworks	***Swiss eHealth Strategy 2.0*** By approving the "Digital Switzerland" Strategy action plan, the Federal Council has formally given a mandate to establish a "Swiss eHealth Strategy 2.0". Swiss Conference of Cantonal Directors of the Health (CDS) committee approved at its meeting of October 27, 2016, the idea of developing the subsequent strategy with the Confederation.	Align approval with existing strategies for digital transformation of healthcare. Other strategies may need to be approved in order to allow the formulation of a specific mHealth / eHealth strategy.

[65] Government of Catalonia, Catalan Ministry of Health. Health Plan for Catalonia 2016-2020. A person-centred system: public, universal and fair. Directorate General for Health Planning (2016) [online]. Available at: https://salutweb.gencat.cat/web/.content/_departament/pla-de-salut/Pla-de-salut-2016-2020/documents/health-plan-catalonia_2016_2020.pdf

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Policy Phase III – Implementation			
Process	**Procedure**	**Example**	**Recommendation**
• **Stakeholder engagement** • **Budget**	• Organisational actions • Channels of communication	***mHealth Catalonia 2015, Region of Catalonia, Spain*** AppSalut mConnecta	Decide who is the entity responsible for the implementation and communicate that decision to allow its practical execution. Create a technical unit (dedicated office). Secure resources to develop the plan.
• **Models of good practice**	• Publish documents, best practices • Update documentation	***Swiss eHealth Strategy 2.0*** Best practice models are documented and updated regularly on the basis of i) existing and future international regulations; ii) findings of "Hospital Infosec Liaison" expert group, and iii) "Implementation assistance concerning protection and safety of data within the framework of EHR" of eHealth Switzerland.	Analyse and publish documentation for dissemination regarding existing and international models of good practices. This will help to maintain the strategy updated with current developments.
• **Sustainability**	• Capturing new technologies approaches • Establishment of expert groups	***Swiss eHealth Strategy 2.0*** It was established a group of experts to analysed new technologies approaches to ensure promotion of cybersecurity and data security within the health system.	Formally establish a group of experts to analyse new technologies and assess their feasibility according to the current reality of the health systems.
• **Organisation model**	• Governance model	***Estonian eHealth Strategic Development 2020, Estonia*** For the implementation of the strategy, it was defined an efficient organisation with a task of ensuring the achievement of the desired strategic eHealth goals by multi-level and inclusive management model, with roles having clear responsibility.	Establish a governance model to ensure the implementation of the strategy. Clear responsibilities should be in place. This is crucial to ensure that not only the implementation happens, but also the monitoring and evaluation activities. Some representatives mentioned during the interviews that in the strategy update process, the lack of clear roles was identified as a negative and unfavourable point for the success of the monitoring and evaluation phase.
Policy Phase IV – Monitoring & Evaluation			
Process	**Procedure**	**Example**	**Recommendation**
• **Review and Revise**	• KPIs • Reform Reports	***mHealth Catalonia 2015, Region of Catalonia, Spain*** A clear framework for monitoring and evaluating the plan is missing. TicSalutSocial, through its governance body, is accountable for the progress done by the mHealth office.	Define a clear framework for monitoring and evaluating the plan. It is critical to identify the accountable governance body, which will have a fundamental role in ensuring and evaluating whether progress and goals / indicators are achieved.
• **Developments monitoring and analysis**	• Collect developments and analysis	***Swiss eHealth Strategy 2.0*** Current developments at national and international levels should be regularly analysed and, if necessary, integrated into own activities.	Consider a dynamic approach where the monitoring and evaluation phase allows to identify developments that can be integrated in the strategy / implementation phase. A regular monitoring approach in the development phase can also help to identify, early on, activities that are not being achieved, or even update existing activities in line to new political decisions.

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Policy Phase I – Formulation			
Process	**Procedure**	**Example**	**Recommendation**
• **Stakeholder Engagement** • **Public Consultation**	• Best practices • Expert group • Evaluation of maturity	***Integration with health information systems, Belgium (also Greece potentially others):*** in the assessment of mHealth apps (M1, M2, M3) there is no mention about integration to health systems; FHIR profiles are an accepted mechanism but does not constitute the implemented approach.	Consider engagement throughout the policy cycles with standards, through an appropriate FHIR accelerator that allows apps such as those for telemedicine to be integrated to EHRs. Link mHealth assessment to health technology assessment to facilitate reimbursement.
• **Access and security** • **Interoperability**	• Definition of access levels	***mSSPA, Region of Andalusia, Spain*** It has been defined a portal to make it possible to configure different levels of security for access to information, being able to restrict the information that is desired to a specific group of developers.	Define rules on security levels. Accessing EHR implies that not all actors will need to have access to all information, especially when it comes to health-related data. Consider interoperability of new mHealth solutions from the start: interoperability should not be an afterthought in R&D projects. Describe the existing environment, both infrastructure and organisation. Detail the architecture of systems, the way they work (technologies, messaging, security, APIs, etc.) so that the integration plans can be based on solid background information.
• **Backend and API Portal** • **Benchmark** • **State of play**	• Definition of backend and API modules to access information	***mSSPA, Region of Andalusia, Spain*** It is currently based on modules from CA Technologies. The CA API gateway component is available, and provides a layer of abstraction, security and decoupling with respect to the information systems of SSPA. In turn, it allows the creation, elimination, and modification of APIs, which can be used by developers. In this way, the orchestration layer and the presentation layer present in the mSSPA platform scheme allow mobile applications to access the information systems of the SSPA in a secure way, making use of the functionalities provided by the CA Technologies modules.	Collect and analyse examples from other countries, especially those that resemble the current system in place. Different countries have set out different models for app integration with EHR. This can help to draw recommendations and analyse gaps.
• **Legislation, Agreement between competent authorities**	• Evaluate existing legislation and new for new regulations. Assess the need for agreements	***ELGA Electronic Health Record, Austria*** ELGA deployment was made possible through different regulatory / legislation / initiatives: - MAGDALENA framework - eCARD - Health Telematics Law - EHR ELGA Act - ELGA regulation 2015 and subsequent admentments - Data protection and privacy - eGovernment act For a target-based health governance the federal government in Austria concluded agreements with the provinces and the social insurance funds, according to Article 15a of the Federal Constitution on target-based health governance. Electronic Health Record Act (ELGA-G), ELGA regulation 2015 included some cross-cutting concerns like accessibility rules, authorization and logging, then	Align policy with previous strategies and existing legal and on-going activities. New regulatory / legislation may be needed to support the implementation of a new policy. Furthermore, in regional and federated context, the different states should be involved in this process to establish agreements. This in turn will set the commitment to deploy at the national level.

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		subsequent amendments in Nov 2015 and 2017 with the purpose of implementing and developing the EHR. e-Government Act: contains "provisions on accessibility and official websites that are also applicable to the access portal for ELGA participants. Furthermore, the e-GovG regulates the identification of citizens through the area-specific personal identification number" As mentioned, the Federal government established different agreements to ensure the implementation of ELGA.	
• **Training plan**	• Definition of a training plan for healthcare professionals and citizens	***Swiss eHealth Strategy 2.0*** The defined objectives include support as part of internal employee training (development of documents, support during training, list of contacts). Models of good practice for fostering e-health skills are developed for communities.	Define a training plan to promote a safe use of the EHR / apps. This will help to enable citizens and professional to handle health-related data in responsible and safer manner, while being aware of the risks. Local and regional actors should be defined to implement this plan.
• **Technical and semantic standards**	• International standards • National standards	***Swiss eHealth Strategy 2.0, and mHealth recommendations I, Switzerland*** Technical and semantic standards for the exchange of information between mHealth applications and Electronic Patient Record are developed. In this context, priority is placed on standards established at international level.	Define technical, semantic and interoperable standards that allow to promote mHealth app integration to EHR. In addition, a solid infrastructure should be in place. Different international standards can be uptake for this task. This will also be valuable to align with the ongoing work towards the European Health Data Space.
• **Standards** • **Framework**	• Define initial framework • Define standards	***ELGA Electronic Health Record, Austria*** The MAGDALENA framework, which was established in 2000, guided the construction of a nationwide Austrian health network. It contains a number of technical and organizational recommendations for the creation of an Austrian Health Data Network, which laid the groundwork for Austria's electronic patient data exchange. Interoperability in ELGA is based on international IT standards and profiles. These standards are mandated via regulations that are issued by the federal health ministry, as laid down in the ELGA law. Currently, ELGA uses HL7 for standardizing electronic communication between health service providers and Clinical Document Architecture (CDA) for networking health data and information. In the addition, the standards in use in Austria include: Transport standards: W3C (SOAP, HTTP), TLS, OASIS SAML, WS-Trust, OASIS ebXML for Cross-Enterprise Document Sharing, HL7® CDA® for nation-wide harmonized clinical documents, HL7® v3.x for patient-identification related communication, DICOM – international imaging standard (WADO). Furthermore, in order to implement interoperability, the federal health ministry has issued a framework guideline for the IT infrastructure for telemonitoring. RDA (Research Data Sharing without barriers) COVID-19 Working Group Recommendations and Guidelines 5th release were followed to achieve data sharing and interoperability in the context of the Covid-19 pandemic.	Consider the use of projects and initiatives to build the framework necessary to implement a EHR and respective integration mechanism. Clearly define standards to be used in the EHR and integration mechanism. This should be synergised with international efforts

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		Austria is also linked to the use of the refined eHealth European Interoperability Framework, being a part of the eHealth Network (eHN) references. In 2018 telerehabilitation started to be supported by the amendment of the general social insurance act. Work is currently ongoing to implement mHealth services as part of the health care system, from which e-prescription and e-vaccination report are already roll out	
• **International alignment**	• Cooperation at EU level • International standards	***Swiss eHealth Strategy 2.0*** The international integration is considered to ensure that Switzerland can also participate in the cross-border medical data exchange. In this regard, international standards have been considered in addition to coordination with the European developments at this level (e.g., national contact point).	Consider international efforts for cross-border healthcare exchange. Incorporate in the formulation phase the definition of criteria necessary to allow for such exchange. Cooperation with EU relevant organizations (e.g., CEF eHDSI, eHealth Network), with Member States, and even with other international countries and relevant organizations will be key to support this effort.
• **Guidance**	• Practical guidance for integration mechanisms with EHR and interoperability	***VIPP, The Netherlands*** The description and use of the Health and Care Information Models is extensively described in four architectural volumes.	Define the responsible actors that will draw and implement the guidelines and information necessary for the integration mechanism between systems and EHR. This will require the definition of interoperability standards. International organizations can be a great supporter in achieving this task (workshops, meetings, etc). Involving the mHealth ecosystem (developers, professionals, patients, etc) will also be important for a more comprehensive approach.
• **Trust mechanism**	• Define a framework with specific architectural, ethical and judicial agreements for a safe and trust communication environment	***The Netherlands MedMij Framework*** The MedMij framework has a set of architectural, ethical and judicial agreements where each party (care-user and care-giver environments) needs to fully comply with and to which one is admitted only after having met the requirements set in the accession criteria. In this way, a framework is established in which both parties know they can trust each other.	Define a framework that ensures a safe and trust communication environment between systems. Legislation changes may need to be considered. Foster cooperation, especially if the components needed for integration are owned / maintained by different organisations.
• **Competent bodies**	• Define involved Regulatory responsibilities and respective roles.	***ELGA Eletronic Health Record, Austria*** In Austria, the federal government is responsible for overall health policy and legislation, particularly the legislative framework for hospitals, as well as determining the rules for healthcare provision, reimbursement, data sharing, and interoperability. Social insurance institutions are responsible for rehabilitation and medication. Hospitals law is implemented and enforced by the nine province competent bodies. ELGA GmBH is responsible for the further development of the IT infrastructure of the EHR, standards used, and the overarching programme control of all necessary projects, as well as the management and implementation of the necessary integration tests and public relations. ELGA GmBH is represented by the federal government, represented by the Federal Ministry for	Consider collaboration between stakeholders, insurance funds at federal or regional level in order to support health governance. Consider the possibility of creating a body to oversee the implementation of the policy if none of the existing bodies have competencies for such. For example, ELGA GmBH represents the different competent authorities and oversees the implementation, execution and future developments of ELGA.

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		Health and Women, all nine federal states and the main association of Austrian social insurance institutions – which represent the main decision-makers and cost carriers in the Austrian health system – with the coordination of technical and organizational construction commissioned by ELGA.	
• **Political support**	• Political endorsement • Resources availability	***The Netherlands MedMij Framework*** MedMij started as a program and it is now an independent foundation funded by the government and health insurances companies.	Seek political endorsement as this is important to allow resource availability and a long-term vision for the EHR implementation and its integration with other systems. Citizen voice can also be a great supporter in this task. For instance, the Personal Health Environment was developed through the efforts and pressure of the patient federation and the lack of success in exchanging reusable information between hospital systems (demand-based).
• **Financing structure**	• Agreement on the organisation and financing of the health care system.	***ELGA Electronic Health Record, Austria*** ELGA has a joint financing structured made by the ELGA system partners: the federal government, the federal states and social security.	Identify the resources to implement the policy, and which bodies are involved in this process. The resources costs should be predicted in this phase, to facilitate the adoption and implementation phase.
• **Expected benefits**	• Analyse and define targets / benefits regarding mHealth integration within EHR for citizens, professionals, and healthcare systems	***Strategic Plan 2013-2017, Turkey*** The following targets related to interoperability and integration of mHealth within EHR were considered: • improve and sustain mobile health services; • support homecare services with mobile technologies; • establish remote follow-up of patients via institutional mobile practices and attachable wireless sensors; • develop an Electronic Health Record system and a portal to collect, monitor and provide safe access to and sharing of personal health records; • establish systems that enable people to reach all their health data and share them with others by using mobile devices; • improve health IT standards to increase e-health practices by service provider and users and to roll out e-health practices; • improve "Interoperability" practices in cooperation with stakeholders.	Define the expected benefits of mHealth integration with the EHR. For instance, mobile technologies can support homecare activities, allow remote follow-up, collect health data and allow its sharing, support patient access to data, and improve interoperability, among others. This will be important for the scope definition, and latter approval of the policy.
• **Assessment framework**	• Assessment framework for app integration	***mSSPA, Region of Andalusia, Spain*** mHealth certification / assessment in place to evaluate apps worthy of integrating into health systems.	Define an assessment or certification framework to ensure that the apps that integrate with EHR / health systems complied with relevant criteria and are worthy of such integration (what is the benefit for the patient / healthcare professional / health system?).[66]

[66] WP2 working group of the European mHealth Hub published a report – *D2.1 Knowledge Tool 1 Health apps assessment framework* – regarding health apps assessment frameworks, which can be used to support countries and regions in designing health apps assessment frameworks. This report can be accessed using the following link: https://mhealth-hub.org/download/d2-1-knowledge-tool-1-health-apps-assessment-frameworks

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Phase II – Adoption			
Process	**Procedure**	**Example**	**Recommendation**
• **Discussion**	• Legal framework	***Croatia*** Their policies are specific to EHRs and on information standards in eHealth. Croatia is currently working on these legal frameworks, or legal acts, to enable them to define the directions to continue working on eHealth. Croatia expects that mHealth will also be covered, implicitly, in this way but no separated or specific policies are being crafted for mHealth. It is expected that mHealth will be covered as a part of overall eHealth strategy on EHRs and associated standards. This may cause an issue as there are specific Protected Health Information (PHI) related aspects to mHealth (like location service) that is not as prevalent or common in the eHealth environment.	Specific / separated mHealth policies must be crafted to ensure that mobile technology specific attributes (such as location services, camera, etc) are factored correctly to ensure that patient identification is not easily compromised. This point may apply to other countries as well, and therefore, needs to be carefully evaluated for each country.
• **Approval**	• National, Legal framework	***United Kingdom*** In 2017, NHS published a "NHS Five Year Forward View" strategy document that highlights the better use of information and technology and how that can help people manage and improve their own health, particularly by increasing the use of apps. Subsequently, in Oct 2020, the UK National Institute for Care and Health Excellence (NICE) published a guideline titled ""Behaviour change: digital and mobile health interventions"" that covers interventions that use a digital or mobile platform, to help people eat more healthily, become more active, stop smoking, reduce their alcohol intake or practise safer sex. The interventions include those delivered by text message, apps, wearable devices, or the internet. In addition, this guideline only includes those that are delivered by the technology itself and not by healthcare professionals using technology to deliver interventions.	Consider the following topics addressed in the 2020 NICE guidelines that include: 1. developing digital and mobile health interventions 2. commissioning digital and mobile health interventions 3. using digital and mobile health interventions 4. interventions for diet and physical activity 5. interventions for smoking 6. interventions for alcohol use 7. interventions for unsafe sexual behaviour since this may be applicable to other countries as well, and therefore, needs to be carefully evaluated for each country. Respective national and regional procedures should be followed for the approval and adoption process.
• **Approval**	• Legislation • Enforcement • Political endorsement	***ELGA Electronic Health Record, Austria*** The ELGA initiative was adopted by the Ministry of Health and incorporated into the measures aimed at reforming the Austrian healthcare system. In this regard, the 2005 Healthcare Reform Act was adopted by parliament and includes a regulation on healthcare telematics. This law defined the minimum standards to safeguard the confidentiality, reproducibility, measures for healthcare information management and the establishment of an e-Health index to facilitate access to healthcare providers.	Consider adopting, according to the legal context, a policy that defines a minimum standards to safeguard the confidentiality, reproducibility, measures for healthcare information management and the establishment of an e-Health index to facilitate access to healthcare providers.
Phase III – Implementation			
Process	**Procedure**	**Example**	**Recommendation**
• **Budget**	• Allocate resources, allocate budget	***The Dutch VIPP5 program, The Netherlands*** The Dutch Government, ministry of Health is allocating substantial amount of money to get (parts of) MedMij implemented. MedMij is a Dutch national trust framework on information exchange between a Personal	Share experience with other regions similar to the Dutch approach of financing multiple projects in terms of 1) data exchange with the patient and 2) data exchange between professionals and with the patient regarding medication.

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		Health Environment (PGO) and a healthcare institution.	
• **Stakeholder Engagement**	• Organizational actions • Channels of communication	***MedMij Framework, The Netherlands*** program is in the phase of implementation, financed by the VIPP5 program.	Share experience with other regions similar to the Dutch experience of decentralized initiatives for the exchange of patient data.
• **General provision**	• Established measures needed for implementation (directly and indirectly involved)	***ELGA Electronic Health Record, Austria*** Upon approval, the Austrian parliament made arrangements to introduce ELGA, such as the adoption of general provisions to optimize the use of ICTs in healthcare telematics, and prepared the ground for ePrescription and eReimbursement.	Ensure all conditions are in place after approval of the policy. In the Austrian case, the federal government established measures to ensure the ICTs and the groundwork needed for the implementation.
• **Guidelines**	• Publish guidelines for users	***ELGA Electronic Health Record, Austria*** ELGA GmbH has published documents with information organizational and technical information for ELGA health service providers (ELGA-GDA) and software manufacturers for physicians, pharmacies and care facilities. It contains both organizational and technical information on the connection and use of ELGA. The ELGA organization manuals summarize the relevant aspects related to the provision of ELGA functionalities in the GDA software systems. Based on the ELGA organization manual for ELGA areas and hospitals, it also provides as an "addendum" for the private practice area, pharmacies and nursing. The interface documents contain technical descriptions for the design of the software connections. Moreover, it has also been published training documents to provide general information about the ELGA electronic health card, which can be used directly in the context of other documents that are used in health facilities to train users of local ELGA implementations.	Publish guidelines and make them easily accessible to the different stakeholders. For example, in the Austrian example, different guidelines were published for health professional and developer software on the integration of ELGA with existing software, and respective use, among others.
• **Allocate resources**	• Financing support • Responsible entities • Agreements in place	***ELGA Electronic Health Record, Austria*** As previously mentioned, ELGA is jointly financed by the “ELGA system partners” – the federal government, the federal states and social security. Between 2010 to 2016, the aforesaid public bodies made a total of 60 million euros available, and for the period 2017 to 2020 a further 41 million euros were made available to finance ELGA. Furthermore, these public bodies fund the measures that they implement in their respective areas of responsibility for the ELGA’s establishment and the respective operating expenses. ELGA GmbH and the Federal Health Commission entities monitor the targeted and economical use of public funds.	Allocate funds for the implementation of the policy and respective development. Ensure agreements are in place involving the different entities responsible. The funding should predict future developments, as well as the monitoring of the targets and economic impact.
• **Coordinated implementation**	• Work items • Responsible entities • Political steering board	Based on the resolutions of the Austrian parliament, several work items for ELGA implementation were defined: i) contents and structure: data that should be contained in ELGA, structure standardization extension, etc ii) organizational measures: what processes need support, access privileges, etc iii) legal basis: access / storage of health data on voluntary vs mandatory basis, etc	Ensure the implementation is coordinated at the national and regional level, and all relevant entities are involved. Consider establishing a steering boar coordinated with the political government to oversee the implementation.

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		iv) technical standards: central or federated local databases, communication standards, etc v) social and ethical issues: sensitive health data, technological impact assessment etc vi) economic aspects: cost / benefit, installation and maintenance of the infrastructure, etc The implementation of ELGA is coordinated at the national and regional levels by a political steering board.	
Phase IV – Monitoring & Evaluation			
Process	**Procedure**	**Example**	**Recommendation**
• **Review and Revise**	• Definition and measurement of KPIs	***Greece*** Integration of ePrescription, appointment scheduling to eHRs.	Measure capacity building, adopt educational measures. The case study of Greece shows that further engagement of stakeholders and sharing of experience with other regions would be very helpful. Same holds true for monitoring and evaluation, where a country or region could set concrete goals in terms of capacity building and stakeholder engagement and advance adoption and sustainability of digital health specifications, with a solid plan for change management. Several countries are focusing on the project at hand, which typically has an end date, rather than thinking sustainability from day one. This pattern was visible in several cases studies including the Greek one.

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Policy Area 3 – Ethical and regulatory issues. Secondary use of data and data security: privacy, confidentiality, integrity, and availability

Policy Phase I – Formulation			
Process	**Procedure**	**Example**	**Recommendation**
• **Public consultation** • **Definition and Stakeholder engagement**	• Define responsibilities, national context. • Redefine organisational processes and responsibilities (its main contribution was redefining the organisational processes and responsibilities and forging a commitment from all parties involved)	***Isaacus, Digital Heatlth Hub, Finland*** Isaacus was one of several pilots, focusing on the re-use of health and well-being data. It was launched in 2015, was led by Sitra and it played an essential role in building an innovation ecosystem and new legislation drawn up by the Ministry of Social Affairs and Health. It also prototyped the one-stop-shop service model, built new technical infrastructures and the "Digital Health HUB" (also referred to as the I "service operator") and established multi-stakeholder collaboration.	Consider an approach where legislation adoption and implementation preparation are conducted simultaneously as it might allow to accelerate the process. For instance, what has been unique in the Finnish approach is that – unlike the traditional approach where implementation follows legislation – experts from ministries, authorities, companies and associations from across the private and public sectors worked together to prepare the implementation simultaneously with the legislation process. The reform is expected to speed up the permit-granting processes, unify decision procedures and develop Findata – a one-stop shop for data. Decisions on using the data are taken by Findata, the national centralised body, the new Data Permit Authority, and sensitive data is handled in a safe and secure environment. Access to data is controlled and only the results of the analytics can be used externally; the data stays secure. - Health data re-use policy as part of the fair data economy; - Inform legislation from a comprehensive pilot of an innovation ecosystem; - Leverage on international experience and good practices; - Engage stakeholders from the start.
• **Political support**	• Political endorsement • Resources availability	***The German Medical Informatics Initiative*** The instruments have been validated by the Federal and German state agencies. This endorsement has been important in order to permit the sharing of health information across state boundaries. An important next step for achieving this will be to define the rules, decision-making and oversight for handling data access request at the Federal level.	Seek political support at national and regional level. This is critical to allow health data sharing across state boundaries. Having this support is also essential to obtain funding for the implementation phase.
• **Actors** • **Requirements**	• Identify relevant actors • Define regulatory and security requirements • Define investments needs considering the mHealth ecosystem	***eHealth Suisse 2.0*** The feasibility of large-scale use of digital applications within the healthcare system is dependent on different factors, such as: - patient and caregiver confidence in the security of apps; - compliance of apps with data protection requirements; - respect for data protection and cybersecurity by all actors (healthcare institutions, healthcare professionals, reference communities, industry sector, patients, etc).	Guarantee protection and data security. This is critical to large-scale use of digital applications. Citizens need to trust digital solutions; thus data security and protection requirements should be defined. A plan to ensure the compliance of these requirements should also be established. Identify investment needs to guarantee the implementation of these protection and data security guarantees.

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		Therefore, this should be a priority and corresponding investments from all stakeholders are required.	
Policy Phase II – Adoption			
Process	**Procedure**	**Example**	**Recommendation**
• **Public-private cooperation** • **Approval**	• Draw act • Legal tools to enforce new acts	***Isaacus, Digital Heatlth Hub, Finland*** The extensive cooperation between public and private sectors was the basis to the development of the work to promote the secondary use of well-being data in Finland. The Ministry of Social Affairs and Health began its preparations for drawing up the Act on the Secondary Use of Health and Social Data in 2015 that finally entered into force on 1 May 2019. The new act facilitates the establishment of a new central data permit authority in Finland.	Engage the private and public sectors and promote a cooperation among them. This is essential to capture both perspectives and increase the chance of adoption and traction in the later phases. For instance, in the example from Finland, experts from ministries, authorities, companies, and associations from across the private and public sectors worked together to prepare the implementation simultaneously with the legislation process. The legislation was then drafted and presented to the responsible government entities (Parliament), which then analysed and approved it. After which the act was published to be enforced. This process helped to accelerate the strategy for the secondary use of health data. The drafting of the new legislation was based on the national health-sector growth strategy.
Policy Phase III – Implementation			
Process	**Procedure**	**Example**	**Recommendation**
• **Governance model** • **Budget**	• Role definition • Coordination between Government and institutions • Decision capacity and scope • Allocate budget	***The German Medical Informatics Initiative*** Coordination between the initiatives and connection to the Federal level is managed by a National Steering Committee (NSC) with governmental representation and members from several key not-for-profit institutes. The NSC has responsibility to specify those aspects of interoperability, security, data protection and use that are necessary to enable Federal level data sharing. The NSC decision-making process is defined through Rules of Procedure. Its scope includes the following areas of coordination and governance: • electronic patient consent declarations; • the role of trusted third parties for identity management; • rules for data use and access committees; • data protection; •semantic interoperability and metadata; • methods and portals for data sharing; • audit criteria and shared use cases; •patient involvement and empowerment; • activities to strengthen research, education and professional development.	Define and implement the responsible body that not only has decision-making capacities to allow the implementation, but also connects and coordinates the relevant institutions and the Government needs. Allocation of budget is essential to allow the implementation of measurements / predicted activities.
• **Public's trust**	• Promoting trust and traction for adoption. • Surveys on attitudes, research	***Isaacus, Digital Heatlth Hub, Finland*** One lesson learned from the Isaacus project was the importance of gaining trust from the public, especially when dealing with sensitive data. Sitra commissioned a survey on attitudes that showed "people are interested in finding out what kind of data is collected about them and where it can be found. In	Consult the public and implement measures to promote trust. Maintaining trust of the public is essential for the secondary use of health data. Therefore, people trust in the government is critical to ensure the successful implementation of such policy. New legislation should take this into consideration to allow a supportive operating model that is able to gain public trust.

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		addition, people are interested in the purposes for which data about them is used and in the related terms, conditions and authorisations.“ In addition, the survey also showed that “recent data breeches have had some effect on people’s trust in digital services. There is also increasing interest in the opportunities that exist to exercise influence over and manage one’s own data.” [67]	In addition, a more human-centric model instead of organization-centric model may help to gain the public trust.
• **Data masking**	• Anonymisation and pseudonymisation services • Responsible entity • Compliance with legislation	***Isaacus, Digital Heatlth Hub, Finland*** Operations are supported by: a permit and information portal, a data description system (metadata) and a collection, processing and remote desktop for the data. Data pseudonymisation and anonymisation services are closely linked with the last item. The new authority is also responsible for the anonymisation services of data for users.	Implement a system to ensure pseudonymisation and anonymisation, as well as the authority body responsible for this service. This is key for the secondary use of health data, and should also comply with existing laws (e.g., GDPR), as well as new legislation / amendments necessary to allow such use of health data.
Policy Phase VI – Monitoring & Evaluation			
Process	**Procedure**	**Example**	**Recommendation**
• **Audit**	• Definition of audit methods, processes, criteria, and responsibilities. • Budget allocation	***The German Medical Informatics Initiative*** Initial recommendations have been agreed for criteria and methods / processes for audits to be performed at the end of the development and networking phase. The audit will evaluate, through systematic and independent investigations, if the quality of the related activities of the organizations established and the associated results are in compliance with the planned guidelines, if those guidelines have been placed into practice efficiently, and whether the guidelines are suitable for achieving the initiative’ goals.[68]	Set in place a suitable method for monitoring the implementation of the strategy and evaluate its main results. For this, a clear budget and responsibilities should be established and attributed. This will allow to collect information on the implementation level, as well as understand if the defined objectives are being accomplished. In addition, this information will be valuable for revision and elaboration of a new initiatives, taking into account lessons learned, difficulties and gaps.

[67] A Finnish model for the secure and effective use of data. SITRA (2019). [online] Available at: https://media.sitra.fi/2019/05/07121654/a-finnish-model-for-the-secure-and-effective-use-of-data.pdf

[68] Ulrich Mansmann, Markus Löffler. Data Sharing Working Group Audit Approach in Connection with the Medical Informatics Initiative. Supporting Project – Central Office of the National Steering Committee (2017) MII_03_Audit-Approach_1-0. [online] Available at: https://www.medizininformatik-initiative.de/sites/default/files/inline-files/MII_03_Audit-Approach_1-0.pdf

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Policy Phase I – Formulation			
Process	**Procedure**	**Example**	**Recommendation**
• **Public consultation** • **Stakeholder engagement** • **Identification** • **Benchmarking**	• Expert groups • Interviews • Define KPIs • Define Responsibilities	***mHealthBelgium initiative, and eHealth roadmaps: 2013 -2015, Belgium*** The second version of the Belgian eHealth roadmap defines the general principles (including the need to consider reimbursement and how) for the inclusion of mHealth applications in the health and eHealth ecosystems. The details were then worked out later with a strong impetus from the industry association, but the principles were not requisitioned.	When including a mHealth-related action in a national / regional roadmap make sure that: - Reimbursement principle and process are foreseen from the very beginning; - Define the reimbursement process in a SMART way; - Identify the main responsible entity and make sure that its own governance process allows to accommodate this new objective.
• **Approved strategies** • **Legal framework** • **Scope**	• Analysis • Plan to create specific actions on the adopted strategy • Scope definition	***The German Digital health apps reimbursement case*** During the discussion regarding the telemedicine / eHealth strategy (eHealth Act 2015), it was decided a completely new access procedure to use mobile apps. Before, mHealth apps were seen simply as medical aids. This phase can be repeated after a first approval. For example, after the first discussion with relevant stakeholders, the legal procedures and normal course resulting in law approval, can generate new steps to make sure the global policy is advanced (e.g., working from a first global eHealth policy to a more specific mHealth policy / lines of actions). The existing regulation for medical devices was also analysed for the reimbursement of health apps. Evidence – how to define evidence and even its scope was also important during the formulation phase.	Align the policy with existing policies that can be complementary, synergistic or that can even lead to the development of a new strategy. The current legal context is an important starting point to design a new policy; for example, the medical device regulation and health apps that are compliant with it can be the starting point for the establishment of a reimbursement model. This first definition will allow to draw a clear scope for the reimbursement model and what type of health apps fall within this scope.
• **Policy gaps** • **Benchmarking**	• Study to evaluate challenges, opportunities, landscape • Analysis of study to capture recommendations	***The German Digital health apps reimbursement case*** The Charisma study[69] put together opportunities and challenges of health apps and tried to map the landscape through the different areas to focus on (e.g., market, privacy, regulatory). The major recommendations from this study were related to the quality of the mHealth apps in the market, transparency in the market, and the possibility to connect to the statutory health system in Germany.	Capture the current landscape at different levels (local / regional / national and transnational) to identify challenges, reference practices and opportunities. This will allow to define recommendations leveraging opportunities and mitigating possible risks. This can also allow to identify important strategic line of actions to consider in the definition of the mHealth policy, such as quality criteria, access to the national healthcare system, among others.
• **Stakeholder engagement** • **Feedback from stakeholder**	• Identification of relevant stakeholder • Timeline • Identification of needs, problems, expectations • Decision-making	***The German Digital health apps reimbursement case*** Identification of experts related to mHealth, as well as providers, start-ups, etc.; with them it was possible to identify problems that they could face if they wanted to accelerate the development. They also approached patients' organizations to understand their needs. Considering the Germany system, it was also needed to	Identify and engage the relevant stakeholders. mHealth ecosystem involves a multitude of stakeholders, which may differ according to each local / region / country context (for example, when evaluating a reimbursement strategy, the entity responsible for the reimbursement needs to be involved from the start). In addition, it is also important to have a timeline to capture this information so

[69] CHARISMHA – Opportunities and Risks of Health Apps. PLRI (2016). [online]. Available at: http://www.charismha.de

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		approach health insurance entities (e.g., they are usually prone to open systems to new technologies, to make sure funds are rightly spent). Furthermore, healthcare providers were also approached, as they will be working directly with most solutions. In this phase, it is also important to include in the discussion the ministry and the different relevant departments. This allow to draw requirements. It is also important to establish a moment to move forward from the discussions in order to define and make decisions.	that the project can move further to achieve concrete decisions.
• **Government support** • **Stakeholder engagement**	• Public and private interaction	***mHealthBelgium initiative, Belgium*** During the definition of the rules for M3 level and to promote its attractiveness to developers, the Federal government supported the industry and developers and a balance was created with a predictable and transparent economic system to make this a reality.	Promote and foster interaction between the public and private sectors since this allows for a more comprehensive understanding of the needs. In the example, the government support increased the chance of developers submitting apps to the platform, as it was noted that they felt it was "risky" to invest without having a certain level of assurance. Another interesting aspect is that the platform is managed by entities of the private sector while the relevant public entities are responsible for the evaluation. This approach had the benefit of reducing the risk and cost maintenance for the government side.
Policy Phase II – Adoption			
Process	**Procedure**	**Example**	**Recommendation**
• **Discussion** • **Approval**	• Responsible entities • Legal framework • Existing frameworks	***mHealthBelgium initiative, Belgium*** The reimbursement framework was an important milestone in the Belgian government's 2015–2018 eHealth plan (action item 19 of the federal e-health roadmap 2.0) to integrate medical apps into the country's healthcare system, as well as increase patients and healthcare professionals' access to these tools. This strategy aligned with the ongoing digital transformation of healthcare in Belgium. While the platform is managed by the private sector, three national authorities – i) FAMHP (Federal Agency for Medicines and Health Products), ii) eHealth Platform (a federal government eHealth institution), and iv) NIHDI (National Institute for Health and Disability Insurance) – are responsible for evaluating the different levels of the mHealth pyramid.	If a first feasibility study is decided, detail from the start which are the elements that will support the final decision and what are the data which will be collected to support the decision. Make sure that the overall process is first endorsed by the same organ which will decide upon individual applications. Align policy document with the existing eHealth (mHealth) plans, so that in the adoption phase the defined policy is endorsed by the responsible body, as it fulfils the needs identified previously on the approved action items.
• **Discussion** • **Approval**	• Legal framework • Amendment • Parliament discussion • Approval by appropriate council / entities • Signature and legal binding	***The German Digital health apps reimbursement case*** The Act to Improve Healthcare Provision through Digitalisation and Innovation or the Digital Healthcare Act enabled the establishment of the legal basis for app reimbursement. The Digital Healthcare Act was adopted as an amendment to the Social Security Code V (Sozialgesetzbuch V – SGB V) by the German parliament (Bundestag) in November 2019. It was later approved by the Federal Council and signed by the German president, becoming legally binding. Section 33§ of the SGB V states that insured persons	Submit the policy to the responsible entity (government, parliament, etc) for discussion and adoption after ensuring that it complies with current procedures for approval. The government in function needs to evaluate and approve the strategy according to the existing processes to allow the incorporation of new policies or amendments to existing strategies. This approval will enable the implementation and execution of the defined policy.

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		in the statutory healthcare insurance system (SHI) are entitled to healthcare through digital health applications (DiGA's).	
Policy Phase III – Implementation			
Process	**Procedure**	**Example**	**Recommendation**
• **Stakeholder engagement** • **Budget**	• Organisational actions • Channels of communication • Timeline definition and monitoring • Negotiation process alignment	***mHealthBelgium initiative, Belgium*** The mHealthBelgium platform is managed by beMedTech and Agoria, which represent the private sector. However, some start-ups, universities and SMEs are not part of these associations, which may limit the voice of these parties. Nevertheless, the government is aware of this situation and has considered it in the pyramid framework. ***The German Digital health apps reimbursement case:*** Considering the mHealth and reimbursement ecosystem, there was a need to implement a system / platform to allow the execution of the policy.	- Involve in the implementation of the evaluation of the solutions possibly reimbursed all the representatives of the value chain. - Define in a transparent way the precise criteria to be used by the evaluators. - Define an (at least indicative) timeframe for the global evaluation process. - Align as much as possible the negotiation process with the producer with best practices of the products. -Involve different stakeholders during the process, considering the global mHealth ecosystem in the respective region / country context.
• **Pilot project**	• Launch call (specific for certain diseases) • Dissemination • Timeline • Budget allocation • Evaluation of projects to finance • Analysis of results	***mHealthBelgium initiative, Belgium*** Action item 19 of the federal e-health roadmap 2.0 addressed mHealth, with the intention to integrate mobile health apps in the Belgian healthcare system. Pilot projects were launched to determine the framework that could ensure that this type of apps would be successfully integrated. In this regard, during 2016, it was launched a call for pilot projects regarding five main themes (stroke, cardiovascular care, diabetes, mental health and chronic pain). About 24 of these projects were subsidy and run for 6- to 12-months. These pilot projects were launched to determine the framework that could ensure these types of apps would be successfully integrated. Therefore, mHealthBelgium was launched by the government in 2018 and went live on 2019, and is the Belgian platform for mobile apps that are CE-marked as a medical device.	Consider the possibility of conducting / launching a call for pilot projects. These projects can help to obtain concrete data regarding the local / region / country context to develop a reimbursement framework for mHealth apps. This also promotes cooperation between the public and private sector, allowing a more comprehensive understanding of the needs of developers to ensure a more successful adoption of the framework in latter phases. This will also allow to define the necessary requirements to integrate apps in the healthcare system.
Policy Phase IV – Monitoring & Evaluation			
Process	**Procedure**	**Example**	**Recommendation**
• **Review and Revise**	• Review and Revise • KPI review • Steering committee meetings • Contact between the different involved entities	***mHealthBelgium initiative, Belgium*** While the pyramid framework and business model are static, the details and practical arrangements can be changed overtime in order to adapt to new needs. Furthermore, there is a steering committee that meets twice a year, in which the status of the framework is discussed. Moreover, the contact between AGORIA / beMedTech and the government is very close. There are planned meetings between the two parties in every 3 weeks to discuss subjects such as eHealth in general but also mHealth. These meetings are a good way to measure the evolution of what is being done and to evaluate if changes are needed (even though these changes may not be big fast evolutions but rather small tweaks). One of the aspects that have been captured is that not all of the applicants have interest in reimbursement / M3 level certification,	- Make sure that the mHealth objective is continuously monitored and that the responsibility to provide the necessary and agreed upon KPIs is clearly assigned to the entity in charge of operationalising the complete framework. - Define the KPIs to be provided so that they offer a clear understanding of: o The overall dynamic of the certification process; o The capacity of the involved public actors to perform their tasks within the agreed upon timeline; o The effective use of the solution after the solution has been approved; - Consider making the results of the evaluation process of successful individual solutions publicly available.

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		but are rather just interested in applying for M1 to receive recognition for quality, as a marketing strategy for their clients.	- Need to be able to adapt to new needs, which can be capture during this phase. - Maintain constant dialogue with the private sector to capture new needs / difficulties in accessing the reimbursement framework. - Identify changes that are feasible to improve and keep track of others that may need to be addressed in a new version of the policy.
• **Continuous monitoring process execution**	• Implementation of the monitoring process • Clear definition of roles and responsibilities • Indicators	***The German Digital health apps reimbursement case*** Monitoring is a constant and continuous process, and an important one as well. For example, the first app that was approved was attacked by hackers, not in a major way, so they must be very focused on quality and security. Adaptation is also key, and that is why prices (reimbursements) were reduce. They must be clear to the minister that they have to constantly adapt the law. Of course, the law must be changed according to EU regulation.	Ensure a monitoring and evaluation process that is able to continuously adapt to changes (changes in the market, government, etc). As mentioned, the process should be constant, continuous, and flexible. To achieve this, clear indication of responsibility (who does what) is fundamental to ensure this process is effective. Definition of clear KPIs is a possible way to quantity the execution and success of the predicted actions. Nonetheless, quality indicators should also be considered.

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Policy Area 5 – Human centred design and patient safety. Patient empowerment, health literacy and digital skills

Policy Phase I - Formulation			
Process	**Procedure**	**Example**	**Recommendation**
• **Improving the efficiency and quality of public services**	• Innovative public procurement	***ProEmpower, Europe*** is a Pre-Commercial Procurement project, financed by EC's Horizon 2020 Programme, aimed to procure innovative ICT solutions for patient empowerment and self-management of Type 2 Diabetes Mellitus. The objective of the project is to purchase research and development services in order to develop a novel ICT tool able to facilitate the lives of people with Type 2 Diabetes Mellitus, supporting them in disease self-monitoring, improving their daily lives and allowing the health organizations to manage their clinical data to prevent diabetes complications.	Consider incorporating options such as innovative public procurement as a mean to facilitate wide diffusion of innovative solutions on the market. By promoting innovation on the demand side and by orienting the development and the first application of innovative solutions to public and market needs, innovative public procurements can allow customers to avoid the costs deriving from unnecessary functions, prevent lock-in to a single supplier and to take into account the long-term needs of the public sector.
• **Multidisciplinary space**	• Co-creation • Stakeholder identification and involvement • Criteria definition	***Living Labs: Agder Living Lab, Norway*** Adger Living Lab (ALL) has developed a quadruple-helix model represented by citizens, industry, academia, and government, offering an experimental arena for universal design to implement welfare technology, eHealth, telemedicine and mobile health solutions. ALL aims to catalyse inclusive innovation in the health sector by creating a multidisciplinary space where end-users (citizen, patient, relative, health professional) and health services can be interlinked making technology accessible to and usable for everybody.	Create a model that includes the main stakeholders – citizens, healthcare professionals, industry, academia and government – in the creation process. This enables the implementation of a multidisciplinary space where end-users can participate to ensure that the developed technology is accessible to and usable for everyone.
• **Awareness-raising campaign**	• Awareness-raising plan • Relevant actors • Budge and resources definition • Responsibility attribution	***Swiss eHealth Strategy 2.0*** Promotion of awareness-raising measures for healthcare institutions and health professionals – short-term – and for the population – medium-term – were considered. In phase 1, the implementation phase will include communication and interactive measures on the workplace. In phase 2, awareness-raising measures were planned, including the relevant financing resources. This will be important to raise the attention of the population and integration into the training system. The Confederation and cantons are responsible for these actions.	Define a plan for awareness-raising measures for healthcare professionals and population. Budget and corresponding resources should be defined as well. At this point, the actors responsible for these actions should also be defined. Involved regional actors to promote this action and reach a more wider audience.

Policy Phase II - Adoption			
Process	**Procedure**	**Example**	**Recommendation**
• **Budget**	• Budget definition and allocation	***ProEmpower, Europe*** The process is complicated and divided into different phases. This could be a problem for those healthcare organizations that need readily available solutions on the market. The development process involves solutions that are not always mature. The project budget represents a limit to the further development of solutions, when the healthcare organization does not decide to invest additional resources.	Define and allocate resource and funding. To rip the benefits of policies and projects aimed at innovative procurement with a patient-centred approach, a strong resource incentive can allow a full development of a beneficial solution. Further policy and funding measures need to be implemented to enable the solutions to be adopted on a larger scale.

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Policy Phase III - Implementation			
Process	**Procedure**	**Example**	**Recommendation**
• **Cooperation**	• Engagement plan • Communication channels	***ProEmpower, Europe*** involves four public procurers across Europe (Turkey, Portugal, Campania and Murcia) that cooperated to develop detailed specifications for new diabetes management processes supported by fully integrated ICT solutions. During the co-design phase, each procurer created a working group that included physicians, nurses, IT managers and patients, who represented the unmet needs of professionals and patients for diabetes management.	There must be a strong role of the demand by public procurers in addressing the development of new solutions that can respond to real critical situations, directly ascertained by end-users (professionals, patients and citizens).
• **Co-design**	• Requirements analysis • Iterative development of uses cases • Iterative development of service process models • Development and conduction of training activities	***ProEmpower, Europe*** The co-design process of the solution encompasses requirements analysis, iterative development of uses cases and service process models, as well as the development and conduction of training activities supporting the necessary change management in each country or region.	Develop new forms of collaboration that favour the use of mHealth solutions in the self-monitoring and management of diseases, enhancing the digital skills of patients and professionals.
Policy Phase IV – Monitoring & Evaluation			
Process	**Procedure**	**Example**	**Recommendation**
• **User / stakeholder feedback**	• Questionnaires • Engagement plan • Review and revise	***ProEmpower, Europe*** Users (Patients and Health Professionals) are actively involved in identifying needs and providing opinion on possible functions (functional requirements), which are given to them through a questionnaire. It contains also open questions to capture users' creative wishes in term of requirements expected from ProEmpower.	Involve end-users in the analysis of needs and in the evaluation of R&D activities to allow a coherent and effective development of solutions, as well as the identification of gaps and weaknesses. The opportunity to test solutions in real healthcare settings allows vendors to receive market feedbacks on prototype solutions and integrate them with healthcare organizations' IT infrastructures and organizational model.

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Policy Area 6 – Assessing the impact of the innovations

Policy Phase I - Formulation			
Process	**Procedure**	**Example**	**Recommendation**
• Guideline	• Existing framework analysis to capture not only the state of play but also complementary work • Review the evidence relevant to the guideline. • Review questions to help define literature searches, inform the planning and process of the evidence review, and act as a guide for the development of the recommendations. • Summary of the evidence • Define committee	***England 2020, Behaviour change: digital and mobile health interventions*** ***England 2019, Evidence standards framework for digital health technologies, NICE*** While developing the NICE guideline, it was noted that digital and mobile health interventions is a rapidly changing and developing area. Thus, it is important to develop a new guideline in line with national supporting frameworks to ensure they are as effective as possible.	Use existing frameworks / recommendations to create / complement new strategies and ensure that the overall scope is aligned with the national / regional / local main eHealth (mHealth) roadmap.
• Stakeholder engagement • Transparency	• Stakeholder identification • Engagement plan • Semi-structured questionnaire • Output publicly available • Draft guideline for consultation • Public consultation • Committee meetings • Guidance notes	***Evidence standards framework for digital health technologies, NICE, England*** Wide and representative range of stakeholders, including companies and industry associations, NHS clinicians and managers, digital health academics and national health and care system organisations, were invited to complete a semi-structured questionnaire. The results are public available.	Envolve a wide range of stakeholders and publicize semi-structured questionnaires to increase the chance of having results and identifying clear patterns for the formulation of the strategy.
• Co-creation	• Engagement plan and action • Workshop • Public consultation • Comments considered; guideline revised	***England 2019, Evidence standards framework for digital health technologies, NICE*** The standards were developed in a collaborative manner by different entities, such as NICE, NHS England, NHS digital, MedCity, Public Health England and Digital health London.	Promote a co-creation environment. For instance, together with relevant stakeholders, a set of standards was co-created, which support innovation while ensuring an appropriate level of rigour and assurance for the health and care system.
• Innovation assessment	• Evidence types • Functional classification • Analysis	***England 2019, Evidence standards framework for digital health technologies, NICE*** For the development of the framework, two types of evidence were defined: i) effectiveness and ii) economic, which lead to the identification of the respective standards.	For the assessment of innovation, create an innovation assessment framework considering the clinical and economic evidence of mHealth. To support this, standards can be developed to provide a guide to evaluate the effectiveness and economic impact. In addition, different innovations will have different risk levels, which will impact the standards. Having this guideline will help to fill in the gaps and provide evidence to further support mHealth in healthcare systems. The co-creation process mentioned previously will be important to ensure the development of a comprehensive framework.

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• Transparency	• All information made publicly available on a proper resource (online tools)	***England 2020, Behaviour change: digital and mobile health interventions*** All history and information on how the guideline was developed is available, including stakeholders lists, draft guidance consultation, declaration of interest, pre-consultation documents released, committee meetings, workshop notes, guidance and scope published.	Clearly define and make publicly available all information on how the policy / strategy was developed. This can create more trust on the defined and approved guidelines, as all processes are well documented and publicly accessible.
• Scope definition	• Clear definition of scope (including to what / who is applicable and not applicable)	***England 2019, Evidence standards framework for digital health technologies, NICE*** According to the request design, the scope was defined regarding to which digital health technologies (DHT) is or not applicable and suitable. This framework was designed for DHTs that are commissioned in the UK Health and Care System, being less relevant to DHTs that are downloaded or purchased directly by users. In addition, it can be used for DHTs that incorporate artificial intelligence using fixed algorithms, but not to DHTs that incorporate artificial intelligence using adaptive algorithms. Separate standards will be applicable to the latter case.	Define a clear scope and respective suitability to help prevent changing requirements mid-way, as well as ensuring a proper implementation.
• Identification of users	• Research relevant stakeholders • Engagement plan • Consider scope definition for this action.	***England 2019, and Evidence standards framework for digital health technologies, NICE*** It states to which the framework was designed for (technology developers, decision makers who are considering whether to commission a DHT) ***England 2020, Behaviour change: digital and mobile health interventions, guideline*** Local policy makers and commissioners; Individuals, groups or organisations wishing to work or working with health and social care service providers; Designers and providers of digital and mobile health interventions and programmes; Behaviour change practitioners; Trained staff working in health and social care services who have contact with the general public; People who want to improve their health-related behaviours (concerning diet and physical activity, smoking, alcohol use and safer sex), their families or carers, and other members of the public.	Clearly identify users to allow a successful implementation. Thus, it is important to have clear identification of the intended "users" (who is it for, who is not for). During the implementation, this will help to engage the key players.

Policy Phase II – Adoption			
Process	**Procedure**	**Example**	**Recommendation**
• Guideline approval	• Guideline signed off and published	***NICE, England*** has a senior team, known as the Guidance Executive, that considers the guideline and signs it off for publication.	Ensure the policy / strategy is only submitted: i) if aligned with original purpose that generated this work, ii) if it has been approved by the entities responsible for this work, and iii) if it is compliant with the country / region's procedures for approval. The respective competent authorities will analyse and approve the framework according to the original intent. If not approved, the framework needs to be revised and reformulated according to the comments made upon its evaluation.

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Policy Phase III – Implementation			
Process	**Procedure**	**Example**	**Recommendation**
• Collaboration	• Engagement plan	***England 2020, Behaviour change: digital and mobile health interventions*** It was agreed that collaboration between developers, stakeholders and potential users would be likely to produce more useful and engaging interventions.	Create a collaborative environment that allows for the relevant stakeholders to contribute to the design and application of useful mHealth interventions.
• Awareness-raising	• Communication and dissemination execution plan • Engagement & sustainability plan	***England 2020, Behaviour change: digital and mobile health interventions; and England 2019, Evidence standards framework for digital health technologies, NICE*** After its approval, the Committee and the Developer work together to communicate, disseminate, promote awareness and implement the guideline at the time of publication and afterwards.	This step is fundamental to ensure the adoption of the framework by its users. Thus, define clear plans for the dissemination of the framework, so that users are aware of it. A co-creation process also facilitates the adoption at this stage, since the relevant stakeholders / users were involved from the start and are aware of its existence. In addition, this should be plan over a long period, to ensure a proper evaluation and monitoring of the implementation phase.
Policy Phase IV – Monitoring & Evaluation			
Process	**Procedure**	**Example**	**Recommendation**
• Support decision makers • Support relevant stakeholders	• Evidence of effectiveness • Evidence of economic impact	***England 2019, Evidence standards framework for digital health technologies, NICE*** The evidence of effectiveness allows to show that the DHT has a plausible mode of action and reflects current standards or best practice in the UK health and social care system, or provides an alternative to standard or best practice that is beneficial to users and the health and social care system. On the other hand, the evidence for economic impact standards is based on the current understanding of the digital healthcare field and NICE's experience in evaluating other medical technologies such as devices and diagnostics. The economic impact standards aim to promote a consistent and streamlined pathway for economic assessment of digital health technologies (DHTs).	Define clear KPIs and standards that allow to evaluate if the framework was able to achieve its intended goal. This in turn will allow to update and adapt the framework according to the results of the evidence, so that it can be kept relevant and updated according to the current needs and good practices. This will also help to fill in the gap of evidence and economic lack of data regarding the impact of mHealth in health interventions programmes.
• Stakeholder engagement	• Feedback by stakeholders • ESF user survey and analysis • Identification of changes needs • Update accordingly with clear identification of changes	***England 2019, Evidence standards framework for digital health technologies, NICE*** The new updated version of the evidence standards for digital health technologies captured the requirements that needed to be met by different types of heath technologies, taking into account feedback from stakeholders after the first version published in December 2018. In 2021, they updated the framework document with changes in response to an ESF user survey, which ran from October to December 2019. The changes are publicly available and clearly identified.	Obtain feedback from stakeholders to evaluate and update new versions. This feedback provides greater clarity and examples, which will help to ensure that the digital health tools developed and introduced into the NHS are safe and backed by evidence. In addition, it allows to maintain the framework updated considering the fast pace associated with the development of new technologies.

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Policy Phase I - Formulation			
Process	**Procedure**	**Example**	**Recommendation**
• **Scope definition** • **Country context**	• Analysis of country context and gaps mapping • Definition of committee	***The Netherlands example*** The implementation of a national EHR was rejected in 2011 by the First Chamber, which led to a new HER coordinated by the 'Vereniging van Zorgaanbieders voor Zorgcommunicatie' (vZVZ) in the form of the 'Landelijk Schakelpunt' (LSP) subsidized by the healthcare insurances. The main difference between both EHR's was the change from a national system to regional systems. ***ELGA Electronic Health Record, Austria*** ELGA IT architecture is based on a distributed system with centralized (shared use) and decentralized components. ELGA Health data, such as discharge letters and findings, are stored at the location where it was created (e.g., hospital, laboratory, etc) and not in ELGA itself (i.e., stored in a decentralize manner). Medication-related data, such as ePrescription, is encrypted and stored centrally in a database at the Main Association of Austrian Social Insurance Institutions.	Consider the country context at the local, regional and national levels. In the example, a national strategy was initially studied for the implementation of this system, however a regional patient portal, LSP, MedMij was seen as a better approach considering the reality of the country. A centralized and decentralized mix may also be considered according to the type of service.
• **Interoperability and exchange principles**	• Definition of committee • Standards definition • Guideline definition for structured exchange	***The Netherlands example*** Due to the different regional practices, there are different policies in place. Therefore, the creation of standards is important to facilitate the connection of the different EHRs. In addition, guidelines were created for structured exchange of information between health care providers. LSP is used for the exchange among providers and MedMij for exchange between providers and patients. While LSP is a centralised architecture, the MedMij is developed through open Application Programming Interfaces.	Define interoperability and relevant standards as these are key to allow the implementation in latter phases. In this example, the standards were defined at five levels: 1. organization (agreements between organizations); 2. care process (care standards and guidelines, e.g., the COPD Care Standard and Guideline Transfer of medication data in the Chain); 3. information (terminology, classifications and information standards, e.g., SNOMED, ICD 10, ICF and GP observation); 4. application (standardized domain data models and syntactic exchange structures, e.g., HL7, Open EHR, FHIR, EDIFACT); 5. IT infrastructure (technical standards, e.g., LSP, IHE XDS).
• **Complementary features**	• Healthcare provider access • Patient access • Digital literacy	***The Netherlands example*** During the formulation, it was important to establish fundamental principles for healthcare professionals to get access to LSP - identified by their unique healthcare identifier pass and pin code. Regarding patients, they can authenticate themselves by DigiD, but this level of security is not enough to give online access to medical patient data. However, they need to give permission for healthcare professionals to enter their health data. Digital literacy was found important to consider due to the increased use of digital	Promote a holistic approach since there are several aspects that need to be considered for an ICT infrastructure and backend technical to be properly implemented. Thus, it is important to have a holistic view of the subject in hand. Digital literacy is an example of such actions, in order to fully advance the MedMij programme, other initiatives are important to develop, such as promoting digital literacy which is connected to the access of these systems.

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		support in care, and the need to increase the necessary digital skills for caregivers and patients. The Government is requested, in cooperation with the Ministries of Interior, Social Affairs, Health, Economic Affairs and Education, to establish a long-term objective leading to an increased digital literacy in The Netherland.	
• **Standards**	• Definition of standards • Existing legal requirements • International standards	***NHS Digital Health Technology Standard, UK*** Industry and health standards were included. It addresses efficacy, safety, security, data protection, robustness, stability, interoperability, accessibility, and responsibility.	Define clear standards, including the technical elements. International references (from countries and organizations) can be uptake to promote harmonization. Verify compliance with existing legal requirements (e.g., Code of Conduct, existing guidelines, data protection).
• **Cross-border interoperability**	• Capturing International standards • International standards prioritization • Definition of EHR exchange standards	***Swiss eHealth Strategy 2.0, and mHealth recommendations I, Switzerland*** Technical and semantic standards for the exchange of information between mHealth applications and EHR are developed. In this context, priority is placed on standards established at international level. Moreover, eHealth Suisse recommends technical and semantic standards for the communication of information between mHealth applications and the EHR. The focus is on standards that have established themselves internationally (for example the IHE Patient Care Device (PCD) Technical Framework, the Continua Design Guidelines, or FHIR from HL7 International).	Established (or reused existing) technical and semantic standards for exchange of EHR. To promote cross-border interoperability, prioritize the standards established at international level.
• **Implementation guidelines**	• Working group • Definition of priority themes • Definition of working meeting	***Swiss eHealth Strategy 2.0, and mHealth recommendations I, Switzerland*** Common minimum standards are formulated with relevant stakeholders, as well as implementation guidelines for the protection and data security. The working groups was composed by IG eHealth, VSFM, and other associations of SIH / SIC suppliers, professional associations, reference communities. The priority theme for this working group was definition of basic functionalities, application cases and provisions to allow deeper system integration of EHR.	Define a working group with relevant expert to define implementation guides. Establish the priority themes to guide the meetings. This can be used to define standards, requirements, specifications, etc.
• **Methodology**	• Strategic planning • SWOT analysis • Indicators • Pillars / goals definition • Digital Economy and Society Index (DESI)	***Hungarian eHealth infrastructure, National Digitalization Strategy 2021-2030*** Definition of basic key issues, the Why, When, What, to Whom and how: 1) Why: revision of the purpose of the strategy, as well as the economic and social impact. They used a pillar structure selected based on the strategically critical points, situation analysis, SWOT analysis, reasons for the goals and sub-goals. 2) When: timeframe for the implementation of the strategy. 3) What: the vision based on the analysis and the focal point of setting the goals. 4) To whom: who are the main actors involved, responsibilities for implementation, the potential user side and the beneficiaries of the measures that have been identified. 5) How: The identification of the differences between the vision and the current situation formed the basis of the Strategy's goal	Align existing strategies. National eHealth infrastructures may fall into different governmental bodies, such as Health and Digitalisation, and both of each can have specific strategies. Thus, when drafting a strategy for a national / regional infrastructure is important to leverage existing efforts in this development. SWOT analysis from these strategies might help to better define and aligned the main goals to be achieved.

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		system, at the highest level of which the overall strategic goals are set out, elaborated and achieved. Alongside this work, definition of the effective measurement and traceability of the results in the formulation and implementation phase, each can be achieved by assigned indicators to each goal. A national eHealth infrastructure is seen as a continuation of the initiatives taken into previous strategies, as thus these should be aligned.	
• **Funding analysis**	• Funding scan and analysis • Digital Economy and Society Index (DESI)	***Hungarian eHealth infrastructure, National Digitalization Strategy 2021-2030*** Publicly available governmental, market and civil strategic documents, proposals, basic documents on the allocation of EU funds, operational programs with information and communications content were capture for the preparation of the Situation Assessment. Fundraising opportunities were captured and aligned with the timeframe and future developments. This is important to analyse existing funding mechanisms that can support the implementation and further developments.	Funding should be analyse not only thinking about the current development, but for future developments. This will allow for the infrastructure to continue to evolve in order to fulfil new needs, and surpass existing barriers, such as lack of structured data, fragmented data, lack interoperability, etc.
• **Stakeholder engagement**	• Consultations • Interviews • Workshops	***Hungarian eHealth infrastructure, National Digitalization Strategy 2021-2030*** Lead actors of the institutional system can be consulted to discuss experiences, strategic ideas, frameworks, process, connections, and synergies. The draft of the policy can be discussed in joint workshop with representatives of different organizations identified as key players. This represents a more comprehensive approach and can help to coordinate opinions and create more focused content.	Involve and engage the key players directly or indirectly associated to the ecosystem surrounding the (further) development of the ICT and backend technical infrastructure. This allows for a more comprehensive, inclusive, and transparent approach. This has the advantage of capturing new ideas, focusing content, and engaging the relevant stakeholders from the start to increase the probably of adoption in the latter phases.
Policy Phase II – Adoption			
Process	**Procedure**	**Example**	**Recommendation**
• **Discussion** • **Approval** • **Budget**	• Government support • Agreement between various parties in healthcare • Allocate budget to allow implementation	***The Netherlands example*** In 2014, the Minister of Health, Welfare and Sport (VWS) established the online access to health records for patients as one of the three objectives to be achieved in 2020. These established objectives at the governmental level help to increase the probability of adopting initiatives for an ICT infrastructure and backend technical infrastructure to allow EHR exchange. Government provides financial incentives to physicians and hospitals to become MedMij certified.	Involve and engage multiple government actors, as well as regional healthcare entities considering the country / region context. Align national strategies with regional ones. Follow the existing procedures for adoption and approval.
Policy Phase III – Implementation			
Process	**Procedure**	**Example**	**Recommendation**
• **Stakeholder engagement**	• Stakeholder engagement execution plan – regional and user context.	***The Netherlands example*** In 2013, vZVZ edited the structure of LSP and this was documented in an agreement between various parties in healthcare. The LSP is divided in 44 regions based on partnerships, with each region managing its region LSP and supporting the implementation of the EHR. Upon patient permission, general practitioners, (hospital) pharmacists and	Involve and engage regional entities, healthcare providers and institutions, since they need to be involved and engaged for this structure to be successfully implemented and in operation; especially when the goal is to connect several regions that might be using different standards.

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		specialists can share patient information within each region. Hospitals can exchange information between regions, however there is no central database with saved patient information at the national level.	
• **Compliance**	• Compliance to rules and standards • Rules and standards update	***The Netherlands example*** *MedMij program* ensures that any citizen / patient, who wishes to, can collect and use health information from many sources in a secure online environment. For that, MedMij establishes rules for the exchange and use of health data. Therefore, organizations and products aiming to be part of the MedMij environment must adhere to these rules, in order for patients to use their products safely and be able to share and secure health information.	Create a system to ensure that rules and standards are implemented. For instance, the ecosystem surrounding the MedMij needs to be involved and aware of the rules and standards to allow an interoperable system that ensures a secure health information access and sharing. Thus, clear definition of rules, standards, implementation and communicate plans will help to assure this awareness and compliance.
• **Future developments**	• Gap analysis	***Hungarian eHealth infrastructure*** The analysis of its implementation has allowed to verify components / issues that still need to be addressed. For example, data-driven operation is still fragmented, and the possibility of logical interoperability, data exchange and comparison with other subsystems are still limited. Moreover, it was verified that data protection and the exploitation of information remains an issue, even though the first steps have been taken at the regulatory level to achieve a balance.	To achieve a higher level of interoperability, the integration of current "island-like" medical system in the infrastructure should be continuously improved. This needs to be identified for the formulation of the new version of the strategy. Support should be provided for future developments because gaps and new needs will be identified during the implementation and monitoring & evaluation phases. The fulfilment of these real needs has to be supported in the future by a comprehensive approach considering the digitalisation of healthcare as a whole with strong political endorsement.
• **Guidelines and norms**	• Guidelines to help implement the measures defined in the strategy	***Swiss eHealth Strategy 2.0, mHealth Recommendations I, Switzerland*** Different efforts have been performed to aligned with mHealth integration into the infrastructure. Different guidelines have been published, for example: - mHealth recommendations I; - catalogue of uniform criteria for self-declaration (criteria for more transparency in healthcare applications); - general concept: connection of mHealth applications; - mHealth and electronic patient record: recommendations relating to the use of technical norms and standards in the field of mHealth; - guide and checklist for developing a safe mobile application.	Develop and publish guidelines to direct the measures predicted in the strategy. For example, - guidance for developers to check what regulations that need to comply with, what standards they need to meet. This guidance should be made available in different languages to capture different companies. - recommendations to promote interoperability between mHealth apps and EHR – technical norms and standards. - criteria on security, and transparency. Establishing a working group will facilitate the definition of this guidelines and norms.
Policy Phase IV – Monitoring & Evaluation			
Process	**Procedure**	**Example**	**Recommendation**
• **Evaluation**	• Regular evaluation and update	***Swiss eHealth Strategy 2.0, mHealth Recommendations I, Switzerland*** The communication plan for the introduction of the EHR is regularly updated. The planned measures and products are implemented gradually, in agreement with the (reference) communities and the cantons.	Regularly evaluated the planned measures and products. A gradual implementation approach may provide a more dynamic approach to be able to adapt these measurements. This is also applicable in a mHealth prespetive.
• **eHealth map**	• Survey • Research	***The Netherlands example*** To monitor the objectives created by the ministry, Nictiz publishes the eHealth monitor each year, displaying an overview of the state of play (research method, where	Collect information on current state of play during the monitoring and evaluation phase to update or amend (if needed) the current strategy. For instance, an overall analysis of the

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	annually Nictiz and Nivel map the availability and use of eHealth in the Netherlands. In addition, incentives, obstacles, effects, and developments are also studied). In the recent report *Toward an integrated health information system in The Netherlands*, OECD 2021[70]: It was stated that "experts interviewed described that most healthcare organisations have engaged software vendors to develop bespoke eHR platforms to specifications that suit their requirements and priorities. In most cases, and in the absence of an overarching national data strategy and governance framework, little attention has been paid to exchanging data. Experts described that many providers are locked into agreements with their vendors, who either limit or charge large sums to retrofit interoperability and exchange capability into their systems." The same report also states that the certification does not include verification that the data within MedMij are interoperable or that the user experience for patients meets reasonable expectations.	eHealth state allows to develop new (update) strategies that ensure a synergistic and complementary approach, which can positively leverage existing infrastructures. Moreover, it is important to consider independent expert studies when updating or creating new strategies, considering the intended objectives and local / regional / national contexts. In addition, make results publicly available for stakeholders and key actors.

[70] OECD (2021). Toward an integrated health information system in the Netherlands. Draft interim brief and recommendations. [online] Available at: https://www.oecd.org/health/Integrated-health-information-system-NLD-Brief-Recommendations.pdf

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Policy Area 8 – Policy for addressing countries health priorities in times of emergency

Policy Phase I – Formulation			
Process	**Procedure**	**Example**	**Recommendation**
• **Scope definition**	• Identification of sources of information and data • Identification of relevant actors and institution • Regional context	***Tuscany Region, Italy*** as well as the Crisis Unit and the Regional Health Emergency Response Task Force, has decided to focus on technology and innovation to develop its integrated information system.	Identify relevant actors and sources of information and data when designing a policy to address health priorities in times of emergency. It is evident that having sources of data and information that are complete, unambiguous and available among all the different actors participating in the emergency management process, is one of the key factors to better tackle the emergency itself.
• **Stakeholder engagement**	• Identification of relevant stakeholders • Definition of engagement model • Definition of engagement plan	***In Trentino, TreC, Italy*** TreC has been developed by following a Living Lab approach, informed by the direct involvement of citizens groups, clinical stakeholders and public-private entities for the implementation and validation of its innovative services. A unique characteristic is that it is an open platform designed to allow integration of third-parties applications through open APIs. This approach has been chosen to facilitate a paradigmatic change in the architecture of healthcare Information systems, which was typically based on rather closed and monolithic architectures, in order to realize an ecosystem of innovative applications provided by both private and public parties. In this way, citizens can easily access high quality healthcare services and applications that are fully integrated with the public healthcare system (offered on B2B2C models instead of typically used B2C apps) whereas, a better partnership between citizens and healthcare providers is established in order to be able to support the development of innovative models of care and prevention.	Consider an open architectural model since it has the advantage of leveraging the innovative applications ecosystem provided by both private and public parties. This in turn allows for applications to be fully integrated with the public healthcare system. It is important to establish an environment that creates or facilitates a better partnership between citizens and healthcare providers by involving both public and private parties.
• **Partnerships**	• Create environment that facilitates partnerships • Agreements	***Austria*** The partnership between the Austrian Red Cross and the Austrian government is an example of a swift collaboration tackling this unprecedented global crisis in the use of new technologies. Part of the world's largest humanitarian organization, the Austrian Red Cross plays a key role in the government's crisis response team. ***Czech Republic*** Regarding multilateral agreements, currently they have agreements with Austria, Slovakia, and Hungary for emergency health care. There is also an app used for emergencies: https://www.zachrankaapp.cz/en. This app is available to facilitate contact with the emergency services or the mountain rescue services. The app not only works in the user's home country but also when citizens travel abroad for business or on holiday.	Foster partnerships: COVID-19 pandemic showed that crisis can be global, and cooperation is fundamental to ensure a prompt reply to face a crisis. Thus, leveraging partnerships between government and existing health-related entities is fundamental, and mHealth can be a connecting element. In addition, strategies that involve neighbouring countries / regions can also be advantageous to better prepare transnational emergencies. Sometimes the closest emergency hospital might be in a neighbouring country and mHealth can facilitate this management.

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Policy Phase II – Adoption			
Process	**Procedure**	**Example**	**Recommendation**
• **Capacity Building**	• Gap analysis • Map digital literacy, training, workforce profile • Define measures for capacity building	***In Campania Region, Italy*** Capacity building requires interventions at organizational level, but also for human resources, since in the absence of adequate training and in a context where there is still a mainly "older" workforce, it is not possible to ensure a proper and timely use of technologies in a difficult or emergency circumstance. With the COVID-19 emergency, the need of a quick response has emerged, preventing, in fact, proper training of operators.	Strengthen the capacity of individuals and institutions as this is crucial for the success of policies, in order to ensure the successful adoption of the initiatives.
• **Endorsement**	• Endorsement by policy makers • Definition of cooperation between public institutions and stakeholders • Regulatory framework (definition of clear boundaries and roles)	***In Trento Region, Italy*** The formal establishment of TS4.0 expresses the strong endorsement of policy makers in the promotion and implementation of digital health and lays the foundations of a sound collaboration among the public institutions (PAT and APSS) and the principal stakeholders involved in digital health. Furthermore, it provides a regulatory framework that clearly defines the boundaries and roles of all those involved in the process of health promotion, prevention, taking charge, care, rehabilitation and assistance of citizens / patients through digital healthcare solutions.	Seek strong endorsement by the competent authorities as this is critical for the formal establishment of a new policy. Thus, existing strategies supporting mHealth increase the chances of a new mHealth strategy. In addition, its adequate implementation depends on the legal and regulatory procedures of each country / region.
Policy Phase III – Implementation			
Process	**Procedure**	**Example**	**Recommendation**
• **Stakeholder engagement** • **Dissemination**	• Dissemination plan execution • Definition of communication channels and execution • Platform implementation	***In Tuscany Region, Italy*** communicating all systems through a regional platform has a dual purpose. Firstly, makes it possible to quickly consult the results, directly within the ordering departments. Secondly, achieve a Rapid analysis of data through a centralized manner. This would allow to manage the emergency phenomenon in conjunction with the Crisis Unit and the regional Task Force through a secure, reliable and always updated data. It is fundamental that all the Regional Health System actors use the available information systems.	Consider developing a regional (or national) platform as it has the advantage of disseminating the results and allowing a centralized analysis of the generated data. The importance of such platform gains increased relevancy on an emergency situation, since it can provide data to allow a prompt reply to face the crisis in question. To make such platform possible, it is important that all Regional (or national) Health System actors use the available information systems. Otherwise, that data will be fragmented without allowing an overview of the state of the region (country).
• **Leveraging existing tools / frameworks**	• Analysis of existing frameworks • Establishment of complementary frameworks to allow implementation of the intended objective	***The Tuscany Region, Italy*** manages the regional "innovation governance" and in order to guarantee the sharing of information, data and interoperability in real time took actions such as: - Made obligatory the use of tools that already exist; - Created connections; - Centralized information collection; - Carried out networking activities among hospitals, laboratories, prevention and public hygiene departments and territory (general practitioners, intermediate territorial structures, special continuity of care units, and also prefects, mayors and police).	Establish the requirements to guarantee that the information and data is exchange and interoperable. According to each country rules, the envisioned system (or already existing systems) should be obligatory or preferred, while being interoperable to allow a centralize collection of information. For instance, the research and the development of a single integrated system at regional level, implemented particularly under the COVID-19 emergency, has to be envisioned as a crucial part of the so-called phase 2. Key actors and institutions (not only health-related) need to be engage during this process.

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• **Centralise**	• Unification of efforts towards delivering a predefined solution	***In the Tuscany Region, Italy*** a single regional platform has been activated and it will have to be implemented in the near future, for the delivery of teleconsultation.	For the emergency phase, ensure the availability of qualified health care for chronic patients by resorting to alternative methods of delivery to the patient's presence in the clinic. However, it is necessary to create a single catalogue of outpatient services and to train staff about the way to deliver teleconsultation, among other services.
Policy Phase IV – Monitoring & Evaluation			
Process	**Procedure**	**Example**	**Recommendation**
• **Input collection** • **Gap collection**	• Tools to capture input from users (e.g., survey, public consultation) • Micro-processes to capture gaps for analysis and revision of framework	***In the Tuscany Region, Italy*** there was a necessity to make systematic capture of gaps.	Create micro-processes for the collection of gaps and the implementation of the tools (input from users).
• **Governance model**	• Overseen by entities responsible for monitoring and revision	***The Tuscany Region, Italy*** manages the regional "innovation governance" and in order to guarantee the sharing of information, data and interoperability in real time, made sure to put in practice the actions mentioned above.	Apply the define data governance and monitoring, checking and decision-making of the interventions to be implemented. Assigning this responsibility is key to ensure this is achieved at this phase.

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Annex I – Template structure for desk research

POLICY AREA No X	
POLICY DESCRIPTION *(Basic information about main goals, expected outcomes…)*	
POLICY OPTIONS (Part I) *Design / Implementation / Evaluation* a) How did they choose the policy? *Where and which was the MOTIVATION? (e.g. political will, external opportunities, societal demands)* b) FACTORS that had big influence in the DECISION	
POLICY OPTIONS (Part II) *Design / Implementation / Evaluation* c) Organizational architecture and actors *Through which POLITICAL BODIES/ENTITIES did the govs of countries/regions choose to design/implement/evaluate the policy? (E.g. Digital Health Departments within govs; non-for profit or independent entities…)*	
POLICY OPTIONS (Plan III) *Design / Implementation / Evaluation* *Summary and description of the different existing policy options (option A, B, C…)*	

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LEGAL CONSTRAINTS leading to shaping up the policy *(identification and description of those legal constraints)*	
IMPLICATIONS OF THE ABOVE CHOICES (Policy options) *Implications in different aspects*	
POLICY EXAMPLE 1 **Title of the example (incl. country name):**	*References used in the desk research:* *(include the files also in WP5 Documentation, numerating them please)* *Free text summarizing the example:* Presence of **ENABLERS**: *Predefined – multiple choice (mark in green, please)* ***User-centred*** Personal factors which shape people engagement and experience • Provider's capacity • Keeping the user in mind • Frontline staff training • Familiarity, ability with digital tools • Awareness of the objectives and/or existence of solutions • Support and promotion of mHealth/telehealth by colleagues • Consumer demand • Experiencing patient and clinical benefits • Perceived ease of use • User involvement in solution development • Experimentation and clinical learning • Training ***Core infrastructure*** (no enablers mentioned in the adopted list) ***Assessment (technology)*** System reliability or dependability • Accuracy of the system • Quality standards • Assessment frameworks in place • Observability (observance, control, verification of the solutions) ***Cost and reimbursement*** Having requisite material resources • Having requisite human resources (IT support, other) • Value-based reimbursement ***Health policy*** Communication and collaboration between stakeholders • Management (strategic planning) • Information and communication technologies considered central components of healthcare services delivery ***Integration - interoperability*** Compatibility with work process • Interoperability of solutions

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	***Other enablers shown in the policy example**: (Add new ones if needed)* *Free text explaining the enablers:*
	Presence of **DISABLERS (barriers)**: *Predefined – multiple choice (mark in red, please)* ***User-centred*** Professionals' lack of familiarity with equipment and procedures • Professionals' lack of training, education and advocacy • Lack of technological knowledge • Unrealistic expectations • Solutions not adapted for physicians • Perceived complexity of solutions and resistance from physicians • Lack of sense of clinical value • Privacy and security concerns • Conservative culture • Patients wish to speak face-to-face with physicians • Lack of ease of use ***Core infrastructure*** Lack of technological infrastructure in underserved areas • Bandwidth issues/internet access ***Assessment (technology)*** Lack of evidence of clinical utility • Lack of cost-effectiveness evidence • Lack of data accuracy ***Cost and reimbursement*** **Lack of reimbursement models** • Lack of implementation support • Costs associated with technology ***Health policy*** • Lack of readiness among key stakeholders • Lack of enabling policy • Conflicting priorities • Lack of governance • Medicolegal issues ***Integration - interoperability*** Lack of integration with workflow leading to increased workload • Lack of interoperability ***Other disablers shown in the policy example**: (Add new ones if needed)* *Free text explaining the disablers:*
Analysis: main findings	
Gaps identified	
Trends identified	
Suggestions / Recommendations (mainly for policy makers & implementers)	

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Annex II – Policy areas research

Annex II presents different use cases related to mHealth / eHealth policies / initiatives across Europe. These use cases were divided according to the main policy area that it is addressed, even though some use cases also address aspects of the other policy areas. This information was extracted for Summary of Recommendations.

The use cases were also analysed in terms of main enablers and disablers, and for each policy area, main findings, gaps and trends were highlighted, together with the presentation of main recommendations targeted to policy makers and implementers.

Policy Area 1 – mHealth strategies, governance models and change management

- **POLICY DESCRIPTION**

Policies and strategies guiding mHealth programmes are key to define the incentives and guidance, types, and operational level of mHealth programmes, and the role of health authorities in developing and adopting mHealth. The governance model and respective operation assist the management in fulfilling the roles and the mechanism by which the mHealth strategy is implemented and monitored. Clear and transparent governance structures are essential to ensure a successful mHealth adoption and implementation. The different elements composing the governance structures should be connected and able to maintain a continuous growth and adaptability. Change management is fundamental to ensure identification and provision of the required resources, as well as supporting individuals and organisations to adopt change to drive organizational success and outcomes. Thus, mHealth change management processes are needed for all ICT systems implementations and require engagement and training of users, as well as continuous functional and technical support.

The following case studies were explored within this policy area:

1. Estonian eHealth Strategic Development 2020 (Estonia)
2. Action Plan for National eHealth Strategy (NSEH) 2016-2020 (Czech Republic)
3. Mobility Master Plan (mHealth.Cat) strategy and action plan (Region of Catalonia, Spain)
4. National Indications for the provision of services in Telemedicine (Italy)
5. TrentinoSalute4.0 (Region of Trentino, Italy)
6. Swiss eHealth Strategy 2.0 (Switzerland)

- **POLICY EXAMPLEs**

  - **Estonian eHealth Strategic Development 2020 (Estonia)**

Estonian eHealth Strategic Development Plan[71] focuses on particular eHealth specific choices and activities, the realisation of which is feasible during the period of 2016 to 2020. The Strategy is based on the assumption that the creation of eHealth, i.e. IT-means and possibilities for health care, is a prerequisite for the achievement of the substantial goals of the health area but does not guarantee the achievement thereof by itself.

The implementation of the Strategy and the activities thereunder are based on the general service development and financing principles applied in the state, according to which all IT investments must be based on the substantial, i.e. the so-called business objectives of the area, and the optimum possibilities for the achievement thereof, including the necessary ancillary activities for successful implementation of e-applications.

[71] Estonian eHealth Strategic Development Plan 2020. [online] Available at: https://www.sm.ee/sites/default/files/content-editors/sisekomm/e-tervise_strateegia_2020_15_en1.pdf

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A permanent strategy council is formed at the Ministry of Social Affairs. The head of the strategy council is the Deputy Secretary General on E-services Development and Innovation, the assistant head is Deputy Secretary General on Health and it should include representatives from:

- Ministry of Education and Research
- Ministry of Economic Affairs and Communications
- Government Office
- Estonian Health Insurance Fund
- Estonian Hospitals Association
- Estonian Family Doctors Association
- Estonian Medical Association
- Estonian Service Industry Association
- Estonian Connected Health cluster
- Tallinn University of Technology
- University of Tartu
- Estonian Chamber of Disabled People
- Think Tank PRAXIS

These are the focus areas of the policy:

- High-quality health information and an infrastructure of health data
- Persons and personal medicine
- Comprehensive case management and cooperation of organisations
- Effectiveness of health services and capacity for analysis
- Development of remote services

For the sake of mHealth our focus here is the last focus area / policy option:

The fifth focus area aggregates the health system development activities related to eHealth from the perspective of remote services: active development of health services based on remote administration to balance out the inevitable reduction in the number of qualified employees in the health and welfare sector, problems with the accessibility of health care service and the increased expenses of institutional service provision. In the event of a service based on remote administration (i.e. remote service), the person and the service provider are not physically in one location (i.e. the definition of the service does not require the determination of the physical location of the service provider), but the prerequisites include real-time communication, connection with a professional and the supporting technology. Remote services include tele-medical care, tele-care and mobile services (m-services).

Remote services require the completeness of the eHealth system, adaptation of the legal space, and the creation of a necessary IT infrastructure to facilitate the implementation of applications (mobile apps, etc.), supporting the adaptation of behaviour based on personal feedback and decision-supporting applications designed for general users.

<u>Implementation options:</u>

1. Development of an eHealth infrastructure supporting remote services between health service providers
   - Conditions are created or ensured for wider use of asynchronous and synchronous e-consultations and video consultations, equally with physical services.
   - Information easily used by the health service provider (pre-analysed summaries of health information to facilitate the provision of remote services) is aggregated and a virtual communication environment is created which enables cross-sectional or case-focused communication of different parties.

2. Development of an eHealth infrastructure supporting remote services between health service providers and people

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- Conditions are created or ensured for implementation of asynchronous and synchronous remote monitoring services and e-visits / consultations and video consultations, equally with physical services.
- A central solution supported by the health information system is developed, which enables interfacing of the data collected under the remote service with other health data, thereby creating a prerequisite for using the data collected by a person or a "machine".
- Possibilities are created in the health information system for participation of data analysis service providers in sharing of health and disease data.
- A feedback environment is created for the health service providers and citizens, creation of a treatment instruction for realisation of the provision of feedback.

3. Development of new possibilities to collect information about the state of health of people, including from healthy people and measured by people themselves
   - Possibilities are created to collect and analyse information outside the provision of health and welfare service and regardless of the location of the data (e.g. smart applications used by the persons themselves, accomplishments at sports clubs or running tracks, various sensor data, etc.) and use it for the purposes of managing personal health and public health.
   - Possibilities are created for submission of the data collected by persons themselves to third parties for use and analysis of the data. A large amount of information collected by persons themselves through remote monitoring increases the need to aggregate the data in a pre-analysed format, so that already pre-analysed information would reach the desktop of a doctor.

4. Policy-making of remote services
   - A plan for development of remote services is created, including the specification of a development process how to stimulate pilot projects and develop validated and widely used health services from those.
   - Constant evaluation of monitoring and application possibilities of innovative remote services for realisation of the business need of the Estonian health area (e.g. annual summaries of new developments and the application requirements and opportunities thereof in Estonia and abroad).
   - A legal space is created to enable and define remote services, governing the validation of the solutions offered and ensuring the legitimacy of e-consultation / remote monitoring or other decision-making based on digital data, and realisation of responsibility for service provision and the result of the service by remote administration. Also, an opportunity is created for persons to share and manage their own data. Advertising and cross-border operation of such services are also reviewed. Increasing of the awareness and improvement of the skills of the users of remote services, in cooperation with the general information society and the activities of increasing people's awareness of e-services are supported.

5. Development and application of remote services in prevention
   - Remote services (including m-services) are developed and implemented in order to prevent diseases, maintaining focus on healthy lifestyle, diet, movement and ensuring access to the relevant information. The goal of the measure is to expand the influence of the disease prevention activities on the target groups, creating new possibilities for the target groups to take responsibility for their health in the digitalising world.

6. Development and implementation of remote services in the provision of general and specialised medical care
   - The possibilities of remote services are applied on a wider scale to support the timely availability of the health care service at the primary level: including support of the new telemedicine service and especially at the primary level, service standards are developed, the legal space is adapted and the procedure for adding the price list of the Health Insurance Fund is agreed.
   - The e-consultation service is expanded to a large number of professions.
   - The work processes of family physicians, specialised medical care and nursing care are optimised upon the addition of e-services / remote services.

7. Development of remote services in rehabilitation and monitoring of people with chronic diseases, integrated with home care services
   - The development and implementation of remote monitoring services is supported, in order to enable the patients with chronic diseases test their necessary vital indicators and submit those to service providers.

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8. Creation of the principles of the cooperation model / financing model of the public and private sector
    - Responsibility for ensuring the necessary e-services in the health area between the public and private sector is determined.
    - Principles are developed for evaluation of the evidence-based nature and cost-efficiency of innovative e-services / products and the underlying technologies, which is a prerequisite for the extensive implementation thereof in the health care system (including inclusion into the service price list of the Health Insurance Fund). The cost-efficiency criterion includes the price, the evidence-based nature includes also the possibility for national certification of the solution used.

9. Increasing awareness and supporting need-based innovation
    - Round tables, trainings and competitions are organised for the parties of the eHealth ecosystem, in order to ensure the awareness of the cluster uniting the health care and welfare service providers, R&D partners, entrepreneurs and enterprises of the health area of the cooperation possibilities and generation of new ideas.
    - For need-based innovation of new value-creating products and services, competitions based on pre-defined needs are organised. Innovation vouchers or product development grants are provided to promote cooperation between sectors, including the involvement of practising doctors and nurses in the innovation process.
    - The support process of implementing innovation is promoted as a whole to promote the birth of new companies – the creation of the so-called incubation programmes is considered to create and market new products and services in the area of eHealth, in cooperation with the measures of entrepreneurship.
    - Test environments (living labs) are developed for validation and fine-tuning of services and products.

<u>Implementation of strategy in terms of organization:</u>

1. Creation of an eHealth strategy council

2. Creation of IT application units responsible for:
    - efficient realisation of IT development projects (if necessary, in cooperation with external development partners);
    - efficient coordination of work groups necessary for development (actively involving the competence of the Product Owner and Service Owner, if necessary);
    - high-quality functioning of the IT component of the e-services at the service level agreement (SLA) agreed with the Product Owner, i.e. the administration of e-services;
    - ensuring the administration of the necessary infrastructure (hardware and software) and the technical standards;
    - the IT capabilities and know-how necessary for the technical development of the eHealth system.

3. Creation of Technical work groups that are involved on a permanent basis to facilitate efficient application of the input necessary in the development projects

4. Involve Health Service Providers

5. Involve partner ministries

6. Plan to have international cooperation

<u>Implementation of Strategy in terms of funding:</u>

1. explore internal and external funding sources, such as Estonian Insurance fund or from EU funded projects

2. explore funding objects

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- **ENABLERS**

User-centred

Provider's capacity • Frontline staff training • Experiencing patient and clinical benefits

Core infrastructure

Creation of a necessary infrastructure and a solution of IT infrastructure facilitating the implementation of applications

Assessment (technology)

Observability (observance, control, verification of the solutions)

Cost and reimbursement

Having requisite material resources

Health policy

Communication and collaboration between stakeholders • Management (strategic planning)

Integration - interoperability

Interoperability of solutions

Other enablers shown in the policy example*:*

1- The implementation of e-consultation for selected professions has been started.

2- video consultations take place in selected cases and we have examples of well-functioning solutions in the area of tele-radiology and pathology at the service providers.

3- There is no clear concept of health data quality in Estonia, which would facilitate efficient management of the creation of high-quality information used in health care.

4- Develop the possibilities for secure administration of the health state information originating from various sources: e.g. providing authorisation for secondary use of data to various parties both in Estonia and abroad, including the health care service providers, providers of medical or health apps and for research; also to integrate the (health) information collected by people themselves outside the provision of health services with the so called medical information.

5- Aggregated health information about a person facilitates person-based case handling supported by preliminary evidence and research-based risk evaluation.

- **DISABLERS**

Assessment (technology)

Lack of evidence of clinical utility • Lack of cost-effectiveness evidence • Lack of data accuracy

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Cost and reimbursement

Lack of implementation support

Health policy

Lack of enabling policy • Lack of governance

Integration - interoperability

Lack of integration with workflow leading to increased workload • Lack of interoperability

Other disablers shown in the policy example:

1- Lack of a central development plan of remote services in the health area.

2- Operation and financing models of the health services using remote administration and an eHealth infrastructure supporting the provision of remote services have not been regulated or developed.

3- Technical solutions of remote services have been available already for some time but the integration thereof into the work process is not common.

4- Vague responsibility and the lack of integrated approach starting from the standards / quality indicators, organisational vagueness of service provision and incomplete regulation of data use.

5- Lack of high-quality data and insufficient reuse of data has negative influence on the achievement of all the result goals of the health system.

6- There are also faults (data quality, technical errors of the system) in the eHealth system already created, both in regard to the creation of data acquisition process data and data display.

7- There are no (substantive and technical) solutions for supporting personal health management, and the participation of people in their own health management is low.

- **Action Plan for National eHealth Strategy (NSEH) 2016-2020 (Czech Republic)**

The Action Plan[72] reflects the requirement of the EC from 2012 consisting in increase in the speed of changes and improvement of the quality of healthcare by clarifying areas where legal uncertainty reigns, improving interoperability between systems, increasing awareness and improving knowledge among patients and healthcare workers, placing patients in the forefront of interest with the aid of initiatives relating to healthcare and support for research in personalised medicine and finally, by facilitating free legal consultancy in the field of eHealth.

[72] National eHealth strategy. NCEZ. (webpage in Czech). [online] Available at: https://ncez.mzcr.cz/cs/narodni-strategie-elektronickeho-zdravotnictvi/narodni-strategie-elektronickeho-zdravotnictvi

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This plan must take into consideration the changing surrounding influences and environment which will continue to develop. Some examples of these influences are:

- Changes in the legislation; foreseeable changes are planned by individual departments, e.g. application of the eIDAS directive and GDPR (personal data protection); unforeseeable changes according to the resulting legislative acts;
- Changes in priorities arising from changes in political representation;
- Financing options; EU grant programmes significantly influence the structure of projects implemented, it is often necessary to adapt the timing and scope of measures and projects implemented to the purpose and schedule of individual calls by the ESI funds;
- Projects of other departments; department are continuously creating new electronic services for citizens, or gradually meeting their obligations from the Action Plan for Development of the Digital Market, in some cases the department concerned is the Ministry of Health and its cooperation is required, in some cases it will be advantageous for the department to use the newly created electronic services of the state; one example of this is the eSick Note;
- Restrictions arising from the Act on Civil Service; implementation of projects often for hundreds of millions of crowns requires significant staffing capacity in the field of information and communication technologies, which there is an ever-increasing lack of in state administration.

Priority areas defined by the Ministry of Health in the NSEH:

- **Creation / amendment of reference registers** which will be the equivalent of the eGovernment Basic Registers and which will be an authoritative source of data for identification of entities, setting of their rights and responsibilities in eHealth.
- **Resolution of electronic identity** of healthcare workers, which ensures and strengthens legal and organisational certainty and continuity of work with electronic documents and medical documentation. Procedure will be followed in line with resolution of electronic identity under eGovernment.
- Ensuring uniform access to eHealth services in line with the principles of eGovernment.
- **ePrescription** – prepare gradual roll-out of fully-fledged electronic prescriptions. This task will require amendment of the legal regulations.
- **Establish / create a National Centre for Electronic Healthcare** the task of which will be, in a programme based and economical manner, to coordinate and support development of digitisation, to maintain and develop the concept of the national system of eHealth

For mHealth focus the priority area to analyse is the ePrescription.

The first stage of launch of ePrescription in accordance with the valid legislation in January 2018 – planned extension of functionalities:

- facilitation of handover of comments by the pharmacist to the doctor,
- use of a web interface for selected groups of users,
- use of mobile applications for selected groups of users (access by doctors to prescriptions without the need to be in “their” medical system in the clinic),
- facilitation of access by the patient to all prescriptions drawn up and issued to him / her,
- facilitation of approval of a prescribed prescription by the reviewing doctor,
- facilitation of notification of the patient by mobile phone or e-mail in selected cases with his / her consent,
- shortening of the ePrescription identifier – 12 figure alphanumeric code with exclusion of certain objectionable characters,
- four ways to hand over the identifier to the patient (SMS, e-mail, accompanying document, web / mobile application),
- full use of eGovernment systems and functionalities (Basic registries, JIP/KAAS, ISDB, PACP – CzechPoint, CSP, eIDAS - NIA),

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- elimination of the need for the user (pharmacies) to use routers for communication.

Second stage of provision of access to patient pharmaceutical records (2018 – 2021):

- change to the Act on Pharmaceuticals and the Act on Addictive Substances and the respective decrees,
- launch of the patient pharmaceutical record – amendment of the legislation, definition of access rights (scope of authorised parties),
- check on duplicity – depends on launch of patient pharmaceutical records,
- interaction – depends on the patient pharmaceutical record and on the professional standpoint how interactions will be defined,
- extension of the number of prescription items on ePrescription – amendment of the legislation,
- ePrescriptions for NPS (prescription for narcotic and psychotropic substances) – amendment of the legislation.

The initiative will be measured in accordance with performance indicators, NSEH specifies the following indicators:

- share of electronic prescriptions issued in all prescriptions issued (85%),
- share of electronically issued pharmaceuticals in all issued prescription pharmaceuticals (95%).

Main obstacles and risks

One risk is insufficient communication of the campaign by the State Institute for Drug Control and MoH.

A risk in the second stage of implementation, for provision of access to pharmaceutical records, is that the required eHealth infrastructure will not be established in time – in particular the NRHP and NRHCP as authoritative sources of data and other parts of the so-called departmental identity system and system for registration and administration of patient consent.

A risk in the second stage is elaboration of the respective legislation in good time.

Indicator system

During monitoring of the Action Plan for NSEH, the status and progress of implementation of National Strategy will be continuously ascertained, information will be updated about the status of implementation and information will be compared with the initial values. Via interim reports on implementation of National Strategy, it will be possible to monitor progress during implementation. Interim reports will contain fulfilment of indicators, but also progress on fulfilment of the hierarchical structure of work and method of risk management

The Action Plan states identifiers for fulfilment of individual activities (project plans) which will also be monitored by submission of interim reports.

Budget and sources of financing

The primary sources of financing to ensure and support implementation projects of National eHealth Strategy are in particular the European Structural and Investment Funds, the European Social Fund within the framework of the programme period 2014-2020, or other financial mechanisms, e.g. the Norwegian Funds, the connection tool Europe CEF, WHO resources (Agreement on cooperation between the MoH and Regional WHO Office for Europe). It is necessary to use synergy and complementary relationships while ensuring financing and ensuring compliance of individual projects. This in particular concerns relationships where projects financed from IROP are supplemented with programmes linked to the European Social Fund. An aspect which is not negligible is ensuring the sustainability of implemented projects, but also the future development of the system in line with the changing requirements of healthcare. Financial provision of implementation of National Strategy will be a continuous, organisationally and professionally demanding process coordinated by the MoH in cooperation with other departments.

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A detailed budget for implementation of the Action Plan for NSEH and sources of financing will be specified during creation of implementation plans for individual strategic objectives. The aim is fulfilment of the following measures:

- Allocation of sufficient funds to ensure participation of all relevant parties, not only in the stage of preparation of eHealth strategy, but also over the course of its implementation and change proceedings. Facilitation of maximum involvement of future system users or their representatives.
- Implementation of projects via the respective calls in operational programmes 2014+, or via other financial mechanisms.
- Creation of the necessary conditions (budget, material, staffing) for the actual implementation projects and coordination of these activities via the National Centre for Electronic Healthcare.

Procedures for monitoring and evaluation of implementation

Within the framework of substantive / financial monitoring of the project, the following aspects are monitored:

Commencement of project implementation

- Commencement of work relating to the project.
- Implementation may be commenced before submission of an application for support if this is allowed by the call.
- The deadline is explained in the Specific rules issued for the respective call.

Conclusion of project implementation

- Demonstrable conclusion of all project activities.
- The date of signature of the record or handover and acceptance of the work must not be later than the date of conclusion of project implementation specified in the legal act.
- The deadline is explained in more detail in the Specific rules issued for the respective call.

Termination of project financing

- The date by which the recipient must pay all expenses to contractors.
- The date is specified in the legal act and is binding for the recipient.

Final evaluation of the project

- Final evaluation of the project represents conclusion of project administration.

Commencement of sustainability

- The period of sustainability is five years.

Fulfilment of indicators

- Fulfilment of target values is determined by the applicant in the application for support.
- The date is specified in the legal act and is binding for the recipient.
- The recipient is obliged to maintain the achieved values of the indicators and to preserve the results of the project for a period of five years from the start of the sustainability period.
- If the recipient fails to meet the determined deadline for achieving a target value or for sustaining it during the sustainability period, they will be penalised in accordance with the Conditions.

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- **ENABLERS**

User-centred

Keeping the user in mind

Other enablers shown in the policy example:

Computerisation of the health service will clearly contribute towards an increase in the efficiency, quality and availability of healthcare services, will help to ensure the availability of healthcare information in the right place and at the right time, but also in the right quality

- **DISABLERS**

Other disablers shown in the policy example:

Insufficient communication of the campaign by the State Institute for Drug Control and MoH.

Required eHealth infrastructure will not be established in time.

Elaboration of the respective legislation in good time.

1. Uncontrollable process of public procurement (Even assuming tender documentation for public contracts is prepared in a very high level of quality, handling public contracts is very complicated in terms of time from the point of view of project management. Especially due to possible misuse of reports to the Office for the Protection of Competition by applicants, even in unjustified cases.)

2. Political risk (Insufficient support for implementation in the event of change in government)

3. Non-adherence to the schedule (Not meeting the deadline for implementation or its individual key activities)

4. Inappropriately set implementation plan (Important facts which will have a fundamental impact on implementation will be overlooked, suitable activities for achieving objectives will not be selected, a realistic schedule or budget will not be set etc.)

5. Staff fluctuation (Frequent changes in the implementation team leading for example to insufficient continuity of work, delays and lower quality outputs.)

6. Reduction of funds from the ESIF (Increased ineligible costs while drawing on funds from the ESIF and reduction of funds, which could have an impact on the state budget.)

7. Inadequate quality of the implementation team (Insufficiently high quality / competent implementation team responsible for implementation, i.e. members of the implementation team do not have the professional qualifications and experience needed for implementation.)

8. Creation of bad quality outputs (Processing of outputs which will not comply with the strategic objectives, will not have added value, will not be applicable in practice or implementation of a solution which was not recommended.)

9. Inadequate staffing or insufficient time capacity of the implementation team (Inadequate staffing capacity to ensure implementation, insufficiently staffed implementation team (i.e. the number of members of the implementation team does

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not correspond to the scope of activities implemented) or insufficient time capacity of members of the implementation team for implementation (e.g. due to them being busy with a different agenda).)

10. Lengthy administration of applications for support from the structural funds

11. Inadequate management (Inadequate management and coordination of individual implementation teams, slow decision-making and approval)

12. Budget overrun (The cost of implementation exceeds its anticipated value determined in the budget.)

13. Failure to secure financing (Failure to secure financing needed for implementation.)

14. Unwillingness to implement projects via financing from the ESIF (Although implementation via projects financed from structural funds brings with it a certain level of administrative burden while processing project applications and submission of monitored reports, it does represent significant savings within the framework of state budget chapters.)

- **Mobility Master Plan (mHealth.Cat) strategy and action plan (Region of Catalonia, Spain)**

Overview

In 2015, the Catalan Government approved the Catalan Master Plan on mHealth with the aim[73] to:

- Develop an mHealth strategy in Catalonia as a means of driving change in the health and social services systems.
- Improve coordination between supply and demand in the system to identify key mHealth projects.
- Provide advisory support to mHealth projects.
- Supervise mHealth services and the development of standards and support services. This work may be carried out in-house or in partnership with third parties.
- Research and contribute to the generation of knowledge, by anticipating challenges and trends related to mHealth.
- Report on the work done and the projects being implemented to ensure adoption of the tools by public and professionals.

The document represents the first and, currently, **the only mHealth specific European Strategy**. It **provides both a Strategic Plan and an Action Plan** to support the development of mHealth in Catalonia. **The Strategic Plan** defines a vision that reflects the reasons for the existence of a mHealth ecosystem in the region, the strategies needed to achieve the defined goals, effective ways to organize and provide services, and aspects related to mHealth architecture and infrastructure. Furthermore, **the Action Plan** defines a roadmap that identifies and defines priorities and development directions, functional and organizational details related to the defined directions, and milestones, as well as indicators to monitor and evaluate their progress. The strategy includes four Annexes that consider elements such as the main features of the mHealth context, analysis of mHealth stakeholders, description of strategic functions, and mHealth architecture.

Actors involved in elaboration of the Plan

The Strategy maps out relevant stakeholders for the mHealth ecosystem. In the elaboration of the Mobility Master Plan, several actors were involved:

- Department of Health (Government of Catalonia)

[73] https://smartcatalonia.gencat.cat mHealth.cat Mobile Health Plan. [online] Available at: http://smartcatalonia.gencat.cat/web/en/projectes/govern/detalls/article/Pla-de-mobilitat-mHealth.cat

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- Department of Social Welfare and Family (Government of Catalonia)
- TicSalut Foundation
- Mobile World Capital Barcelona
- CatSalut

Mobile World Capital and TicSalut Foundation have been the main promotors of the project.

The Plan was framed transversally within the different principles and lines of action of the different Plans and Programs of the Departments of Health, Social Welfare and Family and Presidency: The Health Plan of Catalonia, the Strategic Plan of Social Services of Catalonia and the remote care model in the healthcare and social system of Catalonia. mHealth is seen as a potential promoter of the necessary transformation of the Catalan healthcare and social systems.

The Strategic Plan

The strategy states that the Plan must consider the context affecting mHealth and should be positioned in a way that helps achieve the desired goals. The strategic aim of the Plan is to act as a benchmark for promoting mHealth in Catalonia and as a lever to transform health and healthcare systems, social services, improving the health and social wellbeing of people and, finally, contributing to the sustainability of the system. For this, several **key strategic functions** were defined:

1. **Facilitate:** Help connect supply and demand in the ecosystem to identify key projects for mHealth
2. **Advise:** Provide advice on those projects either from one-off support or full support
3. **Build:** Ensure the construction of services, as well as standards and other support elements, either with own means or in collaboration with third parties
4. **Observe:** Evaluate and contribute to the generation of evidence and knowledge, anticipating challenges and trends on mHealth
5. **Disseminate:** Communicate progress made and projects that are being carried out for citizens or professionals to use

Main vectors for mHealth adoptions and difficulties to overcome

Despite having to overcome certain frictions, mHealth appears in an ideal context for its development, being able to become a key element in the transformation and sustainability of the healthcare system. In the development of strategic Plan, social and economic aspects, regulatory aspects, clinical and care aspects and technological aspects are considered. The Plan considers mHealth as located in the space that is at the intersection between the management and provision of services, health and social welfare and the management and provision of services with mobile technology.

	Vectors for adoption	**Difficulties to overcome**
Social and economic aspects	• Aging population • Greater risk of exclusion in certain groups due to a decrease in available income • Pressure on public resources and rising costs • More demanding users	• Little interaction in mHealth initiatives • Lack of exploration of business models of mHealth success

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	• Growing penetration of mobile devices in all aspects of society	
Regulatory aspects	• Users become aware of their rights • Public administration support: The Health Plan considers the need for a more sustainable and innovative health and social system. A model more oriented to the chronically ill and aims to encourage the personal health channel	• Lack of clarity on validation, accreditation and mHealth certification • Lack of clarity in protection legislation of data
Clinical and care aspects	• Emergence of new therapies, care services and technologies that involve higher costs • Chronicity: mental disorders, COPD, diabetes, cardiovascular diseases, etc • Growing prevalence of unhealthy habits • Specialized care for groups: immigration, young people, women, disabled etc.	• Lack of empirical and clinical evidence on success of mHealth • Lack of information in general
Technological aspects	• Interest in the development of an ecosystem mHealth from the private sector: operators, ICT, development companies, farms and start-ups • Greater ease of developing apps thanks to new frameworks • Tendency to lower the cost of technology	• Lack of interoperability standards • Lack of identification and secure systems

Stakeholders

The Plan **considers all stakeholders involved and how they interfere with the deployment of mHealth**. While the fundamental aim of the Plan is to create services and solutions to improve the health and social wellbeing of the citizens, other groups such as suppliers, researchers, professionals, administration and companies are also considered in the development of mHealth solutions. To ensure the existence and quality of mHealth solutions, the ideal positioning of the administration within the ecosystem and the agents identified above is that of "dynamizer" between supply and demand.

Involved stakeholders:

- Regulators and insurers: Insurers and the public sector
- Research institutes: Biomedical research and research centres, healthcare analytics
- Social and healthcare actors: Pharmaceutical companies, Healthcare professionals, social staff, equipment providers, pharmacists
- Welfare actors from the food sector, sports and leisure sector, and education
- Technology: developers, entrepreneurs
- Citizens: patients and other groups than patients

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The projects and services in the mHealth field that are created must always be aimed at impacting one or more of the elements that make up the cycle of provision of health and social services. The Plan defines three main blocks:

1. **Social welfare**: Services to adopt, change or avoid habits or lifestyles that contribute to maintaining or improving the levels of family, social and work well-being of citizens in general. The solutions that are created within the field of social welfare must be oriented to make an impact in the priority groups, as well as to be based on contributing value through one or more of the transversal typologies.

    - Ensure provision of social welfare services, personal autonomy services, and personal wellness promotions services.

2. **Health:** Services aimed at managing the entire health cycle of the different health conditions of the population. All mHealth solutions and services that are promoted must be aligned with the priorities and lines of action defined in the Health Plan of Catalonia. The Strategy presupposes the creation of so-called “packs”. The role of those responsible for the Plan will be to strategically define these 'packs' and establish clear rules for the technical approval (interoperability, data privacy, usability, security and authentication) and clinical services, and ensure that a recognized third party, by delegation of those responsible, can approve them.

    - Identify existing solutions
    - Provide them if they do not exist
    - Approve the solutions
    - Approve the suppliers of the “packs”

It is recommended to homologate more than one service (with a maximum of four for each condition, phase) to ensure a wide landscape of offers. In case if appropriate services are not found, the administration will have to assume the role of creating it, either through a tender or using own resources. Once approved, these solutions will form a "pack" that will target and address each condition.

3. **Support and provision systems:** Services that facilitate access to data generated in health, welfare, and social information systems and that make the management of services related to health and social welfare more efficient.

For this, several strategic services are needed within each block:

- **Prevention**: Services used to recommend and publicize tips from health and encourage people to adopt or avoid certain behaviours to prevent or control outbreaks of disease or injury.
- **Diagnostic**: Services that help health professionals to determine the causes of symptoms for provision of services for diagnosis or triage.
- **Treatment:** Services that help treat the patient's condition and ensure adherence to the required regimen or protocol. Provision of services of all kinds that contribute to social welfare.
- **Follow-up:** Services for monitoring and remote services for follow-up.

Governance model

The Plan offers a **governance model** that supports the role of *dynamizer* of mHealth in Catalonia, with the organizations that have the mandate and structure to govern and deploy it effectively. The model covers the responsibilities of the following areas:

1. Strategy and Leadership

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The Health Department, Social Welfare and Family Department and Presidency Department should lead and establish the strategy of the Plan. From this leadership, the institutional link will be created with other territories, administrations and organisations, at international, regional and local level.

2. Coordination and execution of the Master Plan of Mobility

The TicSalut Foundation is the driving body responsible for coordinating and monitoring the strategy that has been established, but with contributions and support from different actors involved in the Plan. Main responsibilities are Plan deployment and executing different projects, perform change management in suppliers and professionals, and impact and benefits analysis.

3. Co-execution with global vision.

The Mobile World Capital Foundation is in charge of dynamizing, exporting and importing experiences, companies, and international standards. They will also participate in dissemination activities, as well as observation and analysis of the impact and benefits.

To support those responsible for operating and running mHealth, it will be necessary to set up an office and a **Steering Committee** that **defines, coordinates and reports on the evolution of the Plan.** The Office of Management and Execution of the Master Plan for Mobility (mHealth.Cat) (OGEP) reports directly to the Steering Committees of the Plan and is the one who coordinates and monitors the different projects. It is organized by areas, based on the 5 strategic functions identified previously. To achieve the objectives set out in the Plan, the proposal will carry out an action plan that contemplates four main lines from which the different identified projects are derived.

The Action Plan

To achieve the objectives set out in the Plan, an Action Plan was defined which takes into account the four main lines from which the different identified projects are derived:

Organisation and Government. This line of work is responsible for setting up and operating the strategic functions (facilitator, advisor, construction, observer and dissemination). In addition, it has to ensure the presence of governance bodies and rules. Likewise, it will be necessary to carry out activities aimed at developing impact models that inform about the benefits of mHealth on the system and the various agents which are part of the mHealth ecosystem (at a level of macro analysis).

Identified projects:

- Constitution of the governing bodies
- Establishment and continuous operation of a Plan Management and Execution Office (OGEP)

Welfare. This line of work includes mHealth's initiatives and projects in the field of social welfare, aimed at adopting, changing or avoiding habits or lifestyles that help maintain or improve levels of family welfare, social and labor of the citizens affecting the different steps of the chain of value of health and social welfare of prevention, diagnosis, treatment and monitoring.

Identified projects:

4. Projects in the field of providing social welfare services:

- Training of professionals and non-professionals
- Youth emancipation, and health guidance and prevention

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- Young and family single and numerous family cards
- Distance learning and support for foster families and young people and families in post-adoption stages
- Dissemination of the rights of children and adolescents

5. Projects in the field of personal autonomy services:

- Support and control of mobility of people with neurodegenerative diseases and mental disabilities
- Providing autonomy to people with physical and sensory disabilities, both auditory and visual
- Prevention and monitoring of cases of gender-based violence

6. Projects in the field of personal welfare promotion services:

- Health prevention through geolocation and identification of challenges for the elderly
- City-friendly services for the elderly

Healthcare. This line of work includes mHealth's initiatives and projects in the field of health directly related to prevention, diagnosis, the treatment and follow-up in relation to any condition. Projects on both strategic and more tactical conditions are included.

Identified projects:

7. Definition and approval strategy of the 'packs' or integral solutions of mHealth

8. Approval and governance of chronicity-oriented mHealth solutions

- Solutions based on the management of chronic diseases (e.g. diabetes, ICC, COPD, mental health and addictions, oncology, asthma, etc.)
- Solutions based on phases of the disease life cycle (e.g.: prevention management, diagnosis, treatment or follow-up)
- Solutions based on complexity (e.g.: ICC + COPD + asthma, follow-up + diabetes + COPD, etc.)

9. Approval and governance of system and citizen knowledge-oriented mHealth solutions

- Solutions aimed at communication, personalization and citizen participation
- Solutions aimed at the participation of professionals in the system

Infrastructure. It brings together those projects and activities related to the part of infrastructures and support systems for the health and social welfare cycle defined above. It includes projects or initiatives for the development of aspects on delivery systems, standards, legal requirements, interoperability or security, among others.

Identified projects:

10. Projects in the field of mHealth infrastructure standards:

- Usability and content guide
- Interoperability and messaging
- Requirements and use of security and identity solutions
- Legal criteria to be met by mHealth solutions
- Criteria for certification and compliance with quality standards

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11. BYOD initiatives:

- Pilot launch of service access initiatives via BYOD
- Integration of BYOD initiatives in the future process manager (i-SISS.Cat)

12. Adaptation of the call center (061) to the new vision of mHealth:

- (Re-) Design of the structure and operation of the call center from '061'

Call center training and adaptation based on the '061'

- **ENABLERS**

User-centred

Provider's capacity • Keeping the user in mind • Familiarity, ability with digital tools • Awareness of the objectives and / or existence of solutions • Consumer demand • Experiencing patient and clinical benefits • Perceived ease of use • Experimentation and clinical learning • Training

Assessment (technology)

Quality standards • Assessment frameworks in place

Health policy

Communication and collaboration between stakeholders • Information and communication technologies considered central components of healthcare services delivery

Integration - interoperability

Compatibility with work process • Interoperability of solutions

- **DISABLERS**

User-centred

Professionals' lack of training, education and advocacy • Lack of technological knowledge

User-centred

Lack of reimbursement models

Integration - interoperability

Integration with HER

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- **National indications for the provision of services in Telemedicine (Italy)**

Telemedicine represents an innovative approach to healthcare practice, allowing the provision of remote healthcare services through the use of digital devices, internet, software and telecommunication network sit. It guarantees treatments through a secure exchange of data, images, documents and video calls, between health professionals and patients, and the performance of professional services equivalent to traditional access in some clinical-assistance situations. It can be an innovative opportunity in favour of patients in the field of prevention, diagnosis, treatment and monitoring of clinical parameters, but also to facilitate multidisciplinary collaboration on individual clinical cases and for the exchange of information between professionals.

In Italy, the State-Regions Conference approved, on 17 December 2020, the document prepared by the Ministry of Health entitled "National indications for the provision of telemedicine services". The document, which amends and updates the previous "National guidelines on telemedicine" published in 2014, introduces a series of important innovations for entities that, as part of the health care of the National Health Service, intend to implement within their organisation a system capable of providing remote services. More precisely, the first part of the document is dedicated to the identification of telemedicine services and to the general rules to be observed for the provision of remote services. The second part indicates a series of elements and requirements necessary for the practical provision of distance healthcare activities that, due to some peculiarities and criticalities, deserve a specific in-depth examination.

The recent Guidelines, focusing in particular on outpatient activities, define the services that can be "performed" in telemedicine, specifying some characteristics that were not included in the previous classification of 2014. The fields in which telemedicine is applied are different and, depending on the medical sector, it takes on different denominations, such as, for example: Teleradiology, Telecardiology, Telepathology, Teledermatology, Clinical Teleneurophysiology, Telerehabilitation, Home Teleassistance, etc.

The Ministry of Health subdivides Telemedicine services, with respect to the appropriateness of supply, into four types:

1. services that can be assimilated to any traditional diagnostic and / or therapeutic healthcare service, representing an alternative delivery;
2. services that cannot replace the traditional healthcare service but rather support it by making it more accessible and / or increasing its effectiveness;
3. services that complement the traditional service by making it more effective and more capable of adapting dynamically to the changing needs of patients' care;
4. services that are capable of completely replacing the traditional healthcare service, representing new diagnostic and / or therapeutic methods and / or techniques and thus developing new care practices useful to patients.

These different types of services always introduce more or less marked changes in the previous organizational processes and operating procedures of the various professionals. Therefore, their large-scale adoption in healthcare practice must always be accompanied by adequate scientific evidence concerning the appropriate clinical and care use of present and future technological innovations.

- **ENABLERS**

User-centred

Provider's capacity • Keeping the user in mind • Familiarity, ability with digital tools • Experimentation and clinical learning • Training

Assessment (technology)

Quality standards • Observability (observance, control, verification of the solutions)

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Cost and reimbursement

Having requisite material resources • Having requisite human resources (IT support, other)

Health policy

Communication and collaboration between stakeholders • Information and communication technologies considered central components of healthcare services delivery

Integration - interoperability

Compatibility with work process

- **DISABLERS**

User-centred

Professionals' lack of training, education and advocacy • Lack of technological knowledge • Patients wish to speak face-to-face with physicians • Lack of ease of use

Core infrastructure

Bandwidth issues / internet access

- **TrentinoSalute4.0 (Region of Trentino, Italy)**

TrentinoSalute4.0 is the local Competence Centre on Digital Health of the Autonomous Province of Trento. It is a policy instrument to coordinate the work on digital health in the region.

It represents the meeting point between the health system, research and the territory. It symbolizes the instrument of cohesion between the guidelines of health planning, the innovation needs expressed by the Provincial Health Service and the opportunities offered by research and new digital technologies.

It is a shared space for professionals and technologies to design, develop and deliver digital health services that support health care providers and improve people's lives.

Design / Implementation / Architecture / Actors:

Since 2010, Research and Innovation in health (E health) was included in the health protection law of Trentino Region - Provincial Law from 23 July 2010, n. 16 in which the issue of digital health is dealt with a specific article (n°24) and is included among the priorities identified by the development program of the XVI (16°) legislature.

Thus, the Autonomous Province of Trento identifies digital healthcare as an extraordinary lever for innovating healthcare processes.

In this regard, the applications of electronic health (eHealth) and the introduction of new technologies must support the change of healthcare processes and organizations.

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For this purpose, the Provincial Council of Autonomous Province of Trento appointed the Competence Center on digital health called TrentinoSalute4.0 in December 2016 through the Act of the Local Government n. 2412, as a governance tool for the development of digital health.

"TrentinoSalute4.0" is composed of the Autonomous Province of Trento (PAT) through the Department of Health and Social Policies in the role of decision-maker, the local Healthcare Trust (APSS) in the role of the health service provider, and the Bruno Kessler Foundation (FBK) as the research institute responsible for technological innovation.

TS4.0 also involves citizens, health professionals and sector companies according to a quadruple helix model.

Fields of work:

TrentinoSalute4.0 is working in particular on the following areas: collective prevention, surveillance and primary prevention of chronic diseases which therefore require a great innovative effort of public health.

TrentinoSalute4.0 is also involved in the development of the Trentino digital health platform called TreC which can be represented as an ecosystem of applications and devices to support citizens in the daily management of their health and care.

TrentinoSalute4.0 also participates to European Projects as well as national projects such as research initiatives co-financed by the Italian health minister, regions and provinces

- **ENABLERS**

Assessment (technology)

System reliability or dependability • Accuracy of the system • Quality standards • Assessment frameworks in place • Observability (observance, control, verification of the solutions)

Cost and reimbursement

Having requisite material resources • Having requisite human resources (IT support, other) • Value-based reimbursement

Health policy

Communication and collaboration between stakeholders • Management (strategic planning) • Information and communication technologies considered central components of healthcare services delivery

Integration - interoperability

Compatibility with work process • Interoperability of solutions

- **DISABLERS**

User-centred

Privacy and security concerns • Conservative culture

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Assessment (technology)

Lack of evidence of clinical utility

Other disablers shown in the policy example:

Resistance to change by doctors

- **Swiss eHealth Strategy 2.0 (Switzerland)**

The **Swiss eHealth Strategy 2.0**[74] supports the introduction of the EHR and reflects the vision for the period of 2018–2022. This strategy aims to ensure that this development is done for the benefit of patients and all players of the healthcare systems.

This strategy replaces the **Swiss CyberHealth (eHealth) Strategy of 2007**[75], which ended in 2015. In alignment with this previous strategy, the priority should be the people and not only technology. This "must be at the heart of the process".

The duration of the new strategy is aligned with the deadlines provided by the Federal Law on Electronic Patient Records. For instance, acute care hospitals, rehabilitation clinics and psychiatric institutions must join a certified referral community or community by 2020, and medico-social establishments and birthing centres by 2022.

The **vision** for this strategy includes the following principles:

- Due to digitalization, the health system is qualitatively better, safer and more efficient.
- People in Switzerland are digitally competent and use the possibilities of new technologies optimally for their health.
- Healthcare institutions and health professionals are digitally networked, exchange information electronically along the treatment chain and can use data once entered several times.

The Swiss eHealth Strategy 2.0 includes a total of 25 objectives divided into three **fields of action**:

A. Promote digitalization	"The use of information and communication technologies is less advanced in the health system than in other service sectors. The Confederation and the Cantons want to promote digitization within the health system, within the framework of their powers." ***Main Objective:*** Digital applications, and in particular the electronic patient record, are established within the healthcare system.
B. Align and coordinate digitalization	"The usefulness of digitization is maximum when it is done in a coordinated manner: digital processes must be aligned and interfaces must not present any flaws, so that medical and administrative information can, once entered, be used at any time, for various purposes. The Confederation and the cantons want to see this advantage realized in terms of efficiency."

[74] Stratégie Cybersanté Suisse 2.0. 2018–2022. Swiss Conference of Cantonal Directors (CDS), eHealthSuisse and Swiss Confederation (2018). [pdf]. Available at: https://www.e-health-suisse.ch/fileadmin/user_upload/Dokumente/2018/D/181214_Strategie-eHealth-Suisse-2.0_d.pdf. Swiss eHealth Strategy 2.0. Summary. CSD, eHealth Suisse and Swiss Confederation (2020). [pdf] Available at: https://www.e-health-suisse.ch/fileadmin/user_upload/Dokumente/E/Strategy_2.0_en_summary.pdf

[75] Swiss Conferation. Stratégie Cybersanté (eHealth) Suisse. Office fédéral de la santé publique (2007). [pdf] Available at: https://www.e-health-suisse.ch/fileadmin/user_upload/Dokumente/2007_2008/F/070627_strategie_cybersante_ehealth_suisse_resume_F.pdf

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	***Main Objective**:* Digitization within the health system takes place in a coordinated manner and enables multiple use of data and infrastructure.
C. Enable for digitalization	"It is not enough to create technological possibilities. In order for patients and healthcare professionals to derive the greatest possible benefit from digital healthcare system applications, they must have the necessary skills." ***Main Objective:*** People in Switzerland are digitally competent and able to handle digital patient data responsibly and with awareness of the risks.

Definition of **responsibilities** for the Confederation and Cantons:

Switzerland is a federal state with state powers divided between the Confederation, the Cantons and the Communes. Each of these entities have their own responsibilities. The Federal Constitution lays down the powers of the Confederation and the Cantons, and the latter in turn, defines the powers of their respective Communes[76]. Thus, for this strategy the responsibilities were defined as:

- **Confederation**: is responsible for establishing and operating the essential technical components for electronic patient record (EPR) in accordance with Federal Law on the EPR (LDEP), to inform the population, coordinate the actions of the multiple actors and assess LDEP. Moreover, it can also support the introduction of EPR by providing financial assistance for the establishment and certification of communities / reference communities. However, it is also stated that this financial assistance can only be granted on the condition that the cantons or third parties contribute the same amount.
- **eHealth Suisse** (the coordination and competence body of the Confederation and the Cantons), acting on behalf of the Confederation, is responsible for the execution work in the field of information and coordination, and develops technical bases.
- **Cantons**: The LDEP and the enforcement law do not imply any binding task to the Cantons. Nonetheless, since they are responsible for organizing the provision of care, they are also responsible for their population's access to EPR.

Activities at the national level and legal basis

The Swiss eHealth strategy has already provided important context for the application of the EPR, and this new version is linked to different on-going activities:

Legal Basis	• **Federal Law on the EPR (LDEP)**, which regulates the framework conditions for the introduction of EPR.
National activities	• **mHealth recommendations I**, which were adopted to improve the transparency of the applications offered in the market; this document discusses the use of data collected by mobile devices as part of the EPR. • **Training and accreditation**, those responsible for basic and continuing training for health professionals and for management training in the health sector receive help to integrate "EPR" and "eHealth" into training programs. The guide "E-health: key themes for health professionals" has been written for this purpose. • Exchange format allows direct exchange of data between the various primary systems of healthcare institutions and healthcare professionals. The technical and semantic standards necessary for a unitary information exchange are defined in the specifications of the exchange formats.
Activities in the Cantons	• Some **Cantons** have adopted a pioneer role with interregional health data exchange projects. This was further promoted / motivated by the Swiss Conference of Cantonal Directors (CDS) and the eHealth Suisse.
Link to other strategies	• **Digital Switzerland strategy**: the Swiss eHealth Strategy 2.0 is a subordinate to this strategy of 2018. The strategy pursues four main objectives: - Establish equal opportunities and strengthen solidarity

[76] Ch.ch. Swiss Federalism. Ch.ch, Swiss Confederation [online] Available at: https://www.ch.ch/en/demokratie/federalism/federalism/

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- Guarantee security, trust and transparency
- Strengthen digital skills"
- Ensure the creation of value, growth and prosperity

Updating the "Swiss eHealth Strategy" for 2017 is a measure of the action plan for the implementation of the "Digital Switzerland" Strategy.

- **Law on electronic identification services** (LSIE), the above-mentioned strategy also contains measures for the identity management, for which the Federal Council has adopted LSIE.
- **National Strategy for the Protection of Switzerland against Cyber Risks (SNPC 2018-2022)**, this strategy contains in particular measures to protect the critical sub-sector "Medical care and hospitals".
- **Health2020 (Santé2020),** the "Swiss eHealth Strategy 2.0" should be guided by these health policy priorities and help in their implementation. In the field of the activity "Ensuring and improving the quality of care", the Federal Council has set the objective of increasing the use of e-health. These measures include:
  - Introduction and active promotion of the electronic patient record
  - Establishment and active promotion of e-medication
  - Digital support for treatment processes.
- **National Strategy for the Prevention of Noncommunicable Diseases 2017–2024 (NCD Strategy),** the strategic axis of the field of action 2 "Prevention in the field of care" consists in improving the interfaces between prevention and care. In this regard, the EPR must also contribute by serving as a data exchange platform and thus, helping prevention and treatment to act in parallel and in an individualized manner.

The **international integration** is also considered to ensure that Switzerland can also participate in the cross-border medical data exchange. In this regard, international standards have been considered in addition to coordination with the European developments at this level (e.g., national contact point).

Other topics are also considered in this strategy as strategic and synergistic:

- Secondary use of digital health data
- Personalized medicine
- Big data

Regarding the three fields of action, **mHealth is specifically addressed** in the following points:

Objective	Measure	Responsible entity
Action 4.1.1 Promotion of digitization within the health system in general		
A6 Updating of certification conditions	A6.1 Conceptual and technical foundations are being developed for further development of EPR, particularly for the integration of mHealth applications as well as primary systems.	eHealth Suisse
Action 4.1.3 Promotion of mHealth		
A8 "MHealth recommendations I", implementation / supplement	A8.1 The "mHealth Recommendations I" will be implemented gradually and it will then be verified, as part of strategy 2.0, which measures still to be implemented are relevant and help to achieve the target objectives.	eHealth Suisse

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	A8.2 Current developments at national and international level are regularly analysed and, if necessary, integrated into own activities.	eHealth Suisse
A9 Interaction with EPR	A9.1 Technical and semantic standards for the exchange of information between mHealth applications and EPR are developed. In this context, priority is placed on standards established at international level.	eHealth Suisse
Action 4.3.1 Information and empowerment of the Swiss population		
C1 EPR information	C1.1 The communication plan for the introduction of the EPR is regularly updated. The planned measures and products are implemented gradually, in agreement with the (reference) communities and the cantons.	eHealth Suisse
	C1.2 The cantons are participating in regional information campaigns for the population about the introduction of EPR.	CDS Cantons
	C1.3 The Confederation and the cantons are verifying how it is possible to support the dissemination of the EPR through health policy strategies, as well as corresponding activities of others policy areas.	Confederations CDS
C2 Authorization to use the EPR	C2.1 For the products and measures mentioned in point C1, the issue of empowering people with special needs is taken into account from the start.	eHealth Suisse
	C2.2 The multipliers mentioned in objective C2 are the subject of support as part of internal employee training (development of documents, support during training, list of contacts).	eHealth Suisse
	C2.3 Models of good practice for fostering e-health skills are developed for communities (reference).	eHealth Suisse
	C2.4 The multipliers named in Objective C2 are integrated into the work on EPR or work on e-health strategies in health-care regions.	Cantons

In ***4.1.3 Promotion of mHealth*** is recognized the importance of innovative mHealth applications as a mean to promote health and prevention, and modern systems for the follow-up of patients with chronic disease or long-term monitoring of elderly people. In the context of EPR, mHealth "can play an important role for the involvement of the population: patients can, through mHealth applications, make data entered in EPR accessible to authorized healthcare personnel. MHealth solutions also provide patients with mobile access to medical data and documents contained in their EPR".

The development of mHealth applications is highly depended on vendors and consumers. In addition, in order to promote interaction with EPR, technical conditions (interoperability) and legal frameworks (e.g, data protection and data security) need to be taken into account. As previously mentioned, the eHealth Suisse has developed mHealth recommendation to enable and f

It is noteworthy that for objective A8, the following principles were considered, which were based on previous work:

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- eHealth Swiss: mHealth recommendations I of March 2017
- Walderwyss: legal opinion on mobile health of January 2018
- eHealth Swiss: guides and checklists for the development of safe health applications from March 2018

Switzerland mHealth recommendations I

In order to assess how mHealth can support the objectives defined in the Health 2020 strategy agenda, the eHealth Suisse prepared the eHealth Switzerland mobile Health (mHealth) Recommendation I[77]. This document contains "recommendations for actions aimed at enabling and facilitating the use and dissemination of mHealth applications in the Swiss healthcare system".

eHealth Suisse mandated the University of Applied Sciences of St. Gallen (HES SG) to write a report presenting the issue of "mHealth" mobile health and the link with the EPR, as well as to formulate proposals for a coordinated approach to facilitate the use and dissemination of mHealth applications.

- **ENABLERS**

User-centred

Provider's capacity • Keeping the user in mind • Frontline staff training • Familiarity, ability with digital tools • Awareness of the objectives and / or existence of solutions • Support and promotion of mHealth • Experiencing patient and clinical benefits • Training

Core infrastructure

Strong development of Electronic Patient Record

Assessment (technology)

Quality standards • Assessment frameworks in place • Observability (observance, control, verification of the solutions)

Health policy

Communication and collaboration between stakeholders • Management (strategic planning) • Information and communication technologies considered central components of healthcare services delivery

Integration - interoperability

Compatibility with work process • Interoperability of solutions

[77] eHealth Suisse. Mobile Health (mHealth) Recommandations I. eHealth Suisse, 2017. [pdf] Available at https://www.e-health-suisse.ch/fileadmin/user_upload/Dokumente/2017/F/170316_mHealth_Empfehlungen_I_F_def_FR.pdf

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- **DISABLERS**

User-centred

Professionals' lack of familiarity with equipment and procedures • Professionals' lack of training, education and advocacy • Lack of technological knowledge • Perceived complexity of solutions and resistance from physicians • Lack of sense of clinical value • Privacy and security concerns • Conservative culture • Patients wish to speak face-to-face with physicians

Assessment (technology)

Lack of evidence of clinical utility • Lack of cost-effectiveness evidence

ANALYSIS OF POLICY AREA I

- **MAIN FINDINGS**

The application of the eHealth Strategy on Estonia takes place based on focus areas, grouping various existing e-services and planned activities around the central strategic goals based on the health policy.

On the basis of the "National indications for the provision of telemedicine services" in Italy, it is pointed out that the correct use of Telemedicine services can be particularly useful for the following healthcare purposes:

- **Health emergencies**, exploiting the features of telematic transmissions assisted by software systems to exchange clinical information and reach rescuers by video call, expanding the collaborative possibilities within the health network, to facilitate the management by health professionals of critical patients directly at the place of recovery or at the nearest hospital or health facility, even if lacking specialist services.

- **Control of pathologies** of particular importance for the NHS' governance, such as cardiovascular, respiratory, endocrinological and metabolic pathologies, autoimmune diseases, rare diseases, psychiatric diseases and psychological disorders, disabilities, clinical conditions of surgical interest that require special diagnostic activities in preparation for surgery and / or specific procedures to control the post-operative course.

- **Accessibility to diagnostic** services and continuity of care, in order to provide healthcare services to patients with difficulties in accessing services, reaching patients in decentralized healthcare facilities, in isolated centres and also at home.

- **Remote control and monitoring**, in order to keep under medical control patients classified as being at risk of developing certain diseases or already suffering from diseases with a significant risk of complications, with the aim of reducing the risk of illness and / or reducing the onset of complications or relapses.

Medical certification in Telemedicine, in order to allow the precise collection of the data and information necessary to truthfully describe the reality, which is thus directly observable by the doctor even at a distance.

The Swiss eHealth Strategy 2.0 highlights the importance of innovative mHealth applications as a mean to promote health and prevention, follow-up of chronic patients, and elderly patients, as well as entering data into the EPR and accessing the data. There is a strategic alignment between the eHealth strategy and other ongoing strategies and projects. The governance and responsibilities are identified to ensure the implementation of such measures.

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Clear identification of the governance model implies the identification of the main players, organizations responsible for ensuring the coordination and execution, and the interconnections among them. International cooperation should be promoted.

- **GAPS IDENTIFIED**

Lack of high-quality data and insufficient reuse of data.

The use of the health information distributed between the parties in the eHealth system is largely insufficient, as not all the databases and information systems are capable of exchanging data at the right time and in the right format.

Since there is no quantitatively significant previous experience of the use of telemedicine systems in Italy, the Ministerial Indications advise against the provision of telemedicine services in the following situations, as a precautionary measure:

- Patients with acute pathologies or relapses of chronic pathologies in progress
- Patients with chronic diseases or frailty or disabilities that make it imprudent to stay at home.

Of course, the final assessment of which instruments are suitable for the individual patient is the responsibility of the doctor.

- **TRENDS IDENTIFIED**

Inevitable reduction in the number of qualified employees in the health and welfare sector, problems with the accessibility of health care service and the increased expenses of institutional service provision.

Greater focus on health data quality, be it from healthcare providers or from citizens themselves.

Ensuring training and empowerment of healthcare professionals and the overall population.

Coordinated actions to ensure that digitalization increases the efficiency of processes, and the overall safety of citizens.

- **RECOMMENDATIONS - Targeted to policy makers & implementers**

From the Estonian example, it is possible to notice that the effort to move forward a policy implementation is a shared effort that involves several branches of government and / or regional institutions. Thus here, the recommendation would be to design and approach the implementation and creation of such policies in an coordinated and involved environment with several ministries / organizations that can benefit from a generalized benefit of using mHealth services. This was also highlighted the other use cases, such as from Switzerland and the region of Catalonia, Spain.

mHealth should also be supported by an overall development in eHealth services and infrastructures.

Consider leveraging the use of applications that even healthy people use. Possibilities are created for submission of the data collected by persons themselves to third parties for use and analysis of the data. The consequence can be also an aggregation of information that facilitates the person-centred approach of treatment and health management.

There is also a focus on prevention that is highlighted in the Estonian strategy.

Creation of a concept of data quality to have a sort of cascade of quality improvement in healthcare.

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Ensuring that telemedicine (mHealth) services comply with current privacy and security regulations (Cybersecurity).

Appointing a Managing Director to guarantee the technical-sanitary organisation and the existence of the due performance standards for clinical activities provided in Telemedicine, and identifying a professional subject, with proven and specific skills, responsible for the management and maintenance of technologies and IT infrastructure to guarantee the provision of Telemedicine services.

Delivering telemedicine services, in all their phases, through staff with the necessary qualifications, knowledge and skills, ensuring a periodic training plan guaranteeing up-scaling / re-scaling of the staff in charge, with regard to the management and use of telemedicine services (acquisition, consultation,referral).

Adopting a procedure to ensure adequate information to the citizen on the execution of the "remote" service, as well as to increase the digital competence of citizens and professionals, in order to enable them to handle digital health data in a responsible manner, while being aware of the possible risks.

Ensuring that users can access and consult their own data that have been collected, managed and stored.

Adopt a training plan for the training of users (patients, caregivers, health workers) in the use of the technologies used.

Ensuring the traceability of maintenance, testing and safety control activities for the technologies in use, with related detailed technical reports.

Adopting quality and risk assessment plans including well-defined organisational procedures for the delivery of telemedicine services.

Establishing measurable, reproducible and objective parameters to quantify the success of a programme.

Creating synergies between public health facilities, universities and private technology companies.

Carry out a detailed needs assessment study of the target population.

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Policy Area 2 – Integration Mechanisms with EHR and Interoperability

- **POLICY DESCRIPTION**

For mHealth to achieve its full potential, it needs to be integrated in the healthcare systems. However, integration with existing electronic health records brings forth several challenges, such as patient privacy and interoperability, as well as local and regional capacities of the healthcare systems. All issues concerning cybersecurity, privacy, systems interoperability, and data overload must be tightly regulated and coordinated.

The following use cases were explored within this policy area:

1. mSSPA (Region of Andalucia, Spain)
2. The Netherlands MedMij Framework (The Netherlands)
3. VIPP (The Netherlands)
4. ProEmpower (Europe)
5. ELGA Electronic Health Record (Austria)

- **POLICY EXAMPLEs**

  - **mSSPA (Region of Andalusia, Spain)**

The mSSPA project was a part of 2012 strategy from Andalusian Agency for Healthcare Quality (ACSA) that is called *Estrategia de calidad y seguridad en aplicaciones móviles de salud* (Quality and safety strategy in mobile health applications). This strategy includes an assessment framework already analysed in mHealth Hub in WP2, an recommendation guide for designing mobile apps for health, and a catalogue of apps that already have a seal of approval from the assessment.

mSSPA is an ecosystem that comes from mSalud, that have emerged from the need to have disruptive solutions that allows sustainability for the health system, from the need to have bilateral connectivity and transfer of information.

mSalud was a way to make sense of more than 40,000 health apps and to certify and aggregate them according to their pertinence and use.

mSSPA ecosystem defines certification, commercialization, optimization, integration and personalization of mHealth in one service suite that unifies the access from patients and for professionals.

Integration of mHealth is made through a new integration cover, which is a new open model for integration that have the following components:

- Authentication and Authorization System
- Platform for publication and consumption of services
- New layer of integration and publication of clinical data
- Platform for interaction and personalization of services (professionals and citizens)

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The implementation of mSalud had the following objectives[78]:

Generation of an ecosystem of corporate mobile services

- Set of corporate mobile applications
- Channelling initiatives of third parties (SMEs, individuals, institutions ...)
- Guaranteeing the quality and security of applications

Personalization and Health Promotion

- Self-responsibility and self-care. Patient involvement
- New ways to recommend and give health advice
- Encourage Prescription of apps by professionals
- Share and exchange citizen health information

Generation of Impact

- In citizenship especially in Andalusia through integration
- In the citizenry, especially in Andalusia through integration with corporate systems
- In professionals, improving access to information, and promoting the prescription of mobile applications

Testing of real use and business models

- Optimization of processes
- Cost / benefit and cost / utility analysis
- Cost / benefit and cost / cost analysis utility

The SSPA mobility strategy is based on a technological platform (hereinafter "mSSPA platform") composed of a set of modules, services and mobile applications for the daily provision of information technology services used by citizens and professionals of the SAS (Andalusian Health Service) to exchange information with the regional Electronic Health Record (Diraya).

Currently the mSSPA platform is based on modules from CA Technologies, licensed for both production and non-production or pre-production environments. Specifically, the CA API Gateway component is available, which provides a layer of abstraction, security and decoupling with respect to the information systems of the SSPA. In turn, it allows the creation, elimination and modification of APIs, which can be used by developers. In this way, the orchestration layer and the presentation layer present in the mSSPA platform scheme allow mobile applications to access the information systems of the SSPA in a secure way, making use of the functionalities provided by the CA Technologies modules.

SAS also has CA API Portal licenses for the management and consumption of the platform's APIs. It will also have licenses for CA Mobile API Gateway and CA Precision API Monitoring, which extend the provision of services and the robustness of the platform.

CA API GATEWAY: This module provides a layer of abstraction, security and decoupling with respect to the services, systems and technologies used within the healthcare environment. In turn, it allows the creation, elimination and modification (versioning) of APIs, which can be used by authorized developers. This module is related to the Corporate Interoperability Platform, which allows the Andalusian Public Health System (SSPA) to have an integration architecture based on a robust

[78] Proyecto mSSPA [online] Available at: https://aprenderly.com/doc/3429053/proyecto-msspa

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service bus architecture and a set of services for direct interaction with corporate backends, such as Appointments or Vaccines or the User Database. This architecture allows the interconnection of all health centers and hospitals in the system, as well as the centralization of information and decentralized consumption by them. Another important feature of CA API GATEWAY is the possibility of caching invocations, keeping a local copy of the information sent, as a cache, and allowing duplicate requests not to require new invocations to the basic services.

CA API PORTAL: One of the main modules of the mSSPA technology platform is the management and publication of APIs, which allow access to the services available in the SSPA in a secure way.

CA API PORTAL has a collaborative space where API publishers / creators and app developers who will use them will converge. This collaborative environment is divided into the API Publishing Portal and the Developer Portal described below.

- API publication portal: it is the web space for managing APIs and accessing them. Through this portal, the publisher manages the life cycle, interfaces, security and use policies of the APIs. The authorization of access by the developers to the APIs is also done through this portal.

The following figure shows the functionalities of the API Publishing Portal in a schematic way[79]:

Figure 6 – API publishing portal schematic

Developer portal: it is the web space in which information about the services available and the necessary access procedures can be openly accessed. Through the portal it is possible to request the registration of individuals / companies as developers that make use of the mSSPA platform. It is also possible to manage the life cycle of tokens granted to developers. The contents and modules of this portal are:

- Forum.
- Space for Wiki, FAQs and How-tos.
- Examples of the use of APIs.
- Files with documentation of the APIs as well as links to external URLs.
- API search.

[79] Pliego de prescripciones técnicas que regirán la realización del contrato de "servicios de desarrollo, evolución y mejora de aplicaciones para la plataforma de movilidad del sistema sanitário público de andalucía" [Technical requirements applicable to the execution of the contract for "development, evolution and improvement of applications for the mobility platform of the public health system in Andalusia]. Procedimiento abierto- Exp. 100/18-SP. Ministerio de Economía Y Empresa, Red.es. [pdf]. Available at: https://www.adjudicacionestic.com/front/descarga-adjudicacion.php?tipo=PPT&id=40111

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- User management module and developer tokens.

The portal makes it possible to configure different levels of security for access to information, being able to restrict the information that is desired to a specific group of developers.

CA PRECISION API MONITORING - Provides visibility into API performance using transaction-level alerting and visualization tools in near real time.

CA MOBILE API GATEWAY - Provides a set of tools to accelerate application development while providing the security and capabilities that mobile device applications demand. In addition, it offers an open source SDK that allows advanced functions, such as messaging or geolocation, among others. API caching and traffic coordination enables developers to optimize application performance and support a variety of complex functions.

BACKEND OF THE APP. Software component that serves as a bridge between mobile applications and SSPA information systems, allowing to complement some apps that require it from the server side (currently available for the ClicSalud + app). The need to develop a backend for an app is established in the analysis phase of mobile applications, in case they require managing specific information for their operation that is not available in the SSPA information systems and the backend would be used to perform these intermediate repository functions.

The main characteristics of a backend are:

- Publish REST API interfaces for reading / writing information so that these services are consumed by the apps from their publication in CA.
- Store certain business information, from the configuration of the app itself, to some functional consideration that covers a need that the SSPA systems do not offer.
- Incorporate web screens for consultation, updating or deletion, so that a user who manages the STIC can work on the information.
- Transform certain information retrieved from the SSPA information systems to adapt the information to what is needed by the app, for example, pre-filtering those data that are not useful.

BASE PROJECT, LIBRARIES

mSSPA The Base Project (mobile application, available for iOS and Android), as well as the mSSPA libraries, integrate the most common functionalities of the SSPA mobile application ecosystem, such as notifications, authentication or user information, for reuse in the construction of the rest of mobile applications. In this way, developments are streamlined, while the evolution, security, and maintainability of these common functionalities are centralized. The base project is not published as a mobile application in the markets, being a project for internal use by developers, like the mSSPA libraries.

AUTHENTICATION CIRCUIT - AUTHENTICATION MOBILE WEB Authentication Circuit: The SSPA application ecosystem requires a somewhat more complex authentication than usual in the world of mobility because it offers information with special sensitivity, your health data.

To make identification easier for the user, different alternatives are offered:

- SSPA mobile web
- Digital certificate
- Cl @ ve

The digital certificate and Cl @ ve options can be used by the user in all the applications that require it, and the Mobile Authentication Web (SSPA mobile Web) only in ClicSalud +.

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To use the Mobile Authentication Web, the user needs:

- Electronic certificate.
- A device with its electronic certificate installed and internet access, such as a PC.
- The latest version of the ClicSalud + Android or iOS application installed on your mobile device.
- Access the authentication address http://lajunta.es/autenticacionsspa from where it generates a QR code that will be read from the ClicSalud + app.

If the user uses ClicSalud + for their identification, they will always be able to retrieve that identification in a third app that they access from ClicSalud + (more information at http://lajunta.es/autenticacionsspa).

In order to offer all the security of access to citizens' information, the applications will detect if the user has a native locking system on their device, such as an access pattern, for example. In addition, the SSPA has incorporated a unique 4-digit multi-session and multi-device PIN, associated with its user, so that users can protect the applications they want. To do this, the user only has to authenticate in one of them and indicate it in the preferences check. As an aid in terms of usability, it offers the possibility of associating the device's fingerprint with its PIN, so that users do not have to type it manually each time.

- **ENABLERS**

Assessment (technology)

Assessment frameworks in place

- **DISABLERS**

User-centred

Professionals' lack of training, education and advocacy • Lack of sense of clinical value

Core infrastructure

Lack of technological infrastructure in underserved areas

Assessment (technology)

Lack of evidence of clinical utility

Integration - interoperability

Lack of interoperability

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- **The Netherlands MedMij Framework (The Netherlands)**

MedMij ensures that anyone who so wishes has access to their health data in a personal health environment (PHE, Dutch: PGO) of their choice. This could be an app or a website, for example.

To do this, an app or site must be able to communicate securely with all the locations where the information is stored. These could be the healthcare information system of a hospital, the physician, the well-baby clinic, or the pharmacy.

Global design (see Figure 7 – MedMij framework.): On the left there is the care-user environment – person and the service provider for the person (= PGO, the app, or website). On the right is the care-giver environment with the service provider for the caregiver. Both service providers "talk" to each other through the exchange of Health Care Information Models (HCIM), transmitted in the form of HL7 FHIR resources. The green area is the MedMij framework, a set of architectural, ethical, and judicial agreements where either party needs to fully comply with and to which one is admitted only after having met the requirements set in accession criteria. Thus, a framework is established in which both parties know they can trust each other.

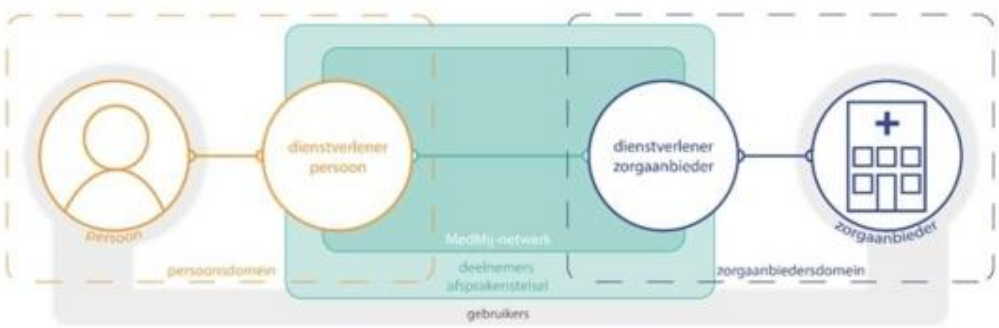

Figure 7 – MedMij framework.

The policy was chosen as an alternative to the national EHR that failed due to privacy and legislation issues. The Dutch Patient Federation (https://www.patientenfederatie.nl/) became a big promotor of this policy that gave the articulate patient a voice in the treatment and monitoring of his / her health. Prevention and maybe even prediction are keywords in the concept of the PHE.

Politically it also seems to have been an effort to finally start semantic interoperable exchange of data, pushed further forward by heavily subsidized acceleration programs, called VIPP (see further on in this document).

The MedMij program was derived from architectural ideas that were developed to realize the National EHR. The Patient federation worked with Nictiz, the National institute of IT in Healthcare, various standardization organisation, e.g. HL7 the Netherlands. MedMij started as a program by these parties but is now an independent foundation funded by the government & the health insurance companies.

Through the efforts and pressure of the patient federation and the lack of success in exchanging reusable information between hospital systems, the Personal Health Environment (PHE) was developed. Not only would the patient be in control of his / her own health process, also the exchange of reusable data would be promoted form a different angle, the side of the care user, the patient.

The policy could be built on the existing standards and framework developed in previous efforts and use the same and well described information exchange principles and techniques.

The whole setup of the MedMij framework is entirely voluntarily. Patient privacy is extremely important and is leading legislation in constraining what and how things are allowed.

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If a patient is enabled through the use of his / her PHE, he will not only be able to collect and work with the data originating in care-giver environments, but also add data of his own, health, fitness and wellness data, which in return can be share to become part of the care-givers network. The PHE will be a lifetime survey of a person's health and wellbeing and thus be a valuable asset in determining the cause of disease.

- **ENABLERS**

User-centred

Personal factors which shape people engagement and experience • Keeping the user in mind • Support and promotion of mHealth / telehealth by colleagues • Consumer demand • Experiencing patient and clinical benefits • User involvement in solution development

Assessment (technology)

Quality standards • Assessment frameworks in place

Cost and reimbursement

Value-based reimbursement

Health policy

Communication and collaboration between stakeholders • Management (strategic planning) • Information and communication technologies considered central components of healthcare services delivery

Integration - interoperability

Compatibility with work process • Interoperability of solutions

Other enablers shown in the policy example:

Dutch Government financially supporting (subsidizing) the realization

- **DISABLERS**

User-centred

Professionals' lack of training, education and advocacy • Unrealistic expectations • Privacy and security concerns

Assessment (technology)

Lack of cost-effectiveness evidence

Health policy

Conflicting priorities

This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Grant Agreement No 737427

- **VIPP (The Netherlands)**

In the Netherlands, a program is underway called VIPP (Acceleration program Information Exchange Patient – Care professional). Part of VIPP is VIPP5. VIPP5 aims to realize the exchange of information between an EHR (hospital, pharmacy, GP, or any care professional owned EHR) and a patient owned PHR (called "Personal Health Environment", PGO). The actual program to realize the exchange of information between a PGO and EHRs is MedMij.

VIPP 5 has three modules of which two are aimed at realizing the MedMij framework:

Module 1: realizing the exchange of a patient summary from caregiver to care-user.

Module 2: realizing the exchange of questionnaires, the use of eHealth modules and exchange of data generated by the eHealth module and use in the information system of the care-giver back to the use (PGO), and the possibility of the user correcting the patient summary received in module 1 by sending proposed changes to the EHR.

The information exchange is defined by Health and Care information models (HCIM), or Clinical Building Blocks, that are used to capture functional, semantic (non-technical) agreements for the standardization of information used in the care process. The HCIM are exchanged through HL7 FHIR resources.

The Dutch government is stimulating the use of eHealth by subsidizing the various VIPP programs and thus stimulating the emergence of eHealth and in this case the PGO's, to give more power to the patient.

The description and use of the HCIM is very extensively described in 4 architectural volumes:

- Volume 1: Architecture Document Volume 1[80]: basic architectural document, dealing with the basic principles of health and care information models (HCIMs) and how they can be used

Architecture Document Volumes 2-4 and the Service management agreements for Health and Care Information Models are at present only available in Dutch[81].

- Volume 2: The practical aspects of implementing HCIMs on the level of applications and data exchange (Dutch)
- Volume 3: The practical aspects of the implementations of HCIMs on the level of the care-process, use cases and datasets (will be available soon)
- Volume 4: The way HCIMs can be used to for the subsistence to registrations (Dutch)

- **ENABLERS**

User-centred

Provider's capacity • Awareness of the objectives and / or existence of solutions • Consumer demand • Experiencing patient and clinical benefits

[80] Netherlands Federation of University Medical Centres, NVZ, Nictiz (2017). Architecture Volume 1 – Basic document. The basic principles of health and care information models (HCIMs) and how they can be used. V1.0 [pdf] Available at: https://zibs.nl/images/4/44/HCIM_Architecture_Document_UK_v1.0.pdf

[81] ZIB Hoofdpagina. Wikipedia, 2020 [online]. Available at: https://zibs.nl/wiki/ZIB_Hoofdpagina#Externe_links_en_achtergrondinformatie

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Assessment (technology)

System reliability or dependability • Accuracy of the system • Quality standards • Assessment frameworks in place

Cost and reimbursement

Having requisite material resources • Having requisite human resources (IT support, other)

Health policy

Communication and collaboration between stakeholders • Information and communication technologies considered central components of healthcare services delivery

Integration - interoperability

Interoperability of solutions

- **DISABLERS**

User-centred

Professionals' lack of familiarity with equipment and procedures • Unrealistic expectations • Perceived complexity of solutions and resistance from physicians • Lack of sense of clinical value • Privacy and security concerns

Assessment (technology)

Lack of data accuracy

Health policy

Lack of readiness among key stakeholders

Integration - interoperability

Lack of integration with workflow leading to increased workload

- **ProEmpower (Europe)**

Overview

Four healthcare providers from Italy, Spain, Portugal and Turkey have tested innovative mHealth solutions for management of type 2 diabetes, supported by the EU project ProEmpower (https://proempower-pcp.eu/). In the project, the healthcare providers launched an open call for Europe's industry to develop innovative mHealth solutions that address several aspects of diabetes management:

- Early detection: allowing for identification of persons with undiagnosed diabetes type 2 using existing relevant patient data.

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- Patient-professional co-ordination: collaboration between the patient and the professionals through a shared care plan that includes relevant patient data and can be used to schedule alerts, set goals and track progress, and facilitate mutual decision making.
- Personal decision support: enhancing medical decisions by personalised decision support tools that summarise patient clinical characteristics, treatment preference and ancillary data at the point of care.
- Comprehensive diabetes training offer: providing comprehensive training to diabetic patients in accordance with the procurers' current training programmes. This includes laying out a training strategy and approach, and the related content and development of appropriate delivery methods (eLearning, blended learning, video, audio, etc.). Most importantly, it should aim at developing the confidence and skills for patient self-management.
- Glucose control loop: collecting, storing and analysing different parameters to provide comprehensive information and advice and effectively manage the patients' diabetes. Especially relevant are factors influencing blood glucose levels like stress, carbohydrate intake and activity allowing to predict glucose levels.
- Healthy lifestyle: educating and motivating patients about healthier lifestyle with diabetes.
- Self-help and peer support: offering an environment (platform) for patients and professionals to exchange information and connect socially.
- Quality & outcome reporting: offering evaluation of treatment methods and benchmarking among physicians.

Due to the nature of the approach used (pre-commercial procurement), the healthcare providers could control the full process, starting from defining requirements of the envisaged mHealth solutions, up to co-developing and testing them in real conditions with end users (diabetes patients, healthcare professionals and informal carers). Another aspect of the pre-commercial procurement is the competitive nature of the R&D, resulting in the development of several different solutions by different industry players, ensuring that there is no market lock-in and the healthcare providers can choose the solution that is most suited to their needs.

The new solutions have to be compatible with the existing infrastructure of the healthcare providers, i.e. with their EHR and PHR systems. For example, the targets that relate to interoperability and integration of mHealth within Electronic Health Records which are stated in Strategic Plan 2013 – 2017[82] of Ministry of Health of Turkey are:

- To improve and sustain mobile health services
- To support homecare services with mobile technologies
- To establish remote follow-up of patients via institutional mobile practices and attachable wireless sensors
- To develop an Electronic Health Record system and a portal to collect, monitor and provide safe access to and sharing of personal health records
- To establish systems that enable people to reach all their health data and share them with others by using mobile devices
- To improve health IT standards to increase e-health practices by service provider and users and to roll out e-health practices
- To improve "Interoperability" practices in cooperation with stakeholders

As the Strategic Plan has a guidance role, no specific activities are listed in the Plan. The Turkish Ministry of Health is responsible for rolling out and implementation of activities. To reach these targets, Ministry of Health of Turkey launched an electronic / personal health record for the use of Turkey's citizens in Turkey in April 2015, E-Nabız. E-Nabız is a highly advanced electronic / personal health record system where you can reach your health-related information including but not limited to:

- healthcare facility visits,
- prescriptions,
- medical reports,

[82] Strategic Plan 2013 – 2017. Ministry of Health of Turkey, 2012 [pdf]. Available at: https://sgb.saglik.gov.tr/Eklenti/34226/0/strategic-plan-2013-2017pdf.pdf

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- diagnoses,
- laboratory results and medical images,
- allergy information,
- blood and organ donations,
- emergency notes and
- documents.

E-Nabız allows integration of medical devices with the system for wireless data communication. It is also a personal health record (data fed into the system by the user himself / herself), and Bluetooth and wireless devices may easily be integrated with one's E-Nabız account. From a health IT standards perspective, all necessary international standards are being used in software, applications, and innovations of Ministry of Health to make interoperability possible in cases of need.

In the developed solutions, diabetes-related data generated by the patients (e.g. blood sugar measurements, calory intake, physical activity) is automatically transferred and available to their treating physicians, enabling real-time response and management. AI algorithms support the process, prioritising and sorting cases, supporting decisions, issuing alerts, recognizing trends, making recommendations, etc.

The healthcare providers defined a number of requirements related to ensuring that the mHealth solutions are developed in a way that ensures interoperability with their existing systems. For this, each healthcare provider detailed in the call the characteristics of their systems – architecture, technology used, messaging standards, authentication and security considerations, etc.

Industry players applying to the call developed their offers based on these requirements. The approach to integrating with the healthcare providers' systems was one of ten evaluation criteria, indicating the importance of the interoperability of the solutions, if they are to be used in the future.

Two solutions were chosen to be developed and tested in an 8-month trial in pilot sites in Italy, Spain, Portugal and Turkey with 100 patients and approx. 10 healthcare professionals per pilot (500 patients and more than 50 healthcare professionals in total).

Solution 1: DiaWatch

DiaWatch is a mHealth and telemedicine solution to provide a more effective and personalised type 2 diabetes management. It is composed by:

- **A sensing system platform**: DiaWatch operates using a smartphone optionally integrated with other devices such as a wristband, a glucose monitoring sensor, a blood pressure meter, a scale and (for insulin-dependent patients) a cooling-box for management of fragile medications;
- **An app for patients** including:
- A Virtual Coach ("DoctorPro"), based on an artificial intelligence (AI) system that exploits continuous machine learning models to profile the patient and make appropriate recommendations for diabetes treatment, exercises and healthy lifestyle;
- A patient personal profile and related data-entry functions, embedded in a Shared Care Plan (SCP) progressively updated with new data from different sources;
- A repository of motivational and training contents for Diabetes Management;
- A social community tool for interaction, communication and peer training;
- A **(desktop and mobile) app for clinicians** which allows clinicians to monitor compliance with the diabetes Shared Care Plan, to communicate with patients (via textual messages, audio and video features) directly from the hospital, and to identify – among their patients or in the general population – people at risk of developing diabetes;
- **A cloud-based platform**, to ensure data exploitation for risk prediction.

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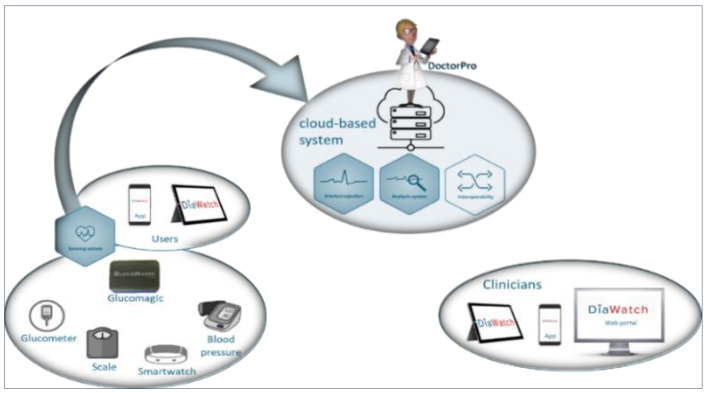

Figure 8 – DiaWatch system.

Solution 2: DM4All

DM4all digital platform is a novel mHealth system dedicated to the effective management of Type 2 Diabetes Mellitus (T2DM). The platform includes web and mobile interfaces along with intelligent medical devices, able to support all the diverse needs of the T2DM care pathway. Patients, Informal Caregivers, and Healthcare professionals are able to manage, communicate, and monitor the disease progression through the system. Thus, this multi-pronged and integrated approach promotes self-care practices, continuous monitoring, and reduces any long-term complications.

DM4all is developed based on the Shared Care Plan, a shared "document" that includes information about lifestyle, treatment plan activities, and disease-related markers. Furthermore, collects information and feedback from the patients through validated questionnaires aiming to increase impact and personalization.

The overall objective of the platform is to encourage: patients and involved actors to adopt best practices in disease management, patients to increase the adherence in the treatments plan and all actors to improve their quality of life.

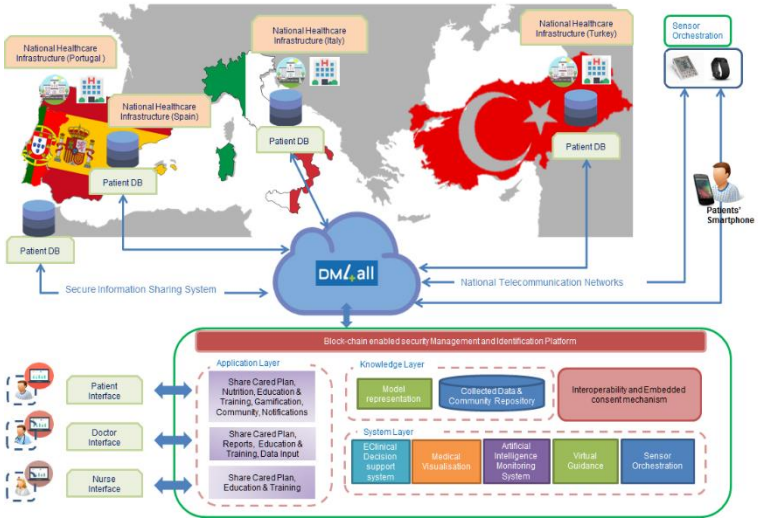

Figure 9 – DM4All System.

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mHealth integration strategies

Depending on the solution and the healthcare provider system, different integration strategies were applied.

The DiaWatch solution is prepared for future integration with any health information system. It supports FHIR HL7 (Fast Healthcare Interoperability Resources) (www.hl7.org/fhir/overview.html) as standard for exchanging healthcare information electronically with other systems. The solution has a robust data model that uses a common international standard for clinical data, which prepares the solution for future needs and in combinations with FHIR for interoperability. Microsoft Azure Cloud is used for hosting, as it fully supports FHIR development and implementation ("HL7 FHIR on Azure", https://info.microsoft.com/HL7FHIRonAzure-Registration.html). It also offers high security standards for storage, data, location within the national borders, encryption, identity and access management, and grants high robustness and guarantees at least 99.9% of service availability. The implementation of the standards during the R&D phase made use of a methodology based on ISO/IEC 12207:2008.

DiaWatch produced a strategy for data exchange between the solution and the EHRs of each healthcare provider. The following example is based on the DiaWatch system at the Turkish healthcare provider and its EHR called eNabiz.

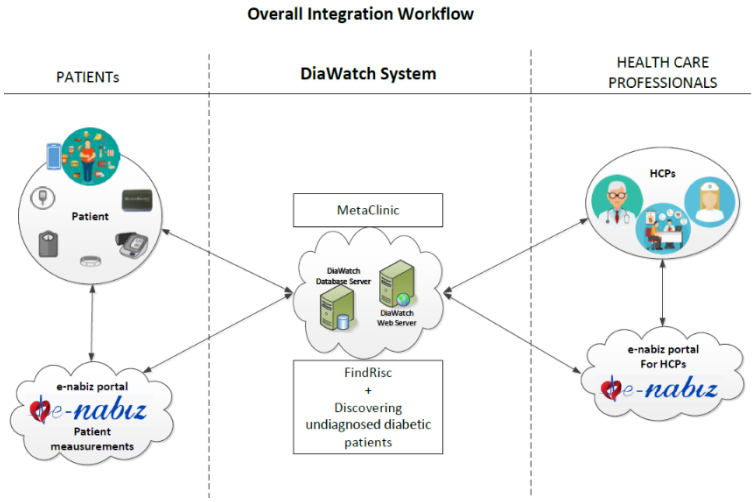

Figure 10 – DiaWatch Integration Workflow.

e-Nabız is an application that citizens and health professionals access to see health data collected from health institutions via internet and mobile devices. Regardless of where examinations and treatments are held, all the information can be accessed by the citizens.

The results from these initiatives are promising, bringing benefits to patients (improved diabetes control, empowerment) and healthcare professionals alike (faster processes, better overview of patients, individualised plans, better adherence to treatment). For ProEmpower evaluation, both clinical and non-clinical parameters were collected, either via measurements at the care centres or via continuous measurements through the solutions themselves. The chosen clinical parameters consisted of glycated haemoglobin (HbA1c) levels, body weight, waist circumference, LDL cholesterol and blood pressure, while the non-clinical parameters evaluated indices such as smoking habits, cognitive impairment, usability of the solutions and others. First data analyses show significant reductions in HbA1c across all four pilots for both solutions, which indicates an overall better management of diabetes, improved glycaemic control, and reduction of macro-and micro-complications in these patients.

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- **ENABLERS**

User-centred

Keeping the user in mind • Frontline staff training • Experiencing patient and clinical benefits • Perceived ease of use • User involvement in solution development • Experimentation and clinical learning • Training

Assessment (technology)

Quality standards • International interoperability standards

Cost and reimbursement

Having requisite human resources (IT support, other)

Health policy

Communication and collaboration between stakeholders • Information and communication technologies considered central components of healthcare services delivery

Integration - interoperability

Interoperability of solutions

- **DISABLERS**

User-centred

Lack of technological knowledge

Cost and reimbursement

Costs associated with technology

- **ELGA Electronic Health Record (Austria)**

ELGA (elektronische Gesundheitsakte [electronic health record]) is an information system that allows access to the EHR by patients and their respective physicians, as well as other healthcare professionals at hospitals, care facilities and pharmacies. ELGA enables the sharing of discharge and care reports, laboratory reports and medical imaging reports which was enacted by the ELGA act 2012[83]. ELGA also provides a medication record to enable decision support for prescribing and dispensing.[84]

[83]Electronic Health Record Act (ELGA-G). BMG (Federal Ministry of Health), 2012. REGV_COO_2026_100_2_654513 [online]. Available at: https://www.ris.bka.gv.at/Dokument.wxe?Abfrage=RegV&Einbringer=&Titel=ELGA-G&BeschlussdatumVon=&BeschlussdatumBis=&ImRisSeitVonDatum=&ImRisSeitBisDatum=&ImRisSeit=Undefined&ResultPageSize=100&Suchworte=&Position=1&SkipToDocumentPage=true&ResultFunctionToken=64009c80-0e54-4567-9943-898f535b3ec0&Dokumentnummer=REGV_COO_2026_100_2_654513

[84] Overview of the national laws on electronic health records in the EU Member States. National Report for Austria. Milieu Ltd and Time.lex, 2014 [pdf]. Available at: https://ec.europa.eu/health/sites/default/files/ehealth/docs/laws_austria_en.pdf

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The implementation of ELGA started in December 2015 in public hospitals and care facilities in Vienna and Styria. Currently, the process is almost completed, with more than 160 facilities successfully working with ELGA throughout Austria.[85]

The ELGA project is a collaboration between the federal government, state governments, and social insurance organizations. Austrian citizens can access their eResults and eMedication-List via the ELGA Portal at any time and from any location. E-vaccination certification was also implemented during the COVID-19 pandemic. To access ELGA, patients will need a Mobile Phone Signature or a Citizen Card to do so. Healthcare professionals and hospitals can retrieve previous diagnoses and treatments. This helps to keep the information flowing in medical, nursing, and therapeutic settings. The Citizen Card works as a key, allowing access to a patient's medical records only when they swipe their card. Participation in ELGA, or portions of it, is entirely voluntary.

For healthcare providers, ELGA is integrated as an additional software (module) that can be added to existing systems, such as clinical and pharmacy software. This approach makes the programme more comfortable and user-friendly for the user in the ordination, pharmacy or hospital. When saving ELGA health data, the links (references) with their storage location that arise at an ELGA health service provider (ELGA-GDA), are entered in a table of contents (reference register). These tables are located in ELGA-areas, which shows the ELGA-GDA storage systems in which ELGA health information is available for a particular patient. Only authorized ELGA-GDA can access ELGA health data on condition that the treatment or care connection is in good standing. Using the central ELGA components to check the identity of the patients, the ELGA-GDA and the authorization rules, the ELGA health data, which were stored in different ELGA-GDAs, are bundled and clearly arranged on a patient-specific basis in the event of authorized access to ELGA the user is displayed on the screen.[86]

Considering the eHealth environment in Austria, there were three important developments, which constitute the framework for the realization of ELGA – nationwide EHR – initiative[87]:

- The **MAGDALENA framework**, which was established in 2000, guided the construction of a nationwide Austrian health network. It contains a number of technical and organizational recommendations for the creation of an Austrian Health Data Network, which laid the groundwork for Austria's electronic patient data exchange.
- "**eCard**" social-security chip card and the adoption of the **Austrian healthcare reform act**, both of which occurred in 2005. The eCard is a key card that is used to control access to the EHR and replaces the original paper-based system of health insurance certificates. It is used for patient identification, obtaining insurance status, and as a key card for controlling access to the EHR.
- The **Health Telematics Law**, passed as part of the Austrian healthcare reform act, established the standards for secure health data interchange and laid the groundwork for the country's future eHealth developments. Prior to any health data exchange, health care providers need to confirm that the receiver' identity and role authorizes the latter to receive the data. This is accomplished by accessing a national eHealth-index, which stores health care providers' names, identities, addresses, and public keys, among others. This law also ensures that any data exchange over a medium that is not exclusively controlled by the sender and receiver must also be encrypted. In addition, it also predicts a opt-out option.

Electronic index of Austrian healthcare providers was established in 2001 by the Austrian Medical Chamber. As mentioned, it is currently used to promote electronic exchange of clinical information by providing the necessary identification data for both automatized and individual queries.

[85] About ELGA. ELGA.gv.at [online]. Available at: https://www.elga.gv.at/en/about-elga/

[86] Technische Grundlagen von ELGA [Technical basics of ELGA]. ELGA.gv.at [online]. Available at: https://www.elga.gv.at/faq/technische-grundlagen-von-elga/

[87] Dorda, E. et al (2005). Introducing the Electronic Health Record in Austria. Stud Health Technol Infor 116:119 [pdf]. Available at: https://www.meduniwien.ac.at/msi/mias/papers/Dorda2005a.pdf; University of Applied Science Techinikum Wien. WP5 – Policy and Innovation. Short Technical Paper. Case study: overview of policies enabling digital health in Austria. European mHealth Hub, 2020 [online]. Available at: https://mhealth-hub.org/download/wp5-policy-and-innovation-short-technical-paper-case-study-overview-of-policies-enabling-digital-health-in-austria

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Other enabling components / regulations:

- **Electronic Health Record Act (ELGA-G)** (Federal law with which a Health Telematics Act 2011 was enacted and the General Social Insurance Act, the Commercial Social Insurance Act, the Farmers Social Insurance Act, the Civil Service Health and Accident Insurance Act, the Genetic Engineering Act, the Health and Nursing Act, the Midwives Act, the Medical Masseur and Therapeutic Masseur Act and the Criminal Code, to be changed): In this law, the rights of the citizens as well as the data protection and data security are defined.[88] The Parliament created the legal basis for ELGA nationwide implementation after extensive negotiations. This included the development of technical component (e.g., ELGA citizen portal, central patient index, health service providers index, authorization and logging system, and local ELGA areas). In addition, it also included a stet-by-step approach for the provision of health data (e.g., initially hospital discharge letters, laboratory, and radiology results).[89]
- **ELGA regulation 2015**[90]: included the establishment of an i) objection point and ii) a service line ELGA-Ombudsman; and defined iii) structure, format and standards of ELGA health data, iv) the interaction relevant, non-prescription drugs, v) the minimal requirements for the content of a notice at ELGA-Health service providers, vi) the access rules to ELGA for underage minors, and vii) the operator of the authorization and logging system.
- **ELGA regulation amendment Nov 2015**[91], with the purpose of implementing and developing the EHR.
- **ELGA regulation amendment 2017**[92], which also amendments ELGA regulation 2015.
- **Data Protection and privacy**: the strictest access restrictions apply to ELGA data. Abuse is punishable by administrative fines as well as criminal accusations. Data can only be accessed via ELGA if the participant is being treated by a healthcare professional and does not object it. This means that a healthcare professional can only access ELGA data if the patient has given his or her consent and if the patient's e-card has been used as a key.[93] Moreover, to protect the integrity of the patient's ELGA health data, the strongest security standards are in place. Separate health networks control communications across the ELGA system, and all data is encrypted. Furthermore, any misuse of ELGA health data would be met with harsh sanctions.[87]
- **Trust and transparency**: patients can monitor who has accessed their data, what data, control data access and erase document references in order for those no longer be available in ELGA.[86]
- **e-Government Act**: contains “provisions on accessibility and official websites that are also applicable to the access portal for ELGA participants. Furthermore, the e-GovG regulates the identification of citizens through the area-specific personal identification number”.[88]

Interoperability in ELGA is based on international IT standards and profiles. These standards are mandated via regulations that are issued by the federal health ministry, as laid down in the ELGA law. Currently, ELGA uses HL7 for standardizing

[88] SCOOP4C Pilot Project. Austrian electronic health records (ELGA). CEF Digical Connecting Europe. EC [online]. Available at: https://ec.europa.eu/cefdigital/wiki/pages/viewpage.action?pageId=119504996

[89] Electronic health record (Austria) - Elektronische Gesundheitsakte (Österreich). Eikimedia Foundation, Inc, 2020 [online]. Available at: https://second.wiki/wiki/elektronische_gesundheitsakte_c396sterreich

[90]Ordinance of the Federal Minister of Health for the implementation and further development of ELGA (ELGA Ordinance 2015 - ELGA-VO 2015) On the basis of Section 28 Paragraph 2 of the Health Telematics Act 2012 (GTelG 2012), Federal Law Gazette I No. 111/2012, in of the 2014 version of the DSG Amendment, Federal Law Gazette I No. 83/2013. [pdf] Available at: https://www.elga.gv.at/fileadmin/user_upload/Dokumente_PDF_MP4/Recht/BMB-VO_BGBLA_2015_II_106.pdf

[91] Ordinance of the Federal Minister of Health amending the ELGA Ordinance 2015 (ELGA Ordinance Amendment 2015 - ELGA-VO-Nov 2015). On the basis of Sections 8 and 28 Paragraph 2 of the Health Telematics Act 2012 (GTelG 2012), Federal Law Gazette I No. 111/2012 , in the version of the DSG Amendment 2014, Federal Law Gazette I No. 83/2013. [pdf] Available at: https://www.elga.gv.at/fileadmin/user_upload/Dokumente_PDF_MP4/Recht/BGBLA_2015_II_373.pdf

[92] Ordinance of the Federal Minister for Health and Women amending the ELGA Ordinance 2015 (ELGA Ordinance Amendment 2017 - ELGA-VO-Nov 2017) on the basis of Section 28 (2) of the Health Telematics Act 2012 (GTelG 2012), Federal Law Gazette I No. 111/2012 , in the version of the Health Reform Implementation Act 2017 - GRUG 2017, Federal Law Gazette I No. 131/2017 [pdf]. Available at: https://www.elga.gv.at/fileadmin/user_upload/Dokumente_PDF_MP4/Recht/BGBLA_2017_II_380.pdf

[93] Gesetzliche Grundlagen von ELGA [Legal basis of ELGA]. Elga.gv.at [online]. Available at: https://www.elga.gv.at/faq/gesetzliche-grundlagen-von-elga/

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electronic communication between health service providers and Clinical Document Architecture (CDA) for networking health data and information. In the addition, the standards in use in Austria include[94]:

- International standards:
  - Transport standards: W3C (SOAP, HTTP), TLS, OASIS SAML, WS-Trust
  - OASIS ebXML for Cross-Enterprise Document Sharing
  - HL7® CDA® for nation-wide harmonized clinical documents
  - HL7® v3.x for patient-identification related communication
  - DICOM – international imaging standard (WADO)
  - IHE different profiles
- Terminologies and classifications:
  - ICD-10, LOINC, SNOMED-CT, Austrian terminologies

ELGA only employs existing, secure networks that are exclusively utilized for health data without exception. Some examples include the social insurance e-card network, the internal social insurance network (SVN) and Healix (communication infrastructure of hospitals with a connection to the e-card service). In addition, the ELGA data is encrypted while being transported.

ELGA Health data, such as discharge letters and findings, are stored at the location where it was created (e.g., hospital, laboratory, etc) and not in ELGA itself (i.e., stored in a decentralize manner). Medication-related data, such as ePrescription, is encrypted and stored centrally in a database at the Main Association of Austrian Social Insurance Institutions.[95]

Technical modules[86]:

- **Central Patient Index (Z-PI):** "directory of all patients and contains basic information about a person, such as name, date of birth and address. The Z-PI is necessary to clearly assign the ELGA health data to a person. At the same time, the Z-PI is an essential prerequisite for giving patients electronic access to their own ELGA health data. The patient directory is derived from the social security data".
- **Health Service Provider Index (GDA-I):** "directory of all persons and institutions in the health care system who are generally legally entitled to view ELGA health data of their patients. The first step will be public hospitals, resident doctors, nursing homes and pharmacies. Outpatient clinics, private hospitals and dentists with health insurance contracts also follow later. The GDA index is created on the basis of reports from professional representatives and supervisory authorities, e.g. the federal states".
- **ELGA-areas:** "contain distributed tables of contents (reference registers) that indicate in which storage systems of the ELGA health service provider (e.g. computer centres of hospital associations, servers of medical practices or their service providers) ELGA health information is available for a specific person".
- **ELGA data memories:** "are those electronic "places" where the ELGA health data can actually be found. Like the reference registers, they are provided exclusively by ELGA-GDA or on their behalf. They are therefore part of the infrastructure".
- **ELGA-ISMS (information security and information management system):** "contains – in addition to the legal requirements – guidelines for operational management and the operational safety of ELGA and its components."
- **ELGA authorization system**: "is that part of ELGA by which basically all access to ELGA health data, be it by ELGA-GDA or the patients themselves, is checked, approved or denied. In addition, the authorization system also specifies to what extent and for how long ELGA health data can be viewed by ELGA-GDA. The will of the patients, e.g. access rights, logging out and logging in to ELGA and ELGA applications, is also registered here".

[94] Brandstätter, B. ELGA: Austrian National eHealth Infrasctruture Use-cases, Policies and Architecture. IHE 2020 [pdf]. Available at: https://www.moh.gov.gr/articles/ehealth/7651-paroysiaseis-sta-plaisia-twn-virtual-country-visits-toy-ergoy-national-ehealth-interoperability-framework-nehif?fdl=17836

[95] Datenschutz und Datensicherheit bei ELGA [Data protection and data security at ELGA]. Elga.gv.at [online]. Available at: https://www.elga.gv.at/faq/datenschutz-und-datensicherheit/

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- **ELGA protocol**: “documents all processes in the context of ELGA. This includes the provision of and inspection of ELGA health data as well as any change in access authorizations. This documentation makes all access to ELGA health data transparent and traceable”.
- **ELGA portal**: “enables patients to inspect their own ELGA health and protocol data as well as to exercise their participation rights. Access is via the health portal www.gesundheit.gv.at”.

ELGA IT architecture is based on a distributed system with centralized (shared use) and decentralized components. The several ELGA-XCA areas (Cross-Community Access) make up the core components of ELGA. This area defines an autonomous security zone that can be accessible via its own XCA gateway. Without the requirement for centralized storage, sensitive data is generally stored in its original media within ELGA areas (e.g., at hospital computer centres). The autonomous ELGA zones, on the other hand, rely on shared services based on centrally processed, high-quality master data. The "Central Patient Index" as well as the "Health Service Provider Index" are included. These services are utilized largely for the authorisation system and are credible sources of shared information.[96]

More information regarding the ELGA architecture can be found on following links:

- ELGA overall architecture: https://www.elga.gv.at/fileadmin/user_upload/Dokumente_PDF_MP4/Technisches/ELGA_Gesamtarchitektur_2.30a.pdf
- Architecture of the cross-divisional exchange of image data (V1.65): https://www.elga.gv.at/fileadmin/user_upload/Dokumente_PDF_MP4/Technisches/AnbindungBilddaten_Gesamtarchitektur.pdf

There are also available documents designed for ELGA service providers and software manufacturers that contain both organization and technical information on the connection and use of ELGA, as well as ELGA training documents:

- ELGA organization manuals: https://www.elga.gv.at/fileadmin/user_upload/Dokumente_PDF_MP4/Technisches/ELGA-Organisationshandb%C3%BCcher.zip
- ELGA document package: https://www.elga.gv.at/fileadmin/user_upload/Dokumente_PDF_MP4/Technisches/Dokumentenpaket.zip
- ELGA training documents for GDA and software manufacturers: https://www.elga.gv.at/fileadmin/user_upload/Dokumente_PDF_MP4/Technisches/ELGA_Basis_fuer_Schulungsunterlagen_V2.0.pdf

Background information

In Austria, the **federal government** is responsible for overall health policy and legislation, particularly the legislative framework for hospitals, as well as determining the rules for healthcare provision, reimbursement, data sharing, and interoperability.

Outside of hospitals, the **social insurance system** is in charge of rehabilitation and medication. The hospital law is implemented and enforced by the **nine provinces**. They also offer social and medical services.

Coordination between these stakeholders gradually grew over time.

[96] Technischer Aufbau im Überblick [Technical structure at a glance]. Elga.gv.at [online]. Available at: https://www.elga.gv.at/technischer-hintergrund/technischer-aufbau-im-ueberblick/

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A target-based health governance system has been in existence since 2013. The federal government, provinces, and social insurance funds reach appropriate agreements (under Article 15a of the Federal Constitution on target-based health governance and Article 15a on the organization and financing of the health-care system) and contracts based on them.[97]

ELGA GmBH was founded in 2009 and is represented by the federal government, represented by the Federal Ministry for Health and Women, all nine federal states and the main association of Austrian social insurance institutions − which represent the main decision-makers and cost carriers in the Austrian health system − with the coordination of technical and organizational construction commissioned by ELGA. ELGA GmBH is responsible for the further development of the IT infrastructure of the EHR, standards used, and the overarching programme control of all necessary projects, as well as the management and implementation of the necessary integrations tests and public relations.[85]

ELGA is jointly **financed** by the "**ELGA system partners**" – the federal government, the federal states and social security. Between 2010 to 2016, the aforesaid public bodies made a total of 60 million euros available, and for the period 2017 to 2020 a further 41 million euros were also made available to finance ELGA. Furthermore, these public bodies fund the measures that they implement in their respective areas of responsibility for the ELGA's establishment and the respective operating expenses. ELGA GmBH and the Federal Health Commission entities monitor the targeted and economical use of public funds. [85]

The position of stakeholders towards ELGA varied a lot initially. On the one hand, physicians were concerned with the possibility of ELGA disturbing their trust relationship with patients, while pharmacist appeared to be supportive. The significant investment costs associated with electronic storage and interoperability were concerns for hospital owners. On the payer side, particularly health insurers were broadly supportive with the expectation that eHealth applications would help to contain cost growth in the health sector. Lastly, patient advocates were generally supportive seeing the potential in ELGA to actively involve patients, increasing the transparency, and contributing to patient empowerment. [98]

Telemonitoring framework

Health applications are already in place in Austria, for disease management in diabetes and cardiomyopathy. These programs are run as pilots by some provinces and social insurance providers. Target-based health governance aims to further develop eHealth and mHealth applications.[99]

Standards-based interoperability is a core goal. To this end, the federal health ministry has issued a framework guideline for the IT infrastructure for telemonitoring. This framework provided the "*preliminary work for the present framework guideline of the BMGF were the results and recommendations of the Telehealth Services Commission and the project group Telehealth Services on behalf of target management and with the participation of the federal government (management), the federal states and social insurance. In the course of this work it was determined that a fundamental technical "guideline" in the form of this framework guideline is required, which should be a sensible and helpful tool for the addressees named below when implementing telemonitoring. The IT architecture presented here cannot currently cover a complete implementation in terms of feasibility and is therefore limited to the acquisition of measurement data in the context of telemonitoring. This framework directive concerns telemonitoring for patients, who want to use additional telemonitoring to treat / monitor their illness. It is envisaged that this framework guideline must be applied to all publicly financed telemonitoring applications. This framework guideline refers exclusively to the subitem surveillance / monitoring / measurement data acquisition of the patient and not*

[97] University of Applied Science Techinikum Wien. WP5 – Policy and Innovation. Short Technical Paper. Case study: overview of policies enabling digital health in Austria. European mHealth Hub, 2020 [online]. Available at: https://mhealth-hub.org/download/wp5-policy-and-innovation-short-technical-paper-case-study-overview-of-policies-enabling-digital-health-in-austria

[98] Hofmarcher, M. M. Eletronic Health record: developments and debates. Austria. BertelsmannStiftung, 2008 [pdf]. Available at: https://www.ihs.ac.at/publications/lib/oa22.pdf

[99] University of Applied Science Techinikum Wien. WP5 – Policy and Innovation. Short Technical Paper. Case study: overview of policies enabling digital health in Austria. European mHealth Hub, 2020 [online]. Available at: https://mhealth-hub.org/download/wp5-policy-and-innovation-short-technical-paper-case-study-overview-of-policies-enabling-digital-health-in-austria

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to the comprehensive communication, which can however be further developed – also in the sense of a "feedback function" GDA to the patient or in keeping, for example, a therapy diary through the Patient".[100]

In 2018 telerehabilitation was included as means of rehabilitative treatments, by the amendment of the general social insurance act. Work is currently ongoing to implement mHealth services as part of the health care system, from which e-prescription and e-vaccination report are already roll out.[99]

- **ENABLERS**

User-centred

• Awareness of the objectives and/or existence of solutions

Core infrastructure

ICT infrastructure in place

Health policy

Communication and collaboration between stakeholders • Information and communication technologies considered central components of healthcare services delivery • Law enforcement • Legislation framework • eHealth strategy in place • Funding available

Cost and reimbursement

National resources for investment

Assessment (technology)

System reliability or dependability • Accuracy of the system • Quality standards • Observability (observance, control, verification of the solutions)

Integration - interoperability

Interoperability of solutions

- **DISABLERS**

User-centered

Unrealistic expectations by users • Perceived complexity of solutions and resistance from physicians • Privacy and security concerns

[100] Federal Ministry of Labour, Social Affairs, Health and Consumer Protection Represented by the section head SC Dr. Except. Rahmenrichtlinie für die IT-Infrastruktur bei der Anwendung von Telemonitoring Messdatenerfassung [Framework Directive for the IT infrastructure at the Use of telemonitoring Measurement data acquisition]. Federal Ministry of Labour, Social Affairs, Health and Consumer Protection, Vienna 2018 [pdf]. Available at: https://www.sozialministerium.at/dam/jcr:c6f54325-0c71-4614-93ff-3358d1cfea27/telemonitoring_rahmenrichtlinie_.pdf

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Cost and reimbursement

High costs associated with maintenance and evolution

- **ANALYSIS OF POLICY AREA II**

- **MAIN FINDINGS**

The boom in development of apps for health management is an opportunity for public institutions to work together with private initiatives.

The APIs are a secure and reliable way to make external solutions to connect with public health entities.

The experience of the four healthcare providers has shown that interoperability is an important aspect of the development of new mHealth products and services. The following lessons can be derived:

- **Think about interoperability of new mHealth solutions from the start:** interoperability should not be an afterthought in R&D projects. It is best to start with an as-is analysis and describe the existing environment, both infrastructure and organisation. Detail the architecture of your legacy systems, the way they work (technologies, messaging, security, APIs, etc.) so that the integration plans can be based on solid background information.

- **Define appropriate interoperability requirements and standards:** aim to apply well-known or open standards as much as possible. A good overview of standards is provided by the EC: https://ec.europa.eu/eip/ageing/standards/healthcare/e-health_en

- **Do not underestimate the time and effort required to ensure full interoperability:** due to the complexity and proprietary nature of some legacy systems, integration is not a straightforward process and new challenges can arise during the process of integration. A good planning with a strong and experienced integration organisation is needed. If the components that need integration are owned / maintained by different organisations, fostering collaboration among them is a must.

- **Promote the benefits of interoperability in an understandable way:** the concept of interoperability is not easily understood by the different stakeholder groups, e.g. patients, healthcare professionals, policy decision makers, etc. Benefits of interoperable systems should be more clearly communicated and substantiated with evaluation data. The language used should be understandable. Supported by the European Commission, the EU project DigitalHealthEurope (https://digitalhealtheurope.eu/) is currently working on providing a platform that promotes interoperability and standards to different stakeholders in an understandable way. https://digital-health-standards.eu/ will describe the issues related to interoperability of IT systems in healthcare, provide examples, discuss the benefits of interoperability, and what actions stakeholders can take to promote it further in Europe.

- **Interoperability and data sharing are crucial for integrating healthcare services from different healthcare providers:** Entities involved at federal level are supposed to take responsibility for the IT infrastructures and for the legal, organisational, and/or technical frameworks to enable interoperability and data sharing.

Overall, the experiences in ProEmpower with both solutions have reinforced the strategies of the involved healthcare providers with regards to applying mHealth solutions and services to improve the health and care provision, empower patients to better deal with their chronic conditions, enable a more efficient communication between patients and the healthcare professionals involved in their care. The seamless integration of those solutions with the existing EHR systems

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ensures that the relevant patient data (clinical and non-clinical) is readily available to the treating physicians and enables them to provide the best care based on the latest patient data.

- **GAPS IDENTIFIED**

There is still a lack of financial support to back this interoperability system to full force.

- **TRENDS IDENTIFIED**

The creation and publication of APIs shows a tendency to have private institutions (SMEs, startups…) contributing to the healthcare system with new apps. This is evidence of a demand from citizens, where adoption is strong, and an acceptance that governments cannot make up for all demand.

- **RECOMMENDATIONS - Targeted to policy makers & implementers**

More involvement of private companies to work together with established health systems in creating the APIs for integration of health data.

Real incentives and concrete interoperability strategy to embrace a cascade of mHealth apps that are created everyday. In the case of Spain, once there were accounted more than 40,000 apps related to health. Today this number can only be larger and there is a lot of potential for connecting health information from these apps into health systems (even if only a fraction).

Use mHealth certification / assessment frameworks as a way to evaluate apps worth of integration into health systems.

Interoperability should be based on IT standards and profiles. These standards should be mandated via regulations that are issued by the federal and/or regional health ministries. They should be implemented through a collaboration between all stakeholders involved: federal government, state governments, and social insurance organizations, communities, patient organizations, healthcare professionals and organizations.

Overview all legal and regulatory aspects associated with integration mechanism at the national and EU level to support the formulation of such policy. Envolve experts in understanding potential liabilities and silos not yet defined. This will help to increase transparency and trust in the process.

Consider developing a system that can be integrated as an additional software (module) to existing systems, such as clinical and pharmacy software. This approach makes the programme more comfortable and user-friendly for the user in the ordination, pharmacy or hospital.

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Policy Area 3 – Ethical and regulatory issues. Secondary use of data and data security: privacy, confidentiality, integrity, and availability

- **POLICY DESCRIPTION**

In recent years, there has been a growing number of MS that have reached or are in the process of developing national consensus on data re-use strategies and governance frameworks for the exploitation of health data in knowledge-based decision-making, innovation and research. This is pursued through policy and innovation support programmes focusing on creating capacities for knowledge management through further digitisation of health and care services, and through integrating Artificial Intelligence in their provision.

Two such country examples have been investigated – **Finland** and **Germany**. In both examples, what is eventually targeted is that citizens are provided with increasingly more and better tools, data-driven applications and services for improving their health and well-being, and that they will benefit from new health technologies and medications.

- **POLICY EXAMPLEs**

  - **Isaacus – Digital Health Hub (Finland)**

Finland has unique healthcare registers with information on individuals, operational since the 1970s. Up until recently use of this data could not be easily made available to researchers and getting permission for research, if granted, would take as long as two to four years.

Finland has recently introduced legislation and a governance framework that is turning this situation into a success story. It has done so through a well-informed decision process, involving the launch of pilots and the building up of evidence providing a solid foundation for the subsequent introduction of enabling legislation and the establishment of the governance framework, which allows for the secondary use of social and health data for scientific and statistical purposes.

What has been unique in the Finnish approach is that – unlike the traditional approach where implementation follows legislation – experts from ministries, authorities, companies and associations from across the private and public sectors worked together to prepare the implementation simultaneously with the legislation process. The reform is expected to speed up the permit-granting processes, unify decision procedures and develop Findata – a one-stop shop for data. Decisions on using the data are taken by Findata, the national centralised body, the new Data Permit Authority, and sensitive data is handled in a safe and secure environment. Access to data is controlled, and only the results of the analytics can be used externally; the data stays secure.

The Act on the Secondary Use of Health and Social Data, which has been one of the first implementations of the GDPR for secondary use of health data into national law, came into force on May 1st 2019, and the data permit authority Findata started operating at the beginning of 2020. The new act covers multiple areas, including scientific research, statistics, development and innovation activities, steering and supervision of authorities, planning and reporting duties by authorities, teaching and knowledge management.

Isaacus was one of these several pilots, focusing on the re-use of health and well-being data. Launched in 2015, it was led by Sitra and it played an essential role in building an innovation ecosystem and new legislation drawn up by the Ministry of Social Affairs and Health. Its main contribution was redefining the organisational processes and responsibilities, and forging a commitment from all parties involved. It also prototyped the one-stop-shop service model, built new technical infrastructures and the "Digital Health HUB" (also referred to as the "service operator") and established multi-stakeholder collaboration. The vision is that within the next few years, the well-being data ecosystem will serve as an environment for a versatile group of different parties, from analytics service providers to various researcher services. The ecosystem utilises extensive technological expertise and automated processes, supports the creation of expert and researcher networks, and

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uses, ethically and securely, the world's best electronic registers and their content as raw material for developing analytics and artificial intelligence.

What is also worth mentioning is, on one hand, the international perspective brought in by a network of Finnish and international experts, which convened with the developers at regular stakeholder meetings to share their input and views and, on the other hand, the extensive body of public opinion on the use of well-being data collected through various workshops, the outcomes of which were fed into the development work. Through this project, Finland has benefited substantially from the knowledge shared by other countries, while Finnish know-how has been exported abroad.

Through Isaacus, Sitra played an essential role in drafting the operating model for the Digital Health HUB. Responsibility for the operating and administration model of the permit authority and the future operator comes under the Ministry of Social Affairs and Health, which defines policy guidelines for the goals of the operations, the co-operation between data controllers, and the rules and co-operation structure required by the operations.

Operations are supported by: a permit and information portal, a data description system (metadata) and a collection, processing and remote desktop for the data. Data pseudonymisation and anonymisation services are closely linked with the last item. The new authority is also responsible for the anonymisation services of data for users.

A Finnish Model For the Secure And Effective Use Of Data[101]**:** This document recounts how the new model for a one-stop shop for the better use of well-being data was built in Finland.

Secondary use of health and social data[102]**:** This on-line paper describes the Finnish legislation on secondary data use.

One-stop shop for well-being data – Isaacus laid the foundations for the future[103]: This is a publication that describes in particular the role and contribution of the Isaacus project to establishing the Finnish framework for secondary health data use and exemplified the holistic approach leading to well informed decisions.

- **ENABLERS**

User-centred

Personal factors which shape people engagement and experience • Provider's capacity • Keeping the user in mind • Awareness of the objectives and / or existence of solutions • Support and promotion of mHealth / telehealth by colleagues • Consumer demand • Experimentation and clinical learning

Health policy

Communication and collaboration between stakeholders • Management (strategic planning) • Information and communication technologies considered central components of healthcare services delivery

[101] Sitra (2019). A Finnish Model For The Secure And Effective Use Of Data. Innovating and promoting the secondary use of social and health data. Heli Parikka (Editor). [online] Available at: https://www.sitra.fi/en/publications/a-finnish-model-for-the-secure-and-effective-use-of-data/

[102] Ministry of Social Affairs and Health of Finland. Secondary use of health and social data. [online] Available at: https://stm.fi/en/secondary-use-of-health-and-social-data?p_p_id=56_INSTANCE_7SjjYVdYeJHp&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view&p_p_col_id=column-2&p_p_col_count=3&_56_INSTANCE_%C2%AD7SjjYVdYeJHp_%C2%ADlanguageId=en_US

[103] Heli Parikka. One-stop shop for well-being data – Isaacus laid the foundations for the future. Sitra (2018) [online] Available at: https://www.sitra.fi/en/articles/one-stop-shop-well-data-isaacus-laid-foundations-future/

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Integration - interoperability

Compatibility with work process • Interoperability of solutions

Other enablers shown in the policy example:

International collaboration • Evidence-based decision making,

- **DISABLERS**

User-centred

Professionals' lack of training, education and advocacy • Privacy and security concerns

Health policy

Lack of enabling policy • Lack of governance

- **Medical Informatics Initiative (Germany)**

The German Medical Informatics Initiative, running from 2016 to 2025, was launched by the German Federal Ministry of Education and Research through a €150 million call for proposals[104]. Four consortia across the country, each comprising a mixture of universities, hospitals and other healthcare provider organisations are implementing infrastructures for learning health systems that will enable healthcare quality improvement and accelerated clinical research. These consortia together cover over 10% of German healthcare provision.

The primary objective of this initiative is to enable the better collection, integration and use of health data to improve patient care, connecting historic data silos and bridging across state level silos. This is mainly being undertaken by establishing data integration centres that will combine data from multiple healthcare provider systems and may later include data provided directly by patients. Each consortium has defined 3-4 use cases that will be the initial focus on their integration of data and learning from it. Some of the resources are allocated to capacity building and education, and there is also budget to connect with some health sites that are not formally part of the four consortia.

Key topics that the consortia are pursuing include interoperability, GDPR compliance, patient consent and data access rules. Each consortium has some freedom to make its own choices about topics like interoperability. Coordination between the initiatives and connection to the Federal level is managed by a National Steering Committee (NSC) with governmental representation and members from several key not-for-profit institutes. The NSC has responsibility to specify those aspects of interoperability, security, data protection and use that are necessary to enable Federal level data sharing. The NSC decision-making process is defined through Rules of Procedure[105]. Its scope includes the following areas of coordination and governance:

- electronic patient consent declarations
- the role of trusted third parties for identity management
- rules for data use and access committees

[104] Gehring, S; Eulenfeld, R (2008). German Medical Informatics Initiative: Unlocking Data for Research and Health Care. Methods Inf Med. 2018, 57(S01):e46-e49. doi: 10.3414/ME18-13-0001.

[105] Results. Medical Informatics Initiative Germany [online]. Available at: https://www.medizininformatik-initiative.de/en/about-initiative/results

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- data protection
- semantic interoperability and metadata
- methods and portals for data sharing
- audit criteria and shared use cases[105]
- patient involvement and empowerment
- activities to strengthen research, education and professional development

A nationally funded not-for-profit institute is responsible for developing the enabling and governance instruments specified by the NSC, such as standard patient information and consent wording, and data sharing agreement terms. These instruments have been validated by the Federal and German state agencies. This endorsement has been important in order to permit the sharing of health information across state boundaries. An important next step for achieving this will be to define the rules, decision-making and oversight for handling data access request at the Federal level.

- **ENABLERS**

User-centred

Provider's capacity • Frontline staff training • Familiarity, ability with digital tools • Awareness of the objectives and / or existence of solutions • Experiencing patient and clinical benefits • Experimentation and clinical learning • Training

Assessment (technology)

System reliability or dependability • Accuracy of the system • Quality standards • Assessment frameworks in place

Cost and reimbursement

Having requisite material resources • Having requisite human resources (IT support, other)

Health policy

Communication and collaboration between stakeholders • Management (strategic planning)

Integration - interoperability

Interoperability of solutions

Other enablers shown in the policy example*:*

The Federal funding is expected to be used to design, implement and deploy these enablers

- **DISABLERS**

User-centred

Professionals' lack of training, education and advocacy • Lack of technological knowledge • Privacy and security concerns

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Assessment (technology)

Lack of data accuracy

Health policy

Medicolegal issues

Integration - interoperability

Lack of interoperability

Other disablers shown in the policy example:

The Federal funding is expected to be used to develop solutions that address these barriers.

- **ANALYSIS OF POLICY AREA III**

- **GAPS IDENTIFIED**

For the secondary use of health data, citizens and healthcare professionals may not have enough training and education to uphold the potential of health data for primary and secondary use. Lack of financial sources apart from national investment can undermine the sustainability on the long-run.

- **TRENDS IDENTIFIED**

Involvement of different stakeholders during the draft of the proposal (private-research-government). Financing pilot projects and public endorsement for the draft of a new legislative proposal.

- **RECOMMENDATIONS - Targeted to policy makers & implementers**

Involvement from the private sector and research institutions in drafting new policies can speed-up the process, taking into account the context of the country and the needs from this sector. Citizens and health professionals should also be involved as they will be the main beneficiaries and can help to build the awareness on the importance of the secondary use of health data. A well-defined responsibility and the overall transparency of the process will play a major influence and even determine the success of the policy implementation.

Ensuring the quality of data, privacy, (cyber)security and ethical principles are defined, as well as mechanisms to ensure its compliance.

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Policy Area 4 – Business models, innovation funds and reimbursement.

- **POLICY DESCRIPTION**

To ensure a continuous mHealth support, sustainability promotion is essential and can be achieved through feasible business models and reimbursement plans, as well as encouraging innovation for development of efficient tools. Existence of reimbursement models can help to promote trust and likelihood of prescribing mHealth solutions, which ultimately promote adoption by citizens and health professionals. In addition, these schemes can also incentivise developers to create and submit mHealth solutions that follow specific criteria, such as data security, quality, privacy, transparency, and even generate evidence of health benefits, among others. Moreover, mHealth policies addressing these aspects should include clear guidance and legislation to ensure the development of transparent reimbursement models, as this will be fundamental to promote its adoption and long-term sustainability.

The following use cases were explored within this policy area:

1. The German Digital health apps reimbursement case (Germany)
2. mHealthBelgium initiative (Belgium)

- **POLICY EXAMPLEs**

  - **The German Digital health apps reimbursement case (Germany)**

In Germany, the legal basis for app reimbursement was established through the Act to Improve Healthcare Provision through Digitalisation and Innovation or The Digital Healthcare Act. The Digital Healthcare Act (Digitale-Versorgung-Gesetz or DVG) was adopted as an amendment to the Social Security Code V (Sozialgesetzbuch V – SGB V) by the German parliament (Bundestag) in November 2019. It was later approved by the Federal Council (Bundesrat) and signed by the German president, becoming legally binding. Section 33a of the SGB V states that insured persons in the statutory healthcare insurance system (SHI) are entitled to healthcare through digital health applications (DiGAs).

In the German system, a DiGA that could be reimbursed is interpreted as having the following characteristics:

- Lower-risk medical devices: risk class I or IIa (under the EU Medical Device Regulation 2017/745 (MDR) or the EU Medical Device Directive 93/42/EEC (MDD))
- The main function of DiGA is based on digital technologies
- The medical purpose is essentially achieved by the main digital function
- The DiGA supports the detection, monitoring, treatment or alleviation of diseases or the detection, treatment, alleviation or compensation of injuries or disabilities
- The DiGA does not serve primary prevention
- The DiGA is used only by the patient or by the service provider and the patient together
- They are used on the basis of prescription of the treating physician or psychotherapists[106]

[106] Insured persons that can provide their SHI funds a proof of a corresponding indication are also eligible to receive a desired DiGA without a prescription. (Source: BfArM)

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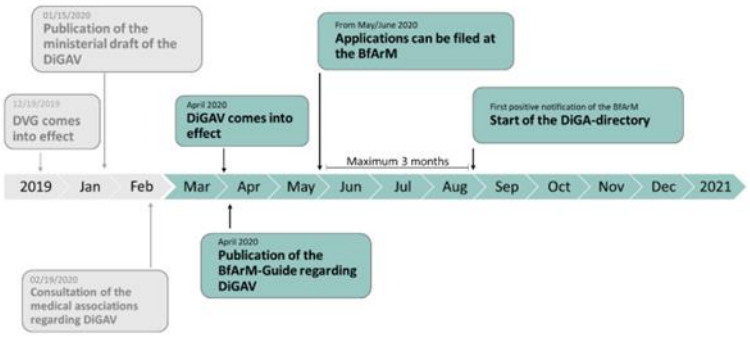

Figure 11 – Implementation of Fast Track procedure.[107]

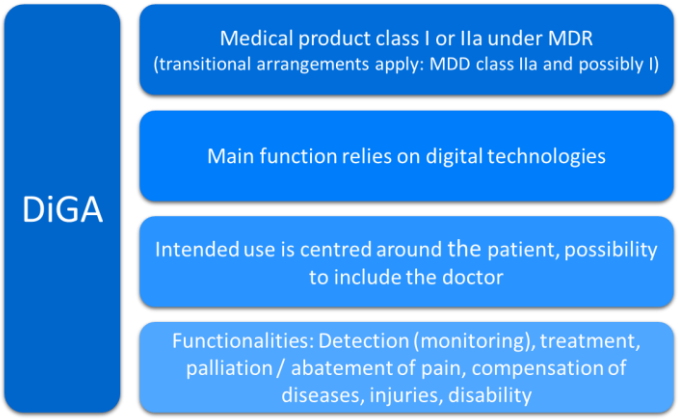

Figure 12 – Definition of DiGA according to § 33a SGB V..

For DiGAs to have reimbursable status, they must pass a certification process established by BfArM[108]. The Federal Ministry of Health (BMG) issued the Digitale Gesundheitsanwendungen-Verordnung (DiGAV), an ordinance which came into effect in April 2020 and regulates the eligibility criteria and procedures for the reimbursement of the health apps. The document includes details regarding the inclusion of the digital health apps in the BfArM repository. The Ordinance includes two annexes:

- Annex 1 contains information regarding data protection and data security and
- Annex 2 details information on the quality criteria.

BfArM also issued the DiGA-Leitfaden[107] for DiGAs according to § 139e SGB V. It is meant as a guide for manufacturers, service providers and users, and provides supplementary details for the submitting procedure at the BfArM.

[107] The Fast-Track Process for Digital Health Applications (DiGA) according to Section 139a SGB V.A Guide for Manufactures, Service Providers and Users. Federal Institute for Drugs and Medical Devices. Available at https://www.bfarm.de/EN/Medical-devices/Tasks/Digital-Health-Applications/_node.html

[108] BfArM or Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices). Apart from authorization and registration of drugs and pharmacovigilance activities, BfArM is responsible for detecting and evaluating the risks of medical devices. The main tasks of the BfArM involve the central collection, analysis and assessment of risks resulting from the application or use of medical devices and in coordinating any measures that must be taken.

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The DVG Fast Track procedure

The procedure is designed as a fast track. The evaluation period for the BfArM is three months after receipt of the complete application. The core of the procedure is the examination of the manufacturer's information on the required product characteristics – from data protection to user-friendliness – as well as the examination of evidence to be provided by the manufacturer for the positive care effects that can be achieved with the health app.

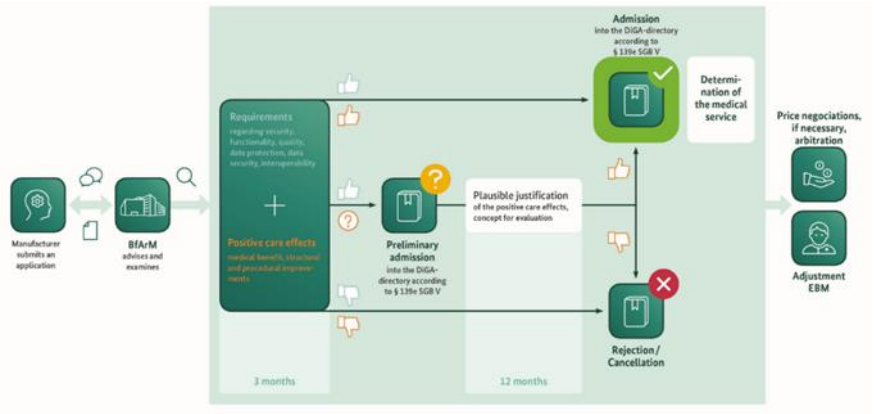

Figure 13 – The DVG Fast Track procedure.[107]

The Fast Track procedure consists of several steps:

- **Application of the manufacturer** on registration in DiGA-registry according to §139e SGB V. The DiGA must **comply** with the **general requirements** (safety, quality, functionality, privacy, and data security) and **must prove positive care effects** (medical benefit and structural and procedural effects).
    - Highly important for the certification process is the demonstration of positive care effects by the DiGA. For this, the manufacturer must submit the results of a systematic data analysis for the use of the application (DiGAV, § 14) – and a scientific evaluation concept for the demonstration of positive effects on care created by an independent institution (SGB V, § 139e(4)).

- **BfArM examines and decides within three months** whether to accept and list the application in the DiGA-registry

    - If the manufacturer cannot provide evidence for a positive healthcare effect, BfArM will do a preliminary listing and provide a 12 months trial period. In this case, the required effectiveness study can be conducted within the 12 months trial phase, which can be prolonged up to two years for some exceptions.

- **Price negotiations are conducted and established between manufacturers and GKV-SV** (National Association of Statutory Health Insurance Funds). BfArM plays a consultancy role and informs the GKV-SV of the need for corresponding remuneration amount.

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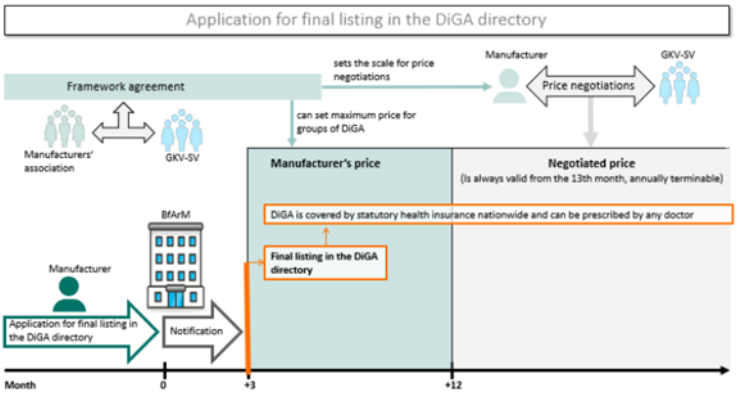

Figure 14 – Application for final listing in the DiGA directory.

If DiGAs are listed in the directory, the **app can be prescribed by physicians and psychotherapists with the permission by health insurance fund.** After DiGAs are listed in the directory, physicians receive an additional reimbursement, if additional medical services are necessary as part of the treatment. Insured persons that are prescribed an app receive a code with which can activate the app.

- **ENABLERS**

User-centred

Experiencing patient and clinical benefits

Assessment (technology)

System reliability or dependability • Accuracy of the system • Quality standards • Assessment frameworks in place • Observability (observance, control, verification of the solutions)

Cost and reimbursement

Having requisite material resources • Having requisite human resources (IT support, other) • Value-based reimbursement

Health policy

Communication and collaboration between stakeholders • Management (strategic planning) • Information and communication technologies considered central components of healthcare services delivery

- **DISABLERS**

Challenges and disablers

1. Limited scope. The DVG has a limited scope, as the act only applies to medical devices of class I or IIa. However, many digital health applications are not classified as medical devices, and, therefore, do not match the requirements of the DVG. The same issue arises for health applications that are classified as class IIb or III devices, which cannot be reimbursed through the DVG.

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2. Privacy issues. The Digital Healthcare Act does not enable patients to opt-out of having their data shared for research purposes. The act allows authorities, research institutes or university hospitals to use demographic data collected by insurance funds. However, the data is pseudonymized when stored and exchanged and measures are being taken to prevent the possibility of reidentification.

3. Pricing negotiation issues. The price is established through negotiation between The National Association of Statutory Health Insurance Funds and the manufacturers. However, the process is not transparent enough, as the negotiations and advisory documents are confidential (SGB V, § 134(1)).

4. Quality management. DiGA manufacturers are required to implement quality-controlling maintenance procedures (Quality Management System) i.e management of third-party software. The new EU Medical Device Regulation states that the medical devices will have to be certified by a notified body, which requires a certification according to ISO 13485. However, this certification can take as much as one year and should happen before starting product development.

5. Advertising restrictions. For DIGAs, adds are prohibited and in-app purchases are only allowed through informational, non-promotional elements. Furthermore, since DiGAs are classified as medical devices, the same advertising restrictions apply.

6. Germany-Specific Design Requirements. Starting with 2021, approved DiGAs must support accessibility and interoperability standards for EHR integration, which will be soon introduced.

7. Effectiveness requirements. For a DiGA to be included on the BfArM approved list of apps, manufacturers need to demonstrate the positive effects on care. However, for an app to prove its effectiveness, it must be on the market for a while or clinical studies need to be done. This can impediment new apps entering the German market. However, BfArM allows for a 12 months trial period, after which manufacturers need to provide proof of effectiveness. They are required to submit the results of a systematic data analysis for the use of the application (DiGAV, § 14) and a scientific evaluation concept to prove its effectiveness that was created by an independent institution ((SGB V, § 139e(4)). The DIGAV and BfArM guidelines state that developers must provide a comparative study that took place in Germany, where with app / without app comparison on the effects of care results are provided (Gerke, S. et al., 2020). Moreover, the studies must be representative of German patients, and generating Germany-specific evidence might be difficult process for the manufacturers.

- **mHealthBelgium initiative (Belgium)**

The mHealth plan was not part of the first original eHealth roadmap approved in 2013. It was added in the second version of that roadmap approved in 2016 and further developed in the third version (2019 – 2021)[109].

mHealthBelgium[110], also known as mobile health Belgium, was established based on the action item 19 of the federal e-health roadmap 2.0. This action item 19 addressed mhealth, with the aim of integrating mobile health apps in the Belgian healthcare system. During 2016, a call for pilot projects was launch with the focus on five main themes: stroke, cardiovascular care, diabetes, mental health and chronic pain. About twenty-four of these projects were subsidy and run for 6- to 12-month period. These pilot projects were launched to determine the framework to ensure this type of apps would be successfully integrated. Based on this work, mHealthBelgium was launched by the government in 2018 and went live on 2019, and is the Belgian platform for mobile apps that are CE-marked as a medical device.

[109] Roadmap 3.0. Portail des services de l'eSanté Belgium. [online] Available at https://www.ehealth.fgov.be/fr/esante/roadmap-30/roadmap-30

[110] https://mhealthbelgium.be/

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This platform centralises all relevant and required information on mobile apps for patients, healthcare professionals and healthcare institutions in three languages (Dutch, French and English). Moreover, the information is related to CE marking, data protection, communication security, interoperability with other IT systems and the way in which the app is financed.

mHealthBelgium consists of a validation pyramid with three levels, which was created upon a period of tests with pilot projects, which lead to the creation of a follow-up structure – the mHealthBelgium validation pyramid (Figure 15).

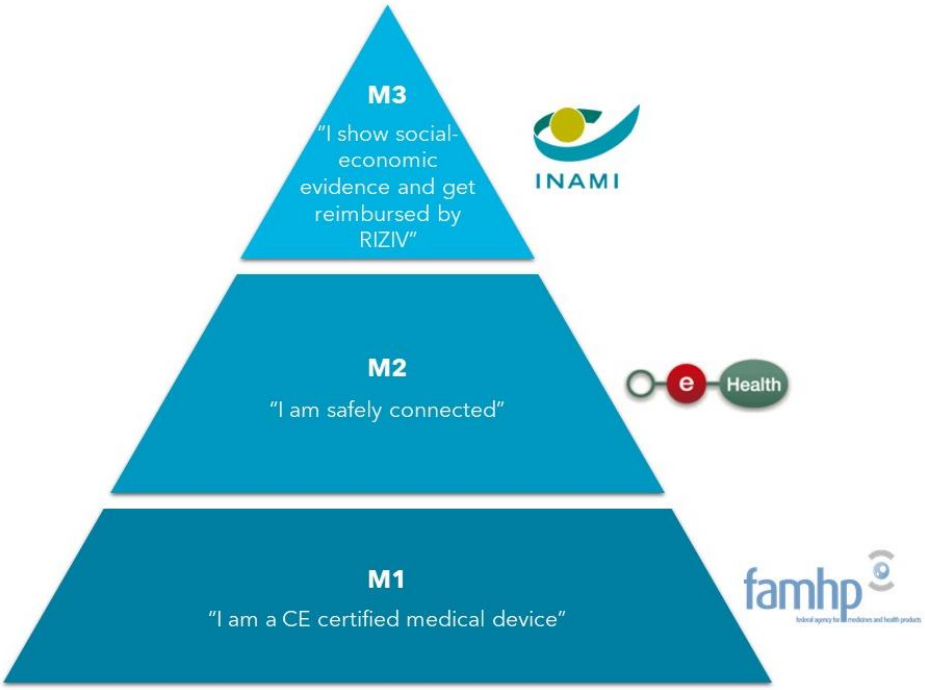

Figure 15 – The validation pyramid of mHealthBelgium, showing the three different requirement levels and the respective competent organization. Adapted from mHealthBelgium, 2021.

While being an initiative of the Belgian Federal Government, mHealthBelgium involves multiple stakeholders. The platform is managed by beMedTech (sector federation for industry of medical technologies) and Agoria (sector federation of technological industry), in close cooperation with three national authorities:

- Federal Agency for Medicines and Health Products (FAMHP): competent authority for quality, safety and efficacy of medicines and health products, including medical devices. It is responsible for level M1 certification within mHealthBelgium.
- eHealth Platform: federal government institution with the mission to promote and support the provision of a well-organised, mutual electronic service and exchange of data between all healthcare stakeholders with safeguards in the areas of data security, the privacy of the patient and the caregiver, respecting medical professional confidentiality. It is responsible for level M2 certification within mHealthBelgium.
- National Institute for Health and Disability Insurance (NIHDI): responsible for the refunding of medicines, medical devices and medical provisions. It is responsible for level M3 certification within mHealthBelgium.

To be certified, a mHealth app must comply with the criteria of each level of the pyramid:

- **Level 1 (M1)** – determines the basic criteria for an app, considering the following three criteria:
  - CE declaration as a medical device submitted.
  - Voluntary notification of the mobile app to the FAMHP, during which the CE marking and the compliance with the rules and regulations for medical devices are confirmed and checked.

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- The app and the company declare that they comply with the EU General Data Protection Regulation (GDPR).

- **Level 2 (M2)** – based on the interoperability and connectivity to the basic services of the eHealth platform. The following criteria are considered:
  - Complies with the basic criteria of M1.
  - Submitted to a risk assessment (developed by an independent organization and included in mHealthBelgium) after which they have proven to meet all imposed criteria regarding authentication, security and the use of local e-health services by means of standardised tests (if applicable).
  - In this phase different criteria are evaluated, such as 1) app classification, 2) identification of the person in need of care, 3) app user authentication, 4) verification of relevant characteristics and relationships of the app user; 5) interoperability, and 6) compliance with GDPR.[111]

- **Level 3 (M3)** – for apps with social-economic added value that have been demonstrated and which are financed, after approval by the NIHDI of their funding request.
  - M3 apps meet all criteria of level 1 and the (applicable) criteria of level 2, after which a company can submit a reimbursement / financial request.
  - After submitting the application, a specific working group is set up and examines the proposal. This working groups includes i) independent experts and experience experts in the respective care process, ii) representative of relevant health care providers, insurers and patients, and iii) representatives of employers and workers organizations (only as in advisory capacity). In case of a positive opinion, the working group proposes the app to be integrate in the reimbursement system. Based on this opinion, the Insurance committee decides whether or not to integrate the mobile application to the care process and the reimbursement system.
  - As a remark, technology can be finance via other means than national reimbursement, such as by hospital innovation budget, and health insurers. However, this is not considered as M3 approved.

In November 2021, 23 apps had received a M1 level classification, 10 reached a M2 level classification, and no apps were found with a M3 level classification. The apps can be used by patients, healthcare professionals and caregivers and for different intended uses (e.g., prevention, diagnosis, treatment, monitoring and medical education). This platform is an important way to drive the ongoing digital transformation of healthcare in Belgium and integrate apps into the country's healthcare system, while increasing access to these tools by patients / caregivers and healthcare professionals.

- **ENABLERS**

User-centred

Experiencing patient and clinical benefits

Assessment (technology)

System reliability or dependability • Accuracy of the system • Quality standards • Assessment frameworks in place

Cost and reimbursement

• Value-based reimbursement

[111] Technical file describing the M2 criteria: https://mhealthbelgium.be/images/downloads/Criteria-mHealth-apps-ENv5.pdf

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Integration - interoperability

Interoperability of solutions • Integration to basic services of the eHealth platform

Health policy

Communication and collaboration between stakeholders • Management (strategic planning) • Information and communication technologies considered central components of healthcare services delivery • Slow process

- **DISABLERS**

Lack of evidence on the benefits • High costs associated with proof of effectiveness • Adoption by healthcare providers and citizens • Low level of interest by developers to apply solutions to M3 level

- **ANALYSIS OF POLICY AREA IV**

- **GAPS IDENTIFIED**

Limited scope as it only applies to apps that are classified as medical devices, and even then, not all classes are allowed (in Germany). Limited user decision on the data that is evaluated and shared, as well as low personalization level to individual needs. Price definition not clear or public; different types of models may exist (free, fee for subscription, for usage, package, based on outcome, etc). Different criteria and standards between countries increases the burden of the reimbursement application process, as applicants need to adapt to different requirements and processes.

- **TRENDS IDENTIFIED**

MHealth apps that are compliant with a medical device classification (according to the MDR[112]) as a basic criterion for app reimbursement entry. Political endorsement and involvement of health insurance institutions. Importance of healthcare professionals' adoption to increase the likelihood of prescription and use of mHealth as tools to support the detection, monitoring, treatment or alleviation of diseases or the detection, treatment, alleviation or compensation of injuries or disabilities. Clear rules on eligibility criteria, assessment framework, submission, and approval process available to applicants.

- **RECOMMENDATIONS - Targeted to policy makers & implementers**

Definition of a clear, transparent and public assessment and certification process, as well as identification of body(ies) responsible for the evaluation and certification, considering existing entities (or need for a new entity).

Definition of eligibility criteria and procedures for reimbursement in a transparent way.

To support the creation of a new policy on mHealth reimbursement, MDR can be used as minimal requirement for mhealth apps selection for a reimbursement model. The MDR already provides a set of definitions to ensure high level of safety and health whilst supporting innovation.

[112] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. OJ L 117, 5.5.2017, p. 1–175. [online] Available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745

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Important to define a process for dissemination to healthcare professionals, so that they know which apps are available for reimbursement.

Clear guidance to developers and manufacturers regarding the different criteria that mHealth solutions need to comply with (e.g., regarding data protection and security), as well as submission procedure and timelines.

To promote the development of innovation, and considering the lack of evidence and the cost associated with its studies, it might be created an incentive model or allow a trial period, after which the proof of effectiveness must be provided.

At the European level, it would be beneficial to develop a process for a mutual recognition agreement. This could facilitate market access, encourage innovation and international harmonisation, as well as compliance of standards while protecting users and prescribers. Moreover, it could also reduce costs to applicants (mHealth apps manufactures, developers, etc).

Policy Area 5 – Human centred design and patient safety. Patient empowerment, health literacy and digital skills.

- **POLICY DESCRIPTION**

Human centred design, health literacy and digital skills are essential elements for enabling patient empowerment and promoting patient safety. Therefore, these elements should be addressed when developing mhealth policies, considering users and healthcare professionals as central players that should be involved / considered in the development of mHealth programmes. In this sense, countries should develop policies that promote user autonomy and empowerment.

Living Labs and the **ProEmpower** experience were explored in this section.

- **POLICY EXAMPLEs**

  - **Living Labs (Europe)**

End-user involvement is a central part in the strategy of public and private organisations to generate user-driven innovative solutions to real-world problems, grounded in the understanding of user's existing and future needs. Living labs are examples of research for user-driven innovation [113,114] where the end-user is involved as a key contributor throughout the entire process of technology innovation: exploration of new forms of usage, design with suppliers, test of prototyped solutions and large-scale deployment with evaluation in real settings.

To date, almost 400 Living labs are recognized in the European Network of Living Labs (ENoLL) since 2006. Living labs cover diverse topics, such as smart-cities, innovative learning approaches and digital health.

Two Living Labs examples are described below:

[113] Følstad, A. (2008). Living labs for innovation and development of information and communication technology: a literature review. The Eletronic Journal for Virtual Organizations and Networks, Volume 10.

[114] Almirall, E., Wareham, J (2011). Living labs: arbiters of mid-and ground-level innovation. Technol. Anal. Strateg. Manag. 23(1), 87–102.

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- **Agder Living Lab, Norway**

A national initiative in Southern Norway has funded the Agder Living Lab[115](ALL) for eHealth, a user-centred innovation environment participated by multi-sectorial public and private partners. ALL implements a quadruple-helix model represented by citizens, industry, academia and government, offering an experimental arena for universal design to implement welfare technology, eHealth, telemedicine and mobile health solutions. ALL aims to catalyse inclusive innovation in the health sector by creating a multidisciplinary space where end-users (citizen, patient, relative, health professional) and health services can be interlinked making technology accessible to and usable for everybody

- **ENABLERS**

Health policy

National eHealth and mHealth strategies, tailored to user-driven innovation • Regional strategy aligned with national ones on eHealth and mHealth • Effective cooperative incentive scheme for stakeholder involvement: research, education and dissemination for public actors; access to real users and facilities for knowledge translation to private actors

- **DISABLERS**

Health policy

Absence of or outdated national / regional eHealth and mHealth strategies • Absence of or unfeasible incentive scheme for all stakeholders

Core infrastructure

Absence of or obsolete physical and digital infrastructure

- **Haapsalu Neurological Rehabilitation Centre (HNRC) Living Lab, Estonia**

User-centred design, as previously said, plays a huge role in the development and production of valuable products or services that meet the needs of patients. At Haapsalu Neurological Rehabilitation Centre[116] (HNRC) in Estonia there is now a possibility to develop and test new products, services, and methods in a real-life environment. To give an example, HNRC in-cooperation with a Latvian start-up has tested individual ankle foot orthoses (AFO-s) meant for children by using innovative 3D printing technology. The objective was to gain experience in using 3D-printed orthoses to support a patient´s ankle functions and compare the results with those of conventional ankle foot orthoses. The developer / testing partner and HNRC were both interested in the orthoses' functionality, ease of use and appearance. During this time, most of the children undergoing rehabilitation at HNRC who needed customer specific AFO-s, were included in the testing initiative.

In the living lab activities, the HNRC is involving specialists and top technology from the rehabilitation HNRC´s hospital, as well as from the Centre of Excellence in Health Promotion and Rehabilitation. People who have rehabilitation at HNRC will be also involved in tests in case there is a need.

[115] Martinez, S., Silje B., and Fensli, R. (2016). Agder Living Lab: co-creation of inclusive health solutions for and with citizens. International Journal of Integrated Care (IJIC) 16.

[116] https://www.hnrk.ee/?lang=en

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- **ENABLERS**

User-centred

Personal factors which shape people engagement and experience • Provider's capacity • Keeping the user in mind • Frontline staff training • Familiarity, ability with digital tools • Awareness of the objectives and/or existence of solutions • Support and promotion of mHealth/telehealth by colleagues • Consumer demand • Experiencing patient and clinical benefits • Perceived ease of use • User involvement in solution development • Experimentation and clinical learning • Training

Assessment (technology)

System reliability or dependability • Accuracy of the system • Quality standards • Assessment frameworks in place • Observability (observance, control, verification of the solutions)

Cost and reimbursement

Having requisite material resources • Having requisite human resources (IT support, other)

Health policy

Communication and collaboration between stakeholders • Management (strategic planning)

Integration - interoperability

Compatibility with work process • Interoperability of solutions

- **DISABLERS**

Assessment (technology)

Lack of evidence of clinical utility

Cost and reimbursement

Lack of reimbursement models

Others

Other main questions (obstacles) in providing living lab activities and services are moments when the developer / producer would like to get more support for development and sales and is less focused on testing. These are unrealistic expectations to a living lab.

Difficulties might appear when trying to match everyday work (therapies and medical activities) with living lab testing as living lab activities are temporary. There is a possibility that the staff will be overloaded during project period.

As in the case of HNRC, the developers / producers are not ready to pay too much on their own and instead expect that costs will be covered either through a program or funds.

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There is a lack of opportunities to prove or validate products or services based on scientific evidence of clinical utilities – being a small living lab, HNRC is not capable of providing that many resources for research activities as expected.

- **Human-centred approach to develop a digital environment for the management of Type 2 Diabetes Mellitus: The ProEmpower experience (Europe)**

Innovative public procurement plays a key role in improving the efficiency and quality of public services and at the same time addressing major societal challenges. They contribute to obtaining the best quality / price ratio, as well as broader economic, environmental and social benefits through the generation of new ideas and their translation into innovative products and services; thus, promoting sustainable economic growth, to the advantage of European companies and Small and Medium Enterprises.

By promoting innovation on the demand side and by orienting the development and the first application of innovative solutions to public and market needs, innovative public procurements can allow customers to avoid the costs deriving from unnecessary functions, prevent lock-in to a single supplier and to take into account the long-term needs of the public sector. Innovative procurement puts the person and their needs, not just health, at the centre of the purchasing process. Innovative Procurements is a competitive R&D process comprising two preparatory steps and four phases:

- Open Market Consultations: dedicated workshops organised by the procurers in their regions to consult with vendors, inform the technical specifications and set realistic, yet innovative procurement objectives;
- Call for Tenders: an international tender launched on the website of the Supplement to the Official Journal of the EU;
- Pre-Commercial Procurement (PCP) Phase I: Concept design, solution architecture and technical specifications;
- PCP Phase II: Development of prototype systems;
- PCP Phase III: Development and testing of pilot systems;
- PPI IV: Public procurement of innovative solutions (PPI).

During the phase of defining the requirements to the market of innovative products and services, the end users themselves represent the specific needs that the solutions must address, through a user-centred approach.

“Procuring innovative ICT for patient empowerment and self-management of type 2 diabetes mellitus” (PROEMPOWER) is a Pre Commercial Procurement project, financed by EC’s Horizon 2020 Programme, aimed to procure innovative Information and Communication Technologies (ICT) solutions for patient empowerment and self-management of Type 2 Diabetes Mellitus. The objective of the project is to purchase research and development services in order to develop a novel ICT tool able to facilitate the lives of people with Type 2 Diabetes Mellitus, supporting them in disease self-monitoring, improving their daily lives and allowing the health organizations to manage their clinical data to prevent diabetes complications.

The project involved four public procurers across Europe (Turkey, Portugal, Campania and Murcia) that cooperated to develop detailed specifications for new diabetes management processes supported by fully integrated ICT solutions. During the co-design phase, each procurer created a working group that included physicians, nurses, IT managers and patients, who represented the unmet needs of professionals and patients for diabetes management. This allowed identifying a set of use cases and process models that guided vendors in developing the solutions. Users (Patients and Health Professionals) are actively involved in identifying needs and providing opinion on possible functions (functional requirements) which are given to them through a questionnaire. It contains also open questions to capture users’ creative wishes in term of requirements expected from ProEmpower. The co-design process of the solution encompasses requirements analysis, iterative development of uses cases and service process models, as well as the development and conduction of training activities supporting the necessary change management in each country or region. The collected information was used to inform the elaboration of functional, non-functional, legal and regulatory requirements. A set of use cases and service process models has been developed in ProEmpower. Each use case is described in full detail with one corresponding process model. Use Case includes information on the different users of the system and their goals. Each use case maintains the same level of

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abstraction throughout the use case. An international call for tenders selected the vendors to implement R&D services for the development of IT solutions addressing Type 2 Diabetes Mellitus.

- **ENABLERS**

User-centred

Personal factors which shape people engagement and experience • Keeping the user in mind • Awareness of the objectives and / or existence of solutions • Consumer demand • User involvement in solution development

Assessment (technology)

Quality standards • Assessment frameworks in place

Health policy

Communication and collaboration between stakeholders • Information and communication technologies considered central components of healthcare services delivery

Integration - interoperability

Compatibility with work process • Interoperability of solutions

The greatest advantage that can be derived from the innovative procurements is the strong role of the demand by public procurers in addressing the development of new solutions that can respond to real critical situations, directly ascertained by end-users (professionals, patients and citizens). The involvement of end-users in the analysis of needs and in the evaluation of R&D activities allows a coherent and effective development of solutions, and the identification of gaps and weaknesses. The opportunity to test solutions in real healthcare settings allows vendors to receive market feedbacks on prototype solutions and integrate them with healthcare organizations' IT infrastructures and organizational model.

- **DISABLERS**

User-centred

Professionals' lack of familiarity with equipment and procedures • Perceived complexity of solutions and resistance from physicians • Conservative culture

Cost and reimbursement

Lack of reimbursement models

Health policy

Lack of readiness among key stakeholders • Lack of enabling policy

The process is complicated and divided into different phases. This could be a problem for those healthcare organizations that need readily available solutions on the market. The development process involves solutions that are not always mature. The project budget represents a limit to the further development of solutions, when the healthcare organization does not decide to invest additional resources.

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- **ANALYSIS OF POLICY AREA V**

- **MAIN FINDINGS**

Living labs can be a useful strategy to create a research environment for user-centred innovation. Innovative procurements support the improvement of the matchmaking between supply and demand of innovation with the aim of reducing market fragmentation, and promoting a collaborative approach to increase the knowledge sharing and the capacity of the Health Systems to express their needs for innovation in a way that allows interested parties to provide adequate and sustainable solutions. Innovative procurements offer the opportunity for stakeholders and suppliers to develop specific requirements for innovative solutions, to contribute to clinical pilots in healthcare settings, and to offer vendors the possibility to exploit the results of the pilots for the development of new ready-to-market solutions.

- **GAPS IDENTIFIED**

The peculiarity and legal complexity of the innovative procurements lies in the way in which the contractors are selected and in the regulation of their relations with the public procurer.

- **TRENDS IDENTIFIED**

Consistent to what happens in the more general scheme of public-private partnership (PPP), the procedural and contractual model of the PCP essentially refers to a form of financing of specific business activities, with consequent sharing of risks and benefits between public and industry sectors.

- **RECOMMENDATIONS - Targeted to policy makers & implementers**

Further policy and funding measures need to be implemented to enable the solutions to be adopted on a larger scale. It is above all necessary to develop new forms of collaboration that favour the use of mHealth solutions in the self-monitoring and management of diseases, enhancing the digital skills of patients and professionals.

Policies to empower patients need to: i) promote a human centred and inclusive design of health solution, ii) testing facilities / living labs for products and services and iii) their validation based on scientific evidence. Moreover, it is equally important to promote health literacy and development of digital skills, as well as incentives schemes for cooperation between the different stakeholders (public, private, research, academia) on access to the digital infrastructure and access to real users.

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Policy Area 6 – Assessing the impact of the innovations

- **POLICY DESCRIPTION**

As previously mentioned, WHO reported that one of the barriers to mHealth adoption is the lack of evidence on the effectiveness of mHealth programs (2016 WHO Report). Consequently, the lack of evidence hinders the adoption, use and reimbursement of this type of mHealth solutions, due to the lack of robust evidence regarding their performance and capacity to improve health and well-being. Therefore, policies that address the assessment of the impact of innovation are important to provide sufficient high-quality data for governments and industries partners to invest resources in nationally or regionally scaled mHealth initiatives. Thus, during the development of mHealth policies, evidence on cost benefits, cost effectiveness and other related aspects of mHealth, as well as reliable processes for measuring mHealth intervention impact should be considered. An example from England is explored within this policy area.

- **POLICY EXAMPLEs**

  - **Evidence standards framework for digital health technologies. Behaviour change: digital and mobile health interventions, NICE (England)**

The NHS England's *Next steps on the NHS Five Year Forward View 2017*[117] strategy highlights that better use of information and technology can help people manage and improve their own health, particularly by increasing the use of apps. Moreover, the strategic document *From evidence into action: opportunities to protect and improve the nation's health*[118] that sets out the Public health England's priorities for the next 5 years, highlights the use of digital technology as an opportunity for behaviour change. In this regard, in 2020, NICE published a guideline titled *Behaviour change: digital and mobile health interventions*[119], that covers interventions that use a digital or mobile platform, to help people eat more healthily, become more active, stop smoking, reduce their alcohol intake or practise safer sex. The interventions include those delivered by text message, apps, wearable devices, or the internet. In addition, this guideline only includes those that are delivered by the technology itself and not by healthcare professionals using technology to deliver interventions. This guideline is intended to be used by:

- Local policy makers and commissioners
- Individuals, groups or organisations wishing to work or working with health and social care service providers
- Designers and providers of digital and mobile health interventions and programmes
- Behaviour change practitioners
- Trained staff working in health and social care services who have contact with the general public
- People who want to improve their health-related behaviours (concerning diet and physical activity, smoking, alcohol use and safer sex), their families or carers, and other members of the public. It also includes children and young people

Importantly, during the development of the guideline, the committee emphasized that "digital and mobile health interventions is a rapidly changing and developing area. As such, they agreed it was important to develop them in line with national supporting frameworks such as the NICE *Evidence standards framework for digital technologies*[120] to ensure they are as effective as possible. In addition, the committee agreed that the government digital service standard could be followed

[117] National Health System. Next Steps on the NHS Five Year Forward View. NHS (2017). England [online] Available at: https://www.england.nhs.uk/wp-content/uploads/2017/03/NEXT-STEPS-ON-THE-NHS-FIVE-YEAR-FORWARD-VIEW.pdf

[118] Public Health England. From evidence into action: opportunities to protect and improve the nation's health. PHE (2014) ref 2014404.

[119] National Institute for Health and Care Excellence. Behaviour change: digital and mobile health interventions. NICE (guideline NG183). (2020) [online] Available at: https://www.nice.org.uk/guidance/ng183/resources/behaviour-change-digital-and-mobile-health-interventions-pdf-66142020002245

[120] National Institute for Health and Care Excellence. Evidence standards framework for digital health technologies. NICE (2019) [online] Available at: https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/evidence-standards-framework/digital-evidence-standards-framework.pdf

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when creating interventions for public services." Therefore, the NICE evidence standards framework for digital technologies should be refer to when developing and evaluating digital and mobile health interventions for behaviour change. In addition, it is recommended to follow the advisory frameworks for assessment when developing and evaluating digital and mobile health interventions for behaviour change, such as:

- Public Health England´s guidance on evaluating digital health products
- NHS Digital's digital assessment questions
- Department of Health and Social Care's code of conduct for data-driven health and care technology.

Furthermore, when commissioning digital and health interventions, it is recommended to check expert sources (e.g., NHS apps library) for any existing evidence-based digital and mobile health interventions, before commissioning the development of a new solution. The same is recommended for the users. Moreover, it is recommended to select interventions that meet the current frameworks, regulatory advice and evidence standards.

The above-mentioned evidence standards framework for digital health technologies (DHTs)[120] was published in 2019 by the NICE in collaboration with NHS England, Public Health England and MedCity, and was commissioned by NHS England. This framework was developed in respond to the increasing pace of digital technology development, and as mean to ensure that new technologies are clinically effective and offer economic value. This framework is intended to be used by technology developers and decision makers who are considering commissioning a DHT. The framework describes standards for evidence that should be available or developed in order to demonstrate the value of the respective DHT to the UK Health and Care System. These standards include evidence of effectiveness relevant to the intended use and of economic impact relative to the financial risk.

This framework was designed for DHTs that are commissioned in the UK Health and Care System, being less relevant to DHTs that are downloaded or purchased directly by users. In addition, it can be used for DHTs that incorporate artificial intelligence using fixed algorithms, but not to DHTs that incorporate artificial intelligence using adaptive algorithms. Separate standards will be applicable to the latter case.

This framework is divided into two main sections of evidence:

- evidence for effectiveness standards
- evidence for economic standards

For the evidence for effectiveness standards, this framework uses a functional classification to differentiate the main functions of the DHTs, which allows to stratify the DHTs into evidence tiers based on the potential risk to users (T1, T2, T3a and T3b, Table 8 - Overview of evidence for effectiveness standards requirements.). The evidence level needed for each tier is proportionate to the potential risk to users presented by the DHTs in that tier. The classification does not consider whether the DHT must be CE marked under the Medical Device Regulations, but T3b is intended to be complementary to those requirements for regulatory approval under the Medical Device regulations. The evidence tiers are cumulative, which means that a DHT must meet all the standards of the previous tier, as well as its own tiers (e.g., T3b must meet the standards from T1, T2, T3a and T3b).

Table 8 - Overview of evidence for effectiveness standards requirements.

	Lower risk → **Higher risk to users**			
	Evidence tier			
	Tier 1	**Tier 2**	**Tier 3a**	**Tier 3b**
Evidence for effectiveness standards	DHTs with potential system benefits but no direct user benefits.	DHTs which help users to understand healthy living and illnesses but are unlikely to have	DHTs for preventing and managing diseases. They may be used alongside treatment and will likely have	DHTs with measurable user benefits, including tools used for treatment and diagnosis, as well as those influencing clinical

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		measurable user outcomes.	measurable user benefits.	management through active monitoring or calculation. It is possible DHTs in this tier will qualify as medical devices.
	Functional classification			
	• System service Improves system efficiency. Unlikely to have direct and measurable individual patient outcomes.	• Inform Provides information and resources to patients or the public. Can include information on specific conditions or about healthy living. • Simple monitoring Allows users to record health parameters to create health diaries. This information is not shared with or sent to others. • Communicate Allows 2-way communication between users and professionals, carers, third-party organisations, or peers. Clinical advice is provided by a professional using the DHT, not by the DHT itself.	• Preventative behaviour change Designed to change user behaviour related to health issues with, for example, smoking, eating, alcohol, sexual health, sleeping and exercise. Prescribed to users by a professional. • Self-manage Aims to help people with a diagnosed condition to manage their health. May include symptom tracking function that connects with a healthcare professional.	• Treat Provides treatment for a diagnosed condition (such as CBT for anxiety), or guides treatment decisions. • Active monitoring Automatically records information and transmits the data to a professional, carer or third-party organisation, without any input from the user, to inform clinical management decisions. • Calculate Tools that perform clinical calculations that are likely to affect clinical care decisions. • Diagnose Tools that perform clinical calculations that are likely to affect clinical care decisions.
	Evidence for effectiveness standards			
	• Credibility with UK health and social care professionals. • Relevance to current care pathways in the UK health and social care system. • Acceptability with users. • Equalities considerations. • Accurate and reliable	• Reliable information content. • Ongoing data collection to show usage of the DHT. • Ongoing data collection to show value of the DHT. • Quality and safeguarding.	• Demonstrating effectiveness. • Use of appropriate behaviour change techniques (if relevant).	• Demonstrating effectiveness.

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	measurements (if relevant). • Accurate and reliable transmission of data (if relevant).			

The evidence for economic impact standards were based on the current understanding of the digital healthcare field and NICE's experience in evaluating other medical technologies. These standards intent to promote a consistent pathway for economic assessment of DHTS, and were designed to help developers and others to identify and understand the information needed for an effective economic analysis. These standards are divided into 3 components: i) key economic information, ii) appropriate economic analysis and iii) economic analysis reporting standards. The costs and benefits should be compared with existing practice (Table 9).

Table 9 - Overview of evidence for economic standards requirements

Evidence for economic impact standards	

Key economic information	• User population size
	• Care pathways
	  ○ Existing pathways
	  ○ Proposed pathways
	• Parameters for the economic model
	  ○ Intervention parameters (health and other outcomes from intended use)
	  ○ Cost parameters
	  ○ Resource use parameters
	  ○ Utilities (when a cost-utility analysis is appropriate)

Appropriate economic analysis	• According to the levels of economic analysis:
	  ○ Basic: Budget impact analysis
	  ○ Low financial commitment:
	  ▪ Cost-consequence analysis
	  ▪ Budget impact analysis
	  ○ High financial commitment:
	  ▪ Cost-utility analysis (for DHTs with health outcomes funded by NHS and Personal Socials Services)
	  ▪ Cost-utility analysis or cost-consequence analysis when the former is not possible (for DHTs funded by public sector with health and non-health outcomes or DHTs that focus on social care)
	  ▪ Budget impact analysis

Economic analysis reporting standards	Each component should be considered from the outset of designing the economic analysis and reported alongside the finding. • Economic perspective • Time horizon • Discounting

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	• Sensitivity analyses • Equity analysis • Descriptions of any additional analytical methods • Critique of the economic analysis.

In the above-mentioned guideline[119] regarding digital and mobile health interventions for behaviour change, it is stated that the evidence for that digital and mobile health interventions is variable and even lacking in certain cases, which makes it difficult to analyse which components and characteristics would lead to a healthy behaviour change in different populations. Therefore, it is important to promote and incorporate evidence requirements early in the digital solution development plan. This may have the advantage of ensuring an easier adoption by the NHS post-launch, as well as increasing the use and reimbursement of a DHT in the NHS for companies that include evidence generation.

- **ENABLERS**

User-centred

Keeping the user in mind • Awareness of the objectives and / or existence of solutions • Experiencing patient and clinical benefits • Differentiated options according to functional uses

Assessment (technology)

Assessment frameworks in place • Observability (observance, control, verification of the solutions) • Consideration of apps without measurable user outcomes • Economic and effectiveness standards

Health policy

Communication and collaboration between stakeholders • Management (strategic planning) • Information and communication technologies considered central components of healthcare services delivery

Integration - interoperability

Interoperability of solutions • Interoperability with systems

- **DISABLERS**

User-centred

Lack / variable information on evidence and benefits • Privacy and security concerns • Patients wish to speak face-to-face with physicians • Lack of patient engagement

Cost and reimbursement

Costs associated with technology

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- **ANALYSIS OF POLICY AREA VI**

- **GAPS IDENTIFIED**

There is limited evidence regarding digital and mobile health interventions; nonetheless, some interventions may work and may be recommended considering them as an option alongside other individual behaviour change services. Digital solutions are rather seen as standalone tools for specific functions, rather than integral parts of care pathways and services.

- **TRENDS IDENTIFIED**

The existence of an assessment framework for innovation allows to coordinate new policies that involved mHealth for the improvement of health and well-being. Evaluation of the compliance with the current frameworks, regulatory and evidence standards. Standards for evaluating clinical efficacy and economic value. Risk and functional-based classification and complementary to MDR.

- **RECOMMENDATIONS - Targeted to policy makers & implementers**

Co-creative and iterative process between different institutions and involving a wide range of stakeholders. Incorporating existing frameworks that are complementary and synergistic with the strategy that is being developed.

Having a measure to evaluate the impact of innovation can help to increase the availability of evidence to support mHealth and intervention programs that benefit the well-being of citizens.

Providing recommendations on areas where research can fill in the gaps.

Provide standards and guidance for the assessment of evidence regarding mHealth solutions' effectiveness and economic impact, considering the functional uses and possible risks to the users. This information should be clear and publicly available to help developers and others identify and understand the information needed for an effective assessment of innovation.

Need for an agile approach considering the fast-moving field associated with digital technologies. It is necessary to maintain continuous and close monitoring of the digital healthcare environment in the country / region / world. In addition, capturing stakeholder feedback to maintain the policy relevant to users' needs.

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Policy Area 7 – ICT Infrastructure nd Backend Technical Infrastructure

- **POLICY DESCRIPTION**

Exchange of patient data between various eHealth and mHealth systems and applications creates a need to increase technical interoperability, develop / choose and implement technical and semantic standards and norms.

This document focuses on policies pertaining to the development of ICT infrastructure and backend technical infrastructure and covers the use of existing standards:

- standardized domain data models and syntactic exchange structures, e.g., HL7, Open EHR, FHIR, EDIFACT
- IT infrastructure technical standards, e.g., LSP, IHE XDS
- terminology, classifications and information standards, e.g., SNOMED, ICD 10
- relevant ISO standards and IEC standards

The goal of this section is to provide an overview of the use of these standards in the individual countries' mHealth policies, providing examples of the UK, the Netherlands, Switzerland and Hungary. In addition, the aim is to explore and include norms or standards that countries may have developed for themselves, if any. Finally, it has been included recommendations related to the ICT infrastructure and backend technical infrastructure policies.

- **POLICY EXAMPLEs**

  - **NHS Digital Health Technology Standard (United Kingdom)**

In the UK, policies are being developed for digital health technology, including mobile applications aimed at patients. One of such policies, named the NHS Digital Health Technology Standard (DHTS)[121] is a description of standards all UK digital health technology products (incl. software) will need to comply with. It was developed to ensure that digital health technologies that improve care, health outcomes or aid the healthcare system, reach service users, patients, carers, clinicians and the wider workforce as easily as possible without compromising safety. The DHTS is based on two high-level policy documents, namely:

- the NHS Long Term Plan[122] ,which highlights the need for digitally enabled care
- the Secretary of State's Technology vision[123], setting key foundation elements for new digital services: user need, privacy and security, interoperability and inclusion.

DHTS was developed by NHSX[124] (a part of NHS) and is based on industry and health standards, addressing efficacy, safety, security, data protection, robustness, stability, interoperability, usability, accessibility and responsibility. NHSX will create a clear process for reviewing, assessing and evaluating digital health technologies in line with the DHTS.

Key elements of DHTS are (highlighting the technical aspects):

[121] J. R (2020). NHS Digital Health Technology Standard Draft. NHSX, 001524, v1. [pdf]. Available at https://assets.nhs.uk/prod/documents/NHS_Digital_Health_Technology_Standard_draft.pdf

[122] The NHS Long Term Plan. NHS, 2019. [pdf]. Available at: https://www.longtermplan.nhs.uk/wp-content/uploads/2019/01/easy-read-long-term-plan-v2.pdf

[123] Policy paper. The future of healthcare: our vision for digital, data and technology in health and care. Department of Health & Social Care, 2018. [online]. Available at: https://www.gov.uk/government/publications/the-future-of-healthcare-our-vision-for-digital-data-and-technology-in-health-and-care/the-future-of-healthcare-our-vision-for-digital-data-and-technology-in-health-and-care

[124]BETA - NHS digital, data and technology standards framework. NHS Digital, 2020 [online]. Available at: https://digital.nhs.uk/about-nhs-digital/our-work/nhs-digital-data-and-technology-standards/framework#the-nhs-digital-data-and-technology-standards

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1. Abide by the Code of Conduct for Data-Driven Health and Care Technologies[125], including data anonymization in line with the ICO's code of conduct on anonymisation.

2. End-users should be involved in any product development and impact of the technology should be clearly stated and evaluated in live with upon NICE guidelines.

3. Products should be user-friendly, meeting the following standards:

   - Ergonomics of human-system interaction — Part 210: Human-centred design for interactive systems ISO 9241-210:2010
   - Applying human factors of medical devices guidelines of the Medicines and Healthcare Products Regulatory Agency[126]
   - Web Content Accessibility Guidelines (WCAG)

4. Clinical safety must be ensured, by following:

   - Clinical Risk Management Standard DCB0129.
   - Clinical Risk Management: its Application in the Deployment and Use of Health IT
   - Systems DCB0160
   - NHS England mandated Safety Standards (SCCI0129)
   - ISO 14971 Medical Devices - Application of risk management to medical devices
   - Relevant Health and safety standards for the setting

5. Data must be collected, stored and processed in line with the UK Data Protection Act[127] and NHS Information Governance requirements.[128]

6. The product must complete the NHS Digital Data Security and Protection Toolkit and follow relevant security standards:

   - OWASP Application Security Verification Standard (ASVS)
   - National Data Guardian's 10 data security standards[129]

7. Depending on the product's purpose, it may need to conform to regulation:

   - If it meets the definition of a medical device, it must be registered with the Medicines and Healthcare Products Regulatory Agency and have a CE mark
   - If it provides a health or social care service that fits in one of the regulated activities, it must be registered with the Care Quality Commission
   - If it constitutes a pharmacy service, it must be registered with the General Pharmaceutical Council

[125] Guidance. A guide to good practice for digital and data-driven health technologies. Department of Health & Social Care. 2021 [online]. Available at: https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology

[126] Guidance on applying human factors and usability engineering to medical devices including drug-device combination products in Great Britain. Medicines & Healthcare products Regulatory Agency, v2.0, 2021 [pdf]. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/645862/HumanFactors_Medical-Devices_v1.0.pdf

[127] Data protection. GOV.UK [online]. Available at: https://www.gov.uk/data-protection

[128] Data security and information governance. NHS Digital [online]. Available at: https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance

[129] Data Security Standards. Overall Guide. Health and Social Care Information Centre, NHS Digital, 2018 [pdf]. Available at: https://www.dsptoolkit.nhs.uk/Help/Attachment/24

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- If it requires registered healthcare professionals to operate, their status and names must be provided

8. The product must comply with:

- Standards mandated by NHS Information standards notice (ISN)
- PRSB standards for content of patient / clinical / professional records
- NHS Data Dictionary
- SNOMED CT and SNOMED refsets.
- ICD-10 and OPCS4 (coding systems for diseases and procedures)
- GS1 for barcoding
- Dm+d (the dictionary of medicines and devices)
- Other datasets which are not national standards but used in national applications in relevant fields
- HTML5 for web sites
- Schema.org metadata
- Unicode for text
- WCAG 2.1 for accessibility
- ISO-8601 for timestamps in data
- OpenAPI v3 for documentation of REST APIs
- OAuth, OpenID Connect, FIDO for authentication
- HL7 FHIR+ FHIR Care Connect
- Standards set out on the NHS Developer site
- Government Digital Services: Open API Best Practices
- If the product is a wearable or device or integrates with them, ISO/IEEE 11073 Personal Health Data (PHD) Standards

9. Product suppliers should have accreditation to an industry wide testing standard (e.g., ISO 9001 or ISO 29119).

10. Evidence that the product achieves clinical, social, economic, or behavioural benefits needs to be provided, in line with the NICE Evidence Standards Framework.

- **ENABLERS**

User-centred

Keeping the user in mind • Awareness of the objectives and / or existence of solutions • Consumer demand • Experiencing patient and clinical benefits • User involvement in solution development

Assessment (technology)

Quality standards • Assessment frameworks in place

Health policy

Information and communication technologies considered central components of healthcare services delivery

Integration - interoperability

Compatibility with work process • Interoperability of solutions

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- **DISABLERS**

User-centred

Professionals' lack of training, education and advocacy

Core infrastructure

Bandwidth issues / internet access

Integration - interoperability

Lack of interoperability

e-Health and patient data exchange landscape in the Netherlands

In the Netherlands, key elements of ICT infrastructure and backend technical infrastructure are being developed, with a focus on authentication, authorization, and data exchange infrastructure to be reused by various specific systems. For a better understanding of this infrastructure, we provide a brief overview of the history of their developments, together with key aspects of specific infrastructure components.

Letter of 20 December 2018[130] from the Minister for Medical Care and Sport and the Minister of Health, Welfare and Sport and the State Secretary for Health, Welfare and Sport, on electronic data exchange in the healthcare sector highlighted faster, mandatory, and timely exchange of information between care providers and with patients as vital to the quality of care. However, it reported inadequate electronic data exchange in the healthcare sector, partly due to a 2011 motion submitted to the Senate which called for the government to terminate its involvement in every form – policy-related, financial and organisational – with the national electronic data processing infrastructure. Hence, in 2011, the centralized National Electronic Health Record was abandoned due to security concerns[131,132]. Since then, the government's digitalisation approach has consisted largely of offering encouragement to relevant parties (e.g., developers and healthcare organisations) in the field. The letter promises to implement more control by the government in addressing this issue.

Patient Data Exchange (between healthcare providers)

Currently, patient data is exchanged through an infrastructure organization, the "Landelijk Schakelpunt" (LSP). LSP is being maintained and overseen by the Association of Healthcare Providers for Healthcare Communication (VZVZ). VZVZ is an organization founded by four umbrella organizations of healthcare providers: the umbrella organizations of general practitioners (LHV), general practitioner posts (InEen), pharmacies (KNMP) and hospitals (NVZ).

Every patient must explicitly give permission for participation, no automatic and mandatory participation by health care providers exists, and instead of a national system, a regional set-up is in place. LSP does not store any medical data but

[130] Kamerbrief over regie op elektronische gegevensuitwisseling in de zorg [Letter to parliament about directing electronic data exchange in healthcare]. Rijksoverheid [online]. Available at: https://www.rijksoverheid.nl/documenten/kamerstukken/2021/10/15/kamerbrief-over-regie-op-elektronische-gegevensuitwisseling-in-de-zorg

[131] The infrastructure for central exchange. Nictiz [online]. Available at: https://www.nictiz.nl/english/exchange-of-electronic-patient-data-in-the-netherlands/the-infrastructure-for-central-exchange/

[132] Exchange of electronic patient data in the Netherlands. Nictiz [online]. Available at: https://www.nictiz.nl/english/exchange-of-electronic-patient-data-in-the-netherlands/

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provides a highly secure infrastructure to transport data. Majority of public and outpatient pharmacies, GP practices, and hospitals in the Netherlands are connected to LSP and can consult medical data of patients in each other's systems.

Healthcare providers are grouped in 44 (geographic) regions. Data exchange within each region is governed by a separate organization (RSO) and the scope might differ from data exchanged via the LSP. RSOs are independent and manage the infrastructure for data exchange themselves, using their own regional manager. Not all areas of the country are covered by an RSO. Healthcare providers can only exchange medical data within their region, with the exception of hospitals, which can request data throughout the whole country. To prevent the exchange of RSO information between RSOs directly, centralized communication via the LSP is currently being developed[131].

LSP defines interoperability and relevant standards at five levels:

- organization (agreements between organizations),
- care process (care standards and guidelines, e.g., the COPD Care Standard and Guideline Transfer of medication data in the Chain),
- information (terminology, classifications and information standards, e.g., SNOMED, ICD 10, ICF and GP observation),
- application (standardized domain data models and syntactic exchange structures, e.g., HL7, Open EHR, FHIR, EDIFACT), and
- IT infrastructure (technical standards, e.g., LSP, IHE XDS)[133].

A full list of standards used is provided on the website[134].

MedMij label for Personal Health Environments (data exchange between patients and healthcare providers)

MedMij is the Dutch standard for the safe exchange of health data between patients and their healthcare providers. All parties that comply with MedMij may use the MedMij label.

To ensure reliable and secure data exchange between the healthcare provider and the patient, the Personal Health Environment supplier and the IT supplier of the healthcare provider must comply with MedMij. This means a set of mandatory guidelines must be followed[135], including (but not limited to) compliance with the prescribed technical standards for various functional areas, based on FHIR[136].

Authorization and authentication interface

AccessVerleningService (TVS) is a single interface for authentication and authorization with different login services recognized under the (yet to be ratified) Digital Government Act. By connecting to TVS, products have a connection to all available recognized login resources and authorization facilities such as DigiD, DigiD Authorization, European recognized login resources (eIDAS regulation), including future recognized login resources[137].

[133] Interoperabiliteit. Nicttiz [online]. Available at: https://www.nictiz.nl/standaardisatie/interoperabiliteit/

[134] Overzicht standaarden [Overview standards]. Nictiz [online]. Available at: https://www.nictiz.nl/overzicht-standaarden/

[135] https://afsprakenstelsel.medmij.nl/display/MedMijAfsprakenstelsel112/MedMij+Afsprakenstelsel+1.1.2

[136] Ontwerpen MedMij [Design MedMij]. Nictiz [online]. Available at: https://informatiestandaarden.nictiz.nl/wiki/MedMij:V2020.01/Ontwerpen

[137] Informatie voor ICT-leveranciers [Information for ICT suppliers]. Ministry of Health, Wellbeing and Sports [online]. Available at: https://www.gegevensuitwisselingindezorg.nl/digitale-toegang/voor-leveranciers

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The interface for TVS is based on SAML 4.4 and uses / provides EncryptedID (with encrypted NameID), identity (BSN) encrypted for healthcare party, POST binding only (AuthnRequest), hashing algorithm SHA256 (and higher), support for cluster connections and support for representation (DigiD Authorization)[138].

No specifics linked to the use of mobile technologies in particular were found for any of the above-mentioned services; only a description of aspects pertaining to electronic communication in general.

- **ENABLERS**

None explicitly found

- **DISABLERS**

None explicitly found

- **eHealthSuisse – mHealth (Switzerland)**

After the establishment of the electronic health record (EHR) in Switzerland, the lack of binding standards and norms prevented mHealth solutions to connect to an EHR. The mHealth is currently very much provider and consumer-driven, a coordinated approach has so far been lacking in Switzerland. eHealth Suisse is therefore developing the basis for coordinated processing and has drawn up initial recommendations[139].

The document contains recommendations for action in the area of "Mobile Health", the main aim of which is to improve the transparency of the applications offered on the market. The paper also addresses the use of mobile data in the context of the EHR.[140]

Regarding ICT infrastructure and backend technical infrastructure, there is **Recommended action:**

eHealth Suisse recommends technical and semantic standards for the communication of information between mHealth applications and the EHR. The focus is on standards that have established themselves internationally (for example the IHE Patient Care Device (PCD) Technical Framework, the Continua Design Guidelines, or FHIR from HL7 International).

Recommended Standards:

- Continua Design Guidelines
- IHE
- HL7
- FHIR

[138]ToegangVerleningService (TVS) [AccessProvision Service (TVS)], Ministry of Health, Wellbeing and Sports [online]. Available at: https://www.gegevensuitwisselingindezorg.nl/digitale-toegang/toegangverleningservice-tvs

[139] mHealth. eHealthSuisse [online]. Available at: https://www.e-health-suisse.ch/de/gemeinschaften-umsetzung/ehealth-aktivitaeten/mhealth.html

[140] Mobile Health (mHealth) Empfehlungen I. eHealthSuisse, 2017 [pdf]. Available at: https://www.e-health-suisse.ch/fileadmin/user_upload/Dokumente/2017/D/170316_mHealth_Empfehlungen_I_d.pdf

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The rough concept for the connection of mHealth applications to an EHR[141] describes the organizational and technical framework for connecting mHealth applications to the EHR. Essentially, the connection of mHealth applications is to take place via a mobile access portal, which is built into the platform of the core communities locally. FHIR was chosen as the standard for this. As the next step, eHealth Suisse will examine together with the Federal Department of Health (FOPH / BAG) how and when the conceptual work can be transferred to execution law.

Recommended Standards:

- FHIR
- IHE
- OpenID Connect
- HL7 SMART App Launch Framework

Recommendations:

- The connection to the EHR (reading & writing) is done via Mobile Access Portal
- Detailed specification for the SMART App Launch Framework needs to be developed and defined in the execution rights
- Mobile Access Portal offers the translation of the eID (UAP-ID) to the MPI-ID according to the IHE-PIXm profile
- For writing documents, Mobile Access Portal must provide the document recipient for the Mobile-Access-to-Health-Documents-Profile (MHD) profile
- To read the documents, Mobile Access Portal must provide the Document Responder for the MHD profile

Recommendations for the use of technical norms and standards in the area of mHealth[142]

The topic of interoperability is of great importance in connection with mobile health (mHealth), because the population should be able to record health data or vital signs with different mobile devices or applications and enter them in the form of documents in the electronic patient record (EHR). To make this possible, the mHealth working group has adopted recommendations for technical standards and norms that allow the integration of mHealth applications into the EHR. The recommendation report contains, on the one hand, an overview of existing technical standards and norms for the area of mHealth and, on the other hand, derives recommendations for the attention of the app developers.

Recommended standards:

- Continua Design Guidelines
- IEEE 1073
- IHE Patient Care Device (PCD)
- FHIR
- SMART (FHIR)
- IHE mobile integration profiles (MHD, PIXm, PDQm, IUA, RESTFul ATNA)
- Standard for mobile health data (IEEE project P1752)
- Consumer Mobile Health Application Functional Framework (cMHAFF), Overview and Update (HL7)
- Cross-Enterprise Document Data Element Extraction Profile (mXDE)

[141] Bignens, S. et al (2019). Grobkonzept Anbindung von mobilen Devices ans EPD [Rough concept for the connection of mobile devices to the EPD]. eHealth Suisse, v 1.0 [pdf]. Available at: https://www.e-health-suisse.ch/fileadmin/user_upload/Dokumente/2019/D/190508_mHealthKonzept_V1_0_final_d.pdf

[142] Mobile Health und das elektronische Patientendossier [Mobile health and the electronic patient record]. eHealthSuisse, 2018 [pdf]. Available at: https://www.e-health-suisse.ch/fileadmin/user_upload/Dokumente/2018/D/181008-Empfehlungen_mHealth_Standards_d.pdf

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Recommendations:

- Use of the Continua Design Guidelines
- Use of service interface: H.812.5 FHIR Observation Upload
- Consent management based on XACML instead of Continua
- Development of an extended form technology (CDA form technology from the Continua Guidelines has not yet been widely implemented and appears to be too complex. In Switzerland, an IHE proposal ORF (Order & Referral Form) is being developed based on FHIR Form resources)
- Anticipate exchange format PHMR based on FHIR
- Follow the SMART-on-FHIR approach
- Include mobile web technologies (OpenID Connect based on OAuth 2.0.)
- Use mobile integration profiles IHE (MHD, PDQm, PIXm)
- The Guide and checklists for developing a safe health app[143]

The mHealth working group has commissioned ISS AG to implement the recommendation for action about medical devices from the recommendation document "mHealth - Recommendations I". This is because developers must ask themselves early on when designing a health app whether their product is a medical device and which regulations they must comply with. ISS AG has drawn up guidelines to support developers in this process. This provides practical assistance for differentiating lifestyle / wellness products and medical products and for preparing and carrying out the certification process as a medical product. The guideline also contains checklists which guide the developers through central questions in order to be able to develop a safe and compliant medical device.

Recommended standards:

- IEC 62304:2006/AMD 1:2015 Medical device software – Software life cycle processes
- IEC 82304-1:2016 Health software – Part 1: General requirements for product safety
- IEC 62366-1:2015 Application of usability engineering to medical devices
- IEC 82304-1:2016 Health software – Part 1: General requirements for product safety
- ISO 14971:2019 Application of risk management to medical devices
- ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes

In Swiss eHealth strategy 2018-2022[144], Objective A8 is for Swiss eHealth to ensure that the implementation of the "mHealth Recommendations I".

There is also a Measure A9.1: Technical and semantic standards for the exchange of information between mobile health applications (mHealth) and EHR are developed. In this context, priority is placed on internationally established standards.

- **ENABLERS**

User-centred

Keeping the user in mind

[143] Guide for app developers, manufacturers and distributors. Pratical Guide. eHealthSuisse, 2020 [pdf]. Available at: https://www.e-health-suisse.ch/fileadmin/user_upload/Dokumente/2018/E/180731_Leitfaden_fuer_App_Entwickler_def_EN.pdf

[144] Swiss eHealth strategy 2018-2022 has been released. Med Tech Reimbursement Consulting, 2019 [online]. Available at: https://mtrconsult.com/news/swiss-ehealth-strategy-2018-2022-has-been-released

This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Grant Agreement No 737427

Assessment (technology)

Observability (observance, control, verification of the solutions)

Health policy

Communication and collaboration between stakeholders • Management (strategic planning) • Information and communication technologies considered central components of healthcare services delivery

Integration - interoperability

Interoperability of solutions

- **DISABLERS**

None explicitly found

- **National eHealth Infrastructure (EESZT) (Hungary)**

In 2017, the Hungarian government launched the **National eHealth Infrastructure EESZT** (Elektronikus Egészségügyi Szolgáltatási Tér) with the aim of transforming the paper-based national healthcare system to a modern up-to-date nationwide eHealth service.[145]

EESZT is a central IT system where the communication interface uses cloud-based technologies and connects public and private healthcare providers, pharmacies and citizens. The architecture is service oriented and consists of a series of components that are connected to each other. EESZT is integrated with existing systems, and thus, clinicians, general practitioners and pharmacists can use their own health information systems. EESZT electronically stores information about the patients, by collecting and providing data to the medical information systems used by the different healthcare professionals.

It includes the following main modules[146]:

- **eProfile** (summary of medical data of patients): the entries must comply with two main requirements: [147]
  - Any medical event, illness, medical intervention, etc. that has occurred during the patient's life that affects the patient's health condition for a long time, or any examinations and treatments that may be necessary must be recorded.
  - It must contain for the necessary period any medical information (or information affecting treatment) that may be relevant to the health care treatment.

- **ePrescription**:
  - For a therapist allows: issuing prescriptions, issuing recurring prescriptions, withdrawal of a prescription, querying a summary list of prescriptions on an SSN basis; querying specific prescriptions.

[145] Horvath, L. Toward smart health care: Building a national health information infrastructure (EESZT) in Hungary. 2017 IEEE 30th Neumann Colloquium (NC), 2017, 10.1109/NC.2017.8263260; Milieu Ltd. *Exemplary Project. Development and improvement of the Hungarian National ehealth platform (EESZT) - HUNGARY April 2018*. ESI Funds for health. Retrieved from: https://docplayer.net/140888457-Exemplary-project-development-and-improvement-of-the-hungarian-national-ehealth-platform-eeszt-hungary-april-2018.html

[146] The following website provides information regarding each module: https://e-egeszsegugy.gov.hu/web/eeszt-information-portal/functionality-of-the-eeszt.

[147] eProfile. EESZT Information Portal [online]. Available at: https://e-egeszsegugy.gov.hu/web/eeszt-information-portal/eprofile

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- For a pharmacist allows: reading the SSN from the patient's e-ID card; querying of prescription by SSN; pharmacy recording of paper-based prescriptions; withdrawal of a prescription recorder at the same pharmacy; querying of a specific prescription; reserving a prescription; releasing a prescription reserved at the same pharmacy; issuing of a prescription; withdrawal of a prescription issued at the same pharmacy; self-check function; manual pharmacy related functions.

- **eReferral** (allows the transmission between the IT system of the physician issuing the referral and the physician / institution to whom the patient is being referred to).

- **eCatalogue** (event records of treatments, diagnosis, visits, etc).

- **Digital Image Forwarding** (DICOM transfer to provide images to teleconsulting doctors):
  - EESZT allows sharing of digital image material for providers connected to the system; participants record the list of images acquired at the institution, which can be downloaded by other providers; images acquired previously by other institutions can be used in reporting as history.
  - It also uses an e-mail system developed for sending images, that does not have size restrictions.
  - The third option includes teleconsultation. The central system keeps a central catalogue of images, while not storing the images themselves. It provides a link to the images and a mechanism to retrieve them. The task of the storing and providing the images falls within the scope of the institutions. While the central component of the system includes a web-based application, the capabilities of the system can only be used by the synchronization of institutional systems (API), which is currently in pilot mode.

Authentication mechanism

While the backend system communicates with the medical systems, the portal allows access to healthcare professionals according to their different roles in the healthcare system (e.g., doctor, nurse, pharmacists, etc), as well as to the patient to be able to access his / her medical data.

The system uses parallel multi-security solutions. Healthcare professionals must use a two-factor authentication mechanism and unique identifier according to their professional credential's information. Currently, the EESZT mobilToken token-based authentication system for remote system can also be used, and functions as an app for mobile devices which can generate a one-time password for the EESZT-login when the user enters their PIN code, allowing medical software to connect to the EESZT framework without the use of e-ID card authentication. The e-ID card is suitable for the identification of both patients and health professionals. The e-ID card and its PIN code ensures secure login to the EESZT as a two-factor (possession and knowledge-authentication device).[148]

For medical professionals:

- e-ID card
- Mobile token (iOS / Android mobile application)

For patients

- e-ID card
- Governmental Customer Gateway ID + password

Other information

The communication (backend) is on pre-defined and documented (WSDL) web service interfaces. Other systems can connect to EESZT after a successful validation and certification process. Connecting medical systems push data to the central EHR

[148] The EESZT and data protection. EESZT Information Portal [online]. Available at: https://e-egeszsegugy.gov.hu/web/eeszt-information-portal/data-protection1

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system online though web service interfaces (REST) partly real-time, partly store-and-forward. XML and HL7 based, pre-defined WSDL are used as messaging standards.

As mentioned, healthcare professionals' users can access the data from EESZT through authentication via accredited healthcare system of the individual healthcare service providers or through miniHIS. The miniHIS is the IT system developed by the government, operating with free web technology for easy EESZT access of healthcare service providers, which is suitable for ensuring mandatory data provision defined by law.[149]

Staff can also access data and functionality through the central portal for professionals.

Background and development timeline:

EESZT was established within the framework of the projects nº TIOP-2.3.2-12/1-2013-0001[150] and TIOP-2.3.1-13/1-2013-0001[151], launched in 2013, under the social infrastructure operating programme with support from the EU and co-funding by the Hungarian State, with a total investment of 4.87 billion Hungarian forints. These projects that ended in November 2015 led to the creation of the IT infrastructure for EESZT.

Different preparatory tasks were advanced in 2016, such as the amendment of the regulatory framework to allow the pilot phase in 2017. During this phase, the EESZT system was submitted to an IT security auditing by national authorities for data protection and information security (NAIH and NEIH). It was important to ensure that the data protection framework of the EESZT complied with the requirements determined by both the national legislation and the GDPR.

On September, 2017, EESZT was opened for all the Hungarian healthcare providers, and by November, it become obligatory by law for every healthcare provider of the Hungarian public health system to provide the data they generate about each patient to the EESZT.[152]

During this process software developers in Hungary updated their medical software to make them able to access EESZT, enabling most of the state financed healthcare providers to use the benefits of this system. There are implementation guides available to help developers certified their system to connect to EESZT, which is only available by request.

New developments

The continuous development of the system is being ensure through a close cooperation between the Hungarian State and the European Union (for example, through projects such as project nº 1.9.6 of the Human Resource Development Operating Programme / EFOP of Hungary).[153]

Current development for the EESZT include[154]:

[149] miniHIS. EESZT Information Portal [online]. Available at: https://e-egeszsegugy.gov.hu/web/eeszt-information-portal/minihis

[150] Project: National Healthcare Information (e-Health) System - Development of electronic public registries and a portal for this branch. NISZ [online]. Available at: https://nisz.hu/en/projektek/national-healthcare-information-e-health-system-development-electronic-public-registries

[151] Project National Healthcare Information (e-Health) System - Development of IT systems providing central, inter-institutional dataflow, introduction of national uniform central solutions. NISZ [online]. Available at: https://nisz.hu/en/projektek/national-healthcare-information-e-health-system-development-it-systems-providing-central

[152] Reporting obligation to the EESZT. EESZT Information Portal [online]. Available at: https://e-egeszsegugy.gov.hu/web/eeszt-information-portal/reporting-obligation

[153] The History of the EESZT. EESZT Information Portal [online]. Available at: https://e-egeszsegugy.gov.hu/web/eeszt-information-portal/history-of-eeszt

[154] Directions for the advanced development of the EESZT. EESZT Information Portal [online]. Available at: https://e-egeszsegugy.gov.hu/web/eeszt-information-portal/development

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- **Establishment of new mobile access channels**: to ensure "secure access to the public services of the Infrastructure for applications developed for various mobile platforms. This solution will also enable, among other things, the forwarding of notifications addressed to individual patients, managed by the Infrastructure. This direction of development has additional benefits. Since mobile devices – smartphones, tablets – are widely used, a large part of the Hungarian population can thereby access additional services, and a health-conscious mindset in society can be significantly strengthened on the basis of data."

- **Standardisation of documents, materials produced in the course of care:** "standardisation of electronic documents generated in the hospital IT systems in the course of healthcare. This step will result in the formal and substantive standardisation of the system referred to in Union recommendations and standards. This requires comprehensive work, as it involves standardisation of electronically issued documents of the hospital information systems (HIS), and introduction of new types of documents will also be necessary on the basis of new needs. This will enable full machine processing and efficient searching of data. Owing to this development, information generated by other health care providers – included in the patient's medical history – will be integrated automatically with the software of the given health care institution. This will amount to profound change, as systematic and processed health data will support medical decisions at a higher level."

- **Data migration:** upload of patient data generated 5 years prior to the launch to EESZT. "The Event catalogue is a key element of such development; it sets up a chronological order of examinations and results performed by health care providers. In the course of providing care, these provide enormous help, as the physician can see the complete medical history of the patient. As part of another development, additional data providers can add important information to the so-called eProfile of patients, where essentially the general practitioner uploads permanent or rarely changing patient data, such as drug intolerance. This means that the eProfile can be supplemented, for example, by the Hungarian National Blood Transfusion Service with blood type data determined during blood testing, and by providers providing data to the implant registry with important characteristics of devices, prostheses and implants in patients. The EHR Repository (EHR) will be an important milestone for data migration within the system. The latter is particularly important, because it enables the central storage of documents generated in the course of health care and their continuous availability to providers."

- **Ambulance service:** electronic provision of rescue control data to hospitals, as well as additional rescue control development. The data generated in the ambulance vehicles, recorder in tablets and uploaded to the EESZT infrastructure will become immediately available for the emergency staff. "This is not limited to data uploads, as the paramedic can also query data from the Infrastructure based on the patient's social security number. This means that he / she can see the care the patient had received and gain access to the eProfile that contains key data. At least as importantly, based on the generated healthcare data, staff of the receiving hospital can prepare care before arrival of the patient – the transfer of data by such means can save lives in critical situations." Additional development plans include ordering ambulance transport, and rescue control mobile app.

- **Support telemedicine services:** "the range of devices and sensors recording patient data even in their homes has significantly increased in recent years. The channelling of information gained through telemedicine solutions into the system offers enormous opportunities. The EESZT will therefore be open to such data as well, with a new branch of service launched for uploading. Information gained this way – obviously, if the patient provides for this – will become accessible to providers, which, for example, can significantly reduce response times. The service can be further elaborated, as it can send responses and even alarms to healthcare professionals on the basis of the preliminary assessment of data."

- **Establishment of special healthcare registers**:registration of typically rare events and processes that are important to healthcare providers. Moreover, introduction of completely electronic pregnancy and children's health booklet (e.g., children's vaccination diary which is currently only accessible on paper); individual vaccination diary; and monitoring of occupational radiation exposure.

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The standardization of EHR, centralized e-consultation, telemedicine framework and centralized imaging databases are important innovative elements necessary for e-consultation. One challenge that these developments faced is the compliance with GDPR, considering the data protection requirements that imposes some difficult requirements that need to be considered in the EESZT planning process.

While GDPR was considered in the development of EESZT, there are some practical challenges that are still being evaluated. Moreover, the funding to support institutions and healthcare providers was not provided, and the infrastructural ecosystem was not yet adapted. Nevertheless, the implementation of EESZT created new opportunities and change the existing paradigm in Hungary.[155]

Since EESZT has a flexible architecture and the key components are customizable according to the local requirements, this system might be replicate by other countries with a centralized eHealth system.

The results of EESZT align with the Hungarian Health care reform process started in 2011 and maintained through the different national strategies, such as the National Health[156] and National Digitalization[157] Strategies.

- **ENABLERS**

User-centred

Keeping the user in mind • Training material provided • Awareness of the objectives and / or existence of solutions

Assessment (technology)

Observability (observance, control, verification of the solutions) • Validation and certification of software for integration

Health policy

Communication and collaboration between stakeholders • Management (strategic planning) • Information and communication technologies considered central components of healthcare services delivery • Law enforcement • Legislation framework • eHealth strategy in place • Funding available

Integration - interoperability

Interoperability of solutions

- **DISABLERS**

User-centred

Perceived complexity of solutions and resistance from physicians • Privacy and security concerns

[155] Vos, E. Hungary's First Steps into Digital Healthcare. Pharma Boardroom, 2019 [online]. Available at: https://pharmaboardroom.com/articles/hungarys-first-steps-into-digital-healthcare/. Takáe

[156] Healthy Hungary 2014-2020" Health Sector Strategy. Prepared by the Ministry of Human Resources State Secretariat for Health, 2015 [online]. Available at: https://okfo.gov.hu/documents/20182/0/Eg%C3%A9szs%C3%A9ges+Magyarorsz%C3%A1g+strat%C3%A9gia/af67e108-7f2e-437c-bf2f-d16590cf3a7f

[157] National Digitalization Strategy 2021 – 2030. Ministry of Innovation and Technology, Ministry of the Interior, 2020 [online]. Available at: https://2015-2019.kormany.hu/download/f/58/d1000/NDS.pdf

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Health policy

Legal and data protection issues for future developments • Dependence on national and EU funding for new developments

Integration – interoperability

Unstructured information and lack of readiness

- **ANALYSIS OF POLICY AREA VII**

- **ANALYSIS: MAIN FINDINGS**

Various organizations in the healthcare sector set standards and norms for data exchange. This includes standardization organizations such as **Integrating the Healthcare Enterprise (IHE)** or **Health Level Seven (HL7),** which provide comprehensive definitions of standards. At the country level, healthcare operators and regulators prescribe which of the standards are to be used nationally. In the area of mHealth, the **Continua Health Alliance** profiles have gained in importance in Europe (**Norway, Denmark** and **Sweden** rely on the Continua standards for connecting mHealth solutions to the national EHR). Continua refers to the integration profiles of the IHE, uses common industry standards and makes specifications to ensure interoperability between mobile devices. Those standards and norms (IHE, HL7, Continua) appear as a fundamental part of eHealth & mHealth ICT infrastructure and backend technical infrastructure country policies.

As part of the eHealth & mHealth ICT infrastructure and backend technical infrastructure country policies**, ISO standards** are usually included (e.g. **UK**, **Switzerland**).

In **Switzerland**, **IEC Standards** are listed in a mHealth applications development guide.

Level of development and implementation of eHealth & mHealth ICT infrastructure and backend technical infrastructure policies differs between the countries. Also, level of details in those policies differ between the countries.

A good example of detailed and thorough digital health policy, which includes mHealth ICT infrastructure and backend technical infrastructure is UK. The UK has (or is in the process of) defined standards for digital health technology, including mobile applications. **NHS Digital Health Technology Standard (DHTS)** is a description of standards all UK digital health technology products (incl. software) need to comply with.

Examples of countries which are currently in policy development and implementation are **Switzerland** and **Netherlands**. In **Switzerland**, the implementation of **mHealth Recommendations** is ongoing as a part of **2018-2022 eHealth strategy**. The Swiss mHealth policies and recommendations are documented separately from eHealth, unlike the Netherlands where it is difficult to determine to what extent policies and recommendations are available for mobile. In the Netherlands, development of key elements of Digital Health ICT infrastructure and backend technical infrastructure policy is also ongoing, with a focus on authentication, authorization, and data exchange.

- **GAPS IDENTIFIED**

Security and privacy issues still place a challenge for successful implementation of ICT infrastructure. Different countries present different levels of development and implementation of eHealth & mHealth ICT infrastructure and backend technical infrastructure, with different policies and legislations. This lack of harmonization hampers interoperability between Member States.

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- **TRENDS IDENTIFIED**

Use of standards provided by international organization such as ISO, HL7 and IHE. Need for legislation amendment / creation of new legislation. Guidance for developers (standards for development, certification for integration). Political endorsement helps to ensure (by creating legislative tools) the advancement of the infrastructure and its respective use (for example, obligation for healthcare providers / institutions to share health data through a national / regional infrastructure to allow communication between systems).

- **RECOMMENDATIONS - Targeted to policy makers & implementers**

From our analysis, the following are the essential elements to consider:

- Definition of clear set of standards and norms considering EU recommendations and national / regional context.
- Consider the current work for the secondary use of data that might impact these infrastructures (European Health Data Space on-going work).
- Policy and regulatory reforms should include multiple operators.
- Harmonization of the strategy with the necessary regulatory framework to allow the deployment of ICT infrastructure and backend technical infrastructure. Analysis of new legislation or amendment to existing ones, incorporating the security and privacy issues.
- Provide guidelines to developers to allow designing software that can be integrated. Ensure these are validated and certified.
- Consider at the design phase the scalability of the infrastructure to be developed. While pilot projects allow to define requirements and specifications for the development of the infrastructure, its scalability to the overall population needs to be planned.
- GDRP and security measures needs to be implemented to safeguard patient's health data, where the patient should be at the centre of the development. This is important for citizens and healthcare providers to trust the platform.
- Consider the investment to allow further developments as the infrastructure evolves.
- mHealth is an important gateway for citizens to access their health data managed at the infrastructure level, thus defining standards for digital health technology, including mobile applications is key for this development.

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Policy Area 8 – Policy For Addressing Countries Health Priorities In Times Of Emergency

- **POLICY DESCRIPTION**

Health systems play a vital role not only in preparing and responding to threats and emergencies, but also to recover from them. The consequences of emergencies and disasters can affect not only local jurisdictions, but also countries and continents. As a result, strategies to address countries health priorities are fundamental to provide coordination, cooperation and collaboration with relevant institutions and stakeholders at all governmental levels in times of emergency. This helps to provide capability-based frameworks to structure emergency preparedness and relevant activities. During the pandemic, mHealth solutions were used as tools to manage and prevent the spread of the new virus. Considering their potential in times of emergency, policies would benefit from considering the extensive capabilities and use of mHealth solutions to not only respond to new epidemics, but also mitigate the negative impacts of other possible catastrophes that can affect the overall public health.

- **POLICY EXAMPLEs**

  - **Focus on mHealth in Italy[158]**

At Italian regional health system levels, the most common digital health applications for mHealth include:

- Education and awareness;
- Diagnostic and treatment support;
- Disease and epidemic outbreak tracking;
- Healthcare supply chain management;
- Remote data collection;
- Remote monitoring;
- Healthcare worker telecommunication and training;
- Telehealth / telemedicine;
- Chronic disease management.

Presently, mHealth services are working as a means of entering patient data into national health information systems, and as remote information tools which provide information to the Italian government, healthcare clinics, home providers, and health workers. Moreover, it helps to identify the individual and community health needs from clinical domain with almost negligible importance on socio-cultural perspectives.

Due to the current COVID-19 pandemic situation, many trends have been strengthened in mHealth applications. In particular:

- Emergency response systems
- Home-based remote patient monitoring
- Human resources coordination, management, and supervision
- Mobile synchronous (voice) and asynchronous (SMS) diagnostic and decision support for remote clinicians
- Point-of-care clinician support which includes an evidence-based formulary, as well as database and decision support information
- Pharmaceutical supply chain integrity
- Patient safety systems
- Remote monitoring and clinical care
- Health extension services

[158] ProMis. Short Technical paper. mHealth Policies in Italy. mHealth Strategies, governance models and change management. European mHealth Hub, WP5, v0.1, 2020 [pdf]. Available at: https://mhealth-hub.org/download/wp5-policy-and-innovation-short-technical-paper-mhealth-policies-in-italy-mhealth-strategies-governance-models-and-change-management

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- Health services monitoring and reporting
- Health-related mLearning for the general public
- Training and continuing professional development for healthcare workers
- Health promotion and community mobilization
- Support for chronic care management such as diabetes, asthma and cancer
- Peer-to-peer personal health management for telemedicine

When combined with diagnostic and immune status testing, mHealth technology is a valuable tool to help mitigate, if not prevent, the next surge of COVID-19 cases. Specifically, mHealth technology provides the means to estimate the probability of infection and prioritize diagnostic testing in individuals whose data suggests a moderate to high probability of infection. Three mHealth technologies suitable to achieve this goal emerged from regional technicians: 1) integrated regional systems, 2) wearable sensors, and 3) digital contact tracing technologies. Combining these technologies into an integrated, holistic mHealth solution would provide the opportunity to deploy an end-to-end solution incorporating tools for screening, risk profiling, achieving early detection, generating referrals for testing, tracking infections, tracking isolation management / quarantine, assuring social distance compliance, proving remote care, and tracking recovery.

With the digital transformation of the healthcare system, mHealth technologies are expected to become better integrated in the clinical workflow. During the COVID-19 pandemic, this transformation of the healthcare system has been dramatically accelerated by new clinical demands including the need to assure continuity of clinical care services. This trend is likely to make us better prepared to address the challenges of future surges of COVID-19 cases and to minimize the effects of future pandemics on routine clinical service.

Policy description

The Tuscany Region, with the aim of supporting health professionals of the hospital and local health units of the Region, as well as the Crisis Unit and the Regional Health Emergency Response Task Force, has decided to focus on technology and innovation and to develop its integrated information system. Indeed, it is evident that having sources of data and information that are complete, unambiguous and available among all the different actors participating in the emergency management process, is one of the key factors to better tackle the emergency itself. Starting from hospitals and their information systems, (including microbiology and virology laboratories), up to the territory, with its centralized information system for epidemiological investigations, ad-hoc integration components have been developed to communicate all the existing systems in real time (intercommunication and interoperability).

Real-time information is required to immediately implement the consequent actions. Therefore, facilitating communication among all systems through a regional platform has a dual purpose. These purposes are: i) allowing quick consultation of the results, directly within the ordering departments and; ii) achieving a rapid analysis of data through a centralized manner. Rapid analysis of data through a centralized manner allows the management of emergency in conjunction with the Crisis Unit and the regional Task Force through a secure, reliable, and updated data. Additionally, the geo-referencing system used was able to easily represent information on the cartographic support in order to better organize interventions in the hospital network and home interventions of healthcare personnel.

Policy options / Implementation options

The introduction of integrated information systems has introduced organisational and digital innovations and challenges. Challenges are being faced by hospitals, but more importantly by the territorial health organisations. All the territorial health organizations have special continuity units for assistance, as required by law. These crews, made up of a doctor and a home nurse, are equipped with a single regional software (APP) in order to carry out and record home visits. Each patient is associated with a QR code and each provided service is registered by using a regional standardized catalogue. In real time, the regional dashboard reports some information regarding the patient such as the performance, the therapeutic indications and all the vital parameters detected during the examination. Therefore, it is fundamental that all the Regional Health System actors use the available information systems. In the short-medium term, there will be the opportunity to discuss needs for developing and customizing the applications, in compliance with information and management standards to be taken into account.

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With regards to the above, the Tuscany Region manages the regional "innovation governance". In order to guarantee sharing of information and data, and interoperability in real time, the Tuscany Region took the following actions:

- Made obligatory the use of tools that mostly already exist
- Created connections
- Centralized information collection
- Carried out networking activities among: hospitals, laboratories, prevention and public hygiene departments and territory (general practitioners, intermediate territorial structures, special continuity of care units but also prefects, mayors and police)

Implications

The research and the development of a single integrated system at regional level, implemented particularly under the COVID-19 emergency, has to be envisioned as a crucial part of the so-called phase 2. However, it has also been seen as an essential part of the new approach regarding the organization and the handling process of the Regional Health System in the upcoming future.

The new approach is entirely data driven. This effectively governed approach allows rapid responses not only in the pandemic phase, but also in ordinary health services.

Legal constraints leading to shaping up the policy

Management of the epidemiological emergency from COVID-19 - Establishment of a technical coordination table for the functional link between the Health Task Force and the regional Coordination for maxi-emergencies.

Examples of policy adoptions:

- *Ordinanza del Presidente della Giunta Regionale* [Order of the President of the Regional Council], nº 34, 14 April 2020: http://www301.regione.toscana.it/bancadati/atti/Contenuto.xml?id=5249808&nomeFile=Ordinanza_del_Presidente_n.34_del_14-04-2020
- *Linee di indirizzo per la gestione del percorso COVID-19 in ambito territoriale* [Guidelines for the management of the COVID-19 path in the local area]: http://www301.regione.toscana.it/bancadati/atti/Contenuto.xml?id=5249809&nomeFile=Ordinanza_del_Presidente_n.34_del_14-04-2020-Allegato-A

- **ENABLERS**

User-centred

Awareness of the objectives and / or existence of solutions

Cost and reimbursement

Having requisite material resources • Having requisite human resources (IT support, other)

Health policy

Communication and collaboration between stakeholders • Management (strategic planning) • Information and communication technologies considered central components of healthcare services delivery

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Integration - interoperability

Interoperability with systems

- **DISABLERS**

User-centred

Professionals' lack of training, education and advocacy • Privacy and security concerns • Conservative culture • Patients wish to speak face-to-face with physicians

Integration - interoperability

Lack of integration with workflow

- **ANALYSIS OF POLICY AREA VIII**

- **MAIN FINDINGS**

In addition to the loss of many human lives, health emergencies are also responsible for introducing new ways of providing services and of thinking about health services. In the emergency phase, it is absolutely necessary to ensure the availability of qualified health care for chronic patients by resorting to alternative methods of delivery to the patient's presence in the clinic. In Tuscany, a single regional platform has been activated and it will have to be implemented in the near future, for the delivery of teleconsultation. However, it is necessary to create a single catalogue of outpatient services and to train staff about the way to deliver teleconsultation.

- **GAPS IDENTIFIED**

Lack of interoperability can undermine the potential of mHealth solutions as a tool to face emergencies. Similarly, the integration of mHealth solutions in care pathways and clinical workflow still needs to be considered and implemented. There is a need to promote training of healthcare professionals to deliver care services through digital solutions.

- **TRENDS IDENTIFIED**

MHealth solutions integrated in regional / national systems for providing a holistic and end-to-end opportunity to manage emergencies, such as epidemics. Remote care pathways using mHealth as interfaces to reach citizens / patients when care cannot be provided physically. The legislative changes introduced during the pandemic to overcome clinical, administrative, and financial barriers facilitated a regulatory enabling environment for mHealth solutions. With COVID-19 and the need to ensure continuity of clinical services, telehealth suffered a boom of usage, which increased the familiarity of citizens and health professionals with these tools. This learning and acceptance can be leveraged to further advance mHealth programmes.

- **RECOMMENDATIONS - Targeted to policy makers & implementers**

From our analysis, the following are the essential elements for activating a health emergency policy:

- Define the actors of the emergency management system which should also include the territory

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- Act by ordinances that force all professionals to be connected to the system to use the digital tool (and strive for the inclusion of the "capable" citizen)
- Creation of micro-processes for the collection of gaps and the implementation of the tools (input from users)
- Centralization of information collection in real time with big data approach
- Data governance and monitoring, checking and decision-making of the interventions to be implemented
- Privacy guarantee
- Attention to the chronic patient who must be monitored / treated at home

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Annex III – Country Interview Guideline

Introduction

This interview guide is structured according to the policy cycle (formulation, adoption, implementation, monitoring / evaluation); the 8 selected policy areas are embedded in the policy cycle.

The Semi-structured interview based on the mHealth Policy Framework and prioritised mHealth policy areas is meant to provide inputs for the formulating of questions for primary research under each of the 8 policy areas.

Four sections structure thus the policy cycle that underpins this guideline:

(1) *Formulation:* Definition, discussion, acceptation or rejection of feasible courses of action. Definition of the structure, goals and cost of the policy. Impact assessment.

(2) Adoption: This phase focuses on the governance, regulatory and legal actions put in place to guarantee the adoption of the policy.

(3) Implementation: Identification of the actors involved in the implementation plan and overall implementation governance structure, Operational integration with health and eHealth objectives and policies, availability of resources dedicated and referentials.

(4) Monitoring and evaluation: Assessing effectiveness and success, did unpredicted effects occur?

The questions listed in each section are meant to guide the interviewer covering all identified angles.

For countries with no obvious dedicated mHealth strategy, it is proposed to use a simplified template to guide the interview. In this case, the template needs to be used more as a reference check-list than a list of topics to be discussed in a specific order.

Section 1. Policy formulation

- Do you have a dedicated mHealth strategy in your country / region? (draft, adopted) ? If not, is mHealth considered in other (more general) health policies or strategies?
- What for?
    - What was the policy gap or new requirement that was identified, and which was addressed by the need for new policy instrument(s)? *Imaginary example: to permit health professional responsibilities to be "delegated" to patients*
    - Was there a previous policy obstacle that had to be overcome? *Imaginary example: if reimbursement was only permitted for in person clinical contacts*
- How was it originally described? (what was the official wording used to justify the inclusion of mhealth in the policy:)
- Has it evolved over time? How?

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- Which were the main stakeholders consulted in the policy-making process?
- Does it define the business model to ensure sustainability?
- How is data security and privacy been addressed?
- Is patient empowerment considered / mentioned in some way in the strategy?
- Are user-centric design principles considered / mentioned in some way in the strategy? (participatory approach)
- Are health inequalities due to digital health illiteracy addressed?
- Was the link to innovation support initiatives made? Like digital hubs
- Which were the main stakeholders consulted in the policy-making process?
- Did the policy rely on specific regulations and / or codes of conduct?
- An allocated budget was defined?

Section 2. Policy adoption

- Please describe the policy adoption process?
- How the decision was made public and disseminated?

Section 3. Policy implementation

- How the implementation is governed? Who are the responsible governing structures?
- Any dedicated IT infrastructure?
- How are integration mechanisms towards EHR addressed?
- How is mHealth interoperability addressed?
- How are security and confidentiality aspects addressed?
- How the private sector is engaged?
- Are public-private partnerships in place? (e.g. open innovation policies; precommercial and procurement initiatives).
- Was secondary use of data for innovation purposes part of the policy formulation? How it was done?
- How patient safety is addressed?

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Section 4. Monitoring and evaluation

- What are the policies to assessing the impact of innovations? We want to see if the country has regulated procedures for impact assessment.

Policy cycle	**mHealth policy areas**
Policy formulation	Existence of overall **mHealth strategies and Governance models** for large scale implementation (core of PF) Business models to ensure sustainability Ethical issues; Data security: privacy, confidentiality, integrity and availability. e-Privacy. Users centricity, Well-being and patient empowerment Digital literacy policies (health workforce / citizens) Reimbursement policies: how you reimburse, how you make innovations part of reimbursement schemes Setting up innovation funds Policy and regulatory settings. ICT infrastructure and backend technical infrastructure. Cybersecurity.
Policy adoption	Change Management: How raise awareness, build capacity of all diff stakeholders, from the end users to the professionals to the providers
Policy implementation	Enable **integration** mechanisms towards EHR (connecting mHealth solutions / programs to health systems). Interoperability. Stimulate **innovations**: Engage with the private sector; public-private partnerships (e.g. Open Innovation policies; Precommercial and procurement initiatives). Return on investment Secondary use of data for innovation purposes Secure and safeguard these innovations, so these innovations are not creating harm. Patient safety.
Monitoring and evaluation	What are the policies to assessing the **impact** of the innovations?

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ALTERNATIVE TEMPLATE TO BE USED FOR COUNTRIES WITHOUT CLEAR DEDICATED MHEALTH POLICY

Definition of mHealth	
Medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices.	
Opening questions	
Do you have successful implementations of mHealth? Please describe the use case and champion.	
Policy formulation	
Do you have a dedicated mHealth strategy in your country / region? Please describe the formulation process	
Which were the main stakeholders consulted in the policy-making process?	
Does the mHealth policy tackle the following aspects?	
• Data security and privacy	
• Interoperability	
• Patient empowerment	

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• Usability	
• Health inequalities	
• Secondary use of data	
• Patient safety	
• Business model and financing	
Policy adoption	
Please describe the policy adoption process?	
How the decision was made public and disseminated?	
Policy implementation	
Who does govern the implementation and how?	
Any dedicated IT infrastructure?	
How are integration mechanisms towards EHR addressed?	
How the private sector is engaged?	
Are public-private partnerships in place?	
Monitoring and evaluation	

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What are the policies to assessing the impact of innovations?	

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Annex IV – Policies Considerations for Artificial Intelligence in Health

More and more Artificial Intelligence (AI) is expanding its reach in healthcare, enhancing our human experience, improving diseased diagnosis, the cognitive and behaviour in patients with Parkinson's disease, early assessment of effectiveness of drugs or detection of a life threatening condition, to name just a few. AI has tremendous potential in early diagnosis of cancer and Alzheimer's. It also enables healthcare institutions to work more efficiently, improving treatment outcomes and reducing costs.

AI-driven **innovations** are expected to have a huge impact on the healthcare systems in the near future, that is why there is a need to promote an interdisciplinary, intersectoral approach to developing AI for health. This development should be supported by **policies and regulations** that are able to **keep up with the pace** of **innovations**. This is only possible if all actors and stakeholders in the field collaborate towards democratization of the healthcare process across the globe.

AI has also the **potential** to accelerating research and drug discovery processes, automation of tasks and complex assessments that incorporate a wide variety of decision-making processes. So, policies need to consider the wide range of technical, organizational, and social factors involved in these processes.

Policy can positively impact the uptake of AI in health by standing ahead of the innovation curve.

A collective **interdisciplinary and intersectoral approach** is needed in order to take advantage of the full potential of AI for healthcare. There is a need for development of sustainable networks and partnerships between public, private, research institutes and **communities of practise** in order to came up with best approaches for the adoption of emerging technologies and AI in healthcare.

Policy makers need to look forward and proactively set sound policy directions to maximize the benefits of healthcare delivery based on latest technologies like AI, big data and research, while safeguarding critical privacy rights and safety.

There is a need to determine how to best capitalize on AI opportunities while taking into consideration the risks. Countries should promote a multilateral inclusive discussion on a plan of action that promotes trustworthy AI in health.

The **AI product development** is expected to follow an **Agile**, **human centred approach**, where patients and communities are given the opportunity to get involved early in the development process by providing feedback and participating in the decision making process.

AI relies on massive data sets so regulations should be put in place for **ethical data collection and processing of data**, but also for removing the barriers of access to real-world data. Big quantities of data are required in order to produce a model that is capable of consistently performing in all healthcare environments and the procurement of this data is extremely time-consuming and costly. As described in the Centre for digital health innovation at UCSF[159], gathering sufficiently diverse data to develop a generalizable healthcare AI is a process that could take up to 36 months, so policies and regulations should be put in place to speed up this process and facilitate the access to data for development. Therefore, there is a need for **policies to enable patients and academic medical organizations to leverage their data to accelerate the pace of healthcare AI innovation**.

People should be **empowered** by supportive policies to take ownership of their own health data and be able to control the transfer of their health data to different health care institutions or even contribute their data for research and public common good.

[159] CDHI. *Changing the Data Access Conversation for Healthcare AI*. CDHI, 2021 [webpage]. Available at: https://www.centerfordigitalhealthinnovation.org/posts/changing-the-data-access-conversation-for-healthcare-ai

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The **algorithms** are at the core of AI development and there is a need to put checks in place to ensure they are transparent, explainable and interpretable. In order for them to be applicable in all health care settings, they must also be **ethnical and geographical agnostic**.[159]

Data access should be provided in a privacy-preserving way and protected health data processed in a confidential computing[160] environment in which, according to CDHI[159] and **BeeKeeperAI**[161]

1. *"The data owner's data never leaves their HIPAA-protected environment;*
2. *The data owner's data is never shared nor exposed for attack; and*
3. *The algorithm owner never has to expose their code base or model weights to a third party."*

Data handling in AI systems should be dictated by data privacy policies in order to avoid harmful use of technology.

According to blog post from CHDI[162], AI can offer diagnose functions that goes beyond the capability of knowledge of the clinician. The **AI development relies on vast amounts of data being generated**, collected, processed, and stored and this should be done according to international privacy laws and regulatory requirements. There are also multiple sources of data: physical, social, behavioural, genomic, pharmacological, pathological, biosensor data, private medical data coupled with contextual data like the one evidenced in national responses to the COVID-19 pandemics, but this wealth of data possess a series of challenges that should be addressed to gain the public confidence in the benefits provided to patients. Therefore, a **right balance needs to be maintained between innovation and data privacy.**

Accenture has described AI as "healthcare's new nervous system" [163] with the AI health market expected to experience compound annual growth of 40% per annum. They report that every EHR breached is likely to incur a cost of $355. So, it is extremely important not only to put in place checks to investigate these legislative breaches, but also to ensure the security and the protection of sensitive information in these applications.

New concepts such as confidential computing[162] are emerging in efforts to **protect both the healthcare AI workloads and the Intellectual Property (IP)** contained in these loads. For example, Fortanix solutions provide healthcare organizations with the ability to protect both e-PHI data and the IP contained in AI algorithms, even on untrusted infrastructure. The integrity and encryption of data is done at rest and in memory throughout the runtime of the algorithm. The unencrypted processing happens only in well-defined trusted perimeters, **thus ensuring protection of the healthcare data required by legal frameworks such as HIPAA and GDPR**. **The AI solutions should ensure** complete end-to-end protection of the healthcare data being processed and the intellectual property within the application code deployed in trusted environments.

Policy recommendations in the field of AI are expected to recognize and address the main AI risks and challenges like:

1. **Societal biases.** The AI has the potential to increase the societal biases. That is why the **AI** healthcare systems, in particular those based on decision-making processes, should ensure that no individuals and groups, in particular those vulnerable or marginalized, are not disadvantaged by the results.

2. **Privacy threat.** Policies and regulations are needed in order to **establish and enable the human agency** and help people **build trust** in AI driven innovation for health, improving the health equity and avoiding the increase of digital divide.

[160] Searle, R. Securing Healthcare AI with Confidential Computing. TechNative, 2021 [online]. Available at: https://technative.io/securing-healthcare-ai-confidential-computing/

[161] Kurtzman, L. UCSF, *Fortanix, Intel, and Microsoft Azure Utilize Privacy-Preserving Analytics to Accelerate AI in Health Care*. UCSF, 2020 [webpage]. Available at: https://www.ucsf.edu/news/2020/10/418736/ucsf-fortanix-intel-and-microsoft-azure-utilize-privacy-preserving-analytics

[162] Searle, R. Securing Healthcare AI with Confidential Computing. CDHI, 2020 [online]. Available at: https://www.centerfordigitalhealthinnovation.org/posts/securing-healthcare-ai-with-confidential-computing

[163] Collier, M et al. Artificial Intelligence: Healthcare's New Nervous System. Accenture, 2017 [pdf]. Available at: https://www.accenture.com/_acnmedia/PDF-49/Accenture-Health-Artificial-Intelligence.pdf#zoom=50

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3. **Increase inequality** and generate economic and social disruption which need to be addressed contextually in both developed and developing worlds. Therefore, an **inclusive** approach should be taken towards lower income and rural areas with poor digital services infrastructures or lack of governance and regulations of technologies.

4. **Lack of appropriate skills** for the development and deployment of AI applications, therefore proper **training** should be provided. Trainings in emerging technologies will contribute to raising awareness on AI and levelling up the comprehension of technologies between different communities, healthcare workers, social scientists, policy makers, so they can all identify and tackle these challenges more effectively.

5. **Surveillance and tracking** for monitoring and prediction of health outbreaks should be done in a responsible way by collecting, analysing and processing reliable data and information, without intrusion into people's private life.

Ethical challenges to AI are highlighted in a June 2021 **WHO Report**[164] that should be taken into account when providing **policies recommendations for AI**:

- Assessment of whether AI should be used
- AI and Digital divide
- Data collection and use. Ensure the appropriate use and collection of health information by public, private sectors and researchers.
- Accountability and responsibility for decision-making with AI
- Autonomous decision-making
- Bias and discrimination associated with AI
- Risks of AI technologies to safety and cybersecurity

The report also contains a set of recommendations on governance of AI that falls under the responsibility of both public and private sector. The IDRC white paper "Artificial intelligence and human development"[165] acknowledges the need for an **ethically and equitably implementation of AI** particularly in developing countries.

The need for **standardization in AI** is recognized worldwide. The US Federal Engagement paper[166] states the need for developing regulatory policies for:

- Standardized development of AI
- Support and conduct AI research and development
- Actively engagement of different communities in AI standards development
- Procuring and deploying standards-based products and services

Efforts in standardization of AI for heath are being undertaken by international organization like ITU and WHO through the Focus Group on "Artificial Intelligence for Health"[167]. This group aims at establishing a standardized assessment framework for the evaluation of AI-based solutions for health, diagnosis, triage or treatment decisions.

At the **European level**, the **OECD AI Policy Observatory**[168] is worth mentioning as a unique platform of information and dialogue on AI. The **OECD AI Network of Experts' research** came up in May 2019 with a set of AI principles towards a human

[164] WHO Health Ethics & Governance Team. Ethics and governance of artificial intelligence for health. WHO, 2021, ISBN: 9789240029200. Available at: https://www.who.int/publications/i/item/9789240029200

[165] Smith, M; Neupane, S. Artificial intelligence and human development: toward a research agenda. White Paper. IDRC, Canada, 2018. Available at: https://idl-bnc-idrc.dspacedirect.org/handle/10625/56949

[166] NIST. U.S. Leadership in AI: A Plan for Federal Engagement in Developing Technical Standards and Related Tools. Prepared in response to Executive Order 13859. Submitted on August 9, 2019. NIST, 2019 [pdf]. Available at: https://www.nist.gov/system/files/documents/2019/08/10/ai_standards_fedengagement_plan_9aug2019.pdf

[167] More information on the Focus Group on "Artificial Intelligence for Health" can be found at the following webpage: https://www.itu.int/en/ITU-T/focusgroups/ai4h/Pages/default.aspx

[168] More information on the OECD AI Policy Observatory can be found in the following webpage: https://oecd.ai/en/

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centred, trustworthy and responsible approach in AI. There are five recommendations[169] to policy makers contained in these **OECD AI Principles**:

1. Invest in AI R&D;
2. Foster a digital ecosystem for AI;
3. Shape an enabling policy environment for AI;
4. Build human capacity and preparing for labour market transformation
5. Foster international co-operation for trustworthy AI

The June 2021 OECD report[169] reflects on the state of implementation of the policy recommendations to governments. The practical implementation of AI policies is envisaged throughout a cycle of design, implementation, intelligence, and approaches for international and multi-stakeholder co-operation on AI, as detailed below:

- Policy design: advice for national AI governance policies and approaches;
- Policy implementation: national implementation examples to illustrate lessons learned to date on aspects related to data, software, regulations, testbeds, standards and codes of conducts, tools for trustworthiness, capacity building, skills and training;
- Policy intelligence: evaluation benchmarking and monitoring of the policy implementation and;
- An overview of AI actors and initiatives at the international level with approaches to international and multi-stakeholder co-operation on AI policy.

The report presents a conceptual framework, provides findings, identifies good practices, and examines emerging trends in AI policy, particularly on how countries are implementing the AI policies recommendations. The report builds both on the i) expert input provided at meetings of the OECD.AI Network of Experts working group on national AI policies that took place online from February 2020 to April 2021, and on ii) the EC-OECD database of national AI strategies and policies. The report also provides insights from National AI policies[170].

The latest AI policy research taking place in different policy communities across the OECD and beyond can be found on the following link: https://oecd.ai/en/policy-areas

Efforts were being made by the **EC and OECD** to analyse emerging trends in European Artificial Intelligence: skills, ethics, data protection, research and innovation[171], to examine how national AI policies are being implemented, as well as key trends and lessons learned.

The **EC** set up the AI Watch[172] project to support the implementation of the **Coordinated Plan on AI**, a joint initiative with the Member States. The EC's latest AI Watch report is part of an ongoing effort to **monitor national AI strategies of EU Member States, Norway and Switzerland**. The 2021 edition of the report "National Strategies on Artificial Intelligence: A European Perspective"[173], suggests that AI national strategies should focus on:

- Strengthening AI education and skills,

- Supporting research and innovation to drive AI developments into successful products and services,

[169] OECD. STATE OF IMPLEMENTATION OF THE OECD AI PRINCIPLES. INSIGHTS FROM NATIONAL AI POLICIES. OECD Digital Economy Papers, July 2021, No 311. Available at: https://www.oecd-ilibrary.org/science-and-technology/state-of-implementation-of-the-oecd-ai-principles_1cd40c44-en

[170] OECD.AI. National AI Policies & Strategies. OECD.AI [online]. Available at: https://oecd.ai/en/dashboards

[171] Knowledge for Policy. Emerging trends in European Artificial Intelligence: skills, ethics, data protection, research and innovation. [online]. EC, 2021, Available at: https://knowledge4policy.ec.europa.eu/news/emerging-trends-european-artificial-intelligence-skills-ethics-data-protection-research_en

[172] Knowledge for Policy. AI Watch. Monitor the development, uptake and impact of Artificial Intelligence for Europe. EC [online]. Available at: https://knowledge4policy.ec.europa.eu/ai-watch/about_en

[173] Van Roy, V., Rossetti, F., Perset, K. and Galindo-Romero, L., AI Watch - National strategies on Artificial Intelligence: A European perspective, 2021 edition, EUR 30745 EN, Publications Office of the European Union, Luxembourg, 2021, ISBN 978-92-76-39081-7, doi:10.2760/069178, JRC122684. Available at: https://publications.jrc.ec.europa.eu/repository/handle/JRC122684

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- Improving collaboration and networking,
- Creating a regulatory framework to address ethical and legal issues, and
- Establishing a cutting-edge data ecosystem and ICT infrastructure.

The report also provides an overview of national competence centres in AI research and outlines **policies to promote data access and sharing**, as well as initiatives to stimulate the use of AI in public services. It also highlights policies on regulatory 'sandboxes', which allow for experimentation in real-life conditions while reducing barriers to test innovations.

The two reports from the EC and OCED mentioned above leverage the joint EC-OECD database[170] of over 650 national AI policies and strategies from over 60 countries and the European Union. In 2021, the database was expanded to include emerging trends in AI policy, use cases in the public sector, COVID-19 responses that include AI and policies to foster AI skills and talent.

From the above, it is possible to draw the conclusion that AI policies should address topics like:

- Incentivizing the adoption of standardized AI
- Data sharing agreements and Integrated consent forms
- Protection of sensitive information and putting in place checks to investigate legislative breaches
- Building infrastructures for secure transfer of EHRs between health care providers
- Encourage best practices for AI research and safe access to health data
- Protect vulnerable populations

According to the **AI dialogue of G20 from 1-2 April 2020**[174], AI has the potential to help achieve the **UN Sustainable Development Goals (SDGs)**. The report states the policies efforts to address the AI potential of achieving the SDGs.

The **G20 AI Principles** are :

- Inclusive growth, sustainable development and well-being;
- Human-centred values and fairness;
- Transparency and explainability;
- Robustness, security and safety; and
- Accountability.

All these are important pillars to foster innovation and trust in AI while ensuring respect for human rights and democratic values.

In **US**, the recommendations and Actionable Opportunities from the February 2019 "Executive Order on Maintaining American Leadership in Artificial Intelligence" are were mentioning. It outlines a number of **strategic objectives** for developing AI, such as[175]:

- *"Promote sustained investment in AI R&D in collaboration with industry, academia and international partners"*
- *"Enhance access to high-quality and fully traceable federal data, models, and computing resources to increase the value of such resources for AI R&D, while maintaining safety, security, privacy, and confidentiality protections consistent with applicable laws and policies."*

The paper also emphasizes the need for **standardization** as means to minimize vulnerability to attacks from malicious actors, increase public trust and confidence in systems that use AI technologies.

[174] OECD. Trustworthy AI in health. Background paper for the G20 AI Dialogue, Digital Economy Task Force. Saudi Arabia, 1-2 April, 2020. OECD. [pdf]. Available at: https://www.oecd.org/health/trustworthy-artificial-intelligence-in-health.pdf

[175] CODE. Sharing and Utilizing Health Data for AI Applications. Roundtable Report. The Center for Open Data Enterprise, 2019 [pdf]. Available at: https://www.hhs.gov/sites/default/files/sharing-and-utilizing-health-data-for-ai-applications.pdf

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In 2018, EC as part of a 2030 vision for Healthcare provides this summary of Policies recommendations on how responsible innovation can lead to a healthier society.[176]

- *"Address organizational and technical barriers to data sharing and data use: Promote the use of open standards to better enable technical interoperability and explore opportunities to create greater incentives for data sharing across organizations.*

- *Enable new technical solutions such as blockchain to improve data provenance, health information exchange and collaboration. Continue EU funding in digital health solutions to enable exchange of health information, and data provenance, including for PROMs.*
- *Address insufficient public trust and the need for a regulatory framework that promotes more access to and use of patient data for research purposes, while addressing privacy and security concerns: Analyse the implementation of research provisions under the GDPR in Member States, and where needed, amend laws or create more clarity through interpretations and guidance, to ensure innovative research projects don't die on the vine.*

- *Demonstrate the value of a 'data commons' and build confidence in all stakeholders through visibility of success stories where data sharing and technological innovation have improved health outcomes. Explore and promote new models for data donation that encourage patients to more easily enable their data to be used for beneficial research purposes. Invest in technical solutions, including through research funding, to enable secure machine learning with multiple data sources / systems. Support commonly used global standards for the controls in national certification schemes for handling of patient health information and promote GDPR harmonized EU-wide certifications and accreditation schemes.*

- *To address the lack of clear rules, or even a tentative discussion framework, governing the ethical and social implications of the growing use of AI and patient data in the field of healthcare: Utilize emerging frameworks that will help ensure AI technologies are safe and reliable, promote fairness and inclusion and avoid bias, protect privacy and security, provide transparency and enable accountability. Invest in more research to explore and enhance methods that enable intelligibility of AI systems. Advance a common framework for documenting and explaining key characteristics of datasets".*

In a recent report from November 2021 on national strategies for AI[177], it was found that there are no specific policies around AI for health adopted by Members States yet, merely proposals of regulatory frameworks around health data. The main barriers are lack of trust in AI-driven decision support, the complexity of integration of new technologies into current practices, lack of awareness and the variety of start-up ecosystems composed primarily by private industry and some supportive networks.

EC also suggests the following Policy Areas to support the development and adoption of AI technologies:

1. a policy and legal framework supporting the further development and adoption of AI aimed at the healthcare sector in particular;
2. initiatives supporting further investment in the area;
3. actions and initiatives that will enable the access, use and exchange of healthcare data with a view to using AI;
4. initiatives to upskill healthcare professionals and to educate AI developers on current clinical practices and needs;
5. actions addressing culture issues and building trust in the use of AI in the healthcare sector;
6. policies supporting the translation of research into clinical practice.

An analysis of the relevant legislation and policy framework around AI is provided for some Member States like Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Latvia, Lithuania,

[176] Floridi, L et al. Healthcare, Artificial Intelligence, Data and Ethics – A 2030 Vision. How responsible innovation can lead to a healthier society. 2018, [pdf]. Available at: https://www.digitaleurope.org/wp/wp-content/uploads/2019/02/Healthcare-AI-Data-Ethics-2030-vision.pdf

[177] EC. Artificial Intelligence in Healthcare report. [online] Available at: https://digital-strategy.ec.europa.eu/en/library/artificial-intelligence-healthcare-report

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Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden. Future activities to promote the adoption of AI for health are expected to be taken by the healthcare sector itself.

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Annex V – WP5 Interdependencies with other Work Packages

D5.1 provided important key strategic elements that feed the loop for the several activities of the Hub project. For instance:

- **WP5 – WP4**: D5.1 is currently being used to provide key recommendations for the Country Assistance activity of WP4. In this regard:
    - In the workshop *Hungary Scoping Workshop ICT technology & infrastructure* held on 11th November 2021, a policy perspective was provided when presenting *The mHealth Landscape to support patients living with diabetes – analysis and recommendations*.
    - On the 20th January 2022, D5.1 will be used to develop a tailored presentation for the on-going activities to support Czech Republic. This work will be published within WP4.

- **WP5 – WP2:** An ongoing dialogue and feedback loop was promoted between WP2 and D5.1 working groups. These working groups had shared elements which allowed an overview of the activities that were taking place in the different WPs. Thus, on the one hand, D5.1 provided a policy perspective for WP2 activities; and, on the other hand, WP2 assisted in analysing the policy ecosystem, and in identifying case studies for Annex II.

Coordination of activities:

- Activities were coordinated with the **communication and dissemination** working group for its proper management and dissemination.
- The coordination team also promoted internal meetings for the identification of interdependencies between the different WPs.

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