Knowledge Tool 3: integration of mHealth in health systems

Deliverable 2.3

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Note: beyond this final report, a KT3 specific section has been developed on the Hub website

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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This deliverable contains original unpublished work except where clearly indicated otherwise.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

AI	Artificial Intelligence
API	Application Programming Interface
BHBM	Be He@lthy, Be Mobile
BMC	Business Model Canvas
CDW	Clinical Data Warehouses
CDSS	Clinical Decision Support System
CIMs	Clinical Information Models
EHR	Electronic Health Record
EIP on AHA	European Innovation Partnership on Active and Healthy Ageing
EU	European Union
FHIR	Fast Healthcare Interoperability Resources (HL7)
GDM	Gestational Diabetes Mellitus
GDPR	General Data Protection Regulation
HIV	Human Immunodeficiency Virus
HL7	Health Level 7
ICT	Information and Communication Technologies
ISO	International Organization for Standardization
IT	Information Technology
ITU	International Telecommunication Union
KT3	Knowledge Tool 3
M&E	Monitoring and Evaluation
MMA	Mobile Medical Applications
NGOs	Non-Governmental Organizations
ODMs	Open Data Models
PCP	Pre-Commercial Procurement
PGHD	Patient Generated Health Data
PREMs	Patient reported experience measures
PROMs	Patient reported outcomes measures
PROMIS	Patient Reported Outcomes Measurement Information System
SMS	Short Message Service

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TEHDAS	Joint Action Towards the European Health Data Space
US NHI	United States - National Institutes of Health
WHO	World Health Organization

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1. Purpose

This guide represents a comprehensive collection of relevant experiences and approaches to implementing mHealth solutions in existing health systems. The experiences have been collected by the European mHealth Hub with a specific focus on elaborating the lessons learnt and the success factors which can be followed by anyone interested in implementing mHealth solutions. Implementation topics are structured to allow easy navigation and to enable the reader to focus on those aspects of the implementation which are of most interest.

2. Methodology

The information gathering for KT3 is based on different sources (Figure 1) such as own initiatives that were provided by mHealth Hub members since October 2019 as well as by an open call in July 2020 addressed to national and regional health systems, desk research as well as structured interviews carried out by Hub partners in the period between December 2020 and January 2021.

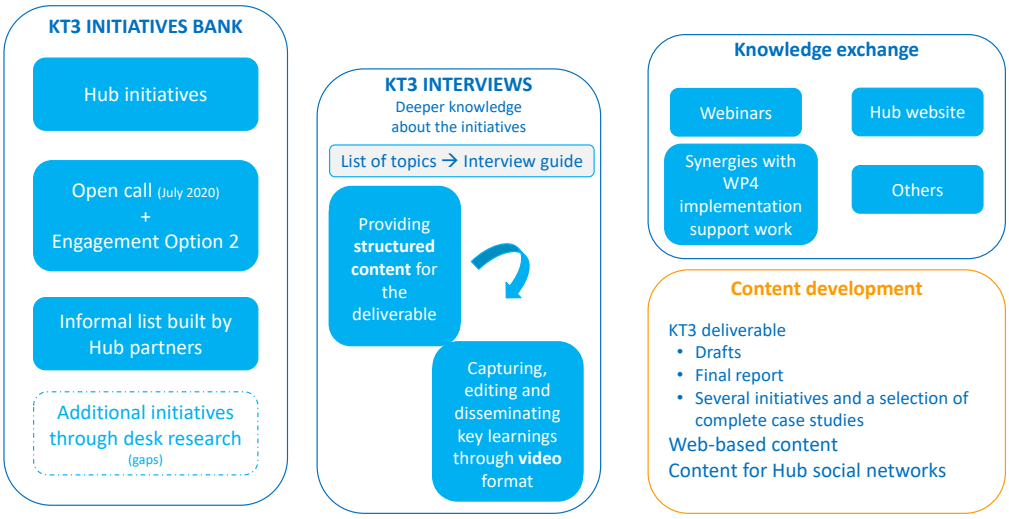

Figure 1. *KT3 overview*

A **guide approach** is used to enable prospective readers to understand the process of implementation of mHealth solutions into their own health system.

How to read this guide

There is no "one size fits all" or a generic approach to implementing mHealth solutions into healthcare systems due to various reasons, such as difference in the healthcare systems of countries and regions, the underlying infrastructure differences and use of legacy systems, etc. However, based on the Hub's exploration of different successful mHealth implementations undertaken throughout Europe, it can be observed that most documented experiences are following a project or process-oriented approach to the implementation. Therefore, for this guide the Hub has adopted a similar approach to categorise and represent different experiences.

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3. Steps for mHealth integration in health system

From a project or process point of view, the implementation of mHealth solutions into the healthcare system can be grouped into four stages (Figure 2):

- **Initiation**: focused on carrying out activities related to enabling a strong foundation for the success of the implementation, such as securing the necessary buy-in and understanding the conditions for success, as well as the environment and the different stakeholders that will ensure that success.

- **Planning**: related to defining the scope of the implementation, setting up a workplan and ensuring all necessary resources are available to carry out the implementation.

- **Execution**: carrying out the implementation, which may involve technical implementation, testing, end-user engagement, etc.

- **Monitoring and evaluation**: ensuring that the mHealth solution is performing as planned and is delivering the desired value and expected impact.

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Figure 2 *Steps for integrating mHealth into health system*

Under each stage, different topics of interest are defined and real-life successful approaches to addressing those topics are provided. Due to the nature of some topics, which may be relevant for several stages (e.g. end-user involvement), they have been assigned to a specific stage. However, in line with the diverse approaches available, it should be noted that the approach used by the Hub does not imply that all topics of interest should be addressed to achieve an implementation, or that there is a specific sequence for topics to be addressed within a given stage.

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3.1. Initiation

This stage is focused on carrying out activities related to enabling a strong foundation for the success of the implementation, such as securing the necessary buy-in and understanding the conditions for success, as well as the environment and stakeholder that will ensure that success.

NEEDS ASSESSMENT

PROEMPOWER is a Pre-Commercial Procurement (PCP) co-funded by the Horizon 2020 programme, which aims to procure a mobile health solution for **self-management** to help address the looming threat of **Type 2 Diabetes Mellitus**. The four participating procurers are: the Turkish Ministry of Health; Murcian Health Service (S*ervicio Murciano de Salud*), Murcia, Spain; Shared Services of the Ministry of Health *(Servico Partilhados do Ministerio de Saude)*, Portugal; and Hospital Universitario Federico II / Regional Health Society (*Società Regionale per la Sanità SpA)*, Campania Region, Italy. The objective is to carry out the development and testing of pilot systems in 4 pilot sites to achieve an early identification of Diabetes together with a shared care plan, personalised treatment and remote monitoring as well as coaching and promotion of healthier lifestyles. Cooperative diabetes support (peer-to-peer support) is not forgotten, as well as training for diabetic patients so that they can learn more about their disease and achieve a better quality of life. This project does not rely on technology, but clearly responds to the specific needs of patients and healthcare professionals in the provision of effective healthcare services.

Learn more: https://mhealth-hub.org/proempower

The ***Mangols Journey*** is an application developed for the **treatment of overweight and obesity** in patients aged **7 to 14** years. Its use is fully integrated with the EHR of *Osakidetza*-Basque Health Service, and combines technology achievements and knowledge from healthcare professionals. The main pillars are serious play, motivational consultations and integration with the EHR. It is designed to be used by different professionals in all healthcare settings. It does not only work on physical and emotional health, but also empowers patients and families, promoting change and improving effective consultation time. It is planned to be implemented throughout the organisation in 2021.

Learn more: https://mhealth-hub.org/the-mangols-journey

If you know any other recent experiences or publications that might be relevant for this topic, please contact us by email info@mhealth-hub.org

STAKEHOLDER AND POLITICAL SUPPORT

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Heilsuvera.is is Iceland's **national health portal**. The Directorate of Health in Iceland developed the portal in collaboration with the Primary Health care of the capital area and a national IT service company (main vendor for EHR in Iceland). They also contributed to the funding.

Fully operational national portal with 100% of primary health care providers using the portal. Furthermore, some of the private practise doctors are using the portal for eBooking. Moreover, implementation has started at the hospital level.

The portal offers citizens and patients an access point for appointments at primary health care and some private practice doctors. It provides people with a platform for secure communication with healthcare providers, vaccinations, medication renewal request, medication history, maternal health record, medication history, organ donation and many other functionalities.

Learn more: https://mhealth-hub.org/heilsuvera-is

The ***Imagine Care*** platform offers different clinical pathways, especially for people with **chronic diseases**. The solution consists of two applications. The app offers patients simple and effective support to take control of their health conditions from home. The healthcare professional web application helps healthcare professionals to standardise and facilitate self-care and communication with their patients who have long-term health problems. Healthcare staff receive automatic notification in cases where reported health values indicate that self-care is not working, and can provide personalised self-care support to the patient via chat, phone or video. The nursing staff can, together with the automated system, guide patients to manage their challenges.

Learn more: https://mhealth-hub.org/imagine-care

The ***TreC Diabetes*** application aims to implement a new organisational asset for the management of patients with **type 1 and type 2 Diabetes**, supported by new technologies. Its main target is **pregnant women** affected by Diabetes, including Gestational Diabetes Mellitus (GDM). The app includes a messaging system to facilitate communication with healthcare staff and an artificial intelligence component that enables a virtual coaching system to support healthy lifestyles and behavioural changes. Healthcare staff members (nurses and doctors) can follow up patients through the online medical dashboard. Thanks to this, communication between patients and healthcare staff has improved considerably, as well as the quality of patient follow-up and management. *TreC Diabetes* has been piloted and fine-tuned from 2015 to 2018 and associations/NGOs have been involved in the design and piloting of the application.

Learn more: https://mhealth-hub.org/trec-diabetes

Examples of literature findings

Healthcare is an environment that has been experiencing dramatic progress in computing technology in order to process and distribute all relevant patient information electronically and overall to improve the quality of care. In particular, mobile health (mHealth) involves a spectrum of information and telecommunication technologies to provide healthcare services to patients.

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Mobile applications are an increasingly important technology for improving the quality of health services especially at the point of care. They enable the formation of virtual teams of care, and timely, effective and quality patient management are the expected outcomes. The role of stakeholders in supporting such innovative applications is vital. The exploration of roles of diverse stakeholders in a mobile health application involving virtual multidisciplinary teams of care is a prerequisite. Diverse stakeholders get involved in different stages of the project implementation and may experience different degrees of knowledge about the system itself, its significance and novelty.

Petersen, Adams and DeMuro[1] describe the importance of identifying the relevant stakeholders and how they might be affected by mHealth interventions. They divide stakeholders into two major groups, primary and miscellaneous secondary stakeholders. Primary stakeholders are patients, formal and informal caregivers, clinicians, healthcare facilities, researchers, payors, purchasers and employers. Secondary stakeholders are vendors, suppliers, distributors, consultants, policy makers and legislators.

LEGAL AND REGULATORY ANALYSIS

The data generated by mHealth solutions might have legal and regulatory concerns regarding data ownership and data use. Regulatory initiatives such as the European Union's General Data Protection Regulation (GDPR) are currently being enforced, however, a unified approach is still missing. With an increasing number of consumers using mobile phones, and therefore also engaging in mHealth, the need for legally secure guidelines is crucial for further progress.

Examples of literature findings

Petersen and DeMuro[2] define common forms of patient-generated health data (PGHD) and describe how PGHD are used in a clinical setting. They raise the issues related to the protection of personal health information, data security, and other potential barriers such as physician licensure. Furthermore, the authors discuss regulatory and legal considerations, that providers and patients should review before using social media and mobile health apps. They suggest that the development and use of standards for data representation and transmission is a key factor, needed to create a secure environment necessary for such apps. According to their work, mobile app developers and providers need to be transparent about the data ownership and data use policies. This would allow patients to make informed decisions based on their needs.

The review of mHealth apps by Nurgalieva et al.[3] summarises recent research related to the areas of security and privacy. The aim is to support researchers, app designers, end-users, and healthcare professionals in designing, evaluating, recommending and adopting mHealth apps. The authors see clear and valid methods for evaluating the data practices within mHealth apps as crucial. At the moment, it is challenging to navigate this space and to choose appropriate techniques for a given context. They identified critical moments of the mHealth app lifecycle at which specific evaluation techniques could be applied. According to the authors, future research should focus on embedding these tools into the digital health development process.

[1] https://mhealth-hub.org/mhealth-dont-forget-all-the-stakeholders-in-the-business-case
[2] https://mhealth-hub.org/legal-and-regulatory-considerations-use-of-patient-generated-health-data-from-social-media-and-mhealth-devices
[3] https://mhealth-hub.org/security-and-privacy-of-mhealth-applications-a-scoping-review

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An extensive review by Mezarina et al.[4] focuses on mHealth apps created and used in Peru. The study raises concerns related to the quality of information that the apps share, data security and privacy, usability, and effectiveness. Currently, there are no local regulations concerning the creation and use of mHealth apps. In total 66 apps meeting their inclusion criteria have identified. From the 10 most used mHealth apps in Peru, almost half of them gathered user information that could be leaked, changed, or lost. This poses a great risk to the end-users. Additionally, 6/10 (60%) of these apps did not mention the source of the information they provide. This seems to be a major issue and poses an urgent need for the development of a regulatory framework based on existing medical device and health information system norms.

Finally, the European mHealth Hub has developed *A Quick Guide to the GDPR*, that can be consulted here

SCOPE AND RESOURCES

The ***mSaúde Platform*** (Galician Public Procurement of Innovation Solutions (PPI) innovation project for patient empowerment), has a successful approach for initiation and execution stages both in scope of resources, its integration with eHR, as well as in testing and validation of the solution. Its flexibility is highlighted as a main feature to allow the adaptation of the tool to the evolution of the evaluation process. The involvement of interested and highly specialised health professionals in the evaluation process is also essential.

Learn more: https://mhealth-hub.org/msaude-platform

If you know any recent experiences or publications that might be relevant for this topic, please contact us by email info@mhealth-hub.org

MHEALTH OPPORTUNITIES

Comprehensive Medication Management Services: as part of their participation in the initiative EIP on AHA, a Croatian delegation visited two Spanish regions (Andalusia and Galicia) to learn more about their health systems and good practices. Having in mind the positive effects of the application of new IT technologies on those contexts, Dom zdravlja Zagreb - Centar and MCS Grupa d.o.o. launched in 2017 a pilot project Zdravlje.net PRO which enabled electronic consultations between doctors of the Health Center, hospital specialists and pharmacologists.

Because they are based on the principle of "information travels, the patient stays", electronic consultations led to significant time and financial savings for patients, doctors and the entire healthcare system, while increasing the standard of healthcare because they made specialist services more accessible.

Learn more: https://mhealth-hub.org/comprehensive-medication-management-services

Examples of literature findings

[4] https://mhealth-hub.org/need-for-the-development-of-a-specific-regulatory-framework-for-evaluation-of-mobile-health-apps-in-peru-systematic-search-on-app-stores-and-content-analysis

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The book "m_Health Current and Future Applications" (Andreoni et al., 2019) describes current trends in mHealth technology, systems, and applications. The book proposes a multifaceted view on mHealth opportunities and requirements starting from four aspects: patient, technology, design and innovation. The analysis is completed by a market segmentation overview and by the most recent research experiences to offer a complete benchmark and vision of mHealth for today and tomorrow. The contributions are based on the outcomes of initiatives on the future of healthcare, funded by the EU in the frame of FP7 and Horizon 2020 and their deployment into real clinical practice. Throughout the book, clinicians, technicians, researchers, and end-users debate their experience, needs, risks, opportunities, and available solutions in this fast-moving field, which can be inspiring for others.

In the mental health field, Marzano et al (2015) discussed in a report the potential of the new mobile digital technologies to transform mental health research and clinical practice. By drawing on results from the INSIGHT research project, they showed how traditional boundaries between research and clinical practice are becoming increasingly blurred and how, in turn, this is leading to exciting new developments in the assessment and management of common mental disorders. Furthermore, they discussed the potential risks and key challenges associated with applying mobile technology to mental health.

The E-Medicine, E-Health, M-Health, Telemedicine, and Telehealth Handbook is a two-volume set written by leading experts and researchers in their respective fields. The second volume, '*Telehealth and Mobile Health*', edited by Eren and Webster (2016), explains, among other things, how the use of new technologies brings many businesses, management, and service opportunities. Moreover, it incorporates clinical applications throughout for practical reference.

Grekin et al. (2019)[5] describe in their article that when using mHealth interventions, common relationship factors such as empathy, positive regard, and genuineness may play a critical role in therapy effectiveness. There are more than 100,000 iPhone and Android apps specifically designed to target health-related behaviours. Barriers related to language, location and time make mHealth interventions easy applicable to nontreatment-seeking persons. These individuals accept a minimal, opportunistic intervention but refuse extended, in-person treatment. On the other hand, some concerns arise regarding the efficiency of the mobile intervention with the absence of therapist-client relationship. Another field of potential opportunities is the Electronic Coach and Relational Agent**.** This kind of electronic/mobile interventions are computerized interventions that may be more effective when coupled with human support. Additionally, the use of mobile interventions as a platform for testing relation factors shows methodological advantages.

In the confidential sexual and reproductive health services (SRH) field, Brandt et al. (2021)[6], describe the organisational barriers to adolescent access to high-quality, low-cost SRH. Given that Federally Qualified Health Centers (FQHC), a type of community health center, are a critical source of health care for medically underserved adolescents, they often lack the capacity and resources to provide specialised SRH services to adolescents. A set of six initiatives are presented in the article with the scope to improve adolescent SRH services at an FQHC. Some of these may be potentially related with future mHealth interventions and solutions.

[5] https://mhealth-hub.org/mobile-health-interventions-exploring-the-use-of-common-relationship-factors

[6] https://mhealth-hub.org/addressing-organizational-barriers-to-adolescent-access-to-high-quality-sexual-and-reproductive-health-services

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3.2. Planning

This stage is related to defining the scope of the implementation, setting up a workplan and ensuring all necessary resources are available to carry out the implementation.

WORKPLAN DEVELOPMENT

One of the first steps in the planning stage is to develop a comprehensive and detailed work plan.

Before developing the methodology to create an effective plan, it can be useful to define some relevant nomenclature. Goals, strategy, objectives and tactics are terms that are often used interchangeably. However, each of them has a specific meaning, being the final goal to create a step-by step worksheet (workplan).

- A **work plan** represents the formal road map for a project. It should clearly articulate the required steps to achieve a stated goal by setting demonstrable objectives and measurable documents or deliverables that can be transformed into concrete actions. An effective plan serves as a guiding document, enabling the realization of an outcome through efficient team collaboration.
- **A goal** defines what you are trying to achieve and represents the mission concept.
- **Strategy** defines the broad strokes that will help achieve that goal. For example, one strategy to make a company more profitable might be to reduce costs or enhance the product offering to increase total addressable market.
- **Objectives** are the measurable deliverables defined against strategies. Setting clear measurable and realistic objectives can help prioritize and track the progress of the operational plan.
- **Tactics** represent the specific checklist of techniques employed to achieve the demonstrable objectives.

Prior to creating a detailed plan, the preliminary steps might involve one or more meetings with key stakeholders to identify individual strategies and tactics to support the key objectives.

On the other hand, planning activities can be accomplished by working backward from the final goal with core initiatives arranged hierarchically.

A good practice about workplan development is ***Mugitzen***, mobile app developed for nurses, that started as pilot idea in 2013, with identification of needs and stakeholders analysis. A solicitation document was drawn up, with an external company and five mobile applications. An architecture was established to see how these applications could work on a large scale; it was seen to be viable and a tender was issued and awarded to a company. The first milestone was the implementation of those five applications in production for all users in the hospitalization area.

The portfolio of services has been extended to other areas beyond hospitalization, also at home, and accessible via the internet. In May 2020, tablets were deployed for Primary Care and Home Care. The apps were adapted to work in these areas: apps for constants, extractions, and medication for home hospitalization (under development). The app for devices and wounds is currently being adapted for the home environment and a specific app has been developed to cover priority needs in home care.

Learn more: https://mhealth-hub.org/mugitzen

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Other examples from desk research for further guidance can be found here by clicking on the specific topic.

CREATING PARTNERSHIPS

While the resources, evidence, and financial support for the implementation of any mHealth solution will undoubtedly vary between countries and medical systems, there are shared challenges and themes to be considered.

Therefore, recognizing and addressing common needs and involving all relevant stakeholders and addressing the needs not of a single organization or single perspective (e.g. medical staff) is of crucial importance for the sucessful implementation.

Participation of regulators (e.g. Ministry), app developers and ICT/AI experts, medical staff, patients and interest groups has to be establihsed. Based on the cases gathered by the European mHealth Hub, formal partnerships should be established early on, especially between regulators, developers and medical users in order to prevent problems such as long certification or approval process for the given solution.

Examples come from **ORCHA**, UK based organization, that made its goal to make digital health reality, through numerous partnership agreements established among various stakeholders.

Our Dorset is a partnership of health and social care organisations working together to deliver Integrated Care Systems. The initative holds the ambition for 750,000 residents in Dorset to lead healthier, fulfilling lives supported by sustainable health and care services. They established a 'digitally-enabled Dorset programme' to increase the use of technology in the health and care system. To understand more about if and how health professionals could recommend the use health apps and what would be needed to support them, a pilot was run with 20 nurses. This revealed the team didn't know where to find good health apps, how to know if they could trust them, if they met policy or who to ask for advice. Without the expertise to establish a closed-loop quality assured programme, or capacity to be able to test health apps, the team recommended partnering with ORCHA.

Commenting on the programme Crystal Dennis, Interim Lead for Public Facing Digital Health Services, Our Dorset Digital said:

> "*ORCHA power our health app library. They help us to break down the barriers and mitigate issues around digital health. Previously our clinical leads didn't recommend digital health technologies as they had no idea where to look, were concerned about implied liability and couldn't tell if a technology was of a good standard. Thanks to ORCHA we are building the trust with clinical teams and have put in place the tools and governance they need*".

Another example is ***Staffordshire County Council***, the top-tier local authority for the county of Staffordshire, England.

Part of the Council's work includes offering advice, support and care for health and wellbeing, to keep residents well and staying healthy. **Staffordshire County Council** decided to develop mobile health solutions, so the Public Health team conducted research, looking at the market and what services are available on G-Cloud. The team eventually engaged ORCHA to enable the Council to connect people with reviewed and trusted health an app care apps, and to integrate these into its lifestyle services. They worked jointly on identifying the most important health challenges its residents face, then identified and mapped the most effective apps to each of these through ORCHA review process.

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An App Library was then built tailored to the Council's branding and health priorities. A carousel of pre-prepared searches for each of the priority health areas was included. ORCHA Pro Accounts were also added to the library https://www.staffordshire.gov.uk/appfinder, which would enable staff to logon to their own account, keep a favourites list of their preferred apps, recommend apps via email or text to residents, and keep a track of who has been recommended an app and if they have downloaded it.

After two months of development, the programme was ready, a training programme was rolled out across Adult Social Care teams, social prescribing teams, the local NHS Trusts, and the information services within libraries. This enabled teams to start recommending apps to service users. Learn more: https://mhealth-hub.org/orcha-and-our-dorset-digital and https://mhealth-hub.org/orcha-and-staffordshire

The above examples show that establishing right formal partnership can speed the process and create effective mobile health solutions in a shorter period of time.

Other examples from desk research for further guidance can be found here by clicking on the specific topic.

TECHNICAL INFRASTRUCTURE REQUIREMENTS

One of the main challenges that has to be addressed when developing mHealth solutions is technical infrastructure and future needs. These include several infrastructural challenges that have to be identified and assessed such as: access to the Internet, cost of the tariff on local market, reliability of power supply especially in rural or island areas, penetration of smart phones as well as age groups that use or not use smart phones, key technologies trends in mobile technology (including greater speed, cost reduction, increased intelligence that blurs distinction between mobile phones and mobile computers, advanced charging such as solar, larger displays, network transparency, greater range of service, partnership between multiple providers).

Osakidetza (Basque Health Service) has created an innovative healthcare system for nurses that allows them to provide care for patients in a more agile, efficient and safe manner, called ***Mugitzen*** (Osakidetza Mugitzen, a mobility strategy aimed at professionals).

The system is part of a clinical care and management project launched by Osakidetza, which combines patient safety, nursing care, mobility and the collection and recording of information at the point of care (primary care at home and in hospital), in real time. One of the main issues in the beginning was the lack of technical resources such as tablets so their solution was to start with a pilot application. Due to the need for data exchange with other systems, developers decided to use 100% open source platform for both devices and infrastructure, which made maintenance of the whole system cheaper and easier.

So, to conclude, when thinking about infrastructure changes and adaptation, examples like Mugitzen showcases that choosing an open source platform can be a good decision both in terms of costs for the maintenance and adaptability for the future development.

Learn more: https://mhealth-hub.org/mugitzen

e-Nabiz (developed by the Ministry of Health of Turkey), showed early in the development stage that there would be requirements connected with technical infrastructure in order to connect all medical facilities into one system, so government started comprehensive

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investments in technical infrastructure as well as interoperability with other government e-services.

Within e-Nabız application, all the data are privately stored by encrypting them. The system provides a secure communication infrastructure between health provider that produces health data and patients.

Thanks to the Private Cloud system, effective resource management is carried out. By utilising Big Data and NoSQL technologies, a 24/7 online and robust system against errors and failures is developed.

e-Nabız is a widely used PHR system in Turkey. Besides, every healthcare facility in Turkey is subject to send all the patients' data as soon as available. To be able to do that, common structure was needed. This issue was considered at the development phase. Also, there are many different firms which provides Hospital Information Management Systems to the heath care facilities. Integration of all these firms into the centralized system e-Nabız takes enormous effort.

Learn more: https://mhealth-hub.org/e-nabiz

As main conclusion, a detailed analysis of infrastructure and future development is crucial in early stages when developing mHealth solutions, as lack of infrastructure can lead to a low use of the solution in the population.

Other examples from desk research for further guidance can be found here by clicking on the specific topic.

INTEROPERABILITY WITH EXISTING SYSTEMS[7]

Interoperability involves many different aspects that have to be taken into account such as legislation, guidelines, contracts and agreement between exchanging parties, governance, maintenance, standardised data elements, applications, technical infrastructure, privacy and data safety, sharable workflows. Only when all aspects as well as all stakeholders are involved in the process, implementation is successful.

- The European Interoperability Framework (EIF) is a set of recommendations that specify how administration, businesses and citizens communicate within Member States and across EU. In terms of health care interoperability, it is the agreed aproach to interoperability for health care organisations that wish to work together towards the joint delivery of health care services. It specifies a set of common elements such as concepts, principles, policies, guidelines, standards, specification and practices.

eHealth EIF model according to EIF has six levels: legal and regulatory, policy, care process, information, applications and IT infrastructure.

Today's healthcare systems, and the lack of interoperability between these systems, reveals that healthcare has to address crucial issues to improve interoperability, including

[7] See Annex II "Key notes on interoperability aspects in health systems" to complement this part.

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standardization of terminology and normalization of data to those standards. In addition, the volume of data healthcare IT systems is producing exacerbate these problems.

Several initiatives have been gathered with interoperability as one of their main topics.

TreC Diabetes is a project developed in Trento, Italy, which aim to better manage pregnant patients with diabetes, including Gestational Diabetes Mellitus (GDM) using ITC and AI technologies. TreC Diabetes enables medical staff to monitor patients through an on-line dashboard. The application integrates clinical and non-clinical data collected from various sources such as personal records, laboratory test data, self reported information through e-diary and allowing chat options between medical staff and patients. One weakness is that the platform is not integrated with automated devices such as glucometers, as well as limited scalability and exportability of the model to other types of patients with diabetes. | Learn more: https://mhealth-hub.org/trec-diabetes

MyNHS Wallet is an app developed by the Shared Services of the Ministry of Health (SPMS) in Portugal. It provides all health and administrative information of a patient on a modular way (like a wallet), where every bit of information is presented in a card. Besides adding the cards, it allows for citizens to record their measurements and have access to a range of services. Currently, myNHS Wallet is integrating: vaccine card, treatment guide, ADSE, vital testament, allergies, rare diseases, COVID-19 and measurements such as steps, blood glucose and blood pressure. Through the app, citizens can also contact their primary care centre, SNS24, and use RSE/Citizen Area, MyNHS, MyNHS Times, and Teleconsultation (through RSE Live) services.

Learn more: https://mhealth-hub.org/mynhs-wallet

The app ***Maccabi*** allows doctors and patients to have full access to all medical information and direct communication between doctors and patients. Simplicity of use and faster exchange secured stakeholders accepted to use it, as they saw advantages.

The app directly contributed to the clinical processes reengineering.

The app is constantly evolving and upgrading, as patients and doctors have additional needs and requests.

Learn more: https://mhealth-hub.org/maccabi-online

Early in the development stage, it was obvious for ***e-Nabiz*** that there would be requirements connected with technical infrastructure in order to connect all medical facilities into one system, so government started comprehensive investments in technical infrastructure as well as in interoperability with other government e-services.

e-Nabız is a widely used PHR system in Turkey. Besides, every healthcare facility in Turkey is subject to transmit all of the patients' data as soon as available. To be able to do that, common structure is needed. This issue was considered at the development phase. Also, there are many different firms which provide Hospital Information Management Systems to the healthcare facilities. Integration of all these firms to the centralized e-Nabız system takes enormous effort; support groups to solve potential obstacles were created.

Learn more: https://mhealth-hub.org/e-nabiz

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Regarding ***Heilsuvera.is***, all primary healthcare centres in Iceland are connected to this portal, as well as some of the private practices. The citizens have an electronic identification (eID) and can add measurements by themselves on blood pressure, glucose, pulse, fever and other medical parameters. These measurements cannot be sent or shared digitally.

The health record is interconnected between hospitals, primary health care, nursing homes and a majority of private practice doctors. Hence, patient health information is shared on a national level. The national health network Hekla is used for communication and sharing of patient information. The health portal has an integrated videoconference function. The portal is a scalable website that can be used on all devices, although they are working on developing a specific mobile application.

Learn more: https://mhealth-hub.org/heilsuvera-is

All the examples above about interoperability highlight the importance of integrating mHealth solutions with different systems and enabling exchange of various types of data among all stakeholders.

mHealth implementers should pay attention early on to analyse technical and technological state-of-the-art, expectations of patients, medical and administrative staff and according to this, develop the solutions.

FEASIBILITY STUDIES

The question of implementation and feasibility is important for the wide-scale adaption of mHealth solutions. A project or technology can only be successful as long as it is accepted by the users and implemented into their routine. Design of solutions that are intuitively understandable and easy to use by end-user are recommended. Main conclusions from the literature review show that mHealth feasibility studies are successful mostly on a small scale, in pilot studies. Until now they have been rarely applied on a national and international level. This includes the use of both mobile apps and SMS systems. The applications of such systems range from tracking health and habits of healthy individuals and therefore providing a prevention tool to avoid future diseases, through obesity control and education, to disease control in developing countries. One of the main and prevailing questions is how feasibility can be measured on a national and international level. Exploring this would allow better comprehension of large-scale studies.

Examples of literature findings

One of the first review and case study performed on the feasibility of mHealth was presented by Latif et al.[8] and focuses on mobile health in the developing world. The authors summarise the use of current sensors in mobile phones and how they can be used in mHealth apps. Such approaches are particularly useful in developing countries, where the use of mobile phone users grows rapidly. In this way, the mHealth apps can be utilized in developing regions with limited financial resources. For example, bulk SMS messaging was used to provide awareness of AIDS in Uganda and Nigeria. The mHealth solutions were also applied in Pakistan in a region with a high risk of Polio, where areas missed by vaccination teams could be reported. This system led to additional 8 million people receiving the vaccine. Epidemic outbreaks were also treated and controlled in Bangladesh, Pakistan, China, India, Peru, Rwanda and Cambodia.

[8] https://mhealth-hub.org/mobile-health-in-the-developing-world-review-from-a-case-study

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Another mHealth solution examined for acceptability and feasibility was an intervention app "MyDayPlan" discussed by Degroote et al.[9] The app is used for inactive adults and helps them to plan and provides tips on how to stay more active via self-regulation techniques. The authors concluded that the app was well-received. The users were engaged and provided feedback leading to future improvement of the app.

The feasibility of mHealth solutions for children was demonstrated by Afonso et al.[10] The authors developed an app focusing on the prevention and treatment of obesity in young children by several methods. For parents, the app provides educational videos and recommendations. The app was well-received by all the parents involved in the study. Children are encouraged to develop healthy eating, drinking and sleeping habits through gamification of the process.

Finally, authors like Bull (2016)[11] highlight that "*it is critical to now move beyond acceptability studies into actual research on the efficacy, effectiveness, cost-effectiveness and scalability of these tools*". More concrete, according to his view, doing so requires study of the dissemination and implementation of new technology tools into care delivery systems, and cost-effectiveness research will establish the return on investment (ROI).

ALIGNMENT WITH CLINICAL GUIDELINES

Tät.nu (eContinence.se) is a research project at Umeå University with financial funding from *Forte, Kampradstiftelsen* (The Kamprad Family Foundation), *Visare Norr* and Region Jämtland Härjedalen.

The app ***Tät®***, an Internet programme and a booklet with focus on pelvic floor exercises have shown effect in women with **stress urinary incontinence** (leakage of urine associated with coughing, jumping or exercise). It is developed for women with other types of urinary incontinence. On the other hand, stress urinary incontinence is common in men after radical surgery for prostate cancer. The *Tät® III app* is intended for use before and after radical prostatectomy, to support men with pelvic floor exercises in cases where exercises have been recommended by medical staff.

A fundamental base for eContinence is the profound clinical knowledge among the participating researchers/developers. The collaboration between the clinical research group and the technicians has always been productive. For example, lots of ongoing detailed discussions in the area of program updating for example.

The *Tät®* app is the only evidence-based app for urinary incontinence that is evaluated for efficacy. Efficacy was demonstrated in a randomized controlled trial (RCT) with clinically important improvements regarding symptoms, quality of life and leakage after three months.

Learn more: https://mhealth-hub.org/the-econtinence-project

Although not being its main topic, the alignment with clinical guidelines was also relevant in the initiative ***United4Health***, that took into consideration international and national clinical

[9] https://mhealth-hub.org/acceptability-and-feasibility-of-the-mhealth-intervention-mydayplan-to-increase-physical-activity-in-a-general-adult-population
[10] https://mhealth-hub.org/fammeal-a-gamified-mobile-application-to-help-healthcare-centers-treat-childhood-obesity
[11] https://mhealth-hub.org/beyond-acceptability-and-feasibility-moving-mhealth-into-impact

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guidelines for COPD, and the algorithms that were developed are still in use in other regional projects. | Learn more: https://mhealth-hub.org/united4health-2

Other examples from desk research for further guidance can be found here by clicking on the specific topic. If you know any recent experiences or publications that might be relevant for this topic, please contact us by email info@mhealth-hub.org

BUSINESS CASE AND REIMBURSEMENT

A business case often provides decision makers, stakeholders and the public with a management tool for evidence-based and transparent decision making. It is important for delivery and performance monitoring of the subsequent policy, strategy or project to follow thereafter.

The resultant project will only be successful if it has been planned realistically, with a clear focus after detailed consideration of the associated risks. It is a business case that clearly presents the risks, opportunities and threats involved putting them in perspective of the investment involved. Thus, a business case is not just a record of the Return on Investment from a financial perspective but will present a summary of all the benefits delivered.

Business Model is understood to describe the rationale of how an organization creates, delivers and captures value, in economic, social, cultural, or other contexts. The process of business model construction and modification is widely referred to business model innovation and forms a part of business strategy.

In this sense, reimbursement can be the best case-study for applying these methods. To identify the feasibility and the benefits of reimbursing mHealth applications it is important to understand their impact. Furthermore, it is important to guarantee the control and quality in these applications and understand the impact on the care delivery.

If you know any recent experiences or publications that might be relevant for this topic, please contact us by email info@mhealth-hub.org

Examples of literature findings

In a study by Whittaker (2012), the lack of sustainable business models and the lack of reimbursement models were identified as issues limiting the further implementation and enrolment of mHealth. A review by Gagnon et al. (2016) on mHealth adoption by healthcare professionals also identified the lack of reimbursement models as a major issue that led to a similar conclusion. This problem is explored in detail in a book by Malvey and Slovensky (2014). In summary, the current research on the topic addresses the lack of reimbursement and business models of mHealth services. Organisations providing mHealth services are, as a result, receiving less funding. This slows down the evolution and implementation of mHealth solutions worldwide.

As a pioneer, Whitten et al (2001).[12] examined the delivery of health care products and services. The authors developed two case studies. First, they examined the potential of online health in major health services. Second, they studied the emerging strategies of two online health service

[12]

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firms. The authors concluded that the best chance for the success of online health might be the combination of traditional business with a physical site and a convenient web presence.

Rounds et al. (2019) explored the reimbursement potential of key global markets. The aim was to explore go-to-market strategies of country prioritization when seeking reimbursement. The authors discovered a substantial difference in the reimbursement feasibility across markets. Countries such as UK, Germany and the US are the most progressed in their reimbursement landscapes. Furthermore, countries such as the Nordics and Israel show increasing opportunities for reimbursement, whereas countries including Spain and Italy lag slightly. The authors suggest that the manufacturers of mHealth apps seek reimbursement in "high-feasibility" countries and explore alternative business models in "low-feasibility" countries.

On a different note, deploying patient summary standards in mHealth enhances the value brought by standards. To do this, it is important to define business models around it to explain how these standards may be understood as the strategic and financial incentives for organisations and countries.

One paper that does this identification and discussion on the business models for the deployment of summary standards, such as International Patient Summary (IPS) is Tageo et al. (2020)[13].

The paper revisits some concepts and background information, namely the concept of IPS, Standards associated with IPS and what a Business Model is. Then, the article goes into some detail in the Business Model Canvas (BMC), developed by Osterwalder and Pigneur (2010) to develop the analysis for the deployment of IPS in mHealth. In such models, and specially for presenting a business case, it is paramount to do a stakeholder identification. Tageo et al uses a comprehensive list of identified stakeholders, being the following ones the most crucial for analysis in regard to the development of the business strategy and models: developers, governments, healthcare providers, insurance providers, health and care professionals, citizens.

Two potential BMCs were developed by the paper based on experiences in two very different case settings. The first case relates to the benefits derived from IPS standards adoption in the context of disaster management. By contrast, the second case relates to how IPS standards can be utilised to enhance child health appraisal and child vaccination activity.

The findings highlight not only the resulting analysis on which scenario the use of IPS standards is more beneficial, but it clearly makes use and highlights the benefits of using business models (to make a business case) in deployment of solutions in healthcare (particularly in mHealth).

On a different context, Moshi et al.[14] identifies and analyses existing evaluation frameworks for mobile medical applications (MMA) and determine their suitability. With this as a scope of the paper, it is part of a larger research project to develop or adapt an evaluation framework for MMAs and determine the feasibility of a reimbursement pathway for MMAs in Australia. Specifically, they conducted four studies on (i) a policy analysis on international mHealth app regulation; (ii) a case study on American and Australian app regulation; (iii) a methodological systematic review on the suitability of current mHealth evaluation frameworks for reimbursement purposes; and (iv) the identification of HTA pathways and impediments to app

[13] https://mhealth-hub.org/business-model-canvas-for-adoption-of-international-patient-summary-standards-in-mhealth-industry
[14] https://mhealth-hub.org/op144-mhealth-app-evaluation-framework-for-reimbursement-decision-making

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reimbursement through stakeholder interviews to create a framework that can evaluate mHealth apps for reimbursement decision making. They concluded that software changes, connectivity, and cybersecurity need to be considered when evaluating mHealth apps for reimbursement purposes.

CULTURAL CHANGE AND DIGITAL SKILLS

The wide-scale adoption of mobile health solutions can prepare patients to manage long-term conditions better, provide smart guidance in the event of a complication including when to escalate their situation to a health professional, provide background education and other health guidance. In order to be successful, patients need education in digital skills and knowledge on how to use already provided or recommended to use mobile health solutions. They need coaching on how they should utilise the capabilities of the digital solution to monitor, regulate or improve their health situation and the scenarios in which they should make contact with their health and care professionals, perhaps urgently.

There is a significant educational investment in patients that is required and most health and care professionals today have not been trained in how to deliver these areas of training to their patients. In addition, *the* relationship between patients and their health and care professionals can be transformed by using mobile health solutions.These are more empowering and patients will be in a position to take decisions about their self-management that in the past they received instructions from their health and care professionals. That sharing of responsibility and what it means for the sharing of accountability (and maybe also for liability) is a second area of change that is introduced through many mobile health solutions. The third area of change is that clinical workflows and care pathways may need to be modified because certain elements of care are no longer directly being provided by health and care professionals but are being mediated through technology. Of course, education and remote support of patients has to be incorporated as new elements within care pathways and workflows which may have workload implications.

In the experience ***E-Consultations in screening for familial hypercholesterolemia in city of Zagreb***, one of the main considerations proved to be the need for cultural change and increase in the use of digital skills especially in the age groups 65+, who are not using smart phones or used to communicate via mobile apps and SMS. On the other hand, it was noticed that doctors were also rejecting the use of the initiative as they needed to improve their digital skills. Therefore, before full scale implementation there is a need for systemic education for both medical staff and patients in digital skills.

Learn more: https://mhealth-hub.org/econsultations

One of the key aspects in the ***ImagineCare*** platform was that planning the implementation takes a lot of time and effort because it includes planning from the technical perspective but also a need for the organisation to understand the benefits and a need to organise a dedicated organisation for the change. It is not easy to enter into existing ways of working as there is a resistance when implementing new ways of working. In summary, this experience showcases that it takes time to do a major change in the ways that healthcare systems operate.

Learn more: https://mhealth-hub.org/imagine-care

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Examples of literature findings

It is ideal that future generations of health professionals receive training as part of their undergraduate education or higher professional education, or as continuing professional development. Little work has been done to date on the kind of training syllabus that is needed and how much time is needed in health professional education relating to mobile health adoption. The paper by Armstrong (2019)[15] is a good example of a publication that reports on the design and implementation of such a training programme. The authors summarise the training programme, which is delivered over eight days and its learning objectives. The programme covers the evidence-base regarding the use of mobile apps, understanding the integration of mobile health solutions within clinical workflows and what clinician documentation practices should be, the security and privacy requirements and practices that should be adopted, ethical issues that may arise in the use of mobile health solutions and cultural considerations. These various components have been written up in more detail in other papers which the authors reference. This paper importantly also presents the results of an evaluation of the programme, over three years of delivery, on the attitude of health professionals regarding future intentions to utilise mobile health solutions as part of the ways in which they will care for their patients. The authors report from just under half to nearly all indicating a future intention to utilise mobile, which is a sustained effect. This paper is useful to potential mobile health program developers because it provides the evidence that investment in health professional training is worthwhile. More details about that training are given in supplementary papers that are referenced.

Another challenge with the adoption of mobile is patient selection. Because of the perceived risk of transferring a greater extent of care decision-making responsibility to patients, anecdotally there is a reluctance to issue mobile health tools to patients who are in older age groups, who might be less digitally literate, might have multiple long-term conditions increasing the complexity of managing each one and may already have some complications from a long-term condition. However, it is also possible that these patients would benefit hugely from the use of mobile health solutions if these can be successfully used. Cosco et al.(2019)[16] present a thoughtful analysis of the challenges and barriers that may make it difficult for mobile health solutions to be used successfully by all the patients and offer suggestions on how older patients might be prepared, trained and supported to make use of mobile health. They emphasise two kinds of digital divide, the level of investment made by older persons in up-to-date technology such as mobile phones and the level of skill they have on how to use advanced technological solutions. They also explore in detail the different ways in which data input might be obtained from patients, directly or indirectly using sensor-based devices. This is a useful introductory text to the issues and challenges that should be considered when designing a mobile health programme for older persons to use.

Other examples from desk research for further guidance can be found here by clicking on the specific topic

GOVERNANCE FOR MHEALTH

[15] https://mhealth-hub.org/mobile-health-provider-training
[16] https://mhealth-hub.org/mobilizing-mhealth-data-collection-in-older-adults-challenges-and-opportunities

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e-Nabız, built as a two-sides system, gives an opportunity to exchange data among all levels of healthcare system to empower citizens to have a say in their health. The app was developed by the Ministry of Health of Turkey and it has been fully operational since 2015.

Early in the development stage it was obvious that there would be requirements connected with technical infrastructure in order to connect all medical facilities into one system, so government started comprehensive investments in technical infrastructure as well as interoperability with other government e-services.

For the first app, the main weakness was that not all stakeholders were involved in the process, which caused problems in the use of the app, but now all sides are actively involved.

On the other hand, the app directly contributed to reengineering of clinical processes and significantly shortened the time for the patients to get appropriate medical assistance.

Learn more: https://mhealth-hub.org/e-nabiz

Examples of literature findings

In their work, Vesselkov et al. (2019) highlighted that the proliferation of mHealth has contributed to an increasing amount of heterogeneous data. To increase the value of devices and applications by facilitating new ways of using them, mHealth companies often provide a web application programming interface (API) to their cloud data repositories, allowing third-party developers to access end-user data after receiving consent. Managing this type of data sharing requires design and governance decisions that balance between encouraging generativity to facilitate complementary inputs and maintaining control to prevent unwanted use of the platform. Despite the increasing ubiquity of data sharing platforms on the web, researchers have not yet sufficiently analysed their design and governance. Vesselkov et al. (2019) identified 18 design and governance decisions that mHealth companies need to make to manage data sharing and discussed their role in maintaining the balance between platform generativity and control. Those decisions are:

High-level data sharing strategy (all actors)	1) Data-sharing role 2) Data-platform role
Governance of data scope (data providers, platform providers)	3) Data types shared 4) Granularity of provided data 5) Timeliness of provided data
Platform design (platform providers)	6) Number of APIs to a data platform 7) Platform API rights 8) Architectural style of API 9) Data change detection mechanisms 10) Data access authorization 11) Supported data format
Platform governance (platform providers)	12) Platform openness 13) API usage-rate limits 14) Price of API usage 15) Revenue sharing / affiliate program 16) Directory of partners using API 17) Secondary sharing of data that platform provides

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18) Platform consumers' use of historical data after the integration is terminated

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USER-CENTERED DESIGN CONSIDERATIONS

User-centered design of mobile health solutions aims to develop interactive systems that are usable and useful focusing on their users, their needs and requirements. Other user factors such as adoption, acceptance and trust are influenced, when not determined, by systematically involving users in the design, development, and evaluation of mobile health solutions. However, evidence on effective use of standards and guidelines is scarce. Communities of best practices and regulations would be needed to establish the backbone of mobile health implementation in healthcare services.

In the project ***United4Health***, there was involvement of all stakeholders (patients, healthcare professionals, other actors) for the design, development, deployment and evaluation of the technology solution.

Workshops with key stakeholders enabled end-user representativeness throughout all the stages of the project. These included user tests and validation tests over a test network. A field study was carried out with patients and health professionals in a pre-implementation phase to preliminarily analyse the usability of technology in real settings.

The stakeholders were from different organisations and had multiple levels of administration and different economy and service models. One obstacle was to come to realisation of benefits from the new services.

Learn more: https://mhealth-hub.org/united4health-2

The ***Assuta Doctors*** app (Israel) is a solution that enables doctors to monitor patients and patients to be prepared for all the medical procedures.

The main lesson learnt is the need of co-design with the users and to build apps to support the workflow, particularly when dealing with doctors. In the first version, doctors complained, so developers realized that they should sit with doctors while creating the app. The first version of the app had only a portal for doctors and a function to exchange messages with patients. In later versions, each time new and improved features were added and focused more on patients.

Another key idea is that all stakeholders have to be involved in the process, not only doctors. Otherwise, the app will not be used as it is supposed to. There is as well a need within the app to have tutorials to explain patients and doctors all the steps and how to use the app.

Learn more: https://mhealth-hub.org/assuta-doctors

Several other real experiences have shared learnings about the importance of this topic of user centered design considerations.

Learn more:

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Megi app
Orcha and Staffordshire County Council
Orcha and Our Dorset Digital
e-Consultations in screening for familial hypercholesterolemia in City of Zagreb
Reports online
Early detection of diabetic retinopathy
e-Continence project

Examples of literature findings

Mobile technologies offer opportunities for real-time assessment of symptoms of chronic diseases, such as multiple sclerosis, chronic obstructive pulmonary disease, cancer and others. However, based on Simblett et al. (2019) paper, the acceptability of these tools for patients needs careful consideration, with special attention to potential barriers and facilitators. Chronic diseases typically carry out a fluctuation in the physical, psychological, and spiritual status of the patients. Perceived and effective resources (e.g., costs) need to be allocated strategically in the context of providing choice and control.

Consumers value mobile health solutions that promote well-being, social connectivity and health care control, but they are not always universally embraced. Mobile heath applications (apps) need to cater for user accessibility and health needs. A deeper understanding of what hinders frequent users of digital technologies and those with long-term conditions is required to secure wider adoption and scalability. In this sense, Somers et al. (2019) article outlines the importance of investing in upskilling digital skills and on accessible and usable apps that will contribute to expedite uptake and utilization of such digital health and well-being apps.

COMMISSIONING MHEALTH

If you know any recent experiences or publications that might be relevant for this topic, please contact us by email info@mhealth-hub.org

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3.3. Execution

This stage is focused on carrying out the implementation, which may involve technical implementation, testing, end-user engagement, etc.

INTEGRATION WITH EHR AND OTHER SYSTEMS

The adoption of digital health technology will be on an upward trajectory over the next decade. This growth makes the need to integrate digital health, namely mHealth tools into the EHR increasingly critical for health systems. EHR integration brings forward and leverages data and insights from digital health tools to provide relevant information, alerts to threats and opportunities and financial and operational guidance at the point of care.

EHR (Electronic Health Record) integration is incorporation of digital health products, both in terms of data as well as clinical workflow. As the adoption of digital health technology is rapidly growing across healthcare industry, it is of crucial importance to speed on the advantage of integrating EHR and digital patient engagment platforms as it is giving practitioners greater visibility into the patient experience.

Mangols Journey ("El viaje de Mangols") is an innovative treatment program and work methodology developed by Osakidetza (Basque Health Service).

The model of integration with EHR, with a prescription, already existed, but they were the first to put it in the Integral program manager (GIP, in Spanish, Gestor Integral de Programas), being this a key aspect.

Learn more: https://mhealth-hub.org/the-mangols-journey

Osakidetza (Basque Country Health Service) has created an innovative healthcare system for nurses, called ***Mugitzen***, a mobility strategy aimed at professionals, which combines patient safety, nursing care, mobility, collection and recording of information at the point of care (primary care at home and in hospital), in real time.

The new Osakidetza applications are designed for lightweight tablets and have been developed from the existing Information Systems at Osakidetza, adapting and selecting the necessary information to the mobile device, improving functionality and thus offering simple and safe care.

In addition to reinforcing clinical security, these applications allow patients to upload the information collected in real time to the electronic medical record, reducing in this way the number of errors.

An architecture was established to see how these applications could work on a large scale, beyond the pilots; a tender was issued and awarded to a company. The first milestone was the implementation of these 5 applications in production environment for all users in the hospital area.

One key learning was that, instead of macro-developments, they have tried to cover the needs with small applications that solve very specific business scenarios and bring high value, although it meant moderate the scope ambition and difficulties with responding to new needs.

On the other hand, they have realised that they have to take into account the real needs of the users, but also to make a clear commitment to bring the medical record closer to the point of

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care. It is not necessary to have a full scope, or to involve the whole existing information systems, but it is key that the action is perceived as useful and crucial.

Learn more: https://mhealth-hub.org/mugitzen

mSaúde platform is an operational app since 2012, as regional patient portal in Galicia, Spain. The platform is fully integrated with the eHR system as in early stage of the development this was stated as one of the crucial conditions.
Learn more: https://mhealth-hub.org/msaude-platform

E-Res Salud is another app that can serve as an example of integration with eHR system. It illustrates the patients' co-creation of their own medical history, providing personal health data through patient portal and integration in the eHR.

One key step was to create the PROMs and PREMs tools templates in the eHR system, as well as to implement the questionnaire both in the eHR system and the patient portal.

This experience is based on the methodology developed through the "*Guideline for the design and implementation of a value-based healthcare program*" (Spanish version).

Learn more: https://mhealth-hub.org/eres-salud

The Portuguese Mobile Medical Electronic Prescription (**PEM Mobile**) allows simultaneous prescription of different types of medications, i.e the same prescription may include reimbursed drugs with non- reimbursed treatments. The system brings advantages to the user, as all the prescribed health products are included in a single prescription, which was not the case before.

In the act of dispensing products in pharmacies, the user may choose to dispense all products and/or prescribed drugs, or only part of them, being possible to collect the rest in different establishments and on different dates.

The dematerialization of the recipe is based on a more efficient and secure process of emission control and dispensing, requiring authenticated electronic access, through a qualified digital certificate. The integration with the national electronic health record enables, among others:

- implementation of the new prescription rules
- availability of an electronic drug prescription application to the entire health system, public and private
- Provide the prescription process with greater rigor and security for the different stakeholders
- Authenticity and non-repudiation of prescription using strong authentication technologies,
- The sophistication of the prescription process, as well as increased control and monitoring of prescription software
- Integration with existing electronic clinical file systems
- Greater safety in the prescription process

Learn more: https://mhealth-hub.org/pem-mobile

In the national portal ***Heilsuvera.is***, citizens have an electronic identification (eID) and can add medical parameters by themselves (i.e. blood pressure, glucose, pulse, fever...)

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The health record is interconnected between hospitals, primary healthcare, nursing homes and a majority of private practice doctors. Hence, patient health information is shared on a national level. The national health network Hekla is used for communication and sharing of patient information. The health portal has an integrated videoconference function. The portal is a scalable website that can be used on all devices, although they are working on developing a specific mobile application.

Learn more: https://mhealth-hub.org/heilsuvera-is

1177 is a secure digital portal to access publicly funded healthcare. Through 1177, residents can communicate 24/7 with healthcare in a secure way and do a variety of functions. The service is available in all regions of the country (Sweden) and is jointly financed by them.

National Service Platform is a technical platform that acts as a hub, or a kind of gear. It simplifies, secures and streamlines the exchange of information between different IT-systems in health and care.

Inera is a limited company owned by regions, municipalities and Swedish Regions and Municipalities organisations. The mission is to create the conditions for digitalisation, by providing the owners with a common digital infrastructure and architecture. Several of Inera's services can be displayed in 1177 e-services:

The medical record - where residents can see their own medical record entered by the healthcare professionals.

Certificates - where residents can read, download and send their digital medical certificates, for example, to the Swedish Social Insurance Agency and the Swedish Transport Agency;.

Sample management - where residents can order and plan their samples and order home sampling kits;.

Support and treatment - where residents can take part in internet-based support and treatment programmes offered by a therapist or start a programme themselves.

Examples of literature findings

Despite the examples given above, Marceglia et al.[17] argue that transfer of information from mHealth apps to EHR systems is still low, and because of that, they propose a standards-based architecture that can be adopted by mHealth apps to exchange information with EHRs to support better quality of care. In the paper it is explained how a system was modelled to integrate the created architecture for EHR/mHealth app integration.

Ndlovu et al.[18] also conducted a study to assess the relevance of eHealth interoperability frameworks that uses mHealth as a way to connect to EHRs. The results of this study indicate "*entailed aspects that are relevant and could be drawn upon when developing an mHealth interoperability framework*" for the specific case of Botswana. Concluding that "*delivery of healthcare is shifting from hospital-based to patient-centered primary healthcare and community-based settings, using mHealth interventions".* This is an important result to support integration of mHealth into EHRs. The study goes further to suggest that the *"impact of*

[17] https://mhealth-hub.org/a-standards-based-architecture-proposal-for-integrating-patient-mhealth-apps-to-electronic-health-record-systems

[18] https://mhealth-hub.org/interoperability-frameworks-linking-mhealth-applications-to-electronic-record-systems

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mHealth solutions can be improved if data generated from them are converted into digital information ready for transmission and incorporation into EHR systems".

AUTHENTICATION - AUTHORIZATION

Nowadays smart phones are the main platform for communication and exchange of data between patients and medical professionals. According to Cisco Visual Networking Index[19], the number of mobile devices per capita will reach 1,5 by 2022. In this context, security and privacy issues are crucial for mHealth apps. In order to ensure confidentiality, integrity and availability of electronic health information it is necessary to enforce administrative, physical and technical safeguards. Confidentiality as well as GDPR requires assurance that electronic personal health information is not made available or disclosed to unauthorized parties.

Imagine Care app is an example on how confidentiality has to be planned at early stage of development as well as the integrity which means that personal information has not been modified or destroyed without authorization. Also, the app is based on the fact that data can be viewed and used only by authorized persons.

Learn more: https://mhealth-hub.org/imagine-care

MyNHS Wallet is based on four principles: security, safety, portability and tailoring. On the security, several technical mechanisms provide a truly secure information exchange and storage. At the safety level, the digital identity of the patient is guaranteed. All citizens with a *Digital Mobile Key* can have access to MyNHS Wallet. To access all features, it is necessary to have a health user number, or otherwise the use is limited.

Typical security requirements should include the following: confidentiality, integrity, audit control, effective user authentication, access control, availability and freshness of data.

Another concern is that data stored on mobile devices is vulnerable to range of security threats that include among others malware infections, unauthorized usage, or theft.

Learn more: https://mhealth-hub.org/mynhs-wallet

1177 care guide e-services (Sweden) has placed great emphasis on protecting personal data, so no unauthorised person could get access to the information sent between caregivers and residents. Residents use e-identification to log in whereas healthcare staff log in to the professionals clinicians platform by using a SITHS card (Swedish smartcard-based eID solution for professional use).

Learn more: https://mhealth-hub.org/1177-care-guide-eservices

In Portugal, to use the Mobile Medical Electronic Prescription (***PEM Mobile***), physicians and dentists need to have an active *Digital Mobile Key* and *digital signature* by Digital Mobile key. In addition, they need to request a registration in the application. The Digital Mobile Key is

[19] https://s3.amazonaws.com/media.mediapost.com/uploads/CiscoForecast.pdf

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considered a high-level secure two-factor method for authentication. The healthcare professionals can authenticate themselves in the PEM mobile by different ways.

After downloading the application, the first step is the activation of PEM Mobile. This activation aims to associate the mobile device with the prescribing physician, for the purposes of digital identification (eID). To perform this parameterization, the Digital Mobile Key (CMD) must be used, and the user must confirm the Tax Identification Number (TIN) plus Mobile Number associated with the CMD. Later, the physician will be asked for the CMD PIN. If the three data are correct, a text message is automatically sent to the mobile phone number provided (and validated at the CMD) with a code (TOTP) that must be entered in the PEM Mobile for activation.

The conclusion of the PEM Mobile activation is done with the user choosing a PIN number that is later encrypted. The prescriber defines a personal PIN that is saved in the last validation phase. The PIN entered by the prescriber is associated with a CMD Token code which is renewed every 15 days. To improve the usability of the PEM Mobile, the PIN can be associated with the fingerprint reading mechanism, if available on the device.

Other examples from desk research for further guidance can be found here by clicking on the specific topic.

In conclusion, as mHealth solutions have potential to replace traditional healthcare services and practices, concerns have to be placed on accessibility and security standards and requirements when developing apps.

PATIENT REPORTED DATA

Good data management is an important success factor for mobile health solutions. The data that is entered directly by patients/caregivers or captured automatically from wearable devices and sensors must be of a good enough quality to support the decision-making that may need to be taken based on the data. These decisions may be automated, in the case of smart guidance systems, or might be delivered through recommendation messages that are acted upon by patients or by their health professionals. Good data management includes making sure that multiple devices that may be connected to, or used by, a patient are themselves interconnected so that a holistic patient centred data ecosystem is constructed, and all the deployed decision-making algorithms and message-generating components leverage all of the data points that they need in order to be accurate. There is a further need: for this patient-generated data ecosystem to integrate with the professionally generated data ecosystem, so that health professionals have the most complete picture possible on their patients during clinic visits and when clinical decisions are being made.

E-Res Salud (Quironsalud 4H Public Hospitals Network, Madrid, Spain) is an example of succesful patient reported data.

This initiative is based on a long-term strategy consisting in giving voice to the patient with a clear, well-defined methodology that encourages their active participation in the care process and stimulate their involvement in planning and implementation of the improvements in the care trajectories based on their experiences and opinions. To do this, e-Res Salud routinely incorporates new outcome indicators into clinical activity that matters to the patient, what help doctors in their daily practice, creating a culture of self-assessment and continuous learning.

The design is implemented in the patient's portal, so patients can easily access them through their smartphones or other portable devices. In the data capture stage, one of the key steps is that the measurement tools are integrated with the eHR, as part of the medical file. It

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means an important dependence on IT department, that has to develop very detailed and specific tasks. On the other hand, the measurement tools are not free of charge, so the high cost of many validated tools hampered the implementation.

E-Res Salud is currently capturing data of more than 8,000 patients in 8 processes (Hematology, HIV, Orthopedic Surgery, Urology, COVID-19, Inflammatory Bowel Disease, Heart Failure, Endometrial Cancer). The future plans are, on one hand, to collect more data by adding more specific tools for a better stratification of processes and patients and on the other hand, to explore expanding the initiative to other processes like Stroke, Cardio-Oncology and Pediatric Asthma.

Regarding data analysis, a platform is being developed to be managed directly by clinicians, to make it easier and faster, so the information collected would have an earlier impact on the clinical activity. All this means a need of a new common language and new transversal work teams.

After the data analysis, the organization provides patients with feedback on their own results in real time, in comparison with people of same age and sex group and a set of personalized recommendations based on their needs identified in the PROMs questionnaires.

Learn more: https://mhealth-hub.org/eres-salud

Examples of literature findings

Schobel et al.[20] examine the issue of data collection and propose design requirements and approaches that should be taken to ensure that the data that is captured by mobile devices is reliable, of a good quality and is suitable for decision-making and delivering guidance. The authors in particular emphasise the importance of flexibility in the design, for example in relation to the user interface. They got support from health professionals being actively involved in the design and sometimes the development of applications. This is a model that can be successful for innovations but is really suitable for scaling up when commercial grade solutions have to be adopted and when the active engagement of health professionals in the development has already taken place and cannot be repeated in every deployment setting.

Sartori[21] highlights the importance of device inter-connectivity and presents a portfolio of good practices that should be adopted through their experiences when developing an interoperability platform for wearable environments and in particular explores the implications for mobile health. The Internet of Things (IoT) offers new opportunities for multi-device connectivity and linkage to expert systems that can be carried or worn by patients. He introduces the concept of a "wearable environment", describes it and presents a formalised representation of such an environment. The paper goes on to describe the API portfolio that is needed for multi-device connectivity and presents a detailed architectural analysis. This paper could be a very useful high-level blueprint for future developers of a sophisticated multi-device monitoring environment, for example for people with functional impairments.

Menychtas et al.[22] consider the next step in the workflow, which is the integration of this multipoint data into the systems that will deliver the feedback loops, such as how to design smart solutions for people and their homes that leverage data derived from multiple ambulatory and home sources. The paper focuses on the technological integration challenges and illustrates

[20] https://mhealth-hub.org/towards-flexible-mobile-data-collection-in-healthcare

[21] https://mhealth-hub.org/an-api-for-wearable-environments-development-and-its-application-to-mhealth-field

[22] https://mhealth-hub.org/on-the-integration-of-wearable-sensors-in-iot-enabled-mhealth-and-quantified-self-apps

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approaches to be adopted, but also discusses how to make sure this integrated solution is usable by patients. The authors present a very readable explanatory paper about the device connectivity standards, their importance, how they should be used and the limitations of what is presently available. This includes the issues of connecting devices to the iOS and Android platforms. This is an excellent introductory paper to somebody pushing to understand the alternative options, standards and challenges wen connecting devices to each other, to monitor platforms on a mobile platform and to EHR systems.

Clinical research, such as clinical trials, is another environment in which mHealth tools may be introduced, either because the digital tool is itself the intervention that is the subject of the trial or introduced as a channel through which data is collected from a patient participating in a trial about some other therapeutic intervention. When setting up a trial involving mobile health tools, design decisions need to be made about which data are most suitable to be collected through the application how to ensure the best possible reliability in that data acquisition and how to deal with data quality issues such as missing data in a statistically valid way. Seewald et al.[23] present a detailed analysis of these factors and make recommendations on how small-scale trials that involve mobile health tools should be designed.

Other examples from desk research for further guidance can be found here by clicking on the specific topic.

OPEN DATA MODELS

The use of technologies for data acquisition, processing and analysis of healthcare data is part of modern healthcare. A lot of data remain trapped in electronic health record (EHR) systems. Exchanging data between different information systems frequently proves difficult. Standards based on common Open Data Models (ODMs) foster exchange, discussion and consensus regarding the data models in the medical domain.

ODMs that are made accessible to the public can provide syntactic and semantic specifications and meta-information about the shared data. They promote transparency and, at the same time, enable efficient data integration and reliable analysis.

Existing Clinical Information Models (CIMs) which are published as ODMs can be reused[24]. Thus, they speed up the development of new applications and ease the maintenance of existing ones.

Various standardization initiatives have been working on the definition of shareable CIM such as the *Clinical Data Interchange Standards Consortium* that develops open standards to improve medical research and to ensure a link with *HL7*, that provides a set of standards for transferring clinical and administrative data between various healthcare providers. The openEHR foundation publishes comprehensive open specifications for a flexible EHR Architecture[25].

[23] https://mhealth-hub.org/practical-considerations-for-data-collection-and-management-in-mobile-health-micro-randomized-trials-2
[24] https://bmcmedinformdecismak.biomedcentral.com/articles/10.1186/s12911-016-0376-2
[25] https://bmcmedinformdecismak.biomedcentral.com/articles/10.1186/s12911-016-0376-2

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ODMs can support Smart Health in various ways, e.g., by providing data schemes for data exchange, enabling automatic artefacts generation for application development and facilitating health data platforms.

ODMs can be regarded as enablers for interconnecting the fragmented and highly diverse stand-alone applications in healthcare.

Some examples from desk research for further guidance can be found here by clicking on the specific topic.

If you know any recent experiences or publications that might be relevant for this topic, please contact us by email info@mhealth-hub.org

INTEROPERABILITY MODELS[26]

Interoperability is defined as the ability for two (or more) systems or components to exchange information and to use the information that has been exchanged. At this point in time, different digital solutions that incorporate mHealth are in use. Each of these solutions usually have a specific need in mind in regard to health benefits and the result is a vast landscape of beneficial mHealth solutions that often fail to communicate with each other or that are simply not able to leverage from this communication. Understanding, integrating and using interoperability models allows a structured approach and a beneficial communication between systems that deal with health data.

Interoperability enables aggregating all available data and data sets such as health data, health plans, patient data that are generated through EHRs, analytic systems, biometric monitoring, etc. and leveraging that data to improve patient diagnosis and treatment. One of the definitions of interoperability is '*the ability of a system to exchange electronic health information with and use electronic health information from other systems without special effort on the part of the user*'. In practical terms it means that access to health data from various sources is automatic.

For example, the ***mConnecta*** platform is going to provide the solution for all mobility devices that collect data from patients that is not collected within the framework of formal healthcare service provision and documentation. It means, data from mobile apps, wearables, and medical devices. All the information is captured on the *mConnecta* platform through an interoperability layer. Inside the platform, authentication, certification process and algorithms that can extract information from the data are defined.

[26] See Annex II "Key notes on interoperability aspects in health systems" to complement this part.

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Figure 3. mConnecta interoperabilty framework

mConnecta is a showcase for use of interoperability in healthcare. Platform is web-based and it is aimed to empower citizens in self-management of their own health. In Catalonia (Spain), there is a central repository for all the clinical data of the patients that are collected in the clinical care. The platform aims to enable integration of patient generated data through accredited applications, web-based apps, wearables and medical devices. It is conceived to be integrated into the Electronic Personal Health Record of each patient and to be made available to health care professionals. As there are numerous services internally on the platform that need to be integrated, microservices that work with docker system architecture are used, so that all interact and share the information. This is one of the main conditions for the platform to grow and be scalable in performance.

Learn more: https://mhealth-hub.org/mconnecta-platform

TreC_FSE is an app that serves as single point of access for the citizens to all health data in Province of Trento in Italy. The app is fully integrated with all healthcare services and enables access to all patient clinical data since 2007, ePrescriptions and communication between medical staff and patient. *TreC_FSE* is aligned with all legal and data security requirements in Italy. It is accessible via webportal for the public on both computers and smartphones and since 2020 integration went further as it enabled doctors for teleconsulting. | Learn more: https://mhealth-hub.org/trec-fse

Trentino Salute+ is an app explicitly developed to promote healthy lifestyle and to enable dialogue between different stakeholders such as citizens, local government and associations. Moreover, it is integrated with several health-related services such as local gyms or healthy food stores. In the development phase, the main described difficulty was integrating the app within proprietary authentication services of large retailers and with small ones The main challenge was to automate the process of claiming and using discounts. | Learn more: https://mhealth-hub.org/trentino-salute

MyCupMarche is an app developed in Marche Region (Italy) to optimize the managment of waiting lists. The app is integrating SMS, chatline, social networks and automated telephone recalls and it can be accessed through PC, portable computer or smartphone. The app is also integrated with a payment system and over 200 labs and specialists nationwide. It is integrated with other regional applications via management software and since the COVID-19 pandemic, additional features were added that enabled tracking and monitoring of patients under quarantine via automatic recall and SMS system. Learn more: https://mhealth-hub.org/mycupmarche

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Reports online is an app developed by the local healthcare provider in Umbria (Italy). It connects radiology with the whole healthcare system and enables all medical staff and patients to access patients imaging and radiology reports Here a different approach is used, as patients are allowed to get access to their health data through an analogical support, a Compact Disk or Online Service. | Learn more: https://mhealth-hub.org/reportsonline

All above real examples show that interoperability is both time and money saving and that it is integral part of the whole system that has to be considered and addressed early on. In order healthcare industry to meet full integration, it must consider current technological and administrative challenges.

Moving from real life examples to some other examples from desk research, it is important to outline that not all manufacturers or mobile health applications adopt interoperability standards for data representation even if they do adopt connectivity standards for the transfer of data to other systems. However, if patient-collected or -acquired data is to be used beyond any application provided by the developer of each specific product, then the generated data must be interoperable, preferably by the means of standards used in healthcare, so that device data and EHR data can be combined and interpreted correctly. This requires an architecture, preferably an open architecture, into which additional devices and applications can be connected over time and it needs also the use of interoperability standards. When it comes to health data interoperability, there is substantial interest and innovations taking place to leverage the HL7 FHIR standard[27] to represent mobile health data.

Examples of literature findings

Chen et al.[28] approach the subject of interoperability not only as an interconnection issue between platforms and a fragmented service landscape but also from a "filtering" issue of relevant information to improve health outcomes. For this, the team tackles the lack of development of more sophisticated and effective tools for data visualization and analysis that legitimate questions regarding mHealth's projected impact on chronic disease management and prevention. To this end, they describe an open architecture for mHealth applications and devices, Open mHealth. This has been created by a not-for-profit organisation as an open-source modular architecture with interfaces to enable this connectivity. This paper also introduces the Open mHealth community of developers, clinicians, researchers and entrepreneurs to build and reuse Open mHealth modules across a broad range of mHealth applications, disease conditions and user populations. The way interoperability is addressed is by showing that an open-source community can bring a standardized level of development that promises mHealth powering the three feedback loops of personal care, clinical decision making and research evidence in a virtuous cycle.

The priority modules, that have been developed so far, focus on data integration, aggregation and a data visualisation component, called *InfoVis*, that incorporates analytic tools, in order to permit sense making and insights from mHealth data. The modular architecture uses open APIs and therefore has the potential for additional new modules through its open community. As for helping gather the most relevant and reliable information that impact health outcomes, the authors also encourage the adoption of standardised outcome measures as published by the US NIH: Patient Reported Outcomes Measurement Information System (PROMIS). It is hoped

[27] https://www.hl7.org/implement/standards/product_section.cfm?section=12
[28] https://mhealth-hub.org/making-sense-of-mobile-health-data-an-open-architecture

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that the open community will continue to grow the number of interoperable modules for the platform.

To add more views on interoperability and how it contributed to better health, El-Sappagh et al. [29] propose a comprehensive mHealth framework to represent a range of diabetes real-time monitoring data collected by various wireless wearable sensors with an integrated Clinical Decision Support System (CDSS) capability that, even if the focus is not completely on interoperability, shows the importance of it as a main requirement to develop an acceptable CDSS. The proposed framework supports the continuous and mobile monitoring of Type 1 Diabetes (T1D) patients based on cloud computing solutions, which provides accessibility, extensibility, flexibility, cost savings and deployment speed.

Using an overarching ontology represented in Web Ontology Language (OWL), this data transformation framework enables data from diverse wearable products and companies to be mapped into a common structural and semantic standard that is already used within healthcare and can therefore be queried by conventional diabetes clinical decision support algorithms. The resulting architecture provides a middleware data harmonisation environment to connect heterogeneous diabetes monitoring devices on multiple patients potentially to multiple EHR systems in different hospitals, enabling more of them to utilise a cloud-based decision support system. The architecture is described in detail, with links to many of the resources that were developed to enable these data transformations. The framework has four main modules: the patient module, the services module, the cloud-based CDSS module and the backend EHR systems module. Each module provides a particular set of functionalities and these modules are integrated in a standard way based on ontology and HL7's FHIR standard.

Since the framework supports data collection from devices, it is important to mention the use of interoperability models to connect these devices to the EHR databases. Such models are also provided by HL7's FHIR.

To sum up, this article provides a good use-case for interoperability and its capability to support several functionalities. This long and in-depth paper therefore provides a technical specification that could be used by any implementor or integrator of diabetes monitoring technologies. The approach taken could potentially be applied to a different monitoring environment around a patient for other diseases.

One of the major interoperability systems in use is HL7 FHIR. This system allows for a modular approach and represents the atomic/granular healthcare data (e.g., heart rate, procedure, medication, allergies, etc.) as independent modular entities called Resources.

Saripalle et al.[30] analyse and explore the HL7 standard to design and prototype an interoperable mobile Personal Health Records (PHR) that conforms to the HL7 PHR Functional Model and allows bi-directional communication with OpenEMR, an open-source Electronic Health Record (EHR) compatible with FHIR. This study goes into detail on how and why the prototype of interoperable PHR was created, how semantic interoperability was achieved or included the requirements for the prototype, the architecture and how it was implemented. The result of this work is a prototype that shows the feasibility of the architecture and capability of HL7 FHIR to achieve interoperability using its modular resources and profiles. This illustrates a unique

[29] https://mhealth-hub.org/a-mobile-health-monitoring-and-treatment-system-based-on-integration-of-the-ssn-sensor-ontology-and-the-hl7-fhir-standard
[30] https://mhealth-hub.org/using-hl7-fhir-to-achieve-interoperability-in-patient-health-record

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perspective and architectural outline for implementing an interoperable PHR using a modern healthcare standard that exposes health data as a service using APIs and RESTful protocol.

This paper is therefore offering a standard based and evidence-based design for a personal health record. The implemented architecture is not yet complete, as there is currently a lack of information security components and it has limited validation. However, this paper could be a useful starting point for a company or program that wishes to implement a mechanism for patients to access their healthcare provider record information on their own mobile device. It also incorporates the potential for patients to capture structured data that is fed back using the same standards into places to the EHR.

In another example taken from desk research, data models for interoperability are evaluated by Blobel et al.[31] and their limitations are viewed in a paper that discusses classification systems for data models and enterprise business architectures and compares them with the ISO Reference Architecture. The team in this article concludes that despite efforts to standardize architecture models for interoperability, these still rely on data models that have their limitations for the use. These limitations range from certain specifications to clinical management approaches.

Other examples from desk research for further guidance can be found here by clicking on the specific topic.

DATA SECURITY AND LEGAL FRAMEWORK

Statistics show that healthcare data breaches and cyberattacks are ongoing threats requiring constant vigilance. Setting up an active and optimized cybersecurity framework is a necessary part of any digital and operational strategy for healthcare systems as well as for their IT vendors. Increased integration enables more exposure to cyberattacks that can impact delivery, safety and privacy. According to statistics, more than 93% of healthcare organizations experienced a data breach between 2017 and 2020 as stated in 2020-2021 Healthcare Cybersecurity Report.

Important aspects of mHealth are the security, privacy and reliability of daily used apps. One of the issues *TIC Salut Social* approached in their ***mConnecta*** platform, was the creation of a certification framework, which established a minimum set of criteria for apps that overcame this process. The guidelines and criteria were published on the website as guidelines or recommendations for those who want to create a health app**.** Providing mHealth models into the healthcare system makes sense if there is trust and a secure environment. *mConnecta* uses this certification model as a first step in a series of many steps, although it is not a restrictive model as far as the integration solution is concerned. The model sets a baseline of criteria to be considered when developing an app. Obtaining the certification is a precondition for future integration into the system. Learn more: https://mhealth-hub.org/mconnecta-platform

One of the strengths of ***TreC_FSE*** is data security, but the strong authentication required by law can even represent a weakness as far as it affects the readiness of use. In fact, after

[31] https://mhealth-hub.org/data-modeling-challenges-of-advanced-interoperability

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installing the app, it is necessary to go to a counter, where an operator will identify the citizen and provide her/him with a QR code that will allow him to activate the app and start using it. Learn more: https://mhealth-hub.org/trec-fse

Same applies for ***Trentino Salute+***, with a privacy and security by design approach in the development of the solution. Learn more: https://mhealth-hub.org/trentino-salute

MyCupMarche is also focused on data security and the importance of including data security planning at early stage of the development. On the other hand, ***Reports online*** is an app developed in Umbria (Italy) and one of the big issues was addressing data security. Learn more: https://mhealth-hub.org/mycupmarche

Other experiences:
https://mhealth-hub.org/reportsonline
https://mhealth-hub.org/1177-care-guide-eservices

mHealth technology comprises many layers that can affect data security, privacy and confidentiality throughout the data life cycle. These layers can have different types of security measures and processes to ensure that information is stored and transmitted safely. One of such methods is encryption that allows the data to be scrambled in a way a human cannot read or understand. Despite these systems, it is also true that sometimes the problem is not about the security system in place, but the data controller, that can pose a serious risk of sharing private health data with unauthorized third parties.

This is a security challenge that must be considered in order to improve mHealth adoption, integration and uptake.

Examples of literature findings

Thilakanathan et al.[32] address the data security issue by providing the user a way of controlling encryption keys independently of the cloud service provider. To achieve such a result, the authors developed one health application as an app for Android mobile phones.

As a starting point, the authors developed a system that allows patients to share their personal health information securely and privately, while ensuring the system is usable. This included the use of a fictitious scenario to assist in defining the requirements of the system, then a review of the state-of-the-art literature to explore the existing works or technologies and then build on these works and develop the new technology. The final stages were tests of the developed system through performance and scalability tests and to evaluate the system in terms of usability.

The way the data is secured, and the way encryption can be controlled by the patient, has to do with how the encrypted keys are stored, shared, sent and divided. It all starts by having two keys, one private and one public, in the app of the patient. Then, at the first run of the app and when the data is sent to the cloud, the app generates a symmetric key and encrypts the data. This symmetric key is encrypted using the public key and then it is uploaded to the cloud with the encrypted data.

For the patient to share the data and for the doctor to access the data, the patient's private key is partitioned. One part is sent directly to the doctor and other part is sent to the cloud service.

[32] https://mhealth-hub.org/facilitating-secure-sharing-of-personal-health-data-in-the-cloud

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Then the doctor receives the encrypted data and the partly decrypted key in order to fully decrypt the data in the doctor's app.

This is a solution that can be put in place in real world scenarios given the result of the security and performance tests made by the authors.

To conclude, data security is a substantial part of any app and has to be considered in early stages of the app development process.

THIRD PARTY INTEGRATORS

An integrated health information system means that electronic data are FAIR (findable, accessible, interoperable, reusable), and can be exchanged and securely used by other actors and institutions that serve the public interest. The result is that information can flow, safely and securely, to where it can be used to advance human health and wellbeing. In simple terms, an integrated health information system enables the secure exchange and movement of organised and standardised 'health data' to where they can create valuable information and knowledge. Health data are data relevant to health and care domains covering the entire population and comprise data created and managed in the health care, public health, and social care sectors/settings.

The importance of an integrated health information system has recently been highlighted in the COVID-19 crysis in many countries, that have reported difficulties with transferring COVID-19 patients between hospitals because their medical information cannot be exchanged electronically. This results in not only delays and inefficiencies – with busy clinicians having to manually transcribe patients' data from the local electronic record to a CD to be sent with the patient – but also the risk of subsequent medical errors that manual transcribing of information entails.

An integrated health information system would help to not only directly improve care quality, outcomes and patient empowerment by enabling patients and their healthcare providers to access health information, it would also raise the country's capacity to use these data for other important purposes, including:

- Managing health system performance on national, regional and network level
- Public health monitoring and surveillance
- Opening new communications channels with patients to improve patient-centred care such as the active use of patient-reported metrics (PROMs and PREMs)
- Introduction of new digital services such as e-prescriptions or telehealth
- Better targeting of reimbursement for services to reward value
- Biomedical research and development
- Innovation such as big data analytics and artificial intelligence that will enhance knowledge-based decisions for patient care and health system governance.

If you know any recent experiences or publications that might be relevant for this topic, please contact us by email info@mhealth-hub.org

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SOLUTION TESTING AND VALIDATION

The ***United4Health*** was an EU FP7 project (2013-2016) with stakeholders collaborating across organisational and administrative levels (municipal and hospital sectors) in the Region of Southern Norway.

A technology solution allowed to telemonitor Chronic Obstructive Pulmonary Disease (COPD) patients at home. The system was deployed into the Norwegian Health Network. A field trial included around 100 patients during the duration of the project. The technology development process took approximately 6 months. The implementation and integration into the National Health Network took another 6 months and created a delay that affected the planned schedule for the project.

A project board was established and a project management in charge of the medical and technology aspects, legal contracts between the stakeholders, and a patient organisation was involved. Workshops with key stakeholders allowed for end-user representativeness throughout all the stages of the project. These included user tests and validation tests over a test network. A field study was carried out with patients and health professionals in a pre-implementation phase to preliminary analyse the usability of the technology in real settings.

Learn more: https://mhealth-hub.org/united4health-2

ProEmpower is a pre-commercial procurement co-funded by the Horizon 2020 programme, which aims to procure a mobile health solution for self-management to help address the looming threat of type 2 diabetes mellitus. The objective is to carry out the Development and testing of pilot systems in 4 pilot sites to achieve an Early Identification of diabetes together with a Shared Care Plan, Personalised treatment and remote monitoring as well as Coaching and promotion of healthier lifestyles. Cooperative diabetes support (peer-to-peer support) is not forgotten, as well as training for diabetic patients so that they can learn more about their disease and achieve a better quality of life.

During phase III two solutions have been tested by 200 end-users each (patients and health professionals) enrolled by healthcare organisations of the four procurers. The aim of the pilot study was to test the feasibility, effectiveness and usability of incorporating the two solutions into the current care pathway for patients with type 2 diabetes.

Study objectives were to evaluate direct and indirect outcomes linked to the use of the novel solutions, including: a) behavioural changes: smoking habits, physical activity, steps, meals, medication adherence b) clinical and quality of life (QoL) outcomes: HbA1c, weight, blood pressure (BP), blood lipids, cholesterol, quality of life c) satisfaction, self-management and usability.

Learn more: https://mhealth-hub.org/proempower

mSaúde platform is an operational app since 2012, as regional patient portal in Galicia, Spain. The platform is fully integrated with eHR as in the early stage of the development this was stated as one of the crucial conditions.

It has a successful approach in the initiation and execution stages both in the scope of resources, its integration with eHR, as well as in the testing and validation of the solution. Its flexibility is highlighted as a main feature to allow the adaptation of the tool to the evolution of the evaluation process. The involvement of interested and highly specialised health professionals in the evaluation process is essential. Finally, it puts the focus on moving towards a "federated model" of applications evaluation in Europe.

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One success factor is the definition of Integration elements based on standards. This approach might take more time when developing the solution, but if standards are not used for the integration, the solution is then limited to just one provider (hard to scale it up). Without standards, the validation process becomes more complex; the standards allow to have a group of tests based on standards, it is considered substantial improvement both for implementation and validation.

Learn more: https://mhealth-hub.org/msaude-platform

The ***app Tät®***, an internet programme and a booklet with focus on pelvic floor exercises have shown effect in women with stress urinary incontinence (leakage of urine associated with coughing, jumping or exercise). It is developed for women with other types of urinary incontinence. Stress urinary incontinence is common in men after radical surgery for prostate cancer.

The Tät® app is the only evidence-based app for urinary incontinence that is evaluated for efficacy. Efficacy was demonstrated in a randomized controlled trial (RCT) with clinically important improvements regarding symptoms, quality of life and leakage after three months. A fundamental base for **eContinence** is the profound clinical knowledge among the participating researchers/developers. Relevant stakeholders have been involved in the development, especially patients through qualitative and quantitative research. Also, accessibility to a functioning treatment and research regarding efficacy, health economy and users' experiences have been the driving forces for the researchers in their involvement.

Three thesis, 15 scientific publications with more to come, this gives the confidence to say, "the Tät® app is an extremely well-validated app", and "yes, it works well".

Learen more: https://mhealth-hub.org/the-econtinence-project

See econtinence.se for links to publications.

Examples of literature findings

As recognized by Kulanga et al. (2016), mHealth has revolutionized the health care service delivery at all levels of healthcare system in both developing and developed world. Both at patient level and service provider level, mHealth has become very useful in areas of decision support, data storage, data processing into useful information, information flow and information use, just to mention a few. For service providers with multiple service deliveries, there is a challenge in managing well the various mHealth applications across the various program deliveries. Standalone applications on different phones or the same phone poses a number of challenges and complications in management and use of these individual applications for patients across the health system.

One solution to such challenges is the use of integrated mHealth solutions. With mHealth integrated application, we can address the challenge of health workers having multiple phones and applications for use in various service deliveries which often target the same audience. Integration also facilitates the continuity of care of patients across different services, usually provided by the same health service point. Integration also ensures optimum use of resources thereby redirecting further resources to other needed areas.

For optimal results when integrating mHealth solutions, it is important to clearly define the problem, outline the intervention in line with the entire healthcare system and provide means to mitigate risks. As a rule of thumb, intensive verification, validation and testing of the

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integrated application is crucial to ensuring an acceptable solution that improves the health care of people (Kulanga et al. 2016).

Following Mathews et al. (2019), the situation is that currently payers cannot easily identify quality in the crowded field of mHealth solutions. Regulatory guidance and oversight are limited, with enforcement restricted to companies that make claims out of proportion to the evidence or where application failures might lead to risks to patient safety. Oversight frameworks of digital health have been proposed, which mainly focus on patient safety. Healthcare needs a robust and transparent validation process for digital health products. All healthcare stakeholders would benefit from a more standardized, objective, rigorous and transparent process for validation. Specifically, the validation domains would be technical validation (e.g., how accurately does the solution measure what it claims?), clinical validation (e.g., does the solution have any support for improving condition-specific outcomes?) and system validation (e.g., does the solution integrate into patients' lives, provider workflows, and healthcare systems?).

Content testing

Although based on a different context, *The mHealth Planning Guide: Key Considerations for Integrating Mobile Technology into Health Programs* developed in 2015[33] offers some practical knowledge about solution testing and validation, that is reproduced below.

Content testing with members of the target population is critical to solution development. Test the content of the solution to ensure it is comprehensible, appropriate, accessible, and effective for the intended users. You do not have to test the content with a large sample size—in fact, to begin, interview 5 or 10 individuals, make changes based on feedback, and repeat the process until it is evident that the content is clear and effective.

Here are some tips[34] for the content testing phase:

- ✓ Test all of the messages or content, one section at a time, in the intended sequence and format. It is ideal if the content can be tested in the anticipated delivery format, such as voice or SMS, to accurately reflect the user experience.
- ✓ Ask a number of probing questions to assess the user's ability to understand, remember, and/or react to the message, video, survey prompt, etc. If appropriate, ask, "What is this message asking you to do?" to capture comprehension. Consider using a "think aloud" approach, during which you ask participants to narrate what they are thinking when they see the content.
- ✓ Observe the participant's verbal and non-verbal cues, noting moments of confusion or pause as well as ease.
- ✓ Ask the user how easy or difficult they find the messages.
- ✓ Explore reactions to, and preferences for, content length, tone, frequency, and the messenger.

[33] https://toolkits.knowledgesuccess.org/sites/default/files/solution_designtesting-key_considerations.pdf

[34] Ministry of Health. Republic of Kenya (2017) Kenya Standards and Guidelines for mHealth Systems. https://www.health.go.ke/wp-content/uploads/2020/02/Revised-Guidelines-For-Mhealth-Systems-May-Version.pdf

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- ✓ Ask for suggestions for word choice, keywords, or visuals for multimedia messages.

Prototype and Usability testing

Following with the mentioned *mHealth Planning Guide*, it outlines that technology development is an iterative process. Many technology groups use agile software development methodologies, including adaptive planning among a cross-functional team, incremental development, and overall flexibility to design and deliver an operational technology. Rather than starting with a binder full of specifications and building the entire solution, agile development breaks the specifications into many components in order to realize the end solution. Steps in an agile development process may look like this:

- At first, the technology might be built as a prototype —a low-cost, simple form of the technology—and tested with a small number of users for feedback.
- Then the technology will be built to address that feedback and meet an initial set of functional requirements and released in a "beta" form. Beta testing with users and administrators helps confirm usability, identify bugs, and improve overall functionality.
- When the technology is further adapted and ready for wide-scale deployment, the software components are packaged together and released, with the understanding that updates to the system will be needed in the future.
- Gathering user insights, preferences, and feedback at each stage of solution development is critical to the future success of the technology.
- Start as small and cheap as possible, and then continue to test, build, and iterate.

Key considerations

- ✓ Does the solution function as intended?
- ✓ What does or does not work well? What do end-users like and dislike about the solution?
- ✓ What could be improved, and how?
- ✓ Are end-users interacting with the technology as expected?
- ✓ Do end-users understand the content?
- ✓ Do they have preferences for when and how often to be contacted?
- ✓ Is the technology platform easy to use for project administrators?
- ✓ What do they like or dislike about the administrative user interface?
- ✓ What improvements can be made?
- ✓ Is data collected as intended, in the correct format?
- ✓ What are anticipated barriers to correct use based on observation and user testimonies?
- ✓ What can be done to overcome these barriers?

The experts say…

> *"[What works well in programs is] design research plus ethnographic practice: [we] wrote software with people using it; [we incorporated a] real-time feedback loop, which allowed midcourse corrections). [This is called] agile software development – you write a little [code] at a time, check with users, and then you write more iteratively (see what they actually do versus what the user tells you). This is core to mHealth development." – Merrick Schaefer, World Bank (with UNICEF at the time of the interview), Programme Mwana, Zambia*

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> *"Usability testing was incorporated at several levels. First, we did a lot of internal testing for the content and platform. Then we did beta testing with a small group representing end-users. Then, after the product's release to general public, we monitored and incorporated feedback from users. Usability testing doesn't stop after release of version 1—the solution should be continuously monitored and improved. Otherwise, people stop using it." – James BonTempo, CCP (with Jhpiego at the time of the interview)*

Data Collection, Monitoring & Evaluation

Following with the mentioned *mHealth Planning Guide*, mHealth implementers need to document the planning and implementation process, including key decisions that have been made. They also must demonstrate positive, measurable outcomes, including impact on health outcomes and health systems. Designing and incorporating a strong monitoring and evaluation (M&E) strategy for a project from the beginning, in conjunction with partners, will not only help ensure long-term support from stakeholders and funders, but will also help strengthen the evidence base for the field of mHealth.

To do this, those planning the M&E strategy need access to current information on the state of mHealth evidence, including where the information gaps lie and what will indicate success.

Key considerations

- ✓ How will the mHealth planning and implementation process, including key decisions and the rationale behind them, be documented?
- ✓ How often will process documentation be analysed in order to evaluate program implementation efforts?
- ✓ What indicators will be used to measure health outcomes?
- ✓ What indicators will be used to measure program success in other ways, such as cost savings?
- ✓ Do the project's M&E indicators meet the evidence and reporting requirements of stakeholders and funders?
- ✓ What, if any, standardized mHealth indicators have been incorporated into the M&E plan?
- ✓ Can data generated by the technology platform be used for evaluation and reporting?
- ✓ Is the proposed evaluation design feasible and appropriate given the resources available?
- ✓ Has a system been designed to measure the financial cost of implementation and to analyse the cost-benefit ratio?
- ✓ How will the information and feedback generated by M&E be incorporated into program design and implementation on an ongoing basis?
- ✓ Do you have appropriate staff on the team to implement the M&E plan?

The experts say...

> *"I [as the project manager] enrolled in the system. I knew that messages come in at about 2pm every day. One weekend, I noticed that I had not received a message by 8pm. I called my staff and our technology partner. They found that there was a group of 35 women who did not get the messages that day. So, our technology partner fixed the problem by resending the messages. We realized that there has to be close monitoring involved to take care of such problems,*

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and as a result, we added a data feature to generate a status report." Priya Jha, Georgetown University's Institute for Reproductive Health, CycleTel, India

LEGAL AND ETHICAL COMPLIANCE

The GDPR, which entered into force on 24 May 2016 and is applicable from 25 May 2018, has created a harmonised set of rules applicable to all personal data processing taking place in the EU.

The objective of this new set of rules is to ensure that personal data enjoys a high standard of protection everywhere in the EU, increasing legal certainty for both individuals and organisations processing data, and offering a higher degree of protection for individuals. For certain sectors, such as health, specific rules apply. In this field, the European mHealth Hub has developed *A Quick Guide to the GDPR*, that can be consulted on the Hub website[35] https://mhealth-hub.org/download/mhealth-and-ethics-a-quick-guide-to-the-gdpr#

The COVID-19 pandemic has focused attention significantly on data sharing, both in the context of public health reporting of disease incidence and contact tracing, and in the need for accessible data for collaborative research across many countries; both within and beyond the EU. Furthermore, such data are needed to evaluate the effects of treatments and vaccines.

The GDPR provides options for Member States for further specifications in order to adapt the application of the Regulation in (existing) national law, in particular in the area of health.

It is noted that in all the real experiences analysed, GDPR and ethical requirements are integral part of the mHealth solution and they were integrated into the app in the early development stage.

A few examples from desk research for further guidance can be found here by clicking on the specific topic. On the other hand, if you know any recent experiences or publications that might be relevant for this topic, please contact us by email info@mhealth-hub.org

[35] https://mhealth-hub.org/download/mhealth-and-ethics-a-quick-guide-to-the-gdpr#

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3.4.Monitoring and evaluation

This stage is focused on ensuring that the mHealth solution is performing as planned and is delivering the desired value and expected impact.

MONITORING AND EVALUATION

Monitoring and evaluation frameworks are essential elements in the mHealth app development and implementation process. Timely monitoring and evaluation of health apps are critical in order to identify achievements on their objectives. Also, it is a matter of the utmost importance for two reasons; firstly, it can play a significant role in assessing to what extent the app has achieved its goals and secondly, it may create a constructive environment among all stakeholders including patients, medical staff, and regulators. Therefore, framework and indicators list has to be created to track progress and evaluate goals.

E-Res Salud is an illustrative example of how to incorporate end-results and patient-experienced into a new assessment methodology in the organization.

After data analysis, the platform will be providing patients with real-time feedback of their own results, comparison with people of same age and sex group and a set of personalized recommendations based on their need identified in the PROMs questionnaires.

Learn more: https://mhealth-hub.org/eres-salud

TreC_FSE has been developed by Trento Region in Italy. After public discussion, an interinstitutional working grou was created in order to define the contents of the Project. The main strength is that the initiative was endorsed b the institutional side and delivered by the public service. The app was implemented in the framework of th competence centre for digital health TrentinoSalute4.0, which also provide for integration with the Provinci Healthcare System and release in the stores.

Learn more: https://mhealth-hub.org/trec-fse

Large-scale deployment of digital health and well-being technologies is dependent on the factors that facilitate or impede mobile health service delivery. Effort is needed to improve the quality and value of monitoring and evaluation in the context of mobile health, from implementers and researchers of digital health but also from policymakers to understand implementation fidelity and its impact. Patient needs are often very dynamic. This fact requires that the health apps must evolve through different stages of maturity. Key questions include whether an app addresses the identified needs, including technical functionality and feasibility. User satisfaction, effectiveness, impact and "value for money" are therefore central indicators for monitoring and evaluation of mobile health applications.

Examples of literature findings

Monitoring and evaluation of mobile health interventions are often carried out in multi-stakeholder environments. Size and diversity are just two of many factors that contribute to the complexity of mobile health implementation processes. Person-centred services require substantial changes in the culture and behaviour of organisations and individuals involved: from both the perspectives of service providers and users. Agbakoba et al.[36] stated that the roll-out

[36] https://mhealth-hub.org/implementation-factors-affecting-large-scale-deployment-digital-health-well-being-technologies

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of digital health and well-being technologies at scale requires a delicate and pragmatic trade-off between user engagement activities (e.g., co-design), the development of innovative services and the efforts allocated to widespread marketing and recruitment initiatives. Promoting and developing a shared sense of understanding of the applications across a broad range of stakeholders is necessary to promote wider access and adoption. However, more research is needed regarding the dimension, scale, and impact of user engagement activities on the subsequent uptake of technologies.

Mobile health has the potential to support care delivery for chronic illness. Despite positive evidence from localized implementations, new technologies have proven slow to become accepted, integrated and routinized at scale. Main stakeholders of the ecosystems of mobile health (researchers, health care practitioners, policy makers) need to understand the current landscape and the targeted actions to prepare the market and accelerate uptake and use in context and at scale. According to Lennon et al. (2017), evidence suggests that a greater investment in national and local infrastructure, implementation of guidelines for the safe and transparent use and assessment, incentivization of interoperability, and investment in upskilling of professionals and the public would help support the normalization of mobile health services. Factors hindering implementation relate to information technology (IT) infrastructure, governance, interoperability, accountability, and a market difficult to navigate. Factors enabling implementation included clinical endorsement, champions who promoted digital health, and public and professional willingness[37].

OUTCOME-BASED REPORTING

Outcomes-based healthcare's primary beneficiaries are the patients it serves. The main benefit to mHealth pursuing outcomes-based healthcare is having a patient-centered vision that motivates everything they do.

Health systems want to provide the best possible care to their communities. An outcomes-based framework requires calculated, thoughtful restructuring to meet current and future needs—and provides an ongoing template for driving continuous improvement.

E-Res Salud (Quironsalud 4H Public Hospitals Network, Madrid, Spain) is a showcase of outcome based reporting.

e-Res Salud routinely incorporates new outcome indicators into clinical activity that matters to the patient, what help doctors in their daily practice, creating a culture of self-assessment and continuous learning.

This initiative is currently capturing data of more than 8,000 patients in different healthcare processes. The future plans are, on one hand, to collect more data by adding more specific tools for a better stratification of processes and patients, and on the other hand, to explore expanding the initiative to other processes.

Regarding data analysis, based on the developed strategy, the collected information will have an earlier impact on the clinical activity. The organization will be providing patients with feedback on their own results in real time, comparison with people of same age and sex group

[37] https://mhealth-hub.org/readiness-for-delivering-digital-health-at-scale-lessons-from-a-longitudinal-qualitative-evaluation-of-a-national-digital-health-innovation-program-in-the-united-kingdom

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and a set of personalized recommendations based on their needs identified in the PROMs questionnaires.

Learn more: https://mhealth-hub.org/eres-salud

In outcomes-based healthcare, health systems focus on reducing variation on how they treat a wide variety of diseases and conditions. Health systems are constantly striving to overcome inefficiencies and provide high quality care to patients. Outcomes-based healthcare targets a more proactive approach, creating a healthcare system that strives to maintain healthy populations and prevent illness.

Outcome-based reporting is an instrument to measure the impact of mobile health interventions in health systems. Quality, improved access and cost of healthcare are relevant indicators, among others, to assess digital health implementations. In order to improvereadines for the uptake of digital health services, there are aspects relevant for the stakeholders involved. For instance, patients and health professionals may want to know what is the clinical value of patient portals and health apps; organisation leaders what factors hinder recruitment; policy-makers what is the scalability potential of mobile health interventions and their impact in the population.

Examples of literature findings

Outcome-based reporting is influenced by implementation challenges when designing and delivering digital health and wellness services at scale. Implementation lessons from the *United Kingdom Delivering Assisted Living Lifestyles at Scale (dallas)* program—a large-scale, national technology program to promote health and well-being – included flexibility, adaptability, and resilience as key implementation facilitators when shifting to new digitally enabled models of care[38]. On the other hand, when looking at recruitment, eight main themes emerged as key factors which hindered participation. These include how the dallas programme was designed and operationalised, constraints imposed by partnerships, technology, branding and recruitment strategies, as well as challenges with the development cycle and organisational culture[39].

Looking closer at stakeholder level, there are design guidelines based on research on clinicians' perspectives on patient generated health data (PGHD) in mental health settings that recommend: (1) improve data interpretation and sharing mechanisms, (2) consider clinical workflow and EHR integration, and (3) support personalized and collaborative care. More research is needed to demonstrate the best practices of PGHD use and to evaluate their effectiveness in improving patient outcomes, according to Wu et al. article[40].

However, despite growing interest from both patients and healthcare providers, there is little clinical guidance on how mobile apps should be utilized to add value to patient care. This is probably due to the fact that there are only a small number of clinical scenarios where published evidence suggests that mHealth apps may improve patient outcomes. These scenarios include:

[38] https://mhealth-hub.org/delivering-digital-health-and-well-being-at-scale-lessons-learned-during-the-implementation-of-the-dallas-program-in-the-united-kingdom-2
[39] https://mhealth-hub.org/engaging-in-large-scale-digital-health-technologies-and-services-what-factors-hinder-recruitment
[40] https://mhealth-hub.org/clinician-perspectives-and-design-implications-in-using-patient-generated-health-data-to-improve-mental-health-practices-mixed-methods-study

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- support clinical diagnosis and/or decision making;
- improve clinical outcomes from established treatment pathways through behaviour change and enhancement of patient adherence and compliance with treatment;
- act as standalone digital therapeutics;
- and primarily to deliver disease related education.

In these scenarios, health apps have the potential to hold value for patients when used as part of a clinical workflow[41]. Regarding patients' access to their health information, patients do not always understand the information or its implications, and digital health data can be difficult to navigate when displayed in a small-format, complex interface. To improve user experience, developers could look towards mobile health apps in design, function, and user interface. Useful features may improve their use and empower patients to track their overall health and disease states. Rigorous evaluation must ensure they meet their potential in improving patient outcomes[42].

A few further examples from desk research for guidance can be found here by clicking on the specific topic. On the other hand, if you know any recent experiences or publications that might be relevant for this topic, please contact us by email info@mhealth-hub.org

SECONDARY USE OF DATA

The introduction of the GDPR in 2018 has created a new framework for the protection of personal data in the European Union. It is particularly relevant to healthcare, where technological advances and the increasing availability of data from a range of sources offer many opportunities for the further processing (or secondary use) of data in scientific research, medicine development and policy making. However, these opportunities come with legal, technological and digital skills challenges.

In health care, the complexity of secondary use of data (Big Data) analysis also arises from combining different types of information. Starting with the collection of individual data elements and moving to the fusion of multiple data sets, the results can reveal entirely new approaches to treating diseases.

Big Data technologies are still in their early stages. Although powerful, there is clearly room for improvement. Regarding clinical data storage, data warehouses are widely employed as a means to integrate data from different clinical sources. Clinical Data Warehouses (CDW), thus, provide a unified view on clinical data. Many implementations of these warehouses rely on the i2b2 infrastructure and must be appropriately adapted to handle molecular biology data, as well as to enable clinical and "omics" data integration.

In February 2021, the Joint Action on the European Health Data Space (TEHDAS)[43] started with the mission to ensure that, in the future, EU citizens, communities and companies benefit from protected and secure access to health data, regardless of where the data are stored. The Joint Action will propose a data governance framework for the European Health Data Space which

[41] https://mhealth-hub.org/what-is-the-clinical-value-of-mhealth-for-patients-2
[42] https://mhealth-hub.org/patient-portals-and-health-apps-pitfalls-promises-and-what-one-might-learn-from-the-other-2

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will include guidelines on health data use in research and policy making, as well as on ethical, legal and social issues. It will also produce a data quality framework. Dialogue with stakeholders will be an important part of the strategy, providing insight into how to strengthen EU citizens' trust in data sharing and increase their capacity to engage with data.

To conclude, GDPR has put data protection high on the agenda. In terms of secondary use of health data and research, challenges exist due the legal intricacies and differences in its interpretation between EU Member States.

If you know any recent experiences or publications that might be relevant for this topic, please contact us by email info@mhealth-hub.org

CONTINUOUS IMPROVEMENT

A mHealth care system is a complex collection of interacting elements, each of which affects the others in myriad ways. Effectively dealing with any healthcare system issue, requires dealing with the various system dynamics in a coordinated way that takes into account how changes in one area will affect the functions in other areas. That is, it requires systems strategies and approaches.

The tools of operations management, industrial engineering and system approaches (such as Lean or Six Sigma, or Deming Plan-Do-Study-Act) have been shown to be successful in increasing process gains and efficiencies and it can be applied also when developing and managing mobile health solutions. The basic building blocks of applying a systems approach to mhealth care include:

- fixing the system orientation on the needs and perspectives of the patient and family;
- understanding the supply and demand elements;
- creating capacity for data analysis and measurement strategies;
- incorporating evolving technologies;
- creating a culture of service excellence;
- assuring accountability and transparency;
- committing to continuous process improvement;
- developing a supportive culture and organizational leadership that empowers those on the front lines to experiment, identify the limitations, and learn from those trials.

  Source: https://www.ncbi.nlm.nih.gov/books/NBK316143/

Maccabi case showed that any mHealth app has to be under constant development and improvement with focus on both patient and medical personnel needs, but considering the continuous changes in the solutions. Ever from the first version of the app, main weakness was that not all stakeholders were involved in the process which caused problems in the use of the app, but now both sides are actively involved in the design and implementation of upgrades or when new apps are created.

It proved to be crucial to involve doctors. All had active roles in testing the app and providing comments for improvement and that is now part of improvement process.

Learn more: https://mhealth-hub.org/maccabi-online

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Assuta Doctors is a good example of app under constant development and it is constantly being improved by inputs provided by both doctors and patients. First version of the app had only portal for doctors and possibility to exchange messages with patients. In further versions each time new and improved features were added and focused more on patients.

Learn more: https://mhealth-hub.org/assuta-doctors

Both examples point out that in order to constantly improve and be up to date, complex ecosystem has to be created and systemic approach using appropriate tools has to be in place early on.

Other examples from desk research for further guidance can be found here by clicking on the specific topic.

QUALITY CONTROL

One of the main conclusions of WHO-OECD-World Bank report "*Delivering quality health services*" on 2018 was "better health outcomes through improvement in quality":

> High-quality health services involve the right care, at the right time, responding to the service users' needs and preferences, while minimizing harm and resource waste. Quality health care increases the likelihood of desired health outcomes and is consistent with seven measurable characteristics: effectiveness, safety, people- centredness, timeliness, equity, integration of care and efficiency.

On the other hand, for building quality mechanisms into the foundations of health care systems, the five foundational elements critical to delivering quality health care services are: health care workers; health care facilities; medicines, devices and other technologies; information systems; and financing.

This same report outlines that quality is a complex and multifaceted concept that requires the design and simultaneous deployment of combinations of discrete interventions. The development, refinement and execution of a quality policy and strategy is a growing priority, in order to systematically improve health system performance.

Seven categories of interventions stand out and are routinely considered by health system stakeholders, including providers, managers and policymakers, when trying to improve the quality of the health care system:

1) changing clinical practice at the front line;
2) setting standards;
3) engaging and empowering patients, families and communities;
4) information and education for health care workers, managers and policy-makers;
5) use of continuous quality improvement programmes and methods;
6) establishing performance-based incentives (financial and non-financial);
7) legislation and regulation (aplicable on the national level).

Quality does not come automatically; it requires planning and should be clearly identified.

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All seven domains of quality of care (effectiveness, safety, people-centredness, timeliness, integration of care, equity and efficiency) have to be considered when developing any mHealth app, and a system for quality control has to be integrated as part of it.

Other examples from desk research for further guidance can be found here by clicking on the specific topic.

4. To sum up: a few success factors

mHealth solutions can improve health outcomes in a cost-efficient and scalable way. They assist healthcare professionals with the management and documentation of medical records, help improve productivity and allow access to information, among other actions.

These tools also help healthcare professionals to communicate findings and reduce error rates, not to mention the reduction of overall healthcare costs. Mobile solutions can also facilitate the treatment process, automate management systems and better manage patient experience.

They use sophisticated data analytics and mobile technologies to help provide the best care possible, at a lower cost, anytime, anywhere. Cloud-based solutions are gaining prominence as data is stored on the internet for easy access, removing the need for storing the data locally. New mobile applications integrate patient data with geo-location information stored on the cloud.

Mobile apps facilitate better and easier health management as provided in numerous examples in this Knowledge Tool 3.

The different experiences and articles included in this KT3 report highlight specific learnings for the different topics in this guide-oriented approach. Each experience can be consulted in the corresponding Annex.

From a general point of view, this report concludes with a **few success factors** observed in the development of this knowledge tool, that could be applied to any mHealth development aiming at the integration with the health system:

- Early and continued involvement of users, both healthcare professionals and patients, in order to get well designed mHealth solutions, acceptance and real impact.
- Teamwork across different disciplines, dialogue and collaboration between clinical, technical and IT profiles
- Clear and concrete explanation of the benefits and impact to all the actors participating in the mHealth intervention
- Partnerships with the right organisations to help speed the mHealth adoption and make it more effective
- A detailed analysis of infrastructure and future developments is crucial in early stages when developing mHealth solutions, as the lack of infrastructure can lead to a low use of the solution in the population

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- The importance of integrating mHealth solutions with different systems and enabling exchange of various types of data among all stakeholders.
- Accessibility, security standards and requirements are key when developing mHealth solutions.
- Good data management is an important success factor for mHealth solutions, with data of good enough quality to support the decision-making.
- Interoperability is both time and money saving, it is an inherent part of the whole system to be considered early on.
- Development of an evaluation framework and set of indicators to track progress and assess goals achievements when deploying mHealth interventions

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Annex I. Summary table

At the moment of writing this report, these below were the real experiences and articles from desk research gathered so far to illustrate the different topics. This table is open to further update through the KT3 specific section on the Hub website.

Topic	Real experiences and literature findings
01. Needs assessment	• ProEmpower • The Mangols Journey
02. Stakeholder and political support	--
03. Stakeholder and ecosystem analysis	• Heilsuvera.is • Remote monitoring and self-care for people suffering from chronic illness (ImagineCare) • TreC Diabetes • Petersen et al. (2015a)
04. Legal and regulatory analysis	• Mezarina et al. (2020) • Nurgalieva et al. (2020) • Petersen et al. (2015b) • A Quick Guide to the GDPR (Hub product)
05. Scope and resources	• mSaúde platform
06. mHealth opportunities	• Comprehensive medication management services • Andreoni et al. (2019) • Eren and Webster (2016) • Marzano et al. (2015) • Grekin et al. (2019) • Brandt et al. (2021)
07. Workplan development	• Mugitzen • Brandt et al. (2021) • eHealth Network mHealth sub-group • Jowett et al. (2021) • de Klerck et al. (2021)
08. Creating partnerships	• Orcha and Staffordshire County Council • Orcha and Our Dorset Digital • Vargas et al. (2020) • Zisman-Ilani et al. (2021)
09. Technical infrastructure requirements	• e-Nabiz • Mugitzen • Gutiérrez et al. (2019) • Paštěka et al. (2017) • Slovensky et al. (2017)
10. Interoperability with existing systems	• Maccabi • E-Nabiz • MyNHS Wallet • TreC Diabetes • Heilsuvera.is

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11. Feasibility studies	• Afonso et al. (2020) • Bull (2016) • Degroote et al. (2020) • Latif et al. (2019)
12. Alignment with clinical guidelines	• The eContinence project • Andersen et al. (2019) • Bowie-DaBreo et al. (2020) • Malvey and Slovensky (2014)
13. Business case and reimbursement	• Gagnon et al. (2016) • Moshi et al. (2019) • Rounds et al. (2019) • Tageo et al. (2020) • Whittaker et al. (2012) • Whitten et al. (2001)
14. Cultural change and digital skills	• E-Consultations in screening for familial hypercholesterolemia in city of Zagreb • Remote monitoring and self-care for people suffering from chronic illness (ImagineCare) • Armstrong (2019) • ~~Attipoe-Dorcoo et al. (2020)~~ • Cosco et al. (2019) • Herzog et al. (2014) • Herzog et al. (2015) • Urbauer et al. (2014)
15. Governance for mHealth	• E-Nabiz • Vesselkov et al. (2019)
16. User centered design considerations	• Megi app – hypertension chatbot • Orcha and Staffordshire County Council • Orcha and Our Dorset Digital • United4Health – Southern Norway • Assuta doctors • E-Consultations in screening for familial hypercholesterolemia in city of Zagreb • Reports online • Early detection of diabetic retinopathy (EDDR) • The eContinence project • Somers et al. (2019) • Simblett et al. (2019)
17. Commissioning mHealth	• --
18. Integration with eHR	• Mobile Medical Electronic Prescription (PEM Mobile) • 1177 care guide e-services • E-Res Salud • mSaúde platform • Mugtizen • TreC Diabetes • Heilsuvera.is • The Mangols Journey • Marceglia et al. (2015) • Ndlovu et al. (2020)
19. Authentication - Authorization	• MyNHS Wallet

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	• Mobile Medical Electronic Prescription (PEM Mobile) • 1177 care guide e-services • Remote monitoring and self-care for people suffering from chronic illness (ImagineCare) • Sauermann et al. (2020) • Teng et al. (2018)
20. Patient reported data	• E-Res Salud • Bradley (2020) • Cosco et al. (2019) • Deshpande et al. (2011) • FDA (2020) • Kelly et al. (2020) • Lavallee et al. (2020) • Menychtas et al. (2017) • O'Connor et al. (2015) • Sartori (2020) • Schobel et al. (2016) • Seewald et al. (2020) • Thilakanathan et al. (2016) • Wu et al. (2020)
21. Open data models	• Delvaux et al. (2018) • Demski et al. (2016) • Sharma et al. (2017) • Van Munster et al. (2016)
22. Interoperability models	• Reports online • MyCupMarche • Trentino Salute+ • mConnecta platform • TreC FSE • Chen et al. (2012) • Saripalle et al. (2019) • El-Sappagh et al. (2019) • Marceglia et al. (2015) • Ndlovu et al. (2020) • Sauermann et al. (2017) • Blobel et al. (2018)
23. Data security and legal framework	• Reports online • 1177 care guide e-services • MyCupMarche • Trentino Salute+ • mConnecta platform • TreC FSE • Thilakanathan et al. (2016)
24. Third party integrators	• --
25. Solution testing and validation	• United4Health – Southern Norway • ProEmpower • mSaúde platform • The eContinence project • Kulanga et al. (2016) • Mathews et al. (2019) • K4Health – mHealth planning guide • Ministry of Health. Republic of Kenya (2017)
26. Legal and ethical compliance	• Muchagata et al. (2018)

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	• Muchagata et al. (2019)
27. Monitoring and evaluation	• E-Res Salud • Trec FSE • Agbakoba et al. (2016) • Lennon et al. (2017)
28. Outcome-based reporting	• E-Res Salud • Agbakoba et al. (2016) • Baldwin et al. (2017) • Devlin et al. (2016) • Fortuin et al. (2016) • Lennon et al. (2017) • O'Connor et al. (2015) • Rowland et al. (2020) • Wu et al. (2020)
29. Secondary use of data	• MyCupMarche
30. Continuous improvement	• Maccabi • Assuta doctors • Wu et al. (2020)
31. Quality control	• WHO, OECD, World Bank (2018) report: Delivering quality health services • Larson (2018)

Table 1. *Summary of real experiences and articles from desk research by KT3 topic*

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Annex II. Key notes on interoperability aspects in health systems

Annex II main contributor: University of Applied Sciences Technikum Wien

State of the art in Europe

The EU has invested substantially into the common market. Doing so, the EU has emphasized the need to efficiently implement coherent IT services, that make use of semantic interoperability in the best possible way.

ISA2

The ISA$_2$ Program - Interoperability solutions for public administrations, businesses and citizens - supports the development of digital solutions that enable public administrations, businesses and citizens in Europe to benefit from interoperable cross-border and cross-sector public services. Find the details about ISA2 on the **ISA2 home page**.

In the EU member states, a large number of solutions have already been deployed, that were supported by ISA2. Go here to learn more about these **ISA2 solutions.**

Connecting Europe Facility (CEF)

The Connecting Europe Facility (CEF) is a key EU funding instrument to promote growth, jobs and competitiveness through targeted infrastructure investment at European level. Learn more on the CEF home page.

eHealth DSI within CEF

Within CEF, specific business domains of the European market implement interoperable IT services. The current focus domains are Energy, Transport and Telecom.

In order to facilitate cooperation and re-use of existing components, CEF works to provide "CEF building blocks" and DEF Digital Service Infrastructures" to implementers of services in the member states.

Within CEF, work is ongoing to implement cross border data exchange to support patient care. Find an incredible number of details at the eHealth DSI Operations Home space.

At this time the focus is on the European Patient Summary and ePresciption. These services are currently rolled out over Europe, see the eHDSI Operations Home. The goal is to provide these services all over Europe by the year 2020.

A large variety of international IT standards are used within the eHealth DSI. Go here for the specifications of the eHealth DSI to see exactly how.

Use of IT Standards for eHealth in the EU

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In 2019 the EU published a **Recommendation on a European Electronic Health Record exchange format**. It is recommended to exchange Patient Summaries, ePrescription/eDispensation, laboratory results, as well as medical imaging data and reports. This recommendation builds on a series of activities in the EU and its member states. Further work is ongoing to provide more detailed guidance on how to implement coherent IT services for health and care to better support citizens in Europe, while maintaining the quality, to sustain health and care on the long term.

Much effort is invested into interoperability in healthcare, across different fields of application. Find here some examples. Future efforts may target to further interconnect and harmonise the IT infrastructures that support the services mentioned here. Both users as well as manufacturers of IT systems in health will benefit from the improved data quality and quantity as well as from increased efficiency. No longer needed to re-enter data that was already entered into an IT system! (Also see the **European legislation on open data and the re-use of public sector information**, e.g. the Open Data Directive and the PSI directive)

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eHealth DSI: Cross border information sharing for patient care

Within the **"Connecting Europe Facility" (CEF) program**, many different **Digital Service Infrastructures (DSIs)** are being developed and deployed, for different business domains of the public services in the EU. "The **eHealth Digital Service Infrastructure (eHDSI or eHealth DSI)** is the initial deployment and operation of services for cross-border health data exchange under the Connecting Europe Facility (CEF). eHDSI sets up and starts deploying the core and generic services, as defined in the CEF, for Patient Summary and ePrescription."

IT services are currently being developed and deployed throughout Europe. **Detailed specifications are available for the eHealth DSI**.

European Reference Networks (ERNs) for patients with rare diseases

European Reference Networks (ERNs) for rare diseases "create a clear governance structure for knowledge sharing and care coordination across the EU. They are networks of centres of expertise, healthcare providers and laboratories that are organised across borders". rare diseases are a very important field, where interoperability can truly deliver. This is exactly what interoperability must enable: Move data to places where it can be processed efficiently. From that, provide great benefits for citizens. Connect those who experience a situation with those who work to better understand and act in the situation.

Many organisations are involved in ERNs. They are running large IT infrastructures to enable sharing information within the ERNs.

- The **RareConnect** network, for example, enables rare disease communities to connect and share information. RareConnect provides moderated online forums.

- The **European Patient Identity Management (EUPID)** system was developed within the ENCCA project (European Network for Cancer Research in Children and Adolescents). It enables to support secondary use of data while maintaining privacy.

- **EURORDIS** is a non-governmental patient-driven alliance of patient organisations representing 864 rare disease patient organisations in 70 countries. **EURORDIS runs a platform**

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to support patients with rare diseases. This platform provides a significant amount of information and services.

Other IT services enable healthcare providers and patients to provide data from individual patients. This data generates valuable evidence to expand the knowledge about specific diseases. This knowledge is then used to support and treat individual patients. In this way, ERNs contribute substantially to collect all available information, to aggregate and review it as a first step. Further on, ERNs then make the best possible use of the available evidence, in that they provide it to patients no matter where they are settled geographically.

Registers / Registries

Registers (also called Registries) for medicine evolved historically over many years. The "London Bills of Mortality" was initiated in the 16th century. It is often referred to as one of the origins of the International Classification of Diseases (ICD). ICD is today managed by the World Health Organisation (WHO), see the **WHO History of the development of the ICD**.

Today, in the EU and internationally numerous registers have emerged. The **European Network of Cancer Registries (ENCR)** is one example of public service. It combines and orchestrates the efforts of local registers in the EU member states. The **Network of Orthopaedic Registries of Europe (NORE)** is an international registry network built up as a standing committee of EFORT and founded in 2015. NORE focuses on medical device surveillance and arthroplasty outcome to support improvements in patient care.

Other registers have emerged from research projects. These registers often encounter challenges as the research funds reach their limits, and it becomes difficult to sustain the effort. Overall hundreds of medical registers exist in the EU and worldwide.

Registers have gained attention in the EU as a result of the changes in the **Medical Device Regulation**. Among the **improvements that the regulators targeted**, we find the **strengthening of post-market surveillance requirements** for medical device manufacturers. Medical registers may provide a valuable source of post-market data that may be used to evaluate the performance of devices in the field. Many device manufacturers find it hard to build their own tools and infrastructures to collect post-marketing data. In this way, registers may serve as a means to support compliance to the MDR.

Automated versus manual data collection - Interoperability between Registries and EHRs

One general challenge of medical registers is to support the medical staff to enter data at a sufficient level of quality, efficiently. Electronic Healthcare Records (EHRs) serve as the primary means for clinicians to record medical observations about their patients. In the best of worlds, this information may be reused in medical registries. A 2014 report of the Agency for Healthcare Research and Quality (AHRQ) suggests that IT-supported data collection and interoperability between EHRs) and medical registries is useful to improve quality: "**Besides enabling health care information to be more readily available for registries and other evidence development purposes, bidirectionally interoperable EHRs may also serve an efferent role of delivering relevant information from a registry back to a clinician (e.g., information about the natural history of the disease, safety, effectiveness, and quality)**." (Senior Editors: Richard E Gliklich, MD and Nancy A Dreyer, MPH, PhD. Editor: Editor: Michelle B Leavy, MPH.: Rockville (MD): Registries for Evaluating Patient Outcomes, 3rd edition

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- A User's Guide. Agency for Healthcare Research and Quality (US); 2014 Apr. Report No.: 13(14)-EHC111. The report also notes that the challenge remains to implement this interoperability in practice.

Interoperability principles to be considered by ICT and health authorities in countries

IT interoperability enables IT systems to share data as they provide services. On top of interoperability, semantic interoperability enables IT systems to automatically process the data that was shared. This then enables the IT systems to better support users, with automated functions like decision support, comfortable searching and re-use of the data.

To achieve this, a lot of aspects must be satisfied, ranging from legal and regulatory aspects, to organisational and then to procedural issues, and finally the semantic and technical details. In the European Union (EU) the **New European Interoperability Framework (EIF)** was established, to define and better understand all these layers of interoperability. This was done to implement interoperable IT services in the public sector in the EU. **See the image of the EIF Conceptual model, under "What has changed", and find more information on the EIF page.**

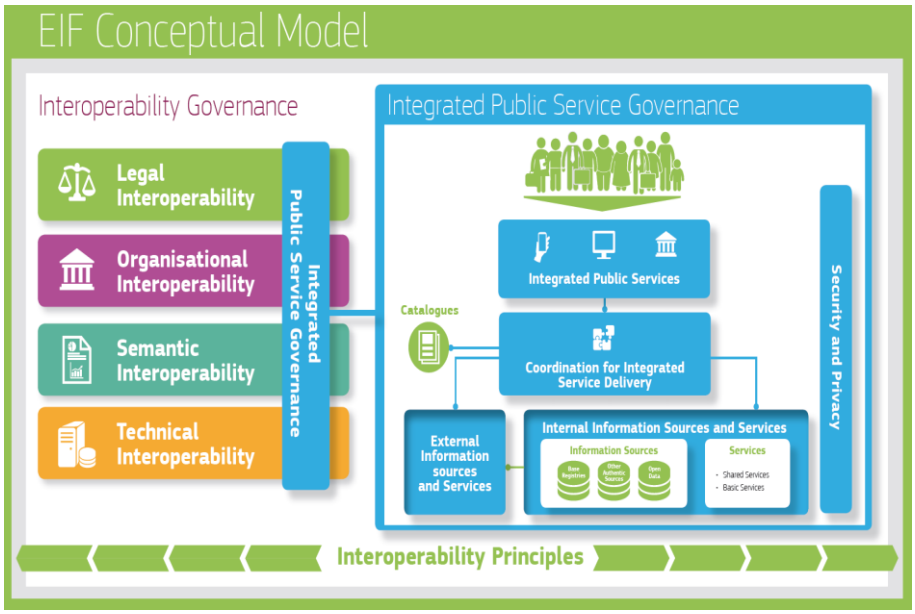

Figure 4 *The European Interoperability Framework (EIF) conceptual model*

This framework promotes the idea of "interoperability-by-design" for the design and operation of European public services.

EIF was taken forward in EU projects and evolved into the "eHealth Network: Refined eHealth European Interoperability Framework" that was finally adopted by consensus by the eHealth Network, Brussels, 23 November 2015.

Wide range of expertise is needed to put this into practice. This is best achieved, by focusing on specific services, following a defined long-term plan, that targets to deliver measurable benefits to the different groups of users (e.g. patients, health care providers, vendors) and stakeholders (e.g. administration, regulators). Long term engagement and buy-in must be achieved, on the levels of lawmakers, administrations, management, healthcare and software implementers.

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Technology alone will not reach this goal. Legal frameworks are essential prerequisites and must evolve in synchrony with technology.

From these long-term plans, priorities will typically arise to implement specific services on shorter term, within one year. At this stage work will start to define use cases for the needed functions. Based on this, IT standards and technologies will be chosen to enable the implementation of the needed functions. This knowledge must be captured in clear and well-defined specifications that are harmonised between all parties. Finally, these specifications must be implemented in software, tested and deployed. Alongside, testing tools and methods are needed, to assure interoperability in practice. The "one-year cycle" has emerged to be most useful: The focus is on the highest priorities, on short term benefits, with the perspective to add more functions in the next years.

This method is often termed as "profiling" approach. It was successfully applied in the EU efforts towards cross border information exchange (CEF eHealth Digital Service Infrastructure for the European Patient Summary and ePrescription). The "Integrating the Healthcare Enterprise" (IHE) initiative has provided substantial input into these efforts, together with other organisations, e.g. Health Level 7 (HL7), Personal Connected Health Alliance (PCHA), IEEE, CEN, ISO and GS1. A global community of implementers emerged, which has generated interoperable solutions in healthcare globally.

"Healthcare professionals seeking to acquire or upgrade systems need a convenient, reliable way of specifying a level of compliance to standards sufficient to achieve truly efficient interoperability. Profiles provide a common language for purchasers and vendors to discuss the integration needs of healthcare sites and the integration capabilities of healthcare IT products. They offer developers a clear implementation path for communication standards supported by industry partners and carefully documented, reviewed and tested. They give purchasers a tool that reduces the complexity, cost and anxiety of implementing interoperable systems. Profiles organize and leverage the integration capabilities that can be achieved by the coordinated implementation of communication standards and security standards. They provide precise definitions of how standards can be implemented to meet specific clinical needs." IHE (https://www.ihe.net/resources/profiles/)

Processes with major influence in the large-scale adoption of mHealth

Keeping in the logic of levels of interoperability is key to succeed with large-scale adoptions. As mentioned already legal bases have to be available before further adoptions can be implemented successfully. These levels of interoperability include in hierarchical order the legal interoperability, the organisational interoperability, semantic and finally technical interoperability.

A given legal framework leads to structured tenders by healthcare organisations and bigger entities keeping in the same structure and requirements for the requested solutions. This will trigger industry to provide solutions, fitting the given technical and organisational requirements. If the latter are agreed upon on a larger scale, between European member states, for example, comparability and functional information interchange - also on a cross-border level - can take place.

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Further prerequisites for the successful implementation of large-scale adoptions also requires a structural change in the reimbursement policy for insurance companies. The investments of companies follow reimbursement principles. The current system is mainly focusing on treatment, rather than prevention. Many mHealth measures support prevention. This must be considered in regulations for payers and reimbursement.

In Austria, long term efforts have brought forward a national electronic healthcare record, Elektronische Gesundheitsakte (ELGA). ELGA enables to share medical reports (laboratory, discharge, imaging) between healthcare providers to support the care for individual patients. ELGA makes substantial use of international IT interoperability standards and specifications, (e.g. IHE and HL7). Based on the ELGA specifications, a framework guideline for the IT infrastructure for telemonitoring was developed and published by the Austrian Federal Ministry of Health, to enable telemonitoring for national disease management programs, e.g. for diabetes and cardiomyopathy.

If interoperability is given in all mentioned levels (from legal to technical), the provided infrastructure, digital solutions and singular devices can be interchanged. This promotes innovation and opens up the market to a higher variety of vendors and allows users to choose from several vendors in procurement. By these means, the economic burden of investing in new healthcare service infrastructure is lowered.

Note: see topic 29 "*secondary use of data*" as complement to the content of this Annex.

Future trends and forecasts

The entire process of healthcare system development is hugely complex and involved many initiatives over the last decades. We see progress on many levels, ranging from medical, legal to technical. So, all together there is light at the end of the tunnel. In this situation, concerted actions that span a wide range of activities on regional, national, European and international level become even more important. Therefore, activities like the mHealth Hub should focus on supporting and coordinating the many existing initiatives, to further strengthen the existing synergies.

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Annex III. Summaries of real experiences of mHealth integration in health systems

Note: all these experiences can be found in a web environment at the KT3 specific section on the Hub website

Initiative summary

1177 Care guide e-services

Topics

1177 Care guide e-services has a successful approach to the following topics:

- Execution
  - **Integration with EHR**
  - **Authentication, authorization**
  - **Data security – legal framework**

Introduction

1177 is a secure digital portal to access publicly funded healthcare. Through 1177, residents can communicate 24/7 with healthcare in a secure way and do a variety of functions, for example book an appointment, renew prescriptions or read their medical records. It gives residents the opportunity to gain better insights and an overview of their health and care status. 1177 is available in all regions of the country (Sweden) and is jointly financed by them.

Communication between residents and clinics

All clinics that are financed by a region can let the residents do care cases in 1177. Residents can communicate with the clinic to, for example, receive general advice, order a journal copy or renew a prescription. Clinics are able to create and shape the type of services they want to offer to their residents.

Guardians with children under the age of 13 can choose to be agents and handle the children's' care cases using their own login credentials and through their own account.

Self-service for residents

It is possible for residents to search and receive information themselves and perform many tasks. For example, access their medical records and get certificates, book appointments, plan sampling and take part in internet-based support and treatment programmes.

Secure handling of personal data

It is safe to use 1177. Great emphasis has been placed on protecting personal data, so no unauthorised person could get access to the information sent between caregivers and residents.

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Residents use e-identification to log in whereas healthcare staff logs in to the professionals-clinicians platform by using a SITHS card.

Let the resident sign up

The listing function allows the resident to register at a preferred clinic into the selected region. Regions could activate the listing function by connecting their listing system with the National Service Platform.

National Service Platform is a technical platform that acts as a hub, or a kind of gear. It simplifies, secures and streamlines the exchange of information between different IT-systems in health and care.

Let the resident book an appointment

Via web time booking, the resident can book, re-book and cancel an appointment at a clinic. The clinics themselves choose which times should be able for booking. The book time function allows the resident to overview booked care visits and times for all clinics in Sweden.

Send messages to the resident's inbox

With the inbox function, it is possible to send messages from external systems such as quality registries and information systems to the resident's inbox in 1177.

Form to fill out

With the form management function, healthcare can retrieve information from residents in a secure and structured way, integrated with the healthcare system. The function can be used in several ways: into own organisation's healthcare information system, into Form Management's web-based personnel tools, or a combination of two.

Inera is a limited company owned by regions, municipalities and Swedish Regions and Municipalities organisation. The mission is to create the conditions for digitalisation, by providing the owners with a common digital infrastructure and architecture. Several of Inera's services can be displayed in 1177 e-services:

- The medical record - where residents can see their own medical record entered by the healthcare professionals.
- Certificates - where residents can read, download and send their digital medical certificates, for example, to the Swedish Social Insurance Agency and the Swedish Transport Agency.
- Sample management - where residents can order and plan their samples and order home sampling kits.
- Support and treatment - where residents can take part in internet-based support and treatment programmes offered by a therapist or start a programme themselves.

Dependencies with other services

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In order for a clinic to be able to use 1177 e-services, the clinic needs to be listed in the Catalog Service HSA and the staff needs to have a SITHS card.
Identification service SITHS is used for secure identification and login of the users.
Directory service HSA is used to control users' permissions.

Some facts for residents:

- 200 million visits under 2020 on national level
- 12,5 million logins on December 2020 on national level
- 2,6 million unique logins on December 2020 on national level
- 88,4% of the users logged in with mobile Bank-id authentication method on national level
- 8,1 million resident accounts on December 2020 on national level
- 102.049 resident accounts in Region Jämtland Härjedalen

Some facts for healthcare professionals:

- 551.694 logins on December 2020

Some facts for number of incoming and closed cases and number of active clinics:

- 778.071 incoming cases on December 2020 on national level
- 771.604 closed cases on December 2020 on national level
- Most popular type of cases: renew prescription, book time, contact us, ask for advice, send messages
- 11.374 active clinics on national level and 117 active clinics in Region Jämtland Härjedalen

1177 and handling of Covid-19

At 1177.se you can read about the latest information about vaccinations and book appointments for vaccinations in the preferred region. Vaccinations are registered through Svevac and there is an automatic reporting to the Public Health Agency's national vaccination register. At 1177.se, visitors can quickly get information at regional and national level about the vaccinations.

Web time booking, to book tests for ongoing covid-19 infection and sampling for antibodies via 1177.se. The resident can easily search for the nearest vaccination center in close area.

Registration of vaccinations in Svevac record system for registering vaccinations and reporting to the national vaccination registry at the Swedish Public Health Agency. Svevac is used by doctors, nurses and other qualified staff who work with vaccinations. They can also check vaccinations a person has received, how many doses, date and care provider.

Updated information in Sil - Sil - Swedish information services for medicines, has carried out the work to secure a fast-track approach so that medicine information about each approved covid-19 vaccine must be entered in the medical record systems before vaccination starts.

Access into sampling and results for residents who are traveling is an important part of reducing the spread of the Covid-19.

Links

https://www.inera.se/tjanster/1177-vardguiden/1177-vardguidens-e-tjanster/
https://www.inera.se/nyheter/nyheter/sa-hjalper-1177-vardguiden-och-inera-till-med-vaccinationerna/

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Interview summary

Interviewees: Rachelle Kaye (International Projects Coordinator)

mHealth Practice:
Assuta Doctors
Interviewers: Ivana Ostoic (DZZC)
Date of interview: 2020-11-29

Topics

Assuta Doctors has a successful approach on the following topics:

- Planning > **User centered design considerations**
- Monitoring and Evaluation > **Continuous improvement**

Summary of main interview ideas

- Objectives of the Assuta-doc app: fully operational app that enables doctors to monitor patients but also enables patients to be prepared for all procedures in the medical centre; to leverage doctor/patient model; to enable rapid response for all "red flag" alerts set up by doctors.
- It proved to be crucial to involve doctors, medical staff, ICT staff, administration and patients.
- The main barrier was to make doctors use the app.
- The main success factors were that doctors started the development, and that the process was technically and organisationally aligned.
- Lessons learnt: you need to co-design with the user and to build apps to support the workflow, particularly when dealing with doctors. In the first version doctors complained, so they realized that they should sit with doctors while developing the app.

Scope of the mHealth practice

- Assuta doctors is a fully operational app that enables doctors to monitor patients but also to enable patients to be prepared for all procedures in the medical centres.
- It leverages doctor/patient model.
- It enables rapid response for all “red flag” alerts set up by doctors.

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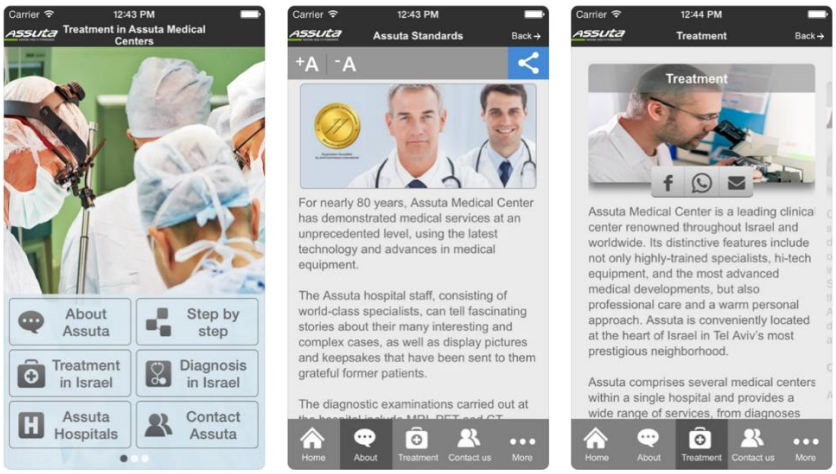

Topic: User centered design considerations

Assuta Medical Centers is the largest, private medical service in Israel, with eleven clinics and hospitals. Assuta provides full range of medical services including innovative surgeries, diagnostic procedures and specialist outpatient care. Most doctors are not employed by Assuta but are credentialed as attending physicians, therefore remote monitoring of the patients is of outmost importance.

Assuta Doc app is an m-health solution that is connected with Assuta electronic medical record and doctors are able to monitor every aspect of their patients' care. The app is regularly updated.

All urgent medical issues are automatically "RED" flagged by the app and send alert to medical staff.

The app also enables communication with the patients.

It took around 6 months for the first version of the app and it has been in use since 2013.

Doctors initiated development as they are not residents but are accredited with clinics and hospitals, so they needed the app to better monitor their patients

Main *strength* is the speed of reaction of the doctors as they can define in which situations apps shall alert them automatically. Not only that app shortens the time of the response but also enables patients to be actively involved in the process.

It proved to be crucial to involve doctors, medical staff, administration, patients an ITC staff of the hospital.

Main *barrier* was to make doctors use the app.

Main *success factors* were that doctors started the development and that technically and organisationally the process was aligned.

The main *lessons learnt* were that you need to co-design with the user and to build apps to support the workflow, particularly when dealing with doctors. For example, in the first version doctors complained, so they realized that they should sit with doctors while developing the app.

Topic: continuous improvement

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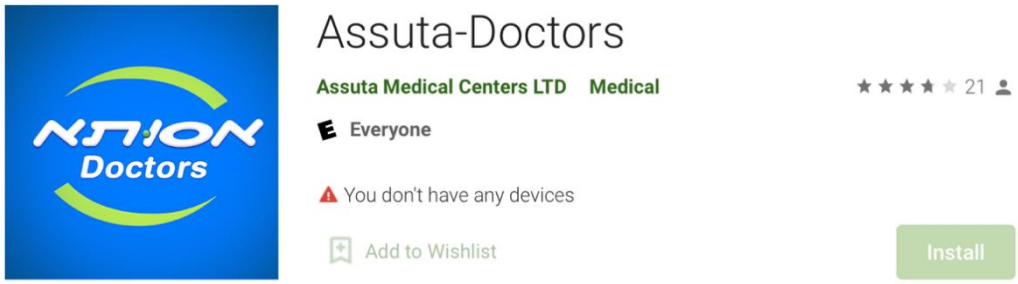
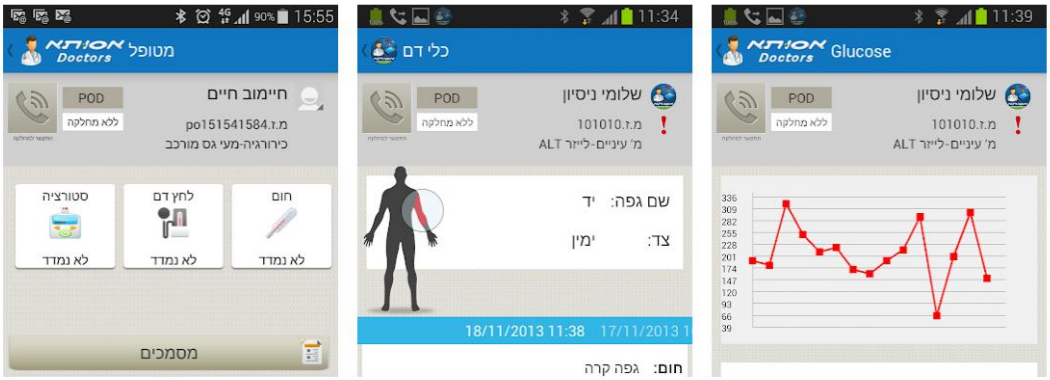
The app is under constant development and it is constantly being improved by inputs provided by both doctors and patients.



First version of the app had only portal for doctors and possibility to exchange messages with patients. In further versions each time new and improved features were added and focused more on patients.



The project started in 2012, and since 2013 the app is operational. The main objective at the start was to develop a tool to enable doctors who are not residents to monitor patients and have rapid response to any emergency. Doctors worked closely with ICT experts in order to develop an app for real and practical use.

Main *lesson learnt* is that all stakeholders have to be involved in the process, not only doctors. Otherwise, the app will not be used as it is supposed to. There is as well a need within the app to have tutorials to explain to patients but also to doctors all the steps and how to use the app.

As Assuta-doc is an in-house application, it did not require any certification process.

Future perspectives: now Assuta is creating an app for the nurses. Also, a number of other apps for the patients have been created, and at some point all will be put together and connected to the main system. Next step is integration between all of the apps created within the hospital and with the medical record.

References

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

- https://www.assuta.co.il/en/ - Assuta Medical Centres home page
- https://en.bookimed.com/clinic/assuta-hospital/ - general info about Assuta Medical Centres
- https://apps.apple.com/il/app/treatment-in-israel-mobile-app/id905926697 - Assuta Doc app
- https://www.connecare.eu/the-consortium/assuta-medical-centers/

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

Interview summary

Interviewee: Ana Mašić (Health Center Zagreb Centar (HCZC)

mHealth Practice:

Comprehensive medication management services

Interviewers: Ivana Ostoic (HCZC)

Date of interview: 2021-01-12

Topics

This initiative about comprehensive medication management has a successful approach to the following topic:

- Initiation
    - **mHealth opportunities**

Summary

Objectives of the app:

- to implement a new practice management system of Comprehensive Medication Management (CMM) services at the county health centre in Croatia
- to evaluate the clinical impact of CMM services in patients with chronic diseases

It enables communication between GPs with both, hospital medical specialists and practising pharmacists providing CMM services, thus creates a unique platform for patient referral and care plan sharing.

Scope of the mHealth Practice

The initiative has two big objectives:

- to implement a new practice management system of comprehensive medication management (CMM) services at the county health centre in Croatia.
- to evaluate the clinical impact of CMM services in patients with chronic diseases.

Topic: mHealth opportunities

Electronic consultation platform **Zdravlje.net** (Health.net) PRO is a web-application for health professionals.

It enables communication between GPs with both, hospital medical specialists and practising pharmacists providing CMM services, thus creates a unique platform for patient referral and care plan sharing.

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

As part of the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA), a delegation from the Zagreb-Center Health Center and partners from the IT industry, state, city and academic institutions visited the Spanish provinces of Andalusia and Galicia to learn more about these health systems and good practices. Having in mind the positive effects of the application of new IT technologies on the Spanish health system, Dom zdravlja Zagreb - Centar and MCS Grupa d.o.o. launched a pilot project Zdravlje.net PRO which enabled electronic consultations between doctors of the Health Center, hospital specialists and pharmacologists.

Family physicians, gynaecologists and pediatricians of the Health Center Zagreb - Center can offer their patients, when this type of consultation is appropriate, electronic consultations with a specialist. In that case, the doctor will send a short history of the disease, the patient's findings and an electronic A5 referral to the specialist via the protected Zdravlje.net PRO interface, and ask for an opinion. Specialists respond in a short time (usually in a few days), which significantly reduces the usual waiting time for a specialist finding. Because they are based on the principle of "information travels, the patient stays", electronic consultations lead to significant time and financial savings for patients, doctors and the entire health system, while increasing the standard of health care because they make specialist services more accessible. The system also enables consultations of doctors with pharmacologists from the pharmacotherapeutic counseling center of the Health Center Zagreb - Center.

The Zdravlje.net PRO pilot project started in October 2017, and so far more than 100 primary health care teams of the Zagreb Health Center and more than 35 specialists (22 specialties) from 5 institutions have been included in the system.

We are continuously working on the technical improvement and expansion of the electronic consultation system, as well as on educating doctors about the use of the system.

Review of the work of the Zdravlje.net PRO system:

References:

https://dzz-centar.hr/projekti/zdravlje-net-pro

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

Interview summary

Interviewee: Antonija Balenović, Tamara Kralj - Health Center Zagreb Centar (HCZC)

mHealth Practice:

Early Detection of Diabetic Retinopathy (EDDR)

Interviewers: HCZC staff

Date of interview: 2020

Topics

EDDR has a successful approach on the following topics:

- Planning
    - **User centered design considerations**

Summary

Objectives of the app:

- A referral route for the assessment of patients eye condition-GP informing general ophthalmologist about patients suffering from diabetes, which need regular eye checkup.
- General ophthalmologist triage out lower risk patients who need minimal ongoing specialist input, takes those patients for checkup as needed so that moderate or lower-risk conditions could be managed outside HES clinics. If necessary, refers the patient to HES where treatment of complications is performed.
- Direct referral to the HES or a fast track urgent referral pathway for patients with complications that need early treatment.
- After realization of necessary procedures, inform the patient's doctor or GP practice about further patient management.

In Health Center Zagreb Centar (HCZC) there are available teams of general ophthalmologists so we developed concept of connecting general practitioners and hospital eye services through digital consultations that enable early action. General ophthalmologist is particularly well placed to oversee the needs of patients suffering from diabetes and interact with primary care services (GP), co-ordinate better control of the flow of patents into and out of the hospital eye services (HES).

Outcomes

GP using the platform reported receiving fast consultations, early refferal of patients to general ophthalmologist. Hospital ophthalmologists reported treatment of patients conditions in early stages. Lower healthcare costs by general ophthalmologists treating low-risk patients.

The initiative was developed with focus on patient and allowing to spend less time in medical facilities.

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

Interview summary

Interviewee: Ana Mašić (Health Center Zagreb Centar (HCZC)

mHealth Practice:

e-Consultations in screening for familial hypercholesterolemia in City of Zagreb

Interviewers: Ivana Ostoic (HCZC)

Date of interview: 2021-01-12

Topics

e-Consultations has a successful approach on the following topics:

- Planning
  - **User centered design considerations**
  - **Cultural change – digital skills**

Summary

Objectives of the app

- eConsulations is primarily used by public health institutions such as University Hospital Center Zagreb and Health Center Zagreb Centar, but will also include general practitioners working in private offices. To detect patients with familial hypercholesterolemia in primary care for primary and secondary prevention.
- To regularly monitor the health status of patients with established familial hypercholesterolemia.

Change management is crucially important.

Proper change management plan could overcome all the resistance coming from the field.

Scope of the mHealth Practice

1. eConsulations is primarily used by public health institutions such as University Hospital Center Zagreb and Health Center Zagreb Centar, but will also include general practitioners working in private offices. To detect patients with familial hypercholesterolemia in primary care for primary and secondary prevention.
2. To regularly monitor the health status of patients with established familial hypercholesterolemia.

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To find patients with a history of cardiovascular incident and poor control of LDL-cholesterol. The initiative is currently meant to be used in City of Zagreb, specifically in Health Center Zagreb Centar and University Hospital Center Zagreb. It is possible to spread the initiative to other healthcare providers.

Topic: User centered design considerations

Zdravlje.net and eConsultations have been integrated into the HCZC primary care digital service system and eConsultations is supplemented to UHCZ hospital information system as well. Specifications for screening for familial hypercholesterolemia in patients in HCZC have been determined and the data is to be collected.

eConsultations platform is connected to Croatian Central Health Information System which enables secure interchange of patients data between medical professionals included in providing healthcare and contains an electronic health record. Selected data of the EHR can be seen by medical professionals and the patient.

The initiative provides the medical professionals with a communication tool for integrated healthcare and a screening tool for familial hypercholesterolemia and/or poorly controlled dyslipidemia. A part of the initiative is a Zdravlje.net application which serves as a communication channel between healthcare professionals and the patients.

The initiative includes Zdravlje.Net mobile patient platform (Health diary, GP-patient messaging and Group messaging) as a communication tool between general practitioner (GP) and the patient.

Zdravlje.Net PRO interface connects the general practitioner with a hospital specialist. With e-Consultations, the GP creates an electronic referral to a specialist using a patient's medical history information, attaching any relevant laboratory results, radiological findings, etc. Specialists can respond or request further information and then recommend a care management.

Topic: Cultural change – digital skills

One of the main considerations proved to be the need for cultural change and increase in the use of digital skills especially in the age groups 65+ who are not using smart phones or used to communication via mobile apps and SMS.

On the other hand, it was noticed that doctors were also rejecting the use of the initiative as they needed improved digital skills.

Therefore before full scale implementation there is a need for systemic education of both medical staff and patients in digital skills.

Main conclusions

Change management is crucially important. Proper change management plan could overcome all the resistance coming from the field.

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

Interview summary

Interviewee: Eva Samuelsson
Principal investigator eContinence project,
Professor Department of public health and clinical medicine
Umeå University, Sweden and Östersund

mHealth Practice:

eContinence/Tät.nu, mHealth for urinary incontinence:

Interviewers: Li Zakrisson; Ioannis Amarantidis
Date of interview: 2020-11-30

Topics

eContinence/Tät.nu has a successful approach on the following topics:

- Planning > Alignment with clinical guidelines
- Planning > User centered design considerations
- Execution > Solution testing and validation

Summary of main interview ideas

The eContinence project: a research project at Umeå university, financed by national grants

- Overall aim: to develop, evaluate, and implement mHealth for urinary incontinence.
- A quarter of all women and one eighth of all men have urinary incontinence (UI).
- Within the project, three apps have been developed. The app Tät®, intended for women with urinary leakage on physical exertion, has been evaluated in several studies and is now available for free at App Store and Google Play in Swedish, English, Arabic, Finnish, German, Norwegian, Danish and Spanish.
- The app Tät®:
    - Information
    - Lifestyle
    - Pelvic Floor E
    - Graphic support
    - Reminders

- Is the Tät® app focusing on information, life style advice and pelvic floor muscle training (PFMT) effective regarding urinary leakage, quality of life and costs?

  Yes! Efficacy was demonstrated in a randomized controlled trial (RCT) with clinically important improvements regarding symptoms, quality of life and leakage after three months. It was also effective in the long-term and cost-effectiveness was established, see publications at www.econtinence.se

- What happened then?

    - The Tät® app was released for free in 2015 and has been updated regularly since then.
    - Currently, the Tät®app has been used by >140 000 women in more than 100 countries.
    - Compared with the RCT, users are younger, and 41% are pregnant or postnatal.

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

- The effectiveness of the app has also been shown in real-world (BMJ Open Jan 2021)

- The Tät® III app
  - Stress urinary incontinence is very common after radical prostatectomy due to prostate cancer
  - Pelvic floor muscle training is recommended to start before surgery and continue after
  - This app is intended for men undergoing radical prostatectomy
  - The app is freely available in Swedish and English
  - Ongoing study, >3000 men have responded to questionnaires

Scope and brief description of the mHealth Practice

Overall aim of the eContinence project is to develop, evaluate, and implement mHealth for urinary incontinence. eContinence.se (Tät.nu®) is a researcher-initiated initiative providing evidence-based apps for self-management and treatment of urinary incontinence in women and men.

It started with stress urinary incontinence in women, by far the most common type of incontinence. Thereafter, apps for urgency and mixed urinary incontinence in women and for male incontinence after prostatectomy have been developed and evaluated. The first app (Tät®) exists in eight languages (Swedish, English, Spanish, German, Finnish, Norwegian, Danish, and Arabic). The app intended for men undergoing prostatectomy (Tät®III) is available in Swedish and English. These apps are free of charge. There is also an Internet programme for stress urinary incontinence in women, under licensed use by researchers in the Netherlands.

Supplier	Umeå University
Size	78,5 MB
Category	Medicine
Compatibility	Needs iOS 8.0 or subsequent. Compatible with iPhone, iPad and iPod touch.
Languages	Swedish, Arabic, English, Finnish, Norwegian, Spanish, Danish, German
Age	17+
Copyright	©Tät.nu Tät®
Price	Free

Scope and timeline of the mHealth good practice implementation

eContinence started 2008 as a web-based solution. With the rise in the use of smartphones app-based services became the focus. Up till now three thesis and 15 international scientific papers have been published from the eContinence group, a team of five researchers.
These works have been financed from different Swedish research grants.

What are the key steps that were undertaken?

A fundamental base for eContinence is the profound clinical knowledge among the participating researchers/developers. Relevant stakeholders have been involved in the development, especially patients through qualitative and quantitative research. A tight continuous collaboration with IT technicians at Umeå University has been in place, as well as collaboration with communication experts and an artist (painter) in the app development.

An important factor in the development of eContinence has been the strong need to address the problem of incontinence, a condition that often is regarded as an embarrassing disorder.

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What are the strengths and weaknesses of the implementation process?

See previous question regarding strengths. Additionally, the research model is continuously developed and adjusted in relation to ongoing testing, re-testing and evaluation, as well as ongoing input from individuals using the app and also from external research projects. A strength has been that the app does not require integration with the electronic health records of care organisations, but at the same time this could in the long run be regarded as a weakness.

Is there a workplan that can be included as a reference? Is there further documentation about the approach?

eContinence follows its research plans. Further information including links to publications can be found at www.econtinence.se

What are the strengths and weaknesses of the solution?

See previous question. Additionally, the close contact in place with all stakeholders has been a strong base from which to operate. This indicates the dual perspective that has been in focus, referring to the population and primary care. Another strength has been the research model for evaluation and improvement. It may have been beneficial that the app use was offered for free from the beginning and that it was financed with research grants. In the long run though, to maintain the system, another form of financing is needed. A commercialisation model is under discussion with the assistance of Umeå University.

Stakeholder involvement

What stakeholders needed to be involved for the good practice to work?

All relevant stakeholders: first of all the patients, and then caregivers (doctors, nurses, midwifes, physiotherapists, and urotherapists), from primary and secondary care. They all need to be involved in the project on a continuous basis. App developers and designers also need to be involved.

Lots of information has been collected from the contacts with personnel within the healthcare system, as well as from questionnaires and interviews with the women using the app. Questions such as “what is satisfactory and what can be improved”?

What are the stakeholders’ roles and activities/effort?

All stakeholders contribute to the ongoing development and evaluation of the app, or to be more correct, the apps (different for men and women, as for different clinical situations and for different languages).
The collaboration between the clinical research group and the technicians has always been productive. Lots of ongoing detailed discussions in the area of program updating for example.

How was involvement and buy-in of the stakeholders secured?

Their involvement was already from the start part of the research protocols. Over time this collaboration/involvement has become more and more structured.

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Barriers

See previous questions regarding financing. One experienced problem has been that the app Tät predominantly is used by women of higher education. To equally reach out to women with lower education, as well as women in low-income countries, is a constant challenge that the researchers are working on.

Success factors

That the apps have been for free and that incontinence is a common and partly a stigmatised problem, have presumably contributed to the initial interest from media, situations that helped to launch the app. Facebook campaigns aiming for recruitment to research studies, have contributed to widespread use. The Tät®app is the only evidence-based app for urinary incontinence that is evaluated for efficacy and this is an advantage. The research group consisting of physicians has frequently communicated the results from research. This has contributed to the trust users and caregivers associate with the app. The app is recommended by many caregivers and maternity care centers.

Lessons learnt

See previous texts for more information regarding which aspects of the app development and usage that have been useful as to lessons learnt.
Accessibility to a functioning treatment and research regarding efficacy, health economy and users experiences have been the driving forces for the researchers in their involvement.

Outcomes (text from app store)

Three thesis, 15 scientific publications with more to come, this gives us the confidence to say, “the Tät® app is an extremely well-validated app”, and “yes, it works well”. See econtinence.se for links to publications.

The Tät® app focuses on information, lifestyle advice and pelvic floor muscle training (PFMT), and it has been shown that it is effective regarding urinary leakage, quality of life and costs.

Efficacy was demonstrated in a randomized controlled trial (RCT) with clinically important improvements regarding symptoms, quality of life and leakage after three months. It was also effective in the long-term and cost-effectiveness was established, see publications at www.econtinence.se

The Tät® app was released for free in 2015 and has been updated regularly since then. Currently, the Tät®app has been used by >140 000 women in more than 100 countries. Compared with the RCT, users are younger, and 41% are pregnant or postnatal.

The effectiveness of the app has also been shown in real-world (BMJ Open Jan 2021)

Stress urinary incontinence is very common in men after radical prostatectomy due to prostate cancer.
Pelvic floor muscle training is recommended to start before surgery and continue after. The Tät®III app includes information and a programme for pelvic floor muscle training intended for men undergoing radical prostatectomy.

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

A study of the users is ongoing study. So far, more than 3000 men have responded to questionnaires.

What were the main outcomes of implementing the mHealth solution?

A program for self-management of urinary incontinence was made accessible through a well validated app in eight languages and being used world-wide. Another app intended for men undergoing radical prostatectomy has now been used by more than 3000 men.

What is the status?

Two apps are in use. The research focus is now mainly on the apps for female urgency urinary incontinence where a tight collaboration with healthcare is needed to exclude potential serious diseases behind the symptoms, and to some extent on male incontinence after prostatectomy.

Continuous learning and outlook

I look forward to a serious validation of apps that can be prescribed by healthcare and that there will be an integration with the patients' electronic health record. The question who pays for the usage of the apps also has to be solved.
Hopefully, there will be a continuation of developing new apps based on further research. We are currently planning for clinical studies of apps that are being developed, and to be followed by implementation into the healthcare system.
We look forward to being able to in the future prescribe apps in the same way as pharmaceuticals. There are related issues that need to be solved in order to realise this, who should pay for the apps and how to integrate the apps into the healthcare systems, specifically in relation to the EHR.

What would you have done differently? What can still be improved?

There needs to be a common structured system for the validation of apps with recommendations to caregivers and patients what apps to use. Presently, there is confusion within the healthcare sector and among patients regarding this.

What is your best tip for others in healthcare who are interested in working in this way with app development?

You need to have one foot each in practical life and in healthcare in order to understand the issues at stake. You must also have a reliable methodology for evaluation and a close collaboration with a broad spectrum of stakeholders.
A solid collaboration with technical personnel and a lot of financial resources are important for success.
Start with a well-documented needs assessment that provides solid information that the app in question fills its function.

What are the future plans for exploiting the mHealth solution? Is there any specific country you want your app to be established in?

We are constantly working on how to increase the apps' usage for persons with short education and in low-income countries, i.e. to make this aspect of health accessible to everyone. A solution where the apps are accessible at an acceptable cost. Additionally, the maintenance and development aspects need to be economically secured. These components need to be developed in the upcoming years.

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Interview summary

Interviewee: Muhammad Ilkay Kaynak, Ministry of Health, Turkey
mHealth Practice:
e-Nabiz
Interviewers: Ivana Ostoic (HCZC)
Date of interview: 2021-01-12

Topics

e-Nabiz has a successful approach to the following topics:

- Planning
  - **Governance for mHealth**
  - **Technical infrastructure requirements**
  - **Interoperability with existing systems**

Summary

e-Nabız gives an opportunity to exchange data among all levels of health care system to empower citizens to have a say in their health. App was developed by the Ministry of Health (Turkey) and it has been fully operational since 2015.

Early in the development stage it was obvious that there would be requirements connected with technical infrastructure in order to connect all medical facilities into one system, so government started comprehensive investments in technical infrastructure as well as in interoperability with other government e-services.

Scope of mHealth Practice

e-Nabız gives an opportunity to exchange data among all levels of health care system to empower citizens to have a say in their health. App was developed by the Ministry of Health (Turkey) and it has been fully operational since 2015.

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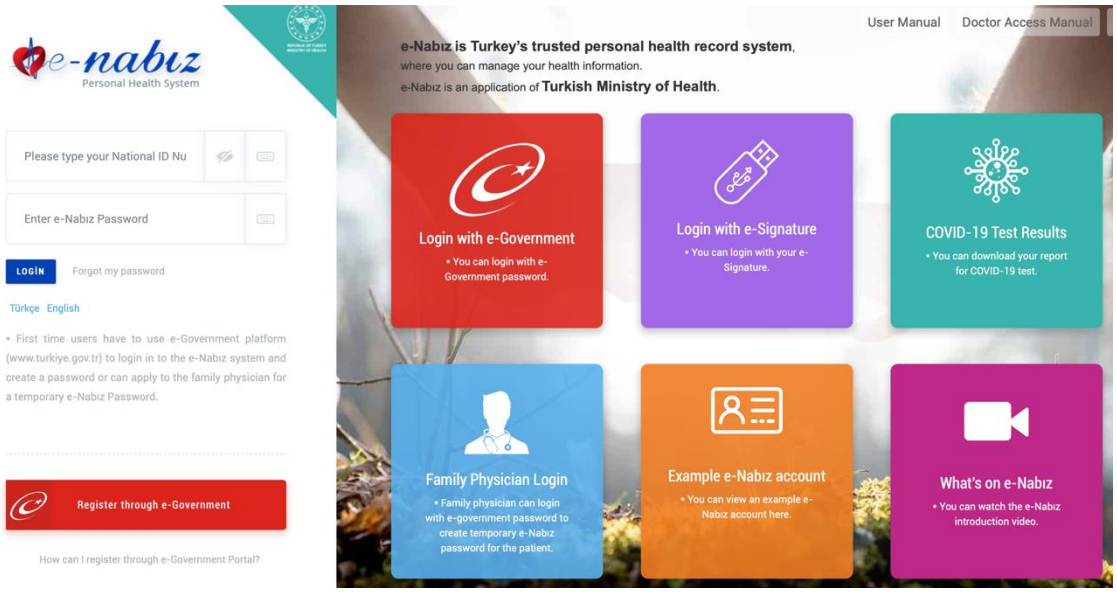


Topic: governance for mHealth

It took around 10 months to develop the first version of the app.

IT experts and medical staff defined the needs for the app and, based on that, IT experts started development. First generation was put in use without involving patients in the development, so there was immediately need for the upgrades and second generation of the app based on user (patient) needs and comments.

For the first app, main **weakness** was that not all stakeholders were involved in the process, which caused problems in the use of the app, but now both sides are actively involved in the design and implementation of upgrades or when new apps are created

All had active roles in testing the app and providing comment

Simplicity of use and faster exchange secured that stakeholders accepted to use it as they saw advantages

The main **barrier** at the beginning was the user friendliness.

Main **success factors** were on organizational side, as now doctors have more time for patients.

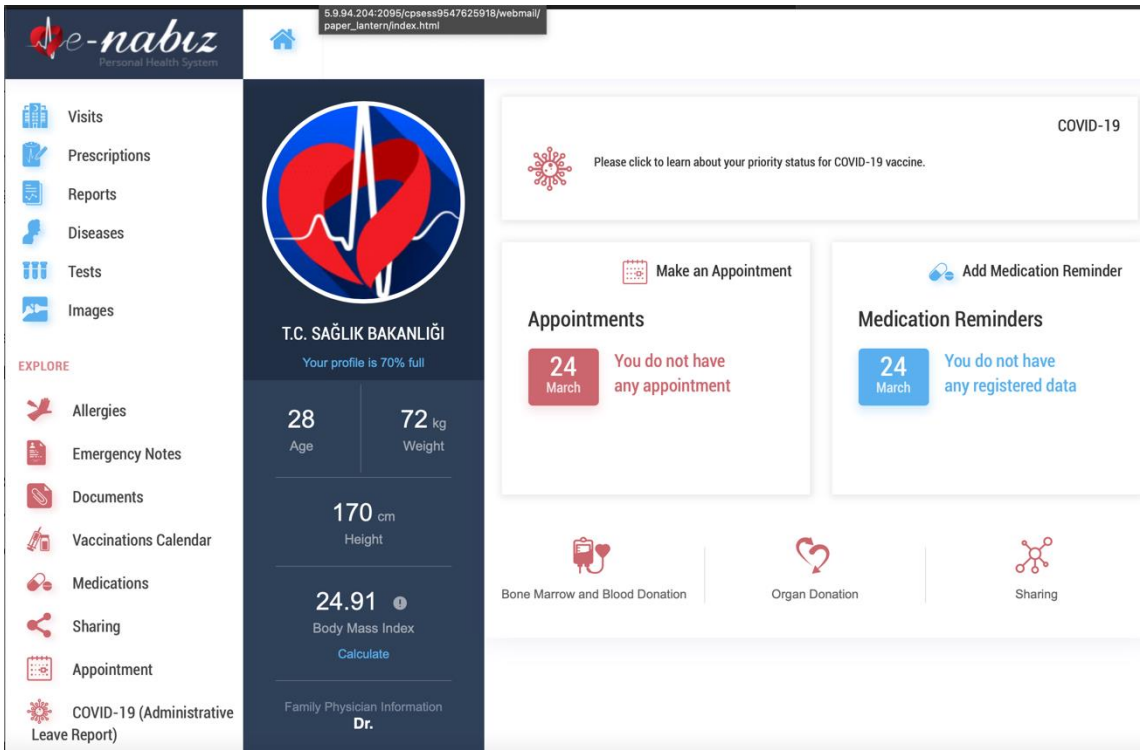
Other barrier was that the doctors at first, were reluctant to use it. Before COVID, there was limit of daily virtual visits per patient per doctor. It took a while for the patients to use and in the second version patient can do self-learning (guidelines) – the barrier was that patients did not know how to use it.

Main **lesson learnt** was that app directly contributed to reengineering of the clinical processes and significantly shortened the time for the patients to get appropriate medical assistance – e.g. instead of physical visit or going to the emergency room patient goes directly to the doctors and gets therapy or aid.

Main **outcomes** are that the patient has all its data, can make appointments, virtual visits, write down requests to the doctors, ask for emergency virtual doctor, recommendations for the preventive care, patient can see all referrals, communication with doctor, there is a chat function (only on laptop), administration – preauthorisation for e.g. MRI

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

e-Nabız is a two-sided system. Patients can see all of their health records. Also, doctors can check their patients' previous health record through e-Nabız during the visitations. Additionally, patients can feed the e-Nabız with their data collected from wearable devices. Patients can also provide data to e-Nabız by manual entry. Also, they can add notes so that health professional can see them not only at visitations but also in case of emergencies.



There is a need to keep developing and upgrading the app as it is constantly evolving as patients and doctors have additional needs and requests

E – Nabiz features:

- Vitals as blood pressure, weight, daily step count, diabetes information are recordable by using wearable devices or smartphones.
- Sleeping data entry is also at our citizens' disposal.
- Image data is available at the system.
- Patients can reach their lab results through e-Nabız by using their smartphones or tablets.
- Health reports given by the health care professionals can be reachable thorough e-Nabız..
- Citizens can see their vaccine information.
- Citizens can add any related additional documents to the e-Nabız.

Topics:

technical infrastructure requirements, interoperability with existing systems

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Early in the development stage it was obvious that there will be requirements connected with technical infrastructure in order to connect all medical facilities into one system, so government started comprehensive investments in technical infrastructure as well interoperability with other government e-services.

e-Nabız is fully in-line with the GDPR of Turkey.

Information security and patient privacy are the most important and primary-considered factors. Within e-Nabız application, all the data are stored in private by encrypting them. System provides a secure communication infrastructure between health provider that produces health data and patients.

Thanks to the Private Cloud system, effective resource management is realized. By utilising Big Data and NoSQL technologies, a 24/7 online and tolerated system against errors and failures is developed.

People can sign up to e-Nabız via e-Government with e-Government password, mobile signature or e-signature, also sign up can be realized by getting temporary e-Nabız passwords from family medicines as SMS.

Healthcare professionals can reach their patients health data trough e-Nabız during visitations by authenticating themselves through their hospital information system.

e-Nabız is a widely used PHR system in Turkey. Besides, every healthcare facility in Turkey is subject to send all of the patients' data as soon as available. To be able to do that, common structure is needed. This issue was considered at the development phase. Also, there are many different firms which provide Hospital Information Management Systems to the health care facilities. Integration of all these firms to the centralized system e-Nabız takes enormous effort. Creating support groups to solve any obstacle is very important for the feature of the initiative.

Main conclusions:

- Change management is crucially important. Proper change management plan could overcome all the resistance coming from the field.
- Similar systems can be examined. Internalisation of the best practices collected by the domain is absolutely recommended to avoid any unpleasant surprises that can be faced. Professionals from different fields should work together and legislation should be involved.
- Continuously search for new features that can be added to the e-Nabız system.
- Create or change necessary rules in medical regulations (e.g documentation, patient pathways, financing, authentication, responsibilities). Prepare long term solutions and recommendations for government decisions.

References: https://enabiz.gov.tr

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

Interview summary

Interviewee: Javier Arcos, MD. Chief Medical Officer, Fundación Jimenez Diaz University Hospital; Madrid, Spain; Clinical & Organizational Innovation Unit, Quironsalud 4H Public Hospitals Network, Madrid, Spain.

mHealth Practice:

E-Res Salud

A value-based healthcare program using patient-reported outcome measurements (PROMs) and Patient-reported experience measurements (PREMs)

Date: March 2021

Topics

E-Res Salud has a successful approach to the following topics:

- Execution:
  - **Integration with eHR**
  - **Patient reported data**

- Monitoring and evaluation:
  - **Monitoring and evaluation**
  - **Outcome-based reporting**
  - **Continuous improvement**

Scope of the mHealth practice

This program arises from the end-results oriented healthcare model of **Quironsalud**, and it comes to incorporate the international innovation initiatives already implemented with the aim of giving voice to patients to co-create the medical assistant process through new technologies such as patient portal accessed through portable devices (laptops, tables, smartphones).

The main objective is to incorporate a new end-results and patient-experienced assessment methodology in the organization with the following principles:

- This end-results patient-oriented strategy is a long-term strategy and not a time-limited pilot study.
- The program is organized in well-defined phases, where different medical and surgical specialities will be joining the program and implementing this methodology in different processes.
- With the application of well-known and validated methodology.
- With cycles of continuous improvement based on learning from acquired knowledge and constant monitoring.
- Use of new eHealth new technologies such as patient portal accessed by app or website.
- Patients' co-creation of their own medical history, providing personal health data through patient portal and integration in the eHR.

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DESIGN stage

Scope and timeline

- *How long did it take for the mHealth practice to be implemented?* 3 months per each process
- *What are the key steps that were undertaken?*
  - Building multidisciplinary teams
  - Selection of processes or disease entities to be measured
  - Define the patient journey
  - Review of literature and scientific evidence
  - Selection of PROMs and PREMs tools
  - Identification of clinical end-results indicators
  - Time points interaction with patients
- *What are the strengths and weaknesses of the implementation process?*

The *strengths* are the multidisciplinary team building and the Hospital network approach. All actors involved in the medical process act as a team giving their expertise and not as an individual person, and the program is running in a network of four different hospitals at the same time, that covers the care of 1 million inhabitants in Madrid region. Also, the design is implemented in the patient's portal, so patients can access to them through their smartphones or other portable devices.

The *weakness* is to create strong alliances among all members to cooperate and the lack of evidence in many processes sometimes.

- *Is there a workplan that can be included as a reference? Is there further documentation about the approach?*

We have our own methodology "Guideline for the design and implementation of a value-based healthcare program" (Spanish version).

- *What are the strengths and weaknesses of the solution?*

This guideline helps clinicians to start working before the kick-off meeting with the Clinical & Organizational Innovation Unit (UICO).

Stakeholder involvement

- *What stakeholders needed to be involved for the good practice to work?*

In this step, the stakeholders are the clinicians selected to build the multidisciplinary team.

- *What are the stakeholders' roles and activities/effort?*

They need to meet periodically to work providing their expertise.

- *How was involvement and buy-in of the stakeholders secured?*

There is a structured schedule of meetings and a deadline to present their findings and proposal.

Barriers, success factors, lessons learnt

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

- *Barriers*

Measurement tools are not free of charge, even those proposed by ICHOM (International Consortium for Health Outcomes Measures). The high cost of many validated tools hampered the implementation of many of them.

- *Success factors*

Commitment of CEO and Chief Medical Officer with clinicians, sharing the same strategic objectives.

- *Lessons learnt*

Leadership of the multidisciplinary team will allow to manage and solve all problems they find in their way.

Outcomes

- *What were the main outcomes of implementing the mHealth solution?*

Team building, new innovative and organizational proposals to be reviewed and assessed by the Manager, see what other institutions do in this field of mHealth solutions to compare with them and do benchmarking.

- *What is the status? (pilot, tested, fully operational).*

Full operational in the first two phases: Hematology, HIV, Orthopedic Surgery, Urology and COVID19 in phase 1; Inflammatory Bowel Disease, Heart Failure and Endometrial Cancer in phase 2.

Continuous learning and outlook

- *What would you have done differently? What can still be improved?*

We would provide better guidance in the measurement tools selection as many of them are not free of charge.

- *What are the future plans for exploiting the mHealth solution?*

To expand this knowledge to other processes in the next steps. The next processes to be explored will be stroke, Cardio-Oncology and Pediatric asthma.

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DATA CAPTURE stage

Scope and timeline

- *How long did it take for the mHealth practice to be implemented?* 3-6 months
- *What are the key steps that were undertaken?*
  - Create in the eHR the PROMs and PREMs tools templates
  - Spread the knowledge of the project among all members of the departments
  - Design a project dashboard
  - Implement the questionnaires in the eHR and the Patient Portal
  - Integration of data submitted through the app in their smartphone into the hospital eHR.
  - Start data capturing and continuous monitoring of system fails.
  - Cycles of continuous improvement
  - Patient education and empowerment for a better adherence to the program
- *What are the strengths and weaknesses of the implementation process?*

The main *strength* is that the measurement tools are integrated in the eHR and are part of the medical file.

The main *weakness* is the dependence on the IT Department.

- *Is there a workplan that can be included as a reference? Is there further documentation about the approach?*

We have our own methodology "Guideline for the design and implementation of a value-based healthcare program" (Spanish version).

- *What are the strengths and weaknesses of the solution?*

We need a strong implication of the medical direction and IT department to prioritize this project.

Stakeholder involvement

- *What stakeholders needed to be involved for the good practice to work?*

IT Department.

- *What are the stakeholders' roles and activities/effort?*

IT Department members must be fully dedicated to this task as it is very detailed and very specific.

Barriers, success factors, lessons learnt

- *Barriers*

Technical barriers.
Identification or hiring people dedicated to the project in the IT Department.

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- *Success factors*

The motivation of the whole team. Use time in managing change. Team members have protected time from their routine clinical activities to work in this project.

- *Lessons learnt*

To involve IT Department in the design of process in the digital health transformation era.

Outcomes

- *What were the main outcomes of implementing the mHealth solution?*

We are capturing data of more than 8,000 patients in the 8 processes where we have already implemented it.

- *What is the status? (pilot, tested, fully operational).* Fully operational

Continuous learning and outlook

- *What would you have done differently? What can still be improved?*

More in-person meetings with IT Department to better explain what we need and the tools they must work on.

- *What are the future plans for exploiting the mHealth solution?*

To collect more data by adding more specific tools for a better stratification of processes and patients.

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DATA ANALYSIS stage

Scope and timeline

- *How long did it take for the mHealth practice to be implemented?*

More than 6 months; still on going. We are developing the data analysis platform using MS Power BI for the Data Mining to be done by clinicians and not by the IT Department to make it easier and faster the data analysis and in an real-time fashion. In this way, the information collected has an earlier impact on the real clinical activity.

- *What are the key steps that were undertaken?*
    - The data analysis platform.
- *What are the strengths and weaknesses of the implementation process?*

Main *strengths*:
- Data analysis platform.
- Clinical leadership.
- A strong IT team available from the beginning.

Main *weakness*:
- The need of a new common language, and new transversal work teams (clinicians, IT members, managers).

- *Is there a workplan that can be included as a reference? Is there further documentation about the approach?*

We have analysed several platforms for this data analysis. At the end, the license to use Microsoft products in the entire organization lead to choose MS Power BI for the data analysis.

- *What are the strengths and weaknesses of the solution?*

The strengths are that this is an accessible platform, already implemented in the organization. The weaknesses could be that we have to manage with the solutions provided and cannot ask for others.

Stakeholder involvement

- *What stakeholders needed to be involved for the good practice to work?*

IT Department, Big Data and AI scientists, patient experience department, and clinical leaders.

- *What are the stakeholders' roles and activities/effort?*

Identification of clinical variables to be cross-matched with the PROMs and PREMs results.

- *How was involvement and buy-in of the stakeholders secured?*

IT Department is part of the team. They belong to the Clinical & Organizational Innovation Unit, and the head of project works closely with the clinical teams.

Barriers, success factors, lessons learnt

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- *Barriers*

Technical barriers.
IT Department members belong to the Clinical & Organizational Innovation Unit, and the head of project works closely with the clinical teams. All of them have protected time to work with clinicians in this project.

- *Success factors*

To work in a flexible platform to be allocate all variables needed for each process.

Outcomes

- *What were the main outcomes of implementing the mHealth solution?*

To improve the patient journey and to allocate resources to those patients that need them more. Being able to respond to the needs of patients who are at home, in real time.

- *What is the status? (pilot, tested, fully operational).* It is being tested in the phase 1 processes

Continuous learning and outlook

- *What would you have done differently? What can still be improved?*

To start working in the data capture platform in advance.

- *What are the future plans for exploiting the mHealth solution?*

After data analysis, we will be providing patients a real-time feed-back of their own results, the comparison with people of their same age and sex group, and a set of personalized recommendations based on their need identified in the PROMs questionnaires.

Other aspects highlighted

The strategy is based on giving voice to the patient with a clear, well-defined methodology that encourages their active participation in the care process and stimulate their involvement in planning and implementation of the improvements in the care trajectories based on their experiences and opinions. To do this, we routinely incorporate new outcome indicators into clinical activity that matters to the patient, what help doctors in their daily practice, creating a culture of self-assessment and continuous learning.

Awards

E-Res Salud has been recognised as Role Model by the international prize “EFQM Global Award”, given to Fundación Jiménez Díaz University Hospital.

Quironsalud 4H Public Hospitals Network has received the Top Value Award 2021, given by IQVIA, aimed to hospitals with value-based healthcare programmes in Spain, where E-Res Salud has played a significant role, and the 2021 Salud Digital Award (Digital Health Award), for the best project in Telemedicine at the national level (Spain).

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

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- E-Res Salud, medición de resultados en salud y experiencia del paciente (E-Res Salud, measuring health outcomes and patient experience) https://www.youtube.com/watch?v=r9HD9zXnkTk

- E-Res Salud Hematología supera los 500 pacientes y da voz para personalizar la atención ofrecida (E-Res Salud Haematology exceeds 500 patients and gives a voice to personalise the care provided) https://www.youtube.com/watch?v=w6AxllKdOvY

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- Poster. ICHOM Annual Conference 2020. E-Res Hematology https://conference.ichom.org/wp-content/uploads/2020/11/POSTER-ICHOM-2020-E-Res-Hematology.pdf

- To learn more:
    - Javier Arcos, MD. Chief Medical Officer. Fundación Jimenez Diaz University Hospital; Madrid, Spain; Clinical & Organizational Innovation Unit, Quironsalud 4H Public Hospitals Network, Madrid, Spain. jarcos@quironsalud.es
    - Raúl Córdoba, MD, PhD. Head of Lymphoma Unit. Fundación Jimenez Diaz University Hospital; Madrid, Spain; Clinical & Organizational Innovation Unit, Quironsalud 4H Public Hospitals Network, Madrid, Spain.raul.cordoba@fjd.es

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Annex: visual materials

▲ PATIENT VOICE	**E-Res Salud** is an **end-results oriented healthcare** model to incorporate the international **innovation** initiatives already implemented with the aim of **giving voice to patients** to co-create the medical assistant process
▲ OUTCOMES	The main objective is to incorporate a new **clinical outcomes and patient-experienced assessment methodology** in the organization with **PROMs** and **PREMs**
▲ METHODOLOGY	It uses a well-know and **validated methodology**
▲ IMPROVEMENT CYCLE	It counts with cycles of **continuous improvement** based on learning from acquired knowledge and **constant monitoring**
▲ TECHNOLOGY ▲ eHEALTH	Use of eHealth **new technologies** such as **patient's portal** by **apps** or internet access
▲ CO-CREATION	Patients' **co-creation** of their own medical history, providing personal health data through patients' portal and integration in the EMR

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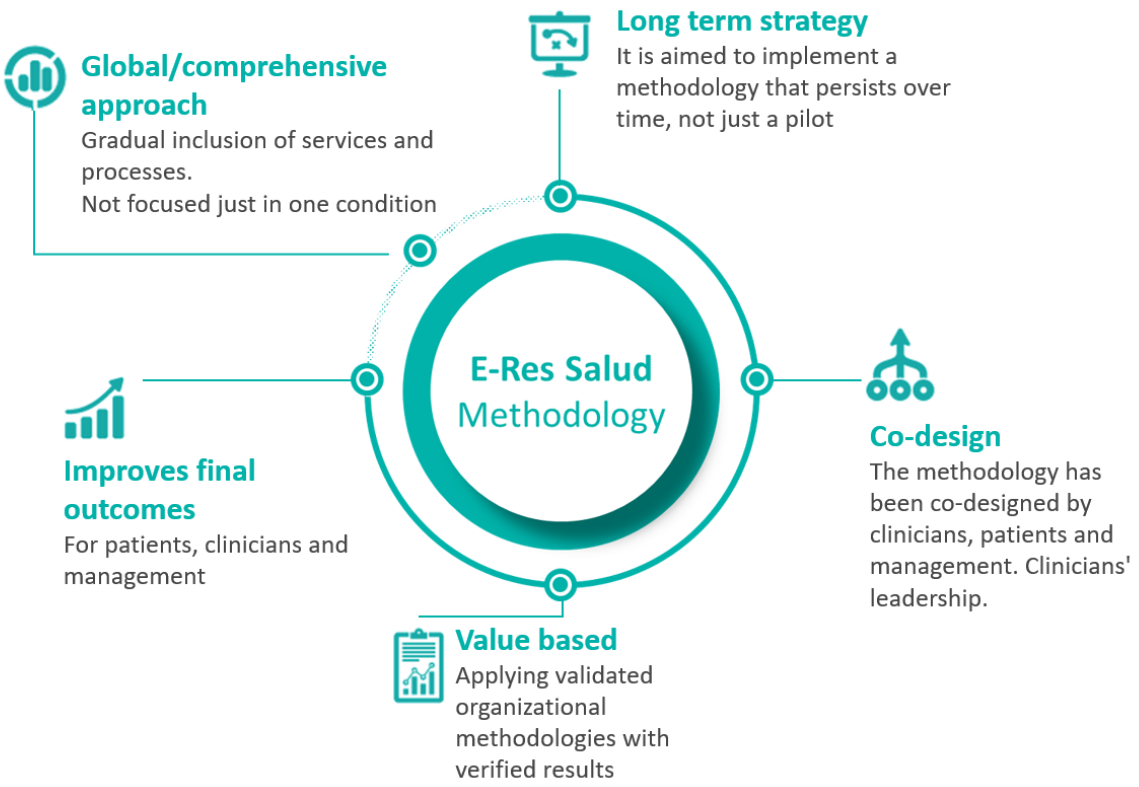

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- **Create multidisciplinary teams**
- **Select patients by condition**
- Review bibliography and **evidence available**
- **Select PROMs and PREMs scales**
- Select **clinical outcomes** indicators.
- Describe the **patient pathway** and define the **interaction points**

- **Create scales** and data collection system
- **Communicate** information and knowledge amongst all the **clinical teams**
- Create a **process dashboard**
- **Activate the circuit** in Casiopea (EMR) and Patient Portal App (smartphone and internet).
- Define the **information patients are getting** at the beginning of the process
- Continuous improvement cycles to increase the adherence to scales

- **Dashboard design** by individual and by typology
- **Design of ways to access to the information**, integrated into the HER, for (1) Patients (2) Clinicians (3) Organization
- Seek of continuous improvement through **benchmarking** amongst hospitals
- **Cost analysis by process**

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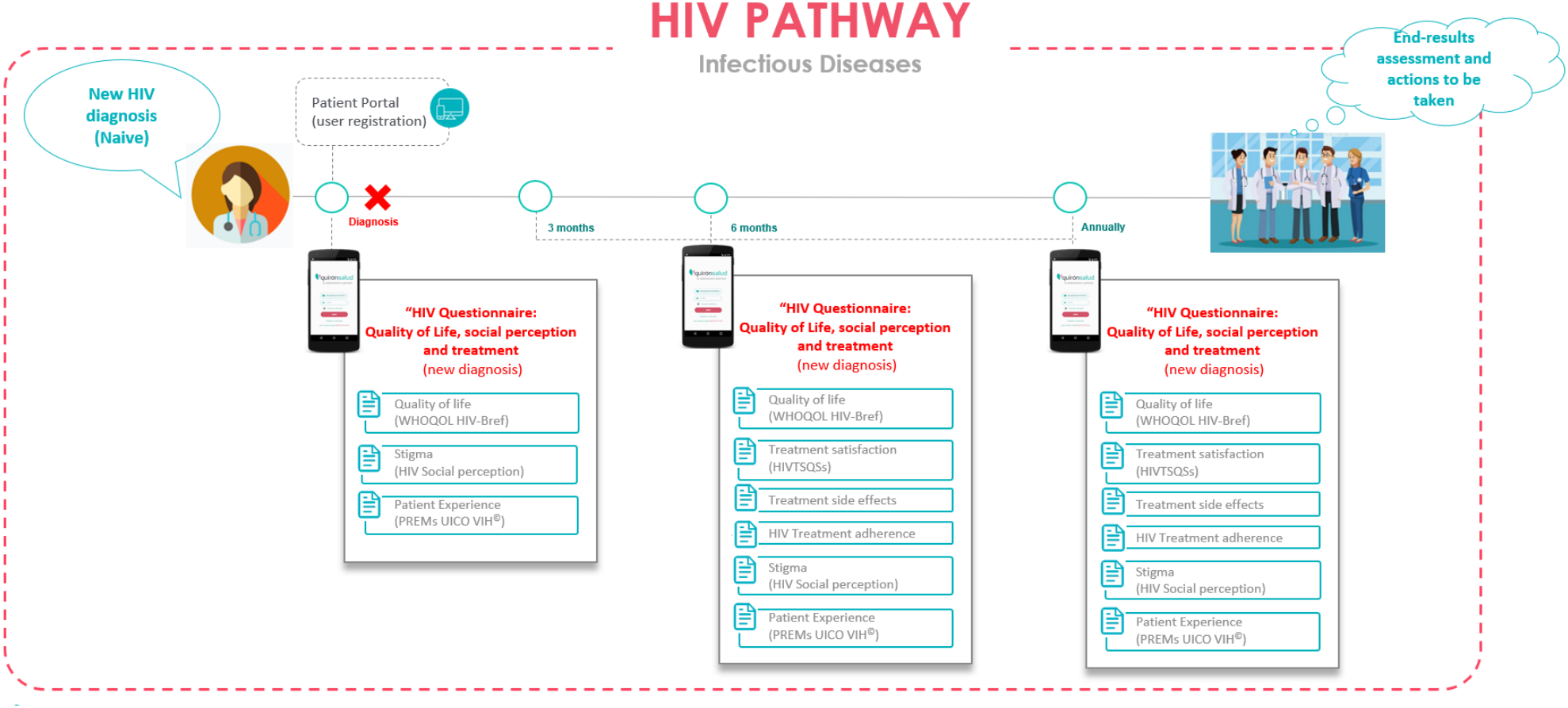
HIV PATHWAY

Infectious Diseases



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Interview summary

Interviewees:

Guðrún Auður Harðardóttir

(Project Manager, National Centre for eHealth, Directorate of Health, Iceland)

Ingi Steinar Ingason

(Head of Division National Centre for eHealth, Directorate of Health, Iceland)

mHealth Practice:

Heilsuvera.is - The Integrated National Portal

(Directorate of E-health, Iceland)
Interviewers: Berglind Smaradottir and Santiago Martinez, University of Agder, Norway
Date of interview: 2020-12-01

Topics

Heilsuvera.is constitutes an example of successful implementation on national level.
It has a successful approach on the following topics:

- Initiation:
  - Stakeholder/ecosystem analysis
- Planning
  - Interoperability with existing systems
- Execution
  - Integration with EHR

Summary of main interview ideas

- National health portal integrated with national EHR
- One point of access for all citizens
- 100% of primary health care providers connected to the portal
- Some private doctors also connected to the portal
- Implementation started in the hospital environment
- Fully operative since 2014
- Scalable website accessible in all platforms and devices
- Mobile app release in 2021
- Reduced physical contact – less risk of spreading COVID-19
- Incentive scheme by the Ministry of Health for primary health care physicians when using the portal (reimbursement)
- Patient empowerment
- Health Questionnaires (pre-operative, quality of life)
- Increased digital access to health services
- Interoperates with existing systems (e.g., EHRs)

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- Saves time for health professionals and health consumers

Scope of mHealth Practice:

- **Heilsuvera.is** is the national health portal in Iceland. The portal gives citizens and patients one point of access for appointments within primary health care and some private practice doctors. It provides individuals with a secure communication platform with health care providers, overview of immunisations, request for medication renewal, medication history, maternal health record, organ donation, and numerous other functionalities.

  All primary health care centres in Iceland are connected to the portal, as well as some of the private practices. The citizen has an electronic identification (eID) and can self add measurements on blood pressure, glucose, pulse, fever and other medical parameters. These measurements cannot be sent or shared digitally. Parents can read information for kids up to 16 years old. Ordering Covid-19 test goes through this portal, and the results and sickness certificate to employers have an automated process through the portal. More than 5000 certificates are sent digitally each week, reducing phone calls and physical visits to General Practitioners (GPs).

  The health record is interconnected between hospitals, primary health care, nursing homes and a majority of private practice doctors. Hence, patient health information is shared on a national level. The national health network Hekla is used for communication and sharing of patient information. The health portal has an integrated videoconference function. More than 43% of citizens over 18 years old used the portal in 2019, and the number of users increases yearly. The portal is a scalable website that can be used on all devices, although a specific mobile application will be released during 2021. The portal has been operated since 2014 and builds on national policies, strategies and laws (security and safety).
- The portal provides then a useful digital service for all Icelandic citizens based on a platform interconnected with all the other necessary health services and databases on a national level.

Scope and timeline of the mHealth good practice implementation:

- How long did it take for the mHealth practice to be implemented? The process to establish

  The portal started in 2013 with public funding and it has been operative since 2014.

- What are the key steps that were undertaken?

  The Directorate of Health in Iceland developed the portal in collaboration with the Primary Health care of the capital area and a national IT service company (main vendor for EHR in Iceland). They also contributed to the funding.

- What are the strengths and weaknesses of the implementation process?

  Start at a small scale (one health centre) to later scale it up to other centres and then nationally deployed.

- What are the strengths and weaknesses of the solution?

Strengths

- The solution is free of charge for the citizens and aligns with the national strategy from authorities to enable patients to take more part in their own treatment.
- The solution has limited storage; most information is stored in the EHR system of the connected organisations. The only data stored in the portal system are patients' own measurements and communication. When a health professional searches for patient, the system retrieves the data stored in other systems (e.g., EHRs) and visualises it.
- It has been a useful service to avoid the spread of Covid-19 due to reduction of physical visits (by the order of thousands) to receive the services that are now available online. The solution

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has automated processes for Covid-19 test, results and certificates. This reduces the physical and telephone contact with health centres.

Weakness

- The videoconference function has a large potential but has not yet been fully implemented. During first phase of Covid-19, it became clear that technical issues such as doctors not having a web-camera (or not an appropriate one) in their desktop/office reduced the use of videoconference. Technical support was then needed for these users.

Barriers

- It is not straight forward to implement new technology for physicians, it they do not see or understand what the benefits are of using the technology. There was resistance among GPs, not fully understanding the policy and potential of the improved IT solution.

Success factors

- Incentive scheme established by the Ministry of Health: reimbursement for practitioners using the portal and this increased the usage. Same procedure will be applied for videoconference consultation in the near future.
- Currently, there are several questionnaires being implemented in the portal: pre-operative questionnaire answered via the portal at home, and other evidence-based questionnaires, such as well-being scores in the treatment of cancer patients and within psychiatry. The score of the questionnaires is automatically calculated and saved within the national electronic health record. Notifications are sent to health professionals when required.
- The portal followed strict requirements for safety and privacy following national data protection regulations.
- Running the portal does not require a high cost. The expenses include hosting the system and its data (yearly license fee). However, due to the higher increase in usage during the Covid-19 pandemic, they have had to double or triple the power capacity of the servers, which has led to some increased cost. In addition, there is an increasing cost connected to sending of text messages linked to specific services. The main cost is connected to the development of new functionalities and services every year. There is an increasing demand from the Ministry of Health to extend the catalogue of services for the citizens. There is a strategy from the Ministry to encourage the patients to take part on their own treatment, particularly in a long-term perspective and chronic diseases.

Lessons learnt

- Use of national indicators for e-health from Nordic Council of Ministers. Compare usage between countries.
- Patient empowerment for managing their own long-term disease (cancer, diabetes) and providing a better overview of own treatment.

Outcomes

- What were the main outcomes of implementing the mHealth solution?

Nation-wide digital health solution integrated with other existing health systems (public and private). It gives digital access to several health services for the citizens, reduced number of physical meetings and mobility in times of Covid-19, sparing time for staff in health centres, particularly for appointments and phone calls. Increased accessibility to digital dialogue with health providers and open to all citizens.

- What is the status?

Fully operational national portal with 100% of primary health care providers using the portal. Furthermore, some of the private practise doctors are using the portal for eBooking. Moreover, implementation has started at the hospital level.

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Continuous learning and outlook

- What are the future plans for exploiting the mHealth solution?

mHealth app release next year. Centralised medication list/card. Text in EHR available for patients.

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Interview summary

Interviewees: Haya Barkai (Maccabi Health services)

mHealth Practice:
Maccabi online
Interviewers: Ivana Ostoic (HCZC)
Date of interview: 2020-12-23

Topics

MACCABI ONLINE has a successful approach to the following topics:

- Planning > **Interoperability with existing systems**
- Monitoring and Evaluation > **Continuous improvement**

Summary

- MACCABI ON LINE is an internal mobile app developed by Maccabi hospitals in Israel, it is used for both private and public health system. The app allows both doctors and patients to have full access to all medical information, as well to allow direct communication between doctors and patients.
- When developing medical apps, it is crucial to involve all stakeholders as early as possible in the design, and all stakeholders have to be actively involved.

Scope of the mHealth practice

MACCABI ON LINE is internal mobile app developed by Maccabi hospitals in Israel and it is used for both private and public health system. App allows both doctors and patients to have full access to all medical information as well to allow direct communication between doctors and patients.

MACCABI ON LINE allows the patient to have all its data, make appointments, virtual visits, write down requests to the doctors, ask for emergency virtual doctor, recommendations for the preventive care, patient can see all referrals, communication with doctor, there is a chat function (only on laptop), administration – preauthorisation i.e. MRI.

The main idea is that, when developing medical apps, it is crucial to involve all stakeholders as early as possible in the design, and all stakeholders have to be actively involved.

Moreover, any m-health app has to be under constant development as there is need for upgrades and additional features. You need to be focused and share the knowledge with the patients all the time, also time response shall be fast, you need to involve the doctors in every step of the development.

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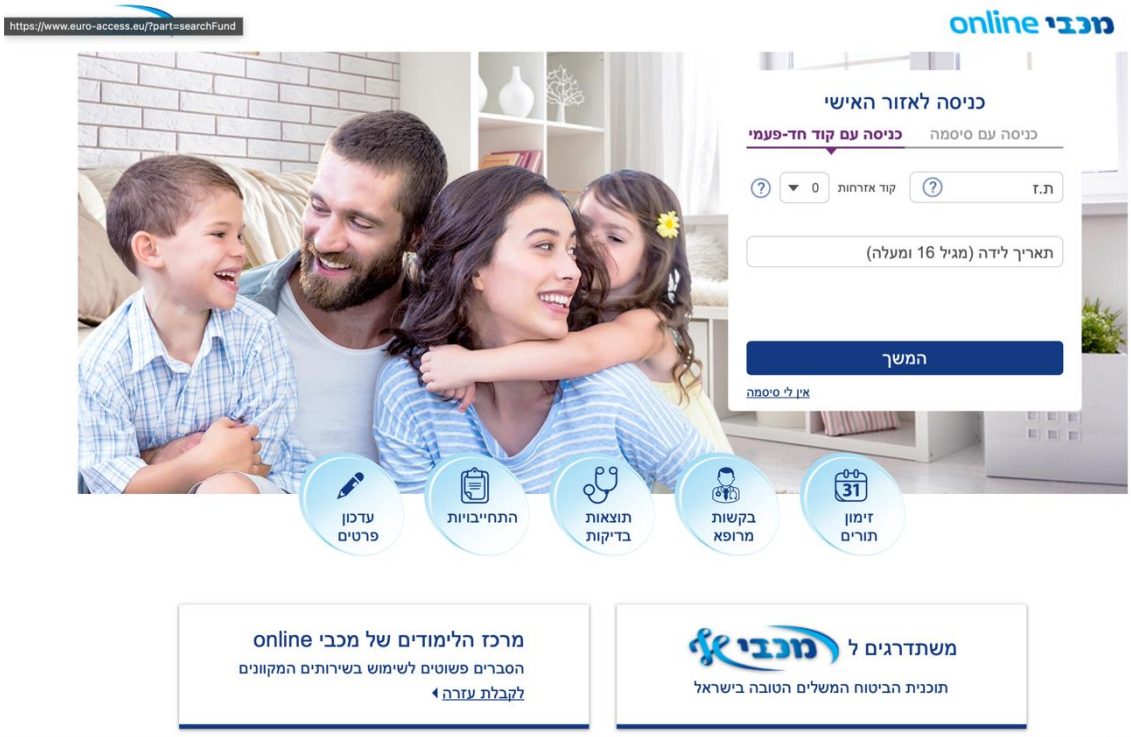

Topics: interoperability with existing systems and continuous improvement

It took around 10 months to get the first version of the app.

IT experts and medical staff defined the needs for the app and, based on that, IT experts started development. First generation was put in use without involving patients in the development, so there was immediately need for the upgrades and second generation of the app based on user (patient) needs and comments.

For the first app, the main *weakness* was that not all stakeholders were involved in the process, which caused problems in the use of the app, but now both sides are actively involved in the design and implementation of upgrades or when new apps are created.

It proved to be crucial to involve doctors. All had active roles in testing the app and providing comments.

Simplicity of use and faster exchange secured that stakeholders accepted to use it, as they saw advantages.

The main *barrier* at the beginning was the development of a user-friendly approach.

Another barrier was that the doctors, at first, were reluctant to use it. Before COVID there was limit of daily virtual visits per patient per doctor. It took a while for the patients to use and in the second version patient can do self-learning (guidelines) – the barrier was that patients did not know how to use it.

Success factors: the main ones were on the organizational side, now doctors have more time for patients.

Main *lesson learnt* was that app directly contributed to the reengineering of the clinical processes and significantly shortened the time for the patients to get appropriate medical assistance – e.g.

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instead of physical visit or going to the emergency room, the patient goes directly to the doctors and gets therapy or aid.

Main *outcomes* are that the patient has all its data, can make appointments, virtual visits, write down requests to the doctors, ask for emergency virtual doctor, recommendations for the preventive care, patient can see all referrals, communication with doctor, there is a chat function (only on laptop), administration – preauthorisation for e.g., MRI

The app is under constant development as there is always room for the improvement. A key aspect is to keep developing and upgrading the app, as it is constantly evolving as patients and doctors have additional needs and requests.

References

- https://www.maccabi4u.co.il/1781-he/Maccabi.aspx

Interview summary

Interviewees: Nicolás González López; Iratxe Salcedo Pacheco

mHealth Practice:

The Mangols Journey *(El viaje de Mangols)*

Interviewers: Dolores Verdoy; Nerea González.
Date of interview: 2020-11-25

Topics:

- Initiation > **Needs assessment** (resulting in the new need for the mHealth solution).
- Execution > **Integration with EHR**

Scope of mHealth Practice

Background info about the good practice

"*El viaje de Mangols*" (*The Mangols Journey*. Walking towards a healthy life", is an innovative treatment program and work methodology developed by Osakidetza-Basque Health Service, the public healthcare system of the Basque Country, as the first line of treatment for overweight and obesity in children. It is aimed at all those Osakidetza patients who meet the criteria for inclusion, children aged 7-14 years with overweight or obesity, ensuring equity and universality of intervention this condition.

The program has been designed to be used by different profiles of health professionals at all care settings. It gives a complete turn to the standard consultation, unifies the treatment and follow-up of patients, simplifies the intervention for health professionals, modifies the form of healthcare professional-patient relationship and turns around the methodology of knowledge acquisition thanks to the educational gamification, enhanced by the individualized motivational consultation developed by the healthcare professionals. It has been designed as a virtual treatment without losing the potential of the human factor.

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The objectives of "*El Viaje de Mangols*" are the following:

- To achieve an effective treatment against overweight and obesity in children. To obtain better results due to the acquisition of knowledge through educational gamification and the power of motivational consultation with health professionals.
- To empower patients and tutors, turning them into expert patients with decision-making capacity, supported by evidence-based holistic content which has been validated by a multidisciplinary team of experts.
- To promote intra-family changes, due to the collaborative work carried out throughout the development of the serious game (the two user profiles, children and tutors, constantly interact and perform joint challenges) and thanks to the individualized motivational consultation.
- To provide a solution to an existing need in the daily clinical practice of health professionals, facilitating their work and intervention in this population group and providing them with specific training and a work schedule and methodology that can be integrated into their daily clinical practice.
- To improve the effective time of consultation, due to the possibility of previous monitoring by the professional of the evolution of the patient and the tutor.

"*El viaje de Mangols*" program has three main pillars:

- Serious game prescribed from the consultations, the patients and their tutors will use it at home, acquiring scientific quality information, of holistic, accessible and pleasant character, achieving a greater fixation of the contents thanks to the gamification.
- Motivational consultations are protocolized, regulated and coordinated with the evolution in the serious game of the patient and his/her tutor.
- Total integration of the serious game with the Electronic Health Record of the Osakidetza patient. The health professional monitors, controls and interacts with the patient and the serious game from the primary care consultation.

Summary of main interview ideas

- Treatment for overweight and obesity in 7-14 years patients.
- Totally integrated with the EHR of Osakidetza-Basque Health Service.
- It brings together technology and health care professionals.
- Main pillars: serious game, motivational consultations and integration with EHR.
- Designed to be used by different professionals at all care settings.
- It works on physical and emotional health.
- It empowers patients and families, promoting change.
- It improves the effective time of consultation.
- Less clicks to enter information and follow up the patients.
- It will be implemented throughout the organization in 2021.

Scope and timeline of the mHealth good practice implementation:

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- How long did it take for the mHealth practice to be implemented?

It started 7 years ago. The tools to address this problem in primary care were very scarce and with very poor results. Health care professionals needed a tool to use in primary care, the gateway to the health system. This is where the idea was born, the idea of generating a comprehensive treatment programme with a basic learning tool for children and families based on the serious game methodology, fully integrated into the clinical practice.

It was seen that there are some fundamental pillars of the initiative: family and emotional aspects related to overweight and obesity.

They had the first meetings four years ago, to start developing it in the organization (Osakidetza-Basque Health Service, the public healthcare system of the Basque Country). The first 1.5 years were a time of support, communication, explanation and convincing the organization.

- What are the key steps that were undertaken?

It was implemented when the funding was obtained; a tender was issued; they were lucky enough to bid on companies specialising in this type of Health game development. It was designed, programmed and implemented in 1 year.

Now they are working with the professionals, training them; so that in February 2021 they can offer it to the rest of the professionals. Teaching how to deal with these consultations.

- What are the strengths and weaknesses of the implementation process?
  - The programme is visible from the workstation.
  - The initiative responds to a problem they have every day in the practice.
  - Integration for use in a normal paediatric schedule.
  - Collaborative intelligence and work: a large group of people with different intelligences and profiles to be shared by everyone.
  - There are no differences at a clinical level between health profiles (doctors and nurses) or care levels (primary and specialised). Any professional working with children can use *The Mangols journey*, because the aim is for this to reach as many children as possible.

- What are the strengths of the solution?

- Osakidetza's technological profile: they are technologists, but they also understand a lot about the business, they have become permeable.
- They have introduced other types of profiles (e.g. equality, language).
- They did not want the professionals to have a thousand isolated tools; they wanted them to be able to use this type of therapy/treatment from their workplace in an easy and totally integrated way.
- Easy to understand text for a child between 7 and 14 years old (data protection for a young child to understand).
- They have worked with two companies that are technically very powerful, very quick to understand, and have worked in unison. They have created/discovered talent in the companies. The game is based on a comic book and a narrative; the company discovered one of its team, a programmer, who has drawn the whole comic (180 pages).

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

Stakeholder involvement

- What stakeholders needed to be involved for the good practice to work?

-They have an active group with a very important technical part and a clinical part of all levels: primary, nursing, paediatrics, specialized, nutritionists, psychiatrists. There is a driving clinical group: paediatrics and nurses from all the Integrated Care Organizations (ICOs) from Osakidetza, who have already started with the real patients in the consultations.

-Equality and health promotion professionals have also been included.

- What are the stakeholders' roles and activities/effort?

- Health professionals: see how to make "El Viaje de Mangols" more flexible and adaptable to almost any type of care. It's key to involve colleagues.
- The care management has supported the communication work of the leader. This work of communication and of bringing the leader closer to the colleagues who are going to carry it out in the consultations is key.
- Technical professionals: knowledge of the system, being aligned with the organization.
- Key: behaving like a health system.

Barriers

- Changes of legislature and these months with the Covid affect, impact, generate uncertainty, but it has been possible to redirect in a constructive way.
- Safety regulations with minors. We had to go through many filters, legal reports on data protection to be able to have every guarantee that they would not have problems. Also filters to be able to take out the applications to google play.
- Financial obstacles.
- Time dedication, countless.
- The model of integration with EHR, with a prescription, existed, but they were the first. They were the first to put it in the Integral program manager (GIP, in Spanish, Gestor Integral de Programas).
- GIP didn't know, it couldn't (at first). Then GIP has learned many things.

Success factors

- Attitude of wanting to work, to share all at the same level, generating a team.
- Commitment of the main stakeholders.
- The idea of organising meeting points where development issues can be initiated, detected, and identified, generating symbiosis.
- The good practice has helped to manage and organize the care delivered to these patients and families.

Lessons learnt

- In addition to the technical issues, the members of the program leading team have also learned about nutrition, physical activity...

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- Way of working: listening, analysing, studying, looking for alternatives; not saying yes or no quickly.
- They have grown a lot professionally and personally.
- Sharing knowledge from the same level.
- Have a very clear definition and do not abuse integration, only what is necessary.
- Less clicks. The health professional cannot go around looking for forms; they have tried to simplify it.

Outcomes

- What were the main outcomes of implementing the mHealth solution?

-The programme collects many variables and indicators; a lot of structuring work has been done to make the information easily extractable and analyzable. This information is collected and structured in EHR.

-Scales for children and parents (anthropometrics, quality of diet, physical activity, perception of physical and emotional health). Everything is collected, integrated, structured within the EHR, so that a continuous evaluation can be made.

- What is the status?

-In process. It is being implemented in some centres and professionals are being trained so that by 2021 it can be implemented throughout the whole organization (Osakidetza-Basque Health Service).

Continuous learning and outlook

- What would you have done differently? What can still be improved?

- They would have liked something more agile.
- They got what they wanted. It is in a constant process of evaluation and improvement.

- What are the future plans for exploiting the mHealth solution?

- Driving group, throughout 2021, more global implementation of Osakidetza, with the training already developed.
- Possibility of scaling up: hopefully, so that it reaches as many families as possible.

Other clarifications

It is important that, even if you download the application, it is not activated until the health professional activates it in the system, until the professional does not prescribe it. You do not want isolated tools, but those that are integrated, shared between professionals; it allows them to be able to dedicate more quality time to patients.

Is it actually used also in the consults in hospital care?

Primary care is the gateway to the system, but there are patients who are already in specialist care, and a solution must be found for them. It manages to enhance treatment, puts the patient at the centre, and it doesn't matter where the care is given.

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Current status?

Future: reach out to education, they would love it; the prevention module is easily adaptable.

"El Viaje de Mangols" is in principle for people between 7-14 years, but is open to younger and older patients. It is not closed.

Integration mechanisms (IT)

The mHealth Game Tool is integrated with the Integral program manager (GIP module of the HER) in the patient's individualized plan.

The tool is supportive; it does not replace the consultation. Health is shared, the patient can be empowered. The professional is allowed to spend more effective time with the patient.

Interoperability

Semantic Syntactic Interoperability, with standards made in Osakidetza with a proprietary dictionary. There is no HL7.

Technical Interoperability: JSON, API standards.

Dependence

Dependence on Mangols can be created. To avoid that, they have developed a serious game controlling the game times, schedule....At night it doesn't work. They have worked on the colours, the voices of the actors and they have also reviewed sensitive religious details.

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Interview summary

Interviewees: Carme Pratdepadua i Bufill; Carlos Mateu Lopez (TicSalut Foundation)

mHealth Practice:

the mConnecta platform

Interviewers: Sonja Müller, Alexandra Prodan
Date of interview: 2020-11-25

Topics

The mConnecta platform has a successful approach on the following topics:

- Execution > Interoperability models
- Execution > Data security – legal framework; privacy

Summary of main interview ideas

Objectives of the mConnecta Platform

- Enabling the integration of data generated by patients through accredited applications, web applications, wearables, or medical devices into the mConnecta platform.
- mConnecta will be integrated into the Electronic Personal Health Record, where the data will be available for standard care on primary and hospital settings.
- Leveraging a patient-centred model between healthcare professionals and patients
- Integrating personal health data captured by mobile applications into electronic personal health records.
- Providing accreditation at usability, functionality, and evidence, technological, and security level.

- In the certification process, developers have the chance here to submit documents used in similar certification processes.
- The committee of experts is revised and adapted according to the needs of this very agile field.
- Everything is following the interoperability framework to guarantee the integration. Data is standardised by using for common syntax HL7 FHIR resources definition for clinical data. Semantic interoperability is ensured by using SNOMED and LOINC.
- The integration of the mobility data into the system does not require only interoperability and technological issues to be tackled, but also is important how the healthcare process will change; mConnecta is also considering change management processes.
- The mConnecta platform is using the cybersecurity norms that are working on the Information Systems of Catalonia, which are already provided.

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- Both new apps and existing apps have the possibility to be integrated with mConnecta.
- Data storage and processing is a challenge, given the amount of data that comes into the system. The time and type of data is decided together with the providers, so all actors involved align.
- Not all data can be integrated in the EHR of the patient. mConnecta, as an intermediate platform, allows for filtering and selection of most important aspects required by the healthcare professionals.
- Involving practitioners in prescribing apps also requires the assessment of digital health literacy of the patient and it needs to be personalised. mConnecta is encouraging and allows for this aspect.
- Healthcare professionals are the "designers of the app" and can choose what type of data to see and what kind of algorithms to apply.
- The Executive Committee of mConnecta is also considering the need to train healthcare professionals to ensure full adoption by the care centres where it is implemented.
- The integration of mobility data makes sense if it follows an interoperability framework that guarantees the quality of the data and maintains its meaning. In addition, the change that this integration implies for the entire healthcare process must be managed.
- The architecture of the platform needs to guarantee scalability in terms of performance, this is a must in a system that have face the challenge to adapt to an unknown number of users, depending on the applications that are going to be aggregated in the future.
- Having a multidisciplinary team working in the certification process and in the definition of requirements of the mConnecta platform allows to have a complete vision of the project and helps in its definition and implementation.

Objectives of the mConnecta Platform

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- Integrating personal health data captured by mobile applications into electronic personal health records.
- Providing accreditation at usability, functionality, and evidence, technological, and security level.

Topic 1: Security, privacy, and reliability

An important aspect of mHealth is the security, privacy and reliability of daily used apps. One of the issues TicSalutSocial approached was the creation a certification framework, which establishes a minimum set of criteria for apps that overcome this process. The guidelines and criteria are published on the website as guidelines or recommendations for those who want to create an app in the health field.

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Providing mHealth models into the healthcare system makes sense if there is trust and a secure environment. mConnecta uses this certification model as a first step in a series of many steps, although it is not a restrictive model as far as the integration solution is concerned. The model sets a baseline of criteria to be considered when developing an app. Obtaining the certification is a precondition for future integration in the system. It is necessary, but not a sufficient condition to integrate the app into the system as the body with executive power is the **mConnecta Execution Committee**, who will decide the areas to integrate and how the integration will look like and take place.

The project started at the beginning in 2016 with a series of objectives:

- define a set of criteria
- classify the apps depending on the risk
- define a workflow for the certification process
- constitute a committee of functional and technological experts
- create a technological architecture
- integrate mobility data into the system (using standards)

The certification process involves four steps:

1. **Apply for certification** – fill in technical and functional information about the app. **Developers have the chance here to submit documents used in similar certification processes**, for e.g. AppSalud in Andalusia. Or send us the CE mark, or a cybersecurity audit.
2. **Pre-validation and classification**. The app is assigned one of the three risk classes, depending on the risk for the patient. Level 1- lower risk, level 3 – higher risk. We use three important parameters:
    a. Number of people who potentially will use the app
    b. What kind of recommendations is the app providing (e.g. medical recommendations or general recommendations)?
    c. If the app processes sensitive data

    The classification of the app will define how strict will be the certification process. Which criteria will be compulsory, desirable or recommended.

    In the pre-validation process the app will be tested, and features such as registration and language will be checked. At the same time, the information provided by the developer is also assessed. This is an important part of the process as sometimes apps that could not perform these basic functions were identified.
3. **Criteria assessment by the experts**. The app is sent to the experts and they check the 120 criteria listed as a checklist, in four main categories:
    a. Design and usability
    b. Content and functionality
    c. Privacy and security
    d. Technological requirements
4. **Certification process**

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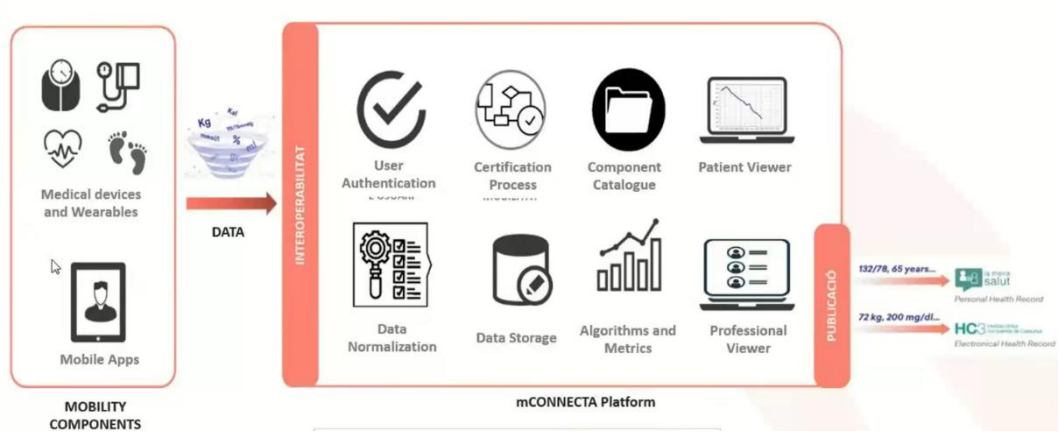
Topic 2: Interoperability

mConnecta is a showcase for mobility components in healthcare, aimed to empower citizens in the self- management of their own health. In Catalonia there is a central repository for all the clinical data of the patients that is collected in the clinical care setting. The mConnecta platform is going to provide the solution for all mobility devices that collect data from the patients that is not collected Within the framework of formal healthcare service provision and documentation, that means data from mobile apps, wearables, and medical devices. All information is captured on the mConnecta platform through an interoperability layer.

The interoperability framework



Inside the platform, authentication, certification process and algorithms that can extract information from the data are defined. The mConnecta has two view modes: one for patients, the so-called Patient Viewer and another one for healthcare professionals, the so-called Professional Viewer. Everything is following the **interoperability framework to guarantee the integration**. Data from apps but also all devices that provide mobility data in the system. It was also designed for monitoring patients at home if they own such a device. The monitoring can be implemented in mConnecta.

Internally, on the platform, there are a lot of services that need to be integrated. This is solved by microservices, working with docker systems architecture. All services must interact and have to be integrated to share the information. This is important for a platform that can grow and be scalable in performance. There are apps integrated that maybe don't need a lot of performance, but some other projects (diabetes).

The platform has, as mentioned above:

- Interface for the citizen
- Interface for practitioner
- Administration services

Data is standardised by using for common syntax HL7 FHIR resources definition for clinical data. Semantic interoperability is ensured by using SNOMED and LOINC.
The platform is integrated with third party services from other existent Catalonian Information Systems, that provide authentication services (LMS), the terminology server (all catalogues and info that we can use for the platform). mConnecta can also publish the data on the central repository, such as data important for physicians.

Crucial steps in implementation

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The accreditation process started in 2016 and ended in 2018 with a pilot that rendered a list of improvements. The project name back then was AppSalut. AppSalut changed to mConnecta in the sense of having a global vision of the mobility data. The integration of the mobility data into the system does not require only interoperability and technological issues to be tackled, but also is important how the healthcare process will change; mConnecta is also considering change management processes.
The mConnecta will go live in approximately 2 months. Currently, the administration viewer is implemented, and the project is in the step of integrating it in the centres.

Committee of Experts

One of the objectives of the project was to create the Committee of Experts and to choose the right members. The Committee of Experts of mConnecta contains members from the following organisations:

- College of doctors
- Nursing school
- Association of Family and Community Nursing
- Catalan Family and Community Medical Society
- Catalan Psychologist Society
- Catalan physical activity and sports Society
- Pharmacy

Every year the possibility of incorporating new organisations in the Committee is considered. For example, two years ago the Catalan physical activity and sport Society was added because there are a lot of apps related to physical activity. The project maintains a flexible approach depending on what kind of apps must be certified, how many apps belong to certain categories, so the Committee of Experts is verified to check whether the right expertise is present. In the beginning the Committee was formed by four entities. After a short while it was realised this spectrum needs to be opened because otherwise it's difficult.

Challenges about cybersecurity

The mConnecta platform is using the cybersecurity norms that are working on the Information Systems of Catalonia, thus re-using and being aligned with the Xxx.

Data challenge

Data storage and processing is a challenge, given the kind of data that comes into the system. Wearables, medical devices are providing a lot of data, that, depending on the type of device, might be easier or harder to structure. The time and type of data is decided together with the providers, so all actors involved align.

Alignment with developers

New solutions: One way to align is having precommercial procurement projects (PCPs). Three important areas were identified: diabetes, mental health (bipolar disorder), and hospitalisation. For diabetes, the CatSalut will release the call for Tenders late 2020/early 2021. All companies can apply for the Tenders. In the end few will gain the process and will go through the test to be integrated. Before the procurement takes place, a consultation with a group of experts interested in the area is organised, in which the type of information and variables needed to be collected from the patients is discussed. In diabetes for example, the provider has a lot of variables. But at the end, the group of experts will decide the minimum variables that will be integrated in the EHR.

Existing solutions: After a solution has passed the certification process, they need to go through the integration process, which is ensured by the interoperability framework published and available. Afterwards, they go through a test with the mConnecta. Accreditation – then test

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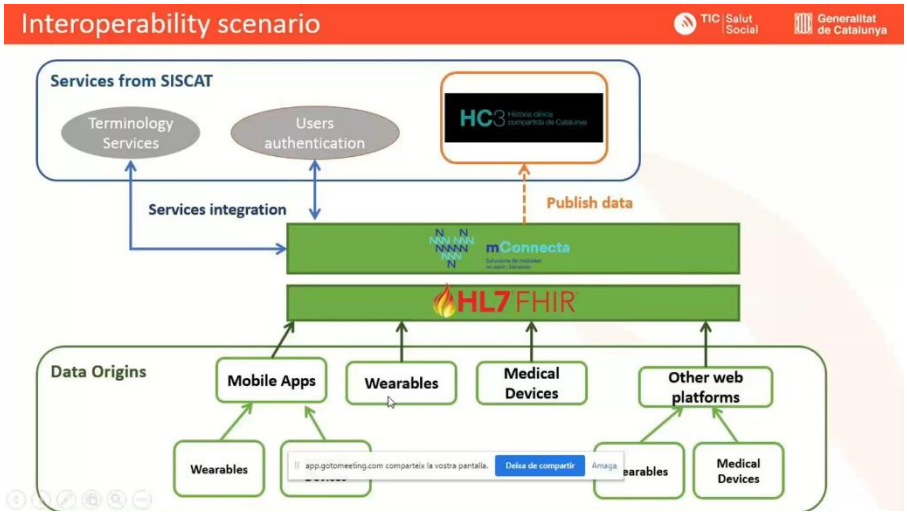
validation to integrate the solution. The data needs to follow the two standards: SNOMED CT/ LOINC.



Privacy concerns

The informed consent is always signed previously. The Privacy Impact Assessment ("PIA") form needs to be implemented by the providers (or all entities that enrol a device)[44]. The PIA is not required for any processing of personal data, but only when there is a high risk to the rights and freedoms of individuals, by the nature of the processing, the scope and context, the purposes or use of new technologies. A lesson learned while carrying out interviews – how the solution works and how they guarantee the safety of data. **Sometimes even if they pass the security audits, but the informed consent is not there.** We are also doing these interviews because it is difficult to expect all entities to implement the form.

How do healthcare professionals interact with the platform?

Practitioners can choose what type of data to see in the practitioner's view. For each app, the platform asks the practitioners: what data you want to see, what kind of algorithms you want to apply on the data. Developers have more or less the same algorithms.

How do you ensure the adoption of the platform by the stakeholders?

The important body in this case is the executive committee, the personal healthcare expertise. There is a person responsible for what information is going to be sent to the citizen. This person is part of the executive committee. The committee decides the areas that need to be integrated. We identified these three areas mentioned above: diabetes, mental health (bipolar disorder), and hospitalisation. The major healthcare providers are who started to work with them to integrate them in the hospital. **In TicSalut Foundation we have a personal responsible to go to the centres, to do trainings with professionals, to help them understand how it works**. Having

[44] template to fill in a PIA by any entity and a Guide with more information:

https://apdcat.gencat.cat/en/documentacio/guies_basiques/Guies-apdcat/Guia-sobre-la-evaluacion-de-impacto-relativa-a-la-proteccion-de-datos-en-el-RGPD/index.html

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this executive committee is a key element to involve all actors into the system. Otherwise, TicSalut, it's hard that people have enough trust to adopt it and use it.
Currently, the platform is going to be integrated in 3-4 centres.
In the case of mental health, the committee published a previous report on the cost-benefit of how to implement mental health, where it has become clear that the bipolar disorder represented a good balance to implement it into the system (Benchmarking, what has been done).

Summary of key strengths

- In the certification process, developers have the chance here to submit documents used in similar certification processes.
- The committee of experts is revised and adapted according to the needs of this very agile field.
- Everything is following the interoperability framework to guarantee the integration. Data is standardised by using for common syntax HL7 FHIR resources definition for clinical data. Semantic interoperability is ensured by using SNOMED and LOINC.
- The integration of the mobility data into the system does not require only interoperability and technological issues to be tackled, but also is important how the healthcare process will change; mConnecta is also considering change management processes.
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- Both new apps and existing apps have the possibility to be integrated with mConnecta.
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- Not all data can be integrated in the EHR of the patient. mConnecta, as an intermediate platform, allows for filtering and selection of most important aspects required by the healthcare professionals.
- Involving practitioners in prescribing apps also requires the assessment of digital health literacy of the patient and it needs to be personalised. mConnecta is encouraging and allows for this aspect.
- Healthcare professionals are the "designers of the app" and can choose what type of data to see and what kind of algorithms to apply.
- The Executive Committee of mConnecta is also considering the need to train healthcare professionals to ensure full adoption by the care centres where it is implemented.

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Initiative summary

mHealth Practice:

Megi app

Online research carried out by: Ivana Ostoic (HCZC), Croatia

Date of interview: 2021-01-20.

Topics

MEGI app (hypertension chatbot) has a successful approach to the following topics:

- Planning > **User centered design considerations**

Scope of the mHealth Practice

MEGI is an app (chatbot) developed for the tracking of blood pressure. The app was developed in collaboration between the start-up company *Mindsmiths* and the *Magdalena Clinic*, specialized for heart conditions.

The knowledge of experts, primarily cardiologists and nurses dealing with cardiology, was used in the production of MEGI. It was developed for six months, followed by 12 months of use. During this period, the system was tested by 74 patients. The initial number was 82, but four gave up because they did not need measurements, and four for some other reason.

One of the benefits that MEGI provides is a significant reduction in the time a doctor spends during an examination. The average examination lasts 22 minutes, of which the doctor gathers information for 15 minutes. If the patient has used MEGI, she will prepare information for the doctor based on the data collected and significantly shorten the time required to talk to the doctor to make communication more effective. In this case, instead of 15 minutes, it will take only four minutes to collect the data, and the excess time can be used to raise the quality of the examination or save money so that more patients can be examined.

It is similar with the application or change of therapy. For example, MEGI can graphically compare the movement of pressure before and after therapy and thus show whether the pressure is regulated thanks to medication. Thanks to MEGI, the time required to adjust therapy can be shortened from six months - which is usually the interval between two examinations in such a situation - to three weeks. Thanks to information about whether a patient's pressure is regulated, doctors can achieve much more efficient use of their time. Unnecessary check-ups for patients whose blood pressure is good can be delayed or canceled, while patients who currently have problems with blood pressure can get their turn faster, and thanks to relief, more time can be devoted to them than before.

Scope and timeline of the mHealth good practice implementation

- How long did it take for the mHealth practice to be implemented?

It took around 12 months and it was tested on 74 patients before it was put in official use.

- What are the key steps that were undertaken?

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IT experts and medical staff defined the needs for the app and based on that IT experts started development. First generation was put in use without involving patients in the development. During the research phase, it was seen that most patients were not skilled enough with cell phone use. The most common problems are lack of experience with downloading and installing applications, long-term non-updated software on the mobile phone, difficulties in accessing web pages due to data settings or finding the application, and insufficient free memory. For this reason, it has been shown that the best choice is communication through text correspondence as it represents the lowest barrier to technology acceptance. Almost all users knew how to use SMS and almost all had some of the applications like WhatsApp and Viber. However, the less used Telegram was chosen as the ideal platform, because it is the most flexible, fully encrypted, more open to developers and therefore allows the easiest testing.

- What are the strengths and weaknesses of the implementation process?

For the first app main weakness was that not all stakeholders were involved in the process which caused problems in the use of the app, but now both sides are actively involved in the design and implementation of upgrades or when new apps are created

Main strength is that doctors now need significantly less time to adjust therapy – now it is done in 3 weeks, as before it was 6 months from first visit to follow up session and immediately response if needed as MEGI is constantly and automatically communicating with patients and doctors.

Stakeholder involvement

- What stakeholders needed to be involved for the good practice to work?

Doctors, IT experts, psychologist and patients needed to be involved in order for the practice to work.

- What are the stakeholders' roles and activities/effort?

Doctors gave inputs for all the features that app should have, type of data they need and outputs that app has to track.

IT experts: based on doctors inputs IT experts developed the app with all functionalities and features, main challenge was which communication platform to use and Telegram was chosen due to data security and stability.

Psychologist was involved from the side of IT team in order to "translate" IT and doctors language and to make the app patient friendly

Patients – they had to learn how to use the app - it was seen that most patients were not skilled enough with cell phone use.

The most common problems were lack of experience with downloading and installing applications, long-term non-updated software on the mobile phone, difficulties in accessing web pages due to data settings or finding the application, and insufficient free memory.

For this reason, it has been shown that the best choice is communication through text correspondence as it represents the lowest barrier to technology acceptance. Almost all users knew how to use SMS and almost all had some of the applications like WhatsApp and Viber.

- How was involvement and buy-in of the stakeholders secured?

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From the start, medical staff was interested in the app as it was obvious that it would significantly shorten the period of data gathering from the patient and would allow doctors to focus on therapy and needs of the patients that really need their expertise.

Patients quickly realized they would save time; there is no need for the waiting list, they are getting answers and therapy adjustments automatically.

Barriers

- Were there any obstacles you experienced? How were they overcome?

Main barrier was to explain to the patients they have to use smart phones (especially age group 70+) but with the help of family or relatives it was overcome.

Success factors

Main success factors are that with using MEGI all data are gathered and exchanged automatically, so waiting for the first exam or regular check-up is significantly shortened, also therapy adjustment is shortened from typically 6 months to 3 weeks. Initial data gathering takes only 4 minutes compared to on average 22 minutes that doctors would need plus waiting period for the first exam and time doctors has to spend.

Outcomes

- What were the main outcomes of implementing the mHealth solution?

Main outcome is higher satisfaction among doctors and patients, shorter waiting lists, significantly shorter period for response and therapy adjustments, lower costs and better quality of medical service.

- What is the status?

MEGI is a fully operational app and in daily use in Magdalena Clinic

Continuous learning and outlook

- What would you have done differently? What can still be improved?

App is under constant development and is regularly updated (data protection, added features)

- What are the future plans for exploiting the mHealth solution?

The app was tested in primary and secondary health care and it the future it will be widely used.

References (in Croatian)

- Meet MEGI, a digital assistant who takes care of pushers and shortens therapy settings from 6 months to 3 weeks: https://www.tportal.hr/tehno/clanak/video-upoznajte-megi-digitalnu-asistenticu-koja-brine-o-tlakasima-i-podesavanje-terapije-skracuje-sa-6-mjeseci-na-3-tjedna-20201208/print
- Megi: https://www.youtube.com/watch?v=1jlQChcLTAE
- Presentation of the results of successful application of AI prototype in healthcare: https://www.youtube.com/watch?v=dGF1te0262Q&t=1131s

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Interview summary

Interviewee: Javier Quiles del Río (Galician Health Service, Galicia, Spain)
mHealth Practice:

mSaúde platform

(Galician PPI[45] innovation Project for Patient Empowerment)
Interviewers: Belén Sotillos
Date of interview: 2020-12-11

Topics

mSaúde platform has a successful approach to the following topics:

- Initiation > **Scope and resources**
- Execution > **Integration with eHR**
- Execution > **Solution testing and validation**

Summary

- Flexibility as a main feature to allow adapting the tool to assessment process evolutions.
- Integration of the platform (mSaúde) with eHR
- Involvement of interested and highly specialized health professionals in the assessment process; agile ways of collaborative work.
- Towards a "federated model" for apps assessment in Europe.

[45] Public Procurement of Innovative solutions (PPI)

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

Scope of the mHealth Practice

Background info about the good practice

- 2012: Information Systems were traditionally more oriented to solve system and health professionals needs. The digital solutions were seen by the organization as an opportunity to empower citizens and patients, within an overall digital health framework.
- "e-Saúde" was launched in 2012 as a regional patient portal, currently there are more than 120,000 users, access to eHR and digital services, patient-oriented.
- "Telea", telemonitoring portal covering the whole health system, more specific, focused on patients with specific diseases.
- 2015: thanks to ERDF funding and Public Procurement of Innovative solutions (PPI), several projects were launched ("Código 100", market consultation developed. Outcomes including: app for diabetic patients; virtual assistant; patient health record as a place to store patient data, and mSaúde itself).

Main topic: Solution testing and validation (Integrating Assessment and Access to Health Apps)

Scope and timeline of the mHealth good practice implementation

See info on the "Scope of the mHealth practice" section

Stakeholder involvement

- What stakeholders needed to be involved for the good practice to work?

  There is a clear need of highly specialized health professionals to participate in the apps assessment.
  Also experts in data protection must be involved and take a leading role.

Barriers

- Apps development as a fast-changing environment.
- Potential weakness of the assessment process: time duration of that process; start-ups need to see it as an agile process; if not, the public authorities will lose the window of opportunity.
- Highly specialized health professionals profiles are not always easy to find.
- Health professionals need time to carry out apps assessment, and they not always have it.
- Health authorities have not received clear and precise orientations from supranational bodies, like EC, about non clinical apps. European efforts seem to be more focused on an HTA-oriented approach that is not fully adapted to the whole scope of clinical apps.

Success factors

- The work developed on innovation is clearly aligned with public funding cycles (competitive calls); that funding enabled to scale up the initiatives to the whole public regional health system (e-Saúde, Telea)
- Start working with those clinical units that see a clear opportunity in using the solution; they would help to "break the ice" for deployment and become innovation champions for the whole organization. Be able to identify suitable units for pilots (i.e. sometimes

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smaller settings can be more dedicated to participating in a specific initiative than a bigger hospital, where there might be many other innovative initiatives).

- Creation of working groups, to build from the beginning a user-oriented solution. Importance of usability, both for citizens and health professionals.
- Flexible assessment process, adaptable to different processes and evaluation criteria. Understandable validation rules, that can be adapted to the organizational context.
- Integration of the platform (mSaúde) with eHR
- The integration with blockchain is intended to function as a decentralised registry that provides security in the exchange of information.
- Synergies between R&D centers and health system.
- Definition of Integration elements based on standards. This approach might take more time when developing the solution, but if standards are not used for the integration, the solution is then limited to just one provider (hard to scale it up).

  Without standards, the validation process becomes more complex; the standards allow to have a group of tests based on standards, it is a substantial improvement both for implementation and validation.

Lessons learnt

- During the innovation "valley stage", a key element is to obtain clear results to convince the managers about the solutions' matureness and readiness to be scaled-up, once pilots are completed.
- Application of different validation levels and flows, depending on the nature of the solution (i.e. wellness apps, clinical apps, apps with elements of integration with health systems, etc).
- The organizational model has also big influence on the design of the assessment process. In the early stages, a collaborative model is more feasible than a stable and structured Committee.

Outcomes

- What were the main outcomes of implementing the mHealth solution?

  Patient empowerment

  It means a support both for the healthcare delivery field, and for the regulatory field (lot of apps, health authorities feel the need to provide some regulation about it, security, etc.)

- What is the status? (pilot, tested, fully operational)

  mSaúde deployment and pilot will be carried out in 2021. After this first stage, the intention is to scale up the platform to all the apps provided by IT companies in the region (Galicia), and beyond.

Continuous learning and outlook.

- Future plans: orientation to a "federated model"; the intention is to create a platform to be integrated in a bigger network (catalogues, patient portals from other organisations).

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The means that each organisation or health system can allocate to assess mHealth solutions is limited. The collaboration between public health systems would be desirable; enable the connection between different official repositories and platforms (i.e. search engine including all the repositories)

- Future plans: assessment costs to be partially assumed by apps developers submitting their specific apps (third party apps), to make the platform sustainable.

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Annex
5 slides provided as supplementary material

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Apps assessment

Supporting the whole process:
From developers to
evaluation authority to
final users.

msaúde

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Adapted to different tests and Apps clasification

mSaúde allows classification of Apps.

- **Matrix for apps evaluation**
  - Technical features
  - Functionalities
  - Five levels to determine Appsrisk level
- **Testing and assessment adapted to risk levels.**

msaúde

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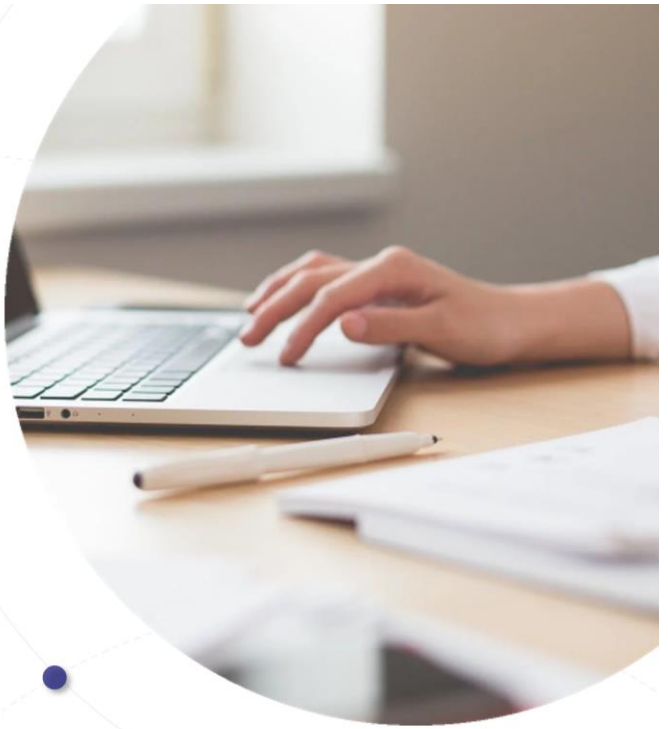
Integration and Federation

mSaúde allows integration in the Electronic Health Record system.

Provides a cataloguethat can be searched using an API

Also third parties are allowed to search and find assessed APPS and find the most suitable one



msaúde

BALIDEA

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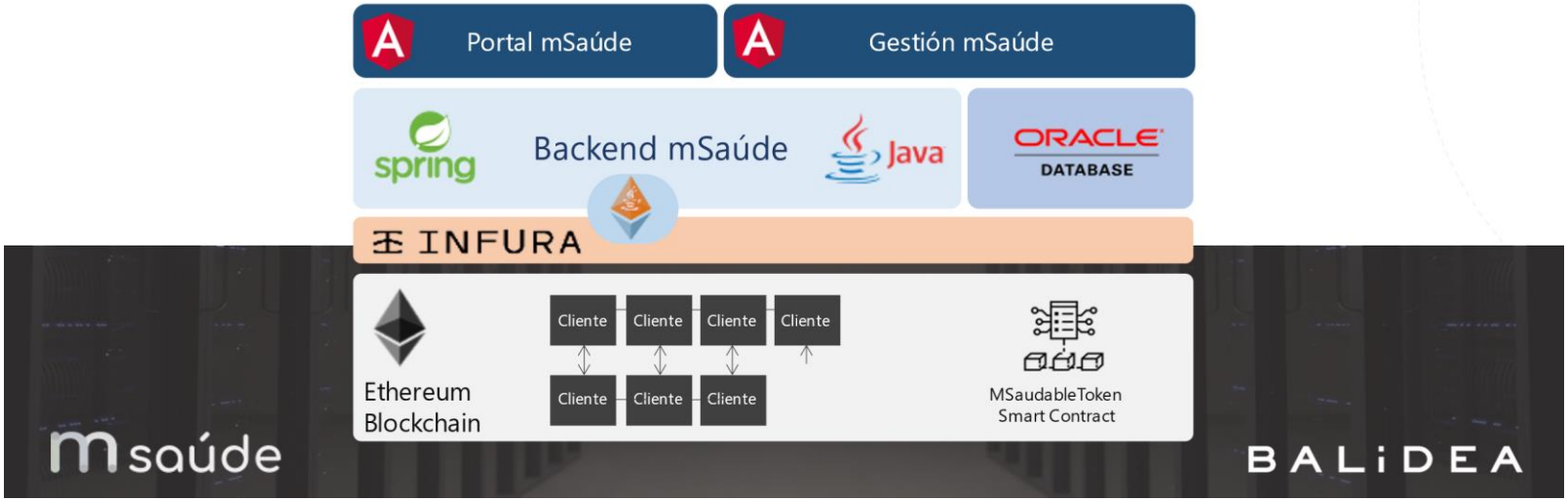
Strong architecture: oriented to integration

Frontend and Backend separated layers.

Java based architecture exposing open services.

Smart contracts on Blockchain



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Interview summary

Interviewee: Miren Garrastatxu Landaluce-Oqueranza and Jose Manuel Perales García.

mHealth Practice:

Mugitzen

Interviewers: Dolores Verdoy and Nerea González.

Date of interview: 2020-12-03.

Topics

Mugtizen has a successful approach to the following topics:

- Planning > **Workplan development** (implementación y strategy)
- Planning > **Technical infrastructure requirements**
- Execution > **Integration with eHR**

Scope of the mHealth Practice

Background info about the good practice

Osakidetza (Basque Country Health Service) has created an innovative healthcare system for nurses that allows them to care for the patients in the most agile, efficient and safe manner. The new system is part of a clinical care and management project launched by Osakidetza (*Osakidetza Mugitzen*, a mobility strategy aimed at professionals), which combines patient safety, nursing care, mobility and the collection and recording of information at the point of care (primary care at home and in hospital), in real time.

The system consists of 5 applications based on the identification of the patient by reading their wristband (hospital environment) or selecting them from a census (home environment). The new Osakidetza applications are designed for lightweight tablets, with a size that allows them to be carried in a uniform pocket, and have been developed from the existing information systems at Osakidetza (Electronic Medical Records, Osabide Global, Osanaia, eosabide...), adapting and selecting the necessary information to the mobile device, improving functionality and thus offering simple and safe care.

This new information access and management system has been initially developed for five daily use applications in nursing:

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- *Constant capture*: allows both consultation and recording of different clinical constants. The recording is reflected immediately and is archived in the patient's health record, as the application is integrated with Osakidetza's electronic health record.
- *Administration of medication*: this allows a patient's prescription chart to be consulted and medication to be administered. The application shows the patient's current treatment and pharmacological history. It also incorporates safety filters such as alerts and allergies in the treatments and allows the medication to be consulted by time periods. The application is integrated with hospital pharmacy (eosabide).
- *Devices and wounds*: allows for the complete registration of clinical devices. The application is integrated with nursing care (OsaNaia).
- *Blood draws*: allows for the reconciliation of the flyers with the draws. Furthermore, it allows to cross and verify the patient's data, the request data and the sample data, confirming to the nursing professional that the procedure is appropriate. The application is integrated with Osakidetza's Laboratory (GestLab).
- *Bed map*: it shows the occupation of the nursing units, as well as the care to be provided to each patient. The information is accessible through various filters. The application is integrated with eosabide, osanaia, and allergies and alerts from Osabide Global.

One of the most outstanding advantages of these applications and devices is the security they offer in terms of care, since the tablet has a scanner that reads the barcode on the patient's wrist, performing an automatic verification, thus avoiding identification errors, and allowing access, through the code, to their clinical data.

In addition to reinforcing clinical security, these applications allow the information collected in real time to be uploaded to the patient's electronic medical record, thus avoiding any possibility of error.

Scope and timeline of the mHealth good practice implementation

- How long did it take for the mHealth practice to be implemented?

Mugitzen, Mobility Nurse, started in 2013, with the first steps, which were more technical. They became pilots in Galdakao (OSI BARRUALDE GALDAKAO): they began to identify needs for access to information, at the bedside; this experience was done with mobiles, it was a laboratory.

Next step: How to bring it to all Osakidetza users? The entire technical environment was set up and operational by October 2015. From 2015 the first pilot of the first application was started. A solicitation document was drawn up, with an external company and 5 applications. An architecture was established to see how these applications could work on a large scale; it was seen to be viable and a tender was issued and awarded to a company. The first milestone was the implementation of these 5 applications in production for all users in the hospitalisation area.

The portfolio of services has been extended to areas other than hospitalisation, also at home, and accessible via the internet. In May 2020, tablets were deployed for Primary Care and Home Care.

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The apps were adapted to work in these areas: apps for constants, extractions, medication for home hospitalisation (under development); the app for devices and wounds is currently being adapted for the home environment and a specific app has been developed to cover priority needs in home care: one for scales and forms, which allows access to the type of scales used in chronic care.

- What are the key steps that were undertaken?

- Dossier and specifications for allocating a portfolio of mobile applications.
- Development of the 5 applications that were considered a priority at that time: constants, extractions and samples, medication administration, device and wound registration, and bed mapping.

- What are the strengths and weaknesses of the implementation process?

Strengths:

- to provide a new tool that allows a quality record to be made, online in real time;
- security: to ensure that there are no mistakes;
- the errors detected coincide in the data with studies already carried out;
- instead of macro-developments, we have tried to cover the needs with mini-applications that resolve very specific business scenarios and where they contribute a lot of value.

Weaknesses:

- technology is advancing very quickly and forces us to be constantly evolving, especially tablets; we have opted for consumer products that are not very expensive, for sustainability, but they are not for professional use; when changes are made to these devices, they affect them; they seek balance in the evolution of applications and at the same time to be able to support their use;
- the speed with which technology evolves and the needs of professionals associated with that technology.

- What are the strengths and weaknesses of the solution?

Strengths:

- the applications that have been designed, which respond to needs detected by the professionals themselves;
- benefit to the patient, benefit to the professional in their daily practice; it facilitates easy and simple access to very important information; it represents an unquestionable improvement in terms of security and quality of information.
- communication capacity between nurses and technical partners (solid and fruitful alliance).

Weaknesses:

- the difficulty of responding to the new needs identified by the good practice.

Stakeholder involvement

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- What stakeholders needed to be involved for the good practice to work?

- Nursing, which is the figure that needs the utility.
- Technical part: developer, interoperability, security communications.
- Project supported, defended by the Sub-directorate of Nursing, within the Directorate of Health Care, and the Directorate of Information Technology.

- What are the stakeholders' roles and activities/effort?

- Nursing: identification of needs, improvements to be made, definition of the scope that the tools must have, their functionality, usability of the designs.
- Technical: development, security, interoperability.

- How was stakeholder participation and engagement ensured?

- A first experience was made in Galdakao. It was seen that the device was viable and was the lever to start the project. The Directorates of Nursing and Information Technology understood the need and bet on it.
- A steering group was set up, which is still in place, and which met once or twice a month. It is made up of members of the Information Technology Services of the Osakidetza General Directorate, the Sub-directorate of Nursing, representatives of some of the organisations that began and of large organisations where many needs arise. The group collects the initiatives that arise (improving scope, functionalities, development of new apps...).
- In addition, in nursing there is a reference group, with 1-2 people from each health organisation. It is in this forum that needs for implementation, user experience and incidents arise.
- These two groups are currently articulated in order to promote the project.

Barriers

- Were there any obstacles you experienced? How were they overcome?

- People's natural resistance to changing habits. In some points it is easier than in others to break these barriers; for example, in hospitalization it is usually easier to introduce changes because it is easier to reach the end-user, who has to use the resources; there is a figure of the supervisor, who is given the task of implementing and who is present in the unit, checking how things are done. But in other settings, such as Primary Care or Home Hospitalization, it depends much more on the interest or experience of the nurse.
- Lack of technical resources, lack of tablets; the pilot model has been out of stock and while others are being obtained, there are units that are undersupplied.
- The hardest part is the device itself.
- The infrastructure also changes very quickly, but we are able to adapt very quickly.
- Patient identification: how to scan patient barcodes with a device that was not intended for that. Today there are areas where this difficulty is not solved because the patient does not have a bracelet.
- Bracelets were not originally intended to be read with a device; bracelets, barcodes, QR codes.

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- Nowadays, if the camera disappears or the component used to scan disappears, it is one of the weakest points, which affects all security.
- First steps: find suppliers that develop these platforms. It is difficult to find technicians with this knowledge.

Success factors

- Nursing is a highly disciplined professional body. It may take more or less time to work through the barriers, but they usually end up joining the initiatives.
- Having established a network of references, who take the lead in implementing the project, who are interlocutors between the users and the driving group; they take on the training in cascade towards the rest of the users, reinforce those who have difficulties, transfer incidents, are a fundamental element in achieving the success of the projects. They are permanently on site.
- 100% open-source platform (device and infrastructure), maintenance is very easy.
- MEM is the only thing that is not free.
- The performance of this architecture is very good and can be used for other types of developments.
- A lot of performance and everything is very light.

Lessons learnt

- Talk to the people who are going to use it, identify users to help define. At the beginning you could have worked more with them in defining the functionalities and scope.
- Now we are in production and the changes need to be thought through and analysed a lot, because they affect many users.
- Always look to the future, to what is on the market. Now we are thinking of taking these applications to mobile phones instead of tablets, because they are designed for other things.

Outcomes

- What were the main outcomes of implementing the mHealth solution?

- Thanks to the applications, identification errors have been detected (obtaining samples, administering medicines...).
- A data console has been built to provide information on the activity carried out with the apps, in a secure and agile manner.
- Creation of a digital culture in the use of resources; a culture of security and care.
- If the user sees benefits, it is successful.

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- The fact that nurses perceive as necessary to access components of the medical history, consult information to provide care, that needs arise associated with the resources they already have, is a success.
- Nurses already trust and rely on the applications, previously they did not trust and had to check.
- The size of the tablet has been taken into account (if it fits in the pocket of the suit, or gown).

Continuous learning and outlook

- What would you have done differently? What can still be improved?

- Different, no. The project was born at a point where the end-user (nursing) and IT were ready for it. Two years earlier it would not have been technically possible.
- To be more ambitious with the scope of some of the applications that have been developed; some developments have been left just short of scope, mainly due to technical issues.

- What are the future plans for exploiting the mHealth solution?

- Evolution of the device issue. They usually go in tow of what is needed. At the same time, applications have been developed for the citizen, which are 100% assistance.
- Pending in the schedule: Extension to medical day hospitals, emergency rooms and emergency rooms. The development of new applications has also been considered (e.g. warning map for primary and home care).

Other clarifications

- Is the initiative integrated with any patient portal or government repository?.

- It is integrated with the Osakidetza patient repository. Interoperate 100% with Osakidetza systems, no integration with other health services. Integrated with the large systems of Osakidetza: E-OSABIDE, OSANAIA, AND Osabide Global. The environment is 100% intranet.

- How does the nursing procedure for administering medicines change?

- It has occurred in all processes that require bracelet reading, not only in medication. As a result of using this medication administration app, the identification of the person is secure. In order to access the app, the sticker on a medication cart corresponding to a specific patient must be read and the patient's wristband must be scanned in order to sign the medication. If there is no match, there is an error. If there is a match, the medication administration can be signed. The process is a little slower, but it provides security.
- The same applies to the extraction of samples; the bracelet is traced with the patient and the sample.

- Have interoperability standards been adopted?

- No interoperability standards are used. They have adopted rest services because they are lighter and give more performance.

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- Does the initiative generate evidence/results on patient safety?

- We have a console where security-related errors are monitored. The errors are recorded and you have the success rate over the error rate.

- What are/were the main obstacles encountered in the design and development of the initiative; how were they overcome?

- The network of references that has been created has helped to overcome these obstacles. They have assumed the leadership in the implementation of the project, they act as interlocutors between the users and the traction group and they transfer everything that is being done, there is constant contact.

- How were the technical problems solved? (e.g. connectivity between the devices and the hospital's Wifi).

- There is no technical support on the device side, with connectivity problems encountered.

- The manufacturer (Samsung) was contacted and a patch was made, but it took time. They are now working with Huawei. They have been approached to stop certain device updates and this is how it works best.

Other additions and highlights of important aspects identified

- If they use devices of this type, taking into account the low number of devices we are talking about, for a manufacturer it is as if they do not exist; they are drifting away from what the manufacturer considers.

- The application is sustainable because the device is cheap, but they are not going to support you.

- Not only do we have to take into account the real needs of the users, but we also have to make a clear commitment to bring the medical record closer to the point of care. It is not necessary to have a full scope, or to involve the whole existing information systems, but it is key that the action is felt it feels useful and that it becomes essential.

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Interview summary

Interviewee: Roberta Papa (Marche Region)

mHealth Practice:

MyCupMarche

Interviewers: Nicola Scomparin - ProMIS Staff

Date of interview: 2020-11-26

Topics

MyCupMarche has a successful approach on the following topics:

- Execution
  - **Interoperability models**
  - **Data security – legal framework**
- Monitoring and Evaluation
  - **Secondary use of data**

Summary

- Multi-channel system developed to optimise the management of the regional Centralised Appointment Centre (CUP) of Marche Region and reduce waiting lists
- The project started in 2017 and took about two years to complete. The system is constantly evolving and additional services are about to start along with a renewed version.
- Main factors of success were the strong political support and the chain of responsibility entrusted to the single entities of the health system.
- Technical obstacles faced were linked to the integration of the platform with existing systems, which have been overcome
- The App was awarded at national level

Strengths

- Single regional CUP
- Integration with other regional applications
- Direct contact of the health system with the citizen
- Reduction of waiting lists

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- Perspective of development towards other dimensions, such as the optimisation of the production processes of health services

Weaknesses

- Need, according to the regulations, to adopt strong authentication credentials to access the system, which could inhibit its widespread diffusion
- Limited access to training and user training material and limited institutional communication about the system towards citizens

COVID context

- integrated with the management software dedicated to monitoring quarantined patients
- ensured, through the automatic recall and SMS system, daily contact with thousands of patients to follow the onset of symptoms in order to alert the general practitioner and the prevention department.
- the system supports a series of activities linked to contact tracing.
- the system has been used to warn clients of the change of their bookings due to the emergency

Scope of the mHealth Practice

The good practice is a multi-channel system developed to optimise the management of the regional Centralised Appointment Centre (CUP) of Marche Region and reduce waiting lists. Citizens can interact with the system via automatic telephone recall, an App, a SMS, a chatline and social networks. The system can be accessed from a PC, tablet and smartphone. The aim is to guarantee constant, multi-channel and transversal interaction, which can accompany the person to the various points of contact with the Healthcare system.

Initially, the system made it possible for citizens to confirm or cancel the appointment booked by means of an automatic telephone reminder. Subsequently, through a dedicated APP, other functions were implemented such as:

- Book and cancel an appointment for about 200 tests and specialist medical examinations monitored nationwide in regards to waiting lists;
- Ask to be contacted by the CUP;
- Pay for the health ticket;
- Have all the details of your appointment - such as the date, time, and any specific warning, - and create specific reminders.

In order to make an appointment the person needs to access the system through strong credentials, while for cancellation and payment no confidential access is required.

The project started in 2017 and took about two years to complete. The system is constantly evolving and we are planning to implement some additional services in conjunction with the launch of the renewed regional CUP soon. The system has seen further expansion during the COVID-19 pandemic, with the addition of some specific functions.

The development process began following a specific request from the President of the Region, such as the identification of a tool to address the management of the waiting lists. Then, we had the idea of developing a multi-channel platform to support the regional CUP. The project was carried out within the framework of an existing contract with a private company in order to

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manage the regional cup software. This contract was then extended with the takeover of another private company, who analysed the existing activities of the cup to develop the additional functionalities to support operators and citizens. The system exploited, for some components, solutions already tested and implemented, which were integrated with the regional infrastructure.

The **strengths** are:

- The presence of a single regional CUP
- Its integration with other regional applications
- The direct contact of the health system with the citizen
- The reduction of waiting lists
- The perspective of development towards other dimensions, such as the optimisation of the production processes of health services.

Some **weak points** are:

- The need, according to the regulations, to adopt strong authentication credentials to access the system, which could inhibit its widespread diffusion
- The limited access to training and user training material and limited institutional communication about the system towards citizens.

The App has been downloaded by over 10,000 citizens of the Marche region. With regard to the recall and SMS services, in 2019 approximately 67,000 visits were reassigned and approximately 145,000 reminders sent via SMS, contributing to the reduction in waiting lists. The advantage for citizens was also that they could feel the health system "closer" and benefit from a personalised reminder on where, at what time and what they should do (e.g. fasting) before coming to the appointment. The economic return was extremely significant, estimated at over one million euros in one year, considering the healthcare activities reassigned (instead of citizens simply missing an appointment) and the savings obtained from activities carried out by the system instead of the operator (e.g. telephone calls).

In the framework of COVID-19 pandemic, the system has proved valuable in its management. It has been integrated with the management software dedicated to monitoring quarantined patients and has ensured, through the automatic recall and SMS system, daily contact with thousands of them to follow the onset of symptoms in order to alert the general practitioner and the prevention department. The system also supports a series of activities linked to contact tracing. Finally, the system has been used to warn clients of the change of their bookings due to the emergency.

MyCupMarche has received several **awards and recognitions**:

- finalist and still in the running for the eHealth4All 2020 Award

  https://ehealth4all.it/wp-content/uploads/2020/10/Presentazioni-Abstract-1.pdf
  https://www.sanita-digitale.com/2020/10/05/i-finalisti-del-premio-ehealth4all-2020/
- finalist in the POLIMI Healthcare Digital Innovation 2020 Award
- winner of the 2019 Sustainable PA Award (Food, Health and Welfare)

  https://www.i-tel.it/it/blog/premi/premio-pasostenibile-mycupmarche-vicitore/

  https://www.regione.marche.it/News-ed-Eventi/Post/50802/MyCUPMarche-premiato-a-Roma-come-progetto-pi%C3%B9-significativo-in-sanit%C3%A0-e-welfare

https://www.youtube.com/watch?v=luKHDBmslRM&feature=emb_logo

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Watch the **video** about this initiative here (access to playlist)

To find out more about implementing large scale mHealth solutions for diabetes in Marche Region, please watch this video from our 6th Hub Talk on patient centric approaches in mHealth (from 31:44 to 45:37)

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Interview summary

Interviewee: Mariana Meira

mHealth Practice:
myNHS Wallet
(*mySNS Carteira*)
Interviewers: Samuel Jacinto, Vanessa Mendes
Date of interview: 2020-11-25

Topics

MyNHS Wallet has a successful approach on the following topics:

- Planning:
  - Technical infrastructure required
  - **Interoperability with existing systems**
- Execution:
  - Technical integration with eHR and other systems
  - **Authentication, authorization mechanisms**
  - Collection and use of patient-generated data
  - Data security and legal framework

In bold are the two topics / areas which were handled especially well in the good practice.

Scope of the mHealth practice

Background info about the good practice

MyNHS Wallet (mySNS Carteira in portuguese) is a free of charge app that functions as platform to help patients to manage their health information. This app, developed by the Shared Services of the Ministry of Health, E. P. E. (SPMS), Portugal, provides all the health and administrative information of the patient on a modular way, like a wallet, where every bit of information is a card. Besides adding the cards, it allows for citizens to record their measurements and have access to a range of services. Currently, myNHS Wallet offers the following options:

- Vaccine card
- Treatment Guide
- ADSE Card
- Vital Testament
- Allergies
- Rare diseases
- New coronavirus
- Registration of measurements (steps, blood glucose and blood pressure)

Through the app, citizens can also contact their primary care centre, SNS24, and use RSE / Citizen Area, MyNHS, MyNHS Times, and Teleconsultation (through RSE Live) services.

The app is based on four principles: security, safety, portability and tailoring. On the security, several technical mechanisms provide a truly secure information exchange and storage. At the

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safety level, the digital identity of the patient is guaranteed. All citizens with a Digital Mobile Key can have access to the MyNHS Wallet, and to access all features, it is necessary to have a health user number, or otherwise the use is limited.

The app can be downloaded through a link on the NHS Portal, in the Health Apps area, or from the Play Store (Android system), or from the App Store (IOS system).

SPMS: The Shared Services of Ministry of Health, E. P. E. is a public enterprise created in 2010, functioning under the guardianship of the Portuguese Ministries of Health and Finance. Its aim is to provide shared services to organisations operating specifically in the area of health, in order to "centralise, optimise and rationalise" the procurement of goods and services within the NHS, in the area of Information and communication systems and technologies.

Summary of main interview ideas

Benchmarking to understand what is happening outside and within the country and then transpose it into our reality, considering our failures, our benefits so that it can meet our population needs.

Example: from the already existing Citizen Portal, statistics of usage of the main functionalities were used to design the mobile app, taking into consideration the differences between a computer-based and a mobile-based system.

Most used functionalities:

- Appointments, the most use functionality
- Request for chronic medication, since it is a process that does not necessarily requires for the patients to go to the consultation, because being a chronic disease, patients need their medication every 3 months.
- Vaccination records.
- Registration of symptoms, which depending on the citizen consent can be shared with healthcare professionals. For example, the citizen can be at home, on his / her computer or mobile and access and register their measurements, such as glycaemia, cholesterol, etc. Then he / she can choice to send this information to his / her doctor, or to just keep it in the portal just for their self-knowledge.
- Request exams and respective results.
- Consultation of prescription.

Barriers:

- Fragmentation of the information, due to the different systems in use, not completely centralized, with local systems still in place; differences on how data is structured.
- Use of digital services by citizens (partly, culture-related)
- Strong authentication method (partly, culture-related)

Enablers:

- International standards (SNOMED, HL7)
- Promote and disseminate the usage of digital services
- Well-structured digital system already in place (during the COVID-19 pandemic, they already had the tools to allow the interaction between patient and health professional at distance)
- Channel (direct or indirect) to get citizen feedback (e.g., SNS24, citizen cabinets/office in the healthcare units) (entry point in the system that allows to get a better understanding

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of the citizen's needs). Important to obtain this feedback and collaborate with those that work directly with the citizen.
- Channel (direct or indirect) to get healthcare professionals' input
- Strong authentication method (Digital Mobile Key allows to access different platforms while safeguarding the concerns about the safety of accessing personal data)

Interviewee role: Mariana Meira is currently managing the team that is responsible for the developing of mobile apps within SPMS, which includes mobile app focus on the citizen (e.g., myNHS Wallet) and also focus on professionals.

Topic: interoperability with existing systems

- *What approach was considered for the interoperability with existing system when planning this solution?*

MyNHS Wallet is available in both Play Store and App Store since January 2017. Prior to this, SPMS had already developed the Citizen Portal, which is available since 2014.

So, when the mobile app was created the first statements that were made, was to take into the consideration the usage of the citizen portal.

So, we made an analysis and a study based on the experience of the prior 3 years with Citizen Portal in order to understand what kind of functionalities and services our citizens were using the most, and with that in mind, we started to create a set of functionalities, but taking into account that not all of this that is possible in computer-based system is possible in a mobile. So, in addition to the statistics of usage by the citizens, we also took into consideration the fact the mobile phone will not have the same behaviour as the computer. This was the main analysis that we did and still do, in order to decide what is important to include in our app for users, and we always use the Portal as a reference since it is available for a longer period of time (based on statistics and usage).

- *Can you give us some example of what services citizens used the most?*
  - Appointments, the most use functionality
  - Request for chronic medication, since it is a process that does not necessarily requires for the patients to go to the consultation, because being a chronic disease, patients need their medication every 3 months.
  - Vaccination records.
  - Registration of symptoms, which depending on the citizen consent can be shared with healthcare professionals. For example, the citizen can be at home, on his / her computer

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or mobile and access and register their measurements, such as glycaemia, cholesterol, etc. Then he / she can choose to send this information to his / her doctor, or to just keep it in the portal just for their self-knowledge.
- Request exams and respective results.
- Consultation of prescriptions.

- *How long does it take to have one of these services implemented in the app?*

It is a trick question, considering the concept of integration, it always depends on the entity that develops the service, and then its availability to present it to citizens, so the time varies. While some are faster, others are more complicate and takes more time.

Additionally, Portugal has a lot of local systems that are spread over primary care units and hospitals entities. So, we have some sort of decentralized health systems in hospitals and primary care units, so sometimes it is difficult to aggregate in a consistent way data from our patients, because they are registered locally. So, it has also been a difficulty and a great challenge in order for us to be able to present information to the citizen in a structured way, because in some cases this data is being collected in irregular formats.

Barriers: Fragmentation off information, with different systems in use; differences on how data is structured.

- *How do you overcome this?*

In order to tackle this, we use International standards, such as SNOMED (in terms of semantics) and HL7 (in terms of technical aspect) in order to normalize and give consistency to the data.

Enablers: international harmonization standards.

- *Are there any more barriers found during the development and implementation of myNHS Wallet?*

In terms of organization there is always few barriers, but these have been easily surpassed.

One barrier is to convince some of our citizens to refer to digital services.

The recent COVID-19 pandemic in a certain way instructed patients to connect with the health systems, as well as finance, etc, in a more digital way.

However, in some aspect is still difficult to do it, because considering the culture aspect, Portuguese citizens like to go to their healthcare centre and talk to their doctors. Even though it is a barrier, we are doing a great work in order to promote and disseminate the usage of digital services, to pass the message that we are not ending the direct contact with their doctors - citizens

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are still going to their doctor - but see it as an alternative way of doing, they are encouraged to use the digital systems.

If we did not have had a well-structured digital system, it would had been even harder to deal with the current pandemic than it is in fact, because we already have tools that allows us to allow interaction between patient and health professional at distance. So, I believe in this point, we were well prepared.

- *What can still be improved concerning the interoperability aspect?*

It always a question of continuous learning, and sometimes this is difficult when we are dealing with the citizen. When we are dealing with healthcare professionals-focus apps, it is easier for us to talk with them or representatives (primary care, hospitals units) and to get their inputs, so it is easier to establish targets of the systems. When we are dealing the citizens-focus apps, we have 10 million possible users, so sometimes it is a bit difficult to establish the target and the focus of the mobile app, because we really need to envision what will be important for the biggest part of the population and that it is not always clear, because there are a lot of needs.

- *Following this last point, people engagement. How is this implemented / tackle in this project?*

To answer this, it is important to mention that SPMS has a another set of areas that focus on the citizen, so apart from the myNHS and citizen Portal, we also have the National Contact Centre (SNS24), telephone-line that is available for anyone that wants to call. They can ask for administrative services, such as to schedule an appointment, for example when they do not have internet, cannot access the Portal, etc. They can also call to request renovation of chronic disease-related medication, after ensuring the citizen identity.

This is a big entry point in the system that allows us to get a better understanding of the citizen's needs.

In the past few years, there has been a better entanglement among the teams that are developing information systems and the people that are actually dealing with (answering the phones) the citizens, in order for us to understand what are the main needs of the citizen. Because they will actually call asking if it is possible to this or that in the line and in the website, so with that we can more easily understand what the patient would like to do digitally and cannot do at the moment.

In addition, it is also articulated with Primary care units and Hospitals institutions. In many of these, they have citizens cabinets / offices where the patient can go to clarify questions, so we also contact these offices in order to better understand what are needs of the patient.

Enabler: there is an opportunity for citizen to go the institution to ask for their needs.

Topic 2: authentication and authorization mechanisms

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- *What were the key steps and timeline to approach the Authentication, authorization mechanisms?*

As I mentioned, myNHS Wallet mobile application was launched Jan 2017. At the time, the authentication was in an intermediate level of security. The citizen would enter his / her date of birth, beneficiary number for the health system and the mobile phone registered in the national system. If all these 3 parameters were correct, he / she would receive a code in the registered mobile phone to enter in the system – this was the authentication mechanism.

By the end of 2018, we implemented the digital mobile key as an alternative method, meaning authentication mechanism were kept.

Since Jan 2020, the first authentication mechanism was removed, and now the authentication process is exclusively done via digital mobile key.

The digital mobile key is strong authentication method developed by Administrative Modernization Agency, I.P, which is governmental entity in Portugal that is responsible for the modernization of the administration. This strong authentication mechanism made available to the citizens when they get their ID Card. The ID Card, which is digital, comes with codes that allows to access multiple governmental and other platforms. In addition to this, they have developed a Digital Mobile Key, which is a sort of alternative and highly secure authentication method to the citizen ID Card itself. The Digital Mobile key is used in several governmental and non-governmental platforms and it is recognized by the Portuguese state as a strong authentication.

- *Possible advantages and barriers to this authentication mechanism?*

In terms of advantages, it can be used in multiple platforms. When you start to use it, you do not have to memorize different codes and passwords for the different services, and you access different platforms with this authentication mechanism.

However, as a barrier, it is a process that is still a little difficult to implement when the population is still not completely used to digital services.

- *Is this authentication mechanism seen as a barrier or enabler for the use of myNHS Wallet?*

It is a working in progress, this is the question that we make ourselves every day. It always depends on the population that we are considering. For example, we already have many citizens who are concern with the security of their data, especially if it is health data, because there is always a fear that the data may be spread over persons or entities that they do not wish to happen. So, we already have many people that truly concerned about the security and privacy of their data. So, for this part of the population, this is a great authentication method, because it is a two-factor authentication, you have one code that only you know, that it is sent to you that moment. So, it is a strong authentication method.

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For people that are not so keen in these questions of technology, it can be a bit hard to leave the common user credentials, user / password method to have this more complex authentication mechanism. So, it is a question of measuring and we truly believe that the future is to grant security, even if this means that at first it will be a little more difficult for people to access our services, but in the mid-time that will be surpassed.

- *Do you have a way of measuring the number of users throughout the time of the app, meaning you mentioned the two types of authentication mechanism, do you have numbers of one solution compared to the other?*

Yes, the prior authentication method was more used because it was easier for citizens to use that method. However, we have started to see that we were receiving requests of people when we removed the prior authentication method. We saw an increase interest in knowing and understanding what is the Digital Mobile Key, so it is a question of evangelisation, I guess. In the first month, the utilization decreased because many people did not have the Digital Mobile Key, but now we are again coming back to our usual numbers of access. We also received feedback from some citizens offices / cabinets. When people start using the Digital Mobile Key, for example in myNHS wallet, because they do not have any alternative, when they go to other platforms (financial, social security, etc), they usually tell us that now they only use the Digital Mobile Key; before when I had options, I went for the option, but now that I have the Digital Mobile Key, I will never memorize 3 or 4 alternative passwords, I will always use this method.

- *Do you have any recommendation for an organization that is trying to implement a similar solution as the myNHS Wallet?*

First of all, benchmarking is always very important. As I mentioned in the beginning of this interview, we have done some benchmarking regarding our Citizen Portal, it is also important to referred that we had also done it for other mobile apps in Europe, in order to better understand the needs, the dynamic associated with this. So, benchmarking is always important to understand what is being done outside and inside, and then probably the most difficult part is to adapt the results from that benchmarking analysis to our own reality, because the same solution will not have the same impact / utilization in different cultures.

Understand what is happening outside and then to be able to transpose into our reality, considering our failures, our benefits in order to satisfy our population.

Summary

mHealth Practice:

Orcha and Our Dorset Digital

Source: info extracted and adapted from:
https://ourdorset.nhs.uk/wp-content/uploads/2018/07/Our_Dorset_STP.pdf
https://www.orchahealth.com/how-dorset-is-becoming-a-digitally-enabled-population/
https://www.orchahealth.com/

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Topics

ORCHA and Our Dorset Digital has a successful approach on the following topics:

- Planning > **Creating partnerships**
- Planning > **User centered design considerations**

Background info and scope of the mHealth practice

Our Dorset is a partnership of health and social care organisations working together to deliver Integrated Care Systems. Our Dorset holds the ambition for its 750,000 residents to lead healthier, fulfilling lives supported by sustainable health and care services. But the organisation faces real challenges. Dorset's population is ageing, bringing more long-term conditions, which places a growing demand on services.

To address its ambitions and challenges, the Integrated Care System has identified a clear plan, in which digital plays an enabling role. It established a **'digitally-enabled Dorset programme**' to increase the use of technology in the health and care system, to support new approaches to service delivery.

The programme first researched and established the building blocks needed to establish public facing digital health. Alongside videos and the NHS choices website, apps were identified as a key building block to enable patients to better manage their own health.

To understand more about if and how health professionals could recommend the use health apps and what would be needed to support them, a pilot was run with 20 nurses. This revealed the team didn't know where to find good health apps, how to know if they could trust them, if they met policy or who to ask for advice.

Without the expertise to establish a closed-loop quality assured programme, or capacity to be able to test health apps, let alone test them again when they are updated, the team recommended partnering with ORCHA, a digital health evaluation and distribution organisation. They selected ORCHA as they had seen how it had delivered testing at a national level and for other regional providers. With ORCHA, Our Dorset could build a programme to mitigate risk and assure clinical teams they are recommending safe apps.

ORCHA curates bespoke Digital Health Libraries and professional recommendation tools for regional and national health and care organisations and bodies. ORCHA provides services to the NHS in 50% of regions in the UK, curating App Libraries and professional recommendation tools across a broad range of settings. It runs national health app accreditation schemes to national bodies worldwide. Its unique review engine assesses apps against over 350 elements across Professional Assurance, Data Privacy, and Usability/Accessibility, plus additional criteria depending on needs.

Description of the mHealth practice

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ORCHA tested apps against 350 standards and measures and worked with Our Dorset to identify the best health apps across each priority health area. A dedicated app library was built to house the apps and enable patients and staff to search. It was also agreed that if an app doesn't appear in the library it will not be recommended by any member of staff. If an app is ever nominated that isn't in the library it will first be reviewed by ORCHA before being used by Our Dorset.

Our Dorset also opted to include a feature to enable staff to recommend apps via email or text message from the app library directly to residents and patients. This eliminated human error and enabled recommendations to be monitored.

Once ready, the team ran a series of 30 onboarding sessions across all ICS providers and governance leads, including all non-clinical teams, including link workers, health coaching and social prescribers. Over one or two sessions, teams were briefed on the value proposition of health apps, walked through the system and key apps were demonstrated. The health app programme also saw the emergence of a local Community of Practice which became a regular fixture on team meetings, prompting people to share learnings, tips and good practice including hearing about cohorts that are responding well to health apps.

Alongside training staff, the app library was launched to the public, forming part of its #HereForYou campaign which reassures Dorset residents that their health services are still available should they need them and that they should seek help and advice despite the Covid-19 pandemic. This included PR, social and paid digital activities.

- *Scalability of the mHealth practice*

As the programme uses ORCHA's digital solution, it is very scalable and so could be opened up at GP level, regional level, or national level.

The apps that appear in the Our Dorset Digital Health Library have all undergone stringent reviews by ORCHA.

Designed by a multidisciplinary team of subject matter experts and clinicians, the ORCHA Review delivers robust, rapid and reliable accreditation for Digital Health worldwide.

The ORCHA Review is dynamic and responds to the focus area and functionality of an app to assess only the relevant compliance issues. ORCHA's platform also enables its Review Team to carry out a "re-review" of an app after every update, ensuring that the Library's information is kept up-to-date and is scalable.

The app reviews are housed on a platform that can be intelligently searched to find apps against a range of criteria. The platform enables bespoke app libraries to be quick and easily built, making the solution scalable across regions and nationally. ORCHA also offers a range of products that can be added to a library, helping professionals to recommend and distribute apps safely to patients, and providing usage insights and measurement.

Main outcomes and testimonials

Since introduction, the teams have actively embedded the app library and the practice of recommending health apps into their service offer. The teams drive home the concept of self-management and pick out effective tools that are available.

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There have been almost 25,000 pages viewed on the site (up to the end of November 2020), and in one month alone, the app library achieved nearly 5,500 page views. Social prescribers are actively recommending apps to service users and vitally, this advice is being acted upon, with almost 1,500 apps recommended to date and 56% of recommended apps downloaded. The most popular search terms include Mental Health MSK, Dementia, Diabetes and Cancer.

Commenting on the programme Crystal Dennis, Interim Lead for Public Facing Digital Health Services, Our Dorset Digital said:

> "ORCHA power our health app library. They help us to break down the barriers and mitigate issues around digital health. Previously our clinical leads didn't recommend digital health technologies as they had no idea where to look, were concerned about implied liability and couldn't tell if a technology was of a good standard. Thanks to ORCHA we are building the trust with clinical teams and have put in place the tools and governance they need".

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- https://www.orchahealth.com/how-dorset-is-becoming-a-digitally-enabled-population/
- https://www.orchahealth.com/

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Summary

mHealth Practice:

Orcha and Staffordshire County Council

Info extracted and adapted from:

https://www.orchahealth.com/staffordshire-public-health-changes-lives-with-digital-health/

https://www.orchahealth.com/

https://www.staffordshire.gov.uk/Care-for-all-ages/Search-for-health-and-wellbeing-apps.aspx

Topics

ORCHA and Staffordshire County Council has a successful approach on the following topics:

- Planning > **Creating partnerships**
- Planning > **User centered design considerations**

Background info and scope of the mHealth practice

Staffordshire County Council is the top-tier local authority for the non-metropolitan county of Staffordshire, England.

Part of the Council's work includes offering advice, support and care for health and wellbeing, to keep residents well and staying healthy. This includes advice on: NHS health checks, mental health and wellbeing, getting active, physical activity for older people, eating and drinking, weight management, drinking less alcohol, stopping smoking, preparing for old age, diabetes, drugs, and preparing for and coping with winter.

For a number of years, the Council has explored using digital technologies to improve support for residents, and so in-line with this thinking, the Public Health team looked at how technology could be best used to reach and engage with people to change behaviours and extend the services offered.

Home to 870,000 people, life expectancy across Staffordshire has risen year on year, but its ageing population still face an average 17.5 years of poor health. To further extend lives, but crucially increase the number of healthy years, Staffordshire County Council runs a range of public health support services.

With around 40% of ill health preventable, and obesity, smoking and diabetes the major factors, the Council's support services aim to help people make better lifestyle choices. This includes one-to-one support sessions; providing advice, medication and information to help people make long term behaviour changes.

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Although effective, the team identified that face to face appointments don't work for everyone, and even during COVID-19, when appointments were moved online, the format still stops many people from engaging. Some people can't make the time of day, others, prior to COVID-19, couldn't get to the clinic, and a significant number don't want to face a person with their lifestyle choices.

On the other hand, ORCHA curates bespoke Digital Health Libraries and professional recommendation tools for regional and national health and care organisations and bodies. ORCHA provides services to the NHS in 50% of regions in the UK, curating App Libraries and professional recommendation tools across a broad range of settings. It runs national health app accreditation schemes to national bodies worldwide. Its unique review engine assesses apps against over 350 elements across Professional Assurance, Data Privacy, and Usability/Accessibility, plus additional criteria depending on needs.

Description of the mHealth practice

The team conducted research, looking at the market and what services are available on G-Cloud. They'd been aware of ORCHA, a digital health evaluation and distribution organisation, and saw that it was the only organisation who could effectively enable the Council to connect people with reviewed and trusted health and care apps, and so the team engaged ORCHA to work with them to integrate these into its lifestyle services.

ORCHA's implementation team worked with the Public Health team to identify the most important health challenges its residents face, then identified and mapped the most effective apps to each of these. ORCHA ensured that each app had been robustly reviewed against 350 measures and, where appropriate, additional COVID-19 criteria.

An App Library was then built tailored to the Council's branding and health priorities. A carousel of pre-prepared searches for each of the priority health areas was included. This was embedded via an iframe within the Council's website, so that it could be easily found: https://www.staffordshire.gov.uk/appfinder ORCHA Pro Accounts were also added to the library, which would enable staff to logon to their own account, keep a favourites list of their preferred apps, recommend apps via email or text to residents, and keep a track of who has been recommended an app and if they have downloaded it.

After two months of development, the programme was ready, a training programme was rolled out across Adult Social Care teams, social prescribing teams, the local NHS Trusts, and the information services within libraries. This enabled teams to start recommending apps to service users.

Engaged with the programme, teams made favourite app lists and when they spotted a new app that wasn't on the library, they asked ORCHA to review it, to make sure it was safe. If it made the grade it was added to the library, but if it didn't (as 85% apps don't), the team knew to warn service users about it.

To make residents aware of the programme, the team created a three-month paid-for social media campaign. It focused on the positive difference apps can make, encouraging people to visit the library and choose an app. The campaign targeted certain groups of people, by geography, demographic and interests. Initially, the focus was placed on those over 50 years old, tailoring the images and messages to maximise engagement.

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- *Scalability of the mHealth practice*

As the programme uses ORCHA's digital solution, it is very scalable and so could be opened up at GP level, regional level, or national level.

The apps that appear in the Staffordshire County Council Digital Health Library have all undergone stringent reviews by ORCHA.

Designed by a multidisciplinary team of subject matter experts and clinicians, the ORCHA Review delivers robust, rapid and reliable accreditation for Digital Health worldwide.

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The app reviews are housed on a platform that can be intelligently searched to find apps against a range of criteria. The platform enables bespoke app libraries to be quick and easily built, making the solution scalable across regions and nationally. ORCHA also offers a range of products that can be added to a library, helping professionals to recommend and distribute apps safely to patients, and providing usage insights and measurement.

Main outcomes and testimonials

The programme has been successful, with good engagement levels by the public through the social media campaign, and strong levels of recommendations by service teams.

Feedback from staff has been extremely positive. They have been comfortable with the library, finding it very easy to use and have been reassured by the review process behind every app selected to be featured. It has made them more comfortable recommending an app to supplement their care delivery.

In its first five months of launching, the library has seen around 4,000 sessions, with approximately 10,000 pages viewed. People have searched for help with everything from Fitness and Nutrition, to Mental Health, Dementia and Diabetes and already downloaded hundreds of apps.

Steve Tranter, Stop Smoking Practitioner, Everyone Health, describes his experience:

> "Its design and ease of use is one of ORCHA's particular highlights. Each specific app is categorised and can be accessed just by using the scroll bar. In addition, you can also just type into the keywords box your specific search and then it gives you a breakdown of all the apps available to assist. There is a huge selection of apps available once have performed your search, it is then just a case of scrolling the huge quantity on offer and using the filters (budget, platform, etc) to help you find the App which you feel will assist the client with the particular issue they need help and support with.
>
> "To recommend or send an app it is just a case of typing in the client's email or mobile number and then clicking to send the recommendation. This will then be sent directly to

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> the client's phone via text or email for them to download. The app that has been sent can then provide them with some additional support right at their fingertips".

The Public Health team see the library as an effective tool it can use to tackle challenges including obesity and smoking. But they don't see the library as a product that after they've purchased the work is done. To keep achieving results, they believe they need to keep it alive. With this view, they continue to educate the workforce on health and care apps to maintain enthusiasm and education. They have also identified champions within each service delivery team, who will continue to find apps for testing and support other members.

Communications have been central to the success of the programme. Following the dedicated social media campaign, the team have embedded the apps library into their wider heath campaigns. Apps have been at the heart of its recent STOPtober campaign, for example, offering a practical, measurable, call to action.

Commenting on the programme, Lucy Gratton, Commissioning Officer, Public Health and Prevention, Health and Care Directorate, Staffordshire Council, summarises:

> "Apps offer a real, practical solution that people can engage with to make a difference to their health. Carried with them all day, they can offer regular motivation and feedback that other formats of intervention can't. They also appeal to people who, for whatever reason, do not want to engage with traditional services.
>
> But lots of apps aren't safe and so it was essential for us to connect our residents with apps we know are assured and will make a difference to their life changes. The ORCHA reviewing and library have been essential for us to achieve and deliver this".
>
> "The programme has been a success. We see the number of recommendations and downloads growing and know that for many, it is helping to change their lives and become healthier."

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Initiative summary

PEM Mobile

Mobile Medical Electronic Prescription

PEM Mobile has a successful approach to the following topics:

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- Execution
  - **Authentication – authorization mechanisms**
  - **Integration with EHR**

Scope of the mHealth practice

The Mobile Medical Electronic Prescription (PEM Mobile) is a mobile application developed by the Shared Services of the Ministry of Health (SPMS) used by physicians for drug prescription. It was developed within the national strategy to fully dematerialized prescriptions, under the Decree Order nº 284-A / 2016[46], Article nº 8A.

The PEM Mobile allows to execute prescription validation and registration in an online mode, ensuring the issue of prescription in a paperless format.

The app is free of charge and is available for IOS and Android systems, by downloading in the respective online store.

In Portugal, the electronic prescription (eP) is the principal method used for prescribing, with few exceptions for manual prescription (e.g, in event of computer system failure, unavailability of the prescription through mobile devices, or in situations where the citizen is unable to receive a dematerialized prescription or to materialize it)[47].

Topic: Authentication / authorization mechanisms

To use the PEM Mobile, physicians / dentists need to have an active Digital Mobile Key and digital signature by Digital Mobile key. In addition, they need to request a registration in the application. The physician / dentist is a legally authorized healthcare provider registered in the respective Portuguese Professional Order.

The Digital Mobile Key is a service provided by the Agency for Administrative Modernization (AMA), and it is considered a high-level secure two-factor method for authentication. Physicians can authenticate themselves in the PEM mobile, by

- Mobile number
- Digital Mobile Key PIN (personal identification number) code
- Single, temporary 6-digit numeric security code sent by SPMS to the mobile phone number or by email.

[46] Decree Order nº 284-A / 2016 published in Diário da República nº 212/2016, 1st Supplement, Series I of 2016-11-04).

[47] Decree Order nº 390/2019 published in Diário da República nº 208/2019, Series I of 2019-10-29.

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After downloading the application, the first step is the activation of PEM Mobile. This activation aims to associate the mobile device with the prescribing physician, for the purposes of digital identification (eID).

To perform this parameterization, the Digital Mobile Key (CMD) must be used, and the user must confirm the Tax Identification Number (TIN) plus Mobile Number associated with the CMD. Later, the physician will be asked for the CMD PIN. If the three data are correct, an text message is automatically sent to the mobile phone number provided (and validated at the CMD) with a code (TOTP) that must be entered in the PEM Mobile for activation. If the data entered is not correct, the application returns a message to the user informing him / her that he /she must verify the data or proceed with registration by CMD, if he / she has not already done so.

The conclusion of the PEM Mobile activation is done with the user choosing a PIN number that is later encrypted. To avoid the CMD authentication process whenever the prescriber accesses the PEM Mobile prescription application, the prescriber defines a personal PIN that is saved in the last validation phase. The PIN entered by the prescriber is associated with a CMD Token code which is renewed every 15 days.

To improve the usability of the PEM Mobile, the PIN can be associated with the fingerprint reading mechanism, if available on the device.

The patient can receive the electronic prescription (eP) in three different forms:

Topic: integration with EHR

The PEM app can be invoked from a certified and secure patients electronic health record software (Electronic Health Record – Professional Area, RSE-AP). When invoked by the local software, patient data (name, date of birth and national health number) is sent to the system and is verified to allow for a prescription through PEM service.

When authenticated to the prescription module, it is possible to obtain some patient health records information related to medication prescription (e.g., patient allergies, previously prescribed medication and chronic medication). During the medication selection, PEM checks for allergies to to the active substance and sets warnings in case of such allergy is detected. This information is validated through the Electronic Health record (HER).

There is a central national registry for

- National Patient Registry (for patient identification, and benefits)
- National physicians / dentists registry (for prescriber identification and authorization, integrated with national professional boards)
- Patient Summary (for allergies and adverse reactions, chronical medication, diseases)
- Patient Portal (to verify consent)
- National Drug Information Database (for drug information, including prices)

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In this central system, there is a layer of services for e-Prescription and e-Dispensation.[48]

After the prescription is recorded on the central database, the patient receives an e-Prescription code, which in addition to his / her citizen ID card or treatment guide allows for the patient to go to a pharmacy to retrieve his / her medication. The pharmacy systems interact with the central system, as well. Through the central record, physician can have access to the prescription information prescribed on both National Health System (NHS) and non-NHS institutions.

At the end, there is also an invoicing process related to the reimbursement, for the National Health System (reimbursement office), which in turn also interacts with the national central system to compare the information of pharmacy with the recorded information of e-prescription.

The patient can receive the information regarding the eP through, text message, email (with treatment guide) or paper (treatment guide). In addition, the citizen can check the information regarding the medication in the citizen portal (Área do Cidadão) or in the app mySNS Carteira (MyNHS Wallet).

References

https://pem.spms.min-saude.pt/sobre/ (English version)

https://www.sciencedirect.com/science/article/pii/S22120173130030l0 (Article)

Interview summary

Interviewee: Maddalena Illario, Federico II University, Italy

mHealth Practice:

Proempower

Interviewers: Vincenzo De Luca
Date of interview: 2020-12-10

Topics

ProEmpower has a successful approach to the following topics:

- Initiation > **Needs assessment**
- Execution > **Solution testing and validation**

Summary

[48] Please see figure 1 in article Procedia technology, 2013, 9, 1313.

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- PROEMPOWER is a Pre Commercial Procurement co-financed by Horizon 2020 programme, aimed to procure a disease self-management mHealth solution to help meet the imminent threat of type 2 diabetes mellitus;
- 4 Procurers: Ministry of Health of Turkey; Servicio Murciano de Salud, Murcia; Servico Partilhados do Ministerio de Saude; Federico II University Hospital / Società Regionale per la Sanità SpA, Campania Region;
- Procurement Budget: € 3.000.000;
- Co-designed method to define the functional and non-functional requirements of the mHealth solutions;
- Development and testing of pilot systems in 4 pilot sites.
- Early identification of diabetes
- Shared Care Plan
- Personalized treatment and remote monitoring
- Coaching and promoting healthier lifestyles
- Co-operative diabetes support (peer-to-peer support)
- Training to diabetic patients
- No technology-driven, but clearly meet specific needs of patients and health professionals in effective healthcare service delivery.

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Scope of mHealth Practice

Background info about the good practice

ProEmpower is an European funded project under Horizon 2020 programme, with the aim of purchasing R&D services, through a Pre Commercial Procurement procedure, in order to develop innovative IT solutions for early diagnosis and management of diabetes, facilitating the lives of people with type 2 diabetes, supporting them in their daily lifestyle choices and giving healthcare professionals access to the clinical data needed for the management of the disease and its complications. The project involves four public procurers across Europe – Turkey, Portugal, Campania and Murcia.

Summary of main interview ideas

The interview covers two main phases of the procedure:

- The method used to define the functional and non-functional requirements of the solutions for patient empowerment and self-management of diabetes;
- The results of the Research and Development activities and the pilot implementation in the 4 pilot sites.

Scope and timeline of the mHealth good practice implementation

- How long did it take for the mHealth practice to be implemented?

ProEmpower is a competitive 40 months R&D process comprising two preparatory steps and three 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;
- 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.

- What are the key steps that were undertaken?

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

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developed in ProEmpower. Each use case is described in full detail with one corresponding process model.

Use Case development includes the following activities:

- Identify all the different **users** of the system;
- Create a user profile for **each category** of user;
- Identify all the significant **goals** the users have that the system will support;
- Create a **use case** for each goal;
- Maintain the same level of abstraction throughout the use case.

An international call for tenders, articulated in phases, selected vendors to implement R&D services for the development of IT solutions addressing Diabetes Type 2.

During phase I, the contractors worked on improving the solution design of the offers made during the call for tenders. The vendors developed in detail the solution design and determined the innovative solutions to be implemented during the subsequent phases. They provided details regarding the technical, financial and commercial feasibility of the proposed concepts and explained the approach to be used to meet the procurement requirements.

During phase II, the suppliers produced two versions of prototypes of their systems. The prototype demonstration was conducted as face-to-face meetings be-tween the supplier and each procurer, at the procurers' premises. The procurers invited healthcare professionals and patient representatives in order to receive feedback to be used in the evaluation process. The feedback was in form of answers to a questionnaire (one for patients and one for the healthcare professionals). The results were considered when evaluating the suppliers based on the award criteria (e.g. value of benefits for patients).

During phase III two solutions have been tested by end-users (patients and health professionals) enrolled by healthcare organisations of the four procurers. The aim of **the pilot study** was to test the **feasibility, effectiveness and usability** of incorporating the two solutions into the **current care pathway** for patients with type 2 diabetes. Study objectives were to evaluate **direct and indirect outcomes** linked to the use of the novel solutions, including:

a) **behavioural changes**:
   i. smoking habits;
   ii. physical activity;
   iii. steps;
   iv. meals;
   v. medication adherence;
b) **clinical and quality of life (QoL) outcomes**:
   i. HbA1c;
   ii. weight;
   iii. blood pressure (BP);
   iv. blood lipids;
   v. cholesterol;
   vi. quality of life;

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c) **satisfaction, self-management and usability**.

- What are the strengths and weaknesses of the implementation process?

In terms of requirements elicitation, **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. Users are understood as diabetic patients, healthcare professionals treating them, and **informal carers** who help patients with their daily diabetes management.

- Is there a workplan that can be included as a reference? Is there further documentation about the approach?

The approach has been presented in the International Conference **ICT4AWE 2019** and published on a Scientific Journal:

- De Luca V. et al. (2020) Developing a Digital Environment for the Management of Chronic Conditions: The ProEmpower Experience of a Horizon 2020 PCP for Type 2 Diabetes. In: Ziefle M., Maciaszek L. (eds) Information and Communication Technologies for Ageing Well and e-Health. ICT4AWE 2019. Communications in Computer and Information Science, vol 1219. Springer, Cham. https://doi.org/10.1007/978-3-030-52677-1_1

- De Luca V, et al. (2019) European Specifications for Value-based Pre-Commercial Procurement of Innovative ICT for Empowerment and Self-management of Diabetes Mellitus Patients. Proceedings of the 5th International Conference on Information and Communication Technologies for Ageing Well and e-Health (ICT4AWE 2019), pages 19-27. doi: 10.5220/0007638700190027

- What are the strengths and weaknesses of the solution?

The aim of the project has been the development of ICT solutions to support healthcare professionals and patients, in the early identification of diabetes, the personalization of treatment and remote monitoring, according to the stage of the disease, the blood pressure and blood glucose control and weight management, promoting healthier lifestyles, training, peer-to-peer support.
The strengths are in the integration of multiple solutions in "one stop shop" for users. Interoperability features might be still strengthened, especially towards GPs.

Stakeholder involvement

- What stakeholders needed to be involved for the good practice to work?

Patients, informal caregivers and Health Professionals (General Practitioners, Diabetologists, Nurses)

- What are the stakeholders' roles and activities/effort?

Proempower is developed according to the **international guidelines for diabetes management**. The solution allows patients to **self-monitor**, periodically updating clinical data and monitoring data related to physical activity and nutrition. Healthcare professionals can remotely monitor the patient's progress towards treatment goals by accessing a set of data, including life-styles, and tailor/adjust interventions.

- How was involvement and buy-in of the stakeholders secured?

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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.

Barriers

Administrative implementation was at first a bottleneck, as it was the first PPI and it was difficult to share with decision makers its added value for the organization and the regional health system at large.

Still the economic resources available to the expert teams supporting the implementation should be improved.

Success factors

Early involvement of clinical experts is a key element to ensure that the solution addresses real issues in service provision. It also facilitates patients involvement. Scientific societies can be a powerful accelerator for identification of key-processes and future scale-up.

Lessons learnt

We learned that PCPs are more sustainable to implement if their goals are aligned with organization priorities and activities, in the framework of a strategy for digital transformation of health and care.

Outcomes

- What were the main outcomes of implementing the mHealth solution?

Two solutions have been selected for phase III and tested with patients in real healthcare settings: **DM4ALL and DiaWatch**.

DM4ALL digital 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 and continuous monitoring. DM4ALL is developed based on the **Shared Care Plan** (SCP), a "document" including information about lifestyles, treatment plan, and disease-related markers. Furthermore, it collects information and feedback from the patients through validated questionnaires aiming at increasing impact and personalization.

DiaWatch is a mHealth and telemedicine solution to provide a more effective and personalised T2DM management. DiaWatch presents a sensing system platform, that operates using a smartphone optionally integrated with other devices such as a wristband, a glucose monitoring sensor, a blood pressure meter and a scale. The DiaWatch's **Virtual Coach** based on an artificial intelligent system to profile the patient and make appropriate recommendations for diabetes treatment, exercises and healthy lifestyles. A patient personal profile and related data-entry functions are embedded in a SCP progressively updated with new data from different sources. The desktop and mobile interface for clinicians allows professionals to monitor compliance to

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treatment and goals, to communicate with patients (via textual messages, audio and video features) directly from the healthcare facility, and to identify people at risk of developing diabetes or acute conditions. DiaWatch presents a **social community tool** for interaction, communication and peer training. A cloud-based platform ensures data exploitation for risk prediction.

- What is the status? (pilot, tested, fully operational)

The ProEmpower project consortium launched a call for tenders, articulated in 3 phases to select solutions. During Phase I, the technical, economic and organizational feasibility of five alternative solutions has been assessed. Phase II aimed to verify the main characteristics of three prototypes. During phase III **two solutions have been tested by 200 end-users each** (patients and health professionals) enrolled by healthcare organisations of the four procurers.

Continuous learning and outlook

- What would you have done differently? What can still be improved?

I would have strengthened engagement with local network of specialists, and connect with patient association. Still unsolved an adequate engagement of policy makers and decision makers, pivotal to speed the scale-up.

- What are the future plans for exploiting the mHealth solution?

During the COVID-19 pandemic, Federico II University Hospital, in order to safely guarantee urgent health services, has activated **telemedicine procedures** and related administrative and clinical-assistance procedures. These procedures required the use of dedicated IT tools, including ProEmpower. The activation of these paths was already started on 30 March 2020, following Campania Region emergency directive aimed at protecting the health of citizens with diabetes.

Therefore, for the purpose of procuring one of the ProEmpower solutions, in addition to **evaluations of an economic nature regarding the reimbursement of the service**, it is necessary to **implement a further clinical trial to verify the effectiveness and safety of the ProEmpower solutions**, in order to make them available to public health organisations. **Federico II University and Hospital expressed their interest** in further development of the clinical testing of solutions both to improve patient monitoring and management, and to pursue its research objectives. Federico II University Hospital would like to test the solutions in more detail, **engaging in dialogue with suppliers through a PPI project** aimed at procuring a more mature version of the solution.

Watch the **video** about this initiative here (access to playlist)

To find out more about ProEmpower, please watch this video from our 6th Hub Talk on patient centric approaches in mHealth (from 06:30 to 18:50)

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Interview summary

Interviewee: Markus Spegel (CPO ImagineCare AB, Sweden)
mHealth Practice:

Remote monitoring and self-care for people suffering from chronic illness

Interviewers: Ioannis Amarantidis, Li Zakrisson (Region Jämtland Härjedalen)
Date of interview: 2020-11-18

Topics

This initiative (Remote monitoring and self-care for people suffering from chronic illness) has a successful approach specially to the following topics:

- Initiation
  - **Stakeholder/ecosystem analysis**
- Planning
  - **Cultural change – digital skills**
- Execution
  - **Authentication - Authorization**

Summary - Scope of mHealth Practice

The solution aims to identify deviations in people's health conditions to make sure that they do not end up with acute events at the emergency rooms and subsequent hospital visits. The solution promotes preventive care, wellness, and healthy habits.

The platform offers different clinical pathways, mostly for people with chronic conditions. The solution consists of two applications.

- The patient app gives the patients a simple and effective support so they can take control of their health conditions at home.
- The healthcare professional web app helps healthcare professionals to standardize and facilitate self-care and communication with their patients dealing with long-term health challenges. The care staff is automatically notified in cases where reported health values indicate that self-care does not work, and it can provide personalised self-care support to the patient via chat, telephone, or video. Nurses can together with the automated system guide patients to handle their challenges.

The solution provides the following care pathways:

- heart failure, hypertension, diabetes, COPD, mental health, respiratory infections, as well as Covid-19.

For each care pathway, a set-up of devices is required, and these are delivered at the patients' homes. The system analyses the deviations and assists the nurses as to where and when to take action. At some point, the system coaches the patient to live and act healthier.

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Currently, state of the solution is implemented in 6-8 healthcare centres with around 500 patients participating totally.

The future plan is to scale-up the solution to cover all healthcare centres in Region Jämtland Härjedalen and target 4.000 patients.

Scope and timeline of the mHealth good practice implementation

How long did it take for the mHealth practice to be implemented?

The first implementation of the solution on national level took place in Region Jämtland Härjedalen January 2018. After more than 2 years of piloting and evaluating, a broader scaling-up followed. This takes time since it is a rather big change to define, understand and execute all these new models.

What are the key steps that were undertaken?

It looks like other similar implementation processes regarding stages.

Key 1: Planning the implementation takes a lot of time and effort because it includes planning from the technical perspective but also a need for the organisation to understand the benefits and a need to organise a dedicated organisation for the change.

Key 2: Define the scope. Working on preventive care could be broad. Start with a small part eg. chronic costly condition. What do you want to pilot?

Key 3: Define the ways of working.

Key 4: Define the KPIs and how you evaluate them.

Key 5: The implementation stage.

Key 6: Go live and pilot. Start with a number of patients and one care pathway. Hypertension or heart failure. Identify suitable patients, those that are able to and want to participate.

Key 7: Communicate with patients that they will be involved in a different way than previous healthcare experiences. Involve patients and deliver the equipment for self-monitoring to their homes.

Key 8: Continue to evaluate and pilot the solution until the healthcare provider (in this case the Region) feels secure enough.

Key 9: After evaluation, improve before scaling-up.

What are the strengths and weaknesses of the implementation process?

It is like many regular implementation processes even though some parts take more time since there is an uncertainty around what you need to take into account.
Strength: easy to setup the system and start the pilot

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Weakness/challenge: legal and regulatory uncertainty, technical and organisational too. It is not easy to enter into existing ways of working as there is a resistance when implementing new ways of working.

Is there a workplan that can be included as a reference?
Is there further documentation about the approach?

It is a constant learning process. It is difficult for some regions to procure such innovative solutions. Continuous improvement is needed. The interviewee has been asked to provide a workplan.

What are the strengths and weaknesses of the solution?

The solution works and we see really good outcomes such as clinical outcomes and a potential cost reduction. Also, the patients' experiences are good. We could quantify the researched data. It is beneficial to involve more patients and have generated data. Also, it is beneficial when working closely together with the healthcare providers to develop the solution together. We are trying to put the pieces of the puzzle together.
It is hard to find balance between existing and new ways of working. The new system needs to fit into the existing one. It is not clear where in the ecosystem the intervention fits in. Furthermore, it is not clear where the generated data will end up. How systems work together. Existing EHR systems and silo solutions – together with apps for patients, these are hard to navigate.

Stakeholder involvement

What stakeholders needed to be involved for the good practice to work?

In general, competencies need to be involved early in the process. Clinical competence from all parts of healthcare, in order to get the big picture. Healthcare is fragmented. Integrated care is a key as there are demands from primary, secondary, and social care to work closely together with some groups of patients. IT competence, legal and regulatory, as well as procurement. How to procure something that is kind of abstract? The key is to have a dialogue-based procurement where healthcare providers try to identify all requirements from the beginning. Finally, patients' involvement is crucial to identify their needs and challenges, but also to be aware of their responsibilities and possibilities.

What are the stakeholders' roles and activities/effort?

The core team or project team consists of members from both sides (company and healthcare provider). A team of around 5-10 members could be involved early in the process It is recommended not to involve more personnel resources from the beginning.

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How was involvement and buy-in of the stakeholders secured?

Remote monitoring of patients is high on the agenda in all regions and all parts of healthcare, therefore, general involvement and buy-in from stakeholders close to the project is not usually a problem. Challenges are more around getting mandates, dedicated resources and internal alignment.

Barriers

Were there any obstacles you experienced? How were they overcome?

Challenge 1: Takes time to do a major change in the ways that the healthcare systems operate.

Challenge 2: Procurement. Hard, different interpretations of how a home-monitoring system should work, what to do and what outcomes to measure. There are lots of overlapping solutions and thus not easy to decide how systems could work together.

Challenge 3: Covid-19 situation with difficulties to find human resources and the financial pressure the situation creates.

Challenge 4: Invest time and money and resources before getting to a point where you can see the value measured as outcomes and organisational impact.

Challenge 5: Legal frameworks.

Challenge 6: Silo organisations. Who is responsible for preventive care? Still unclear. Silo thinking with silo budgets.

Challenge 7: Cloud solutions. You don't want to take the risk. It is still unclear where to store the sensitive data in a secured way. The belief that we are safe if sensitive data is stored locally is not necessarily true.

Challenge 8: Slow adoption. If implemented on top of everything else, it requires someone to give the mandate and do so with guts.

Challenge 9: Short-term financial drivers make you miss the long-term benefits, (social for example).

Challenge 10: Lack of support on national and European level for home-monitoring solutions.

Challenge 11: Knowledge exchange between companies.

Challenge 12: Legal and regulatory uncertainty.

Challenge 13: Resistance when you try to do an intervention in the existing healthcare system.

Challenge 14: Can't implement a system directly without balancing needs of both existing and new ways, of working.

Success factors

- Open collaborative atmosphere mindset is needed. You don´t just buy a service and then start using it.

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- Continuous learning.
- Courageous mindset and bold decisions are needed.
- Management and leadership.
- Internal alignment. Communicate the values to all stakeholders. You need a story to tell before scaling-up.
- Ambassadors within the healthcare organisation to spread the values from different perspectives.
- Understand the gaps in care pathways and try to offer an integrated care.
- This way of innovation brings together regions, municipalities and companies to work together.
- For a rather small company like ImagineCare AB, we can adopt rather quickly our product as we have more flexibility

Lessons learnt

- It is not "the case" that you implement a new digital platform, it is rather to be able to clarify the purpose, the values, and how to organise around these.
- Need courage to test, evaluate and learn.
- Dedicated resources are a prerequisite.

Outcomes

What were the main outcomes of implementing the mHealth solution?

Clinical outcomes: None of the heart failure patients have ended up at the hospital so far (good figure). Can we keep them away from acute incidents? Also, a good result from working preventively the ambulance transportations decrease as well as unnecessary acute care. For hypertension patients, blood pressure is lowered over time by a combination of working in another way by which patients feel more safe, secure, and free of anxiety. Patients feel that they have better access to the healthcare system. Better quality of life for patients.

Healthcare professionals' experiences: It is a more patient-centred approach, and you can as a consequence focus more on patients with greater needs. There is a shift in responsibilities leading to patients managing themselves more and at home. More time is then available to patients in need of the healthcare centre. Feedback from professionals indicates that you can handle more patients daily. Previous level of visits of patients to healthcare centres 5-10, and now using the home-monitoring solution around 50 patients. Nurses can act on time, proactively instead of reactively.

What is the status?

The current state is that the solution is being implemented broadly in the region, both within primary care and specialty care (about 6-8 healthcare units with around 500 patients).

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Continuous learning and outlook

What would you have done differently? What can still be improved?

- Lot of things could be improved in all areas, clinical, technical, and organisational. It is really interesting to work with health and wellbeing as well as to act proactively rather than reactively. Try to stay on top of the technology evolution.
- Take into account the interoperability and use of standards in order to interact with other systems and ecosystems. Region Jämtland Härjedalen is at the forefront when we talk about inviting start-ups, SMEs and industry to pilot and test their products with a potential to scale-up.
- Also, we lowered our expectation on time to market strategy.
- Mistakes are useful to learn from where you need to go.
- Open mindset and close collaboration are crucial.

What are the future plans for exploiting the mHealth solution?

The future plan is to scale-up the solution soon to cover all healthcare centres (around 35 centres) in Region Jämtland Härjedalen and target 4.000 participating patients.
From a product perspective moving more towards preventive care and integrating the service with more devices and health ecosystems.

Quote

"*For us, as a small start-up company in a fast-moving market, being part of a network like the mHealth Hub is crucial to better understand the market and emerging ecosystems, to better position our product for the future of remote monitoring of patients. It also gives us an opportunity to share our learnings with other stakeholders and our services on other European markets*".

Interview summary

Interviewees: Matteo Minestrini, Pasquale Matrone, Blerona Nanushi, Francesca Papa, Graziano Lepri (Umbria Region)

mHealth Practice:

Reports online

Interviewers: ProMIS Staff

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

Date of interview: 2020-11-30

Topics

Reports online, from Umbria Region, has a successful approach on the following topics:

- Planning
  - **User centered design considerations**
- Execution
  - **Interoperability models**
  - **Data security – legal framework**

Summary

- 3 months to implement the system (from July 2015 to October 2015).
- All the professionals have been involved (hospital medical doctors, general practitioners, radiology technologists, front-office staff).
- No one technological, organizational or political issue.
- The only barrier was the analogical culture in patients and healthcare professionals.
- Continuous training for professionals.
- To extend the scope of good practice.

The main **outcomes** of implementing the mHealth solution are:

- To meet the needs of the final users and to improve NHS budget.
- To allow the patients to access their imaging and reports wherever and whenever.
- Improvement of the quality of life.
- To make better the quality of the relationship between patients and healthcare providers.
- During the Sars-Cov-19 pandemic even the patients who underwent a molecular swab can withdraw the report online.

Scope of the mHealth practice

ASL Umbria, the Umbrian local healthcare, started to use RIS-PACS systems in 2000, together with reports digital signature systems and substitutive legal storage systems. So, when in 2013 the DPCM 8/8/2013 was passed, ASL Umbria was ready to meet all the requirements. It took about 3 months to implement the system, from July 2015 to October 2015. First, a feasibility study was done, the step was evaluating the number of reports which were produced yearly, to understand if the system architecture was powerful enough to handle the workload. After the first 2 months a server which generates the codes for the online consultation was installed, and, after a day of testing which proved the system stable, the server was already up and running in October. All the professionals, who would have used the new system to access patients imaging and reports, have been involved: hospital medical doctors, general practitioners, radiology technologists, front-office personnel.

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ASL Umbria 1 was already ready, so we didn't encounter any technological, organisational, or political issue. The barrier we had to overcome was only the analogical culture, which was well rooted both in patients and healthcare professionals.

The **obstacle** was overcome, concerning the professionals, with a continuous process of education and their involvement in all the procedures, and, concerning the final users, thanks to doble modality. At the beginning we gave the patients the possibility to get their imaging and reports either through an analogical support, a Compact Disk, or Online. In order to boost the engagement to the online system we used a call center, in which mostly Technologists worked, to help the users overcome any difficulty and teach them how to be independent in using the new system.

The use of information systems in healthcare, when well organized and with the right resources, is both beneficial to the final users and the state budget, allowing to save considerable amount of money which might be reinvested in the NHS.

In conclusions online reports and imaging withdrawal, although it might seem a mild innovation, it's helping in connecting the citizen with the system, improving the quality of life and the system economical sustainability.

The main **outcomes** of implementing the mHealth solution are:

- Online reports withdrawal is connecting the citizens with the healthcare services, meeting the needs of the final users and improving NHS budget.
- It allows the patients to access their imaging and reports wherever and whenever they need it.
- Improvement of the quality of life, something that allows us to be present even where we are not.

It is sure that technological evolution will offer us a future full of innovations, which will make better the quality of the relationship between patients and healthcare providers, creating a simpler and better future for all.

During the Sars-Cov-19 pandemic even the patients who underwent a molecular swab can withdraw the report online. That improves their safety and confort.

ASL Umbria would not do anything different, because the system is technologically reliable, the service was never interrupted. What could be improved is the digital culture of professionals and citizens. We have reasons to believe that using Information Communication Technology, mhealth, networks and interconnection between citizens simplify and make economically sustainable many aspects of the care and diagnosis pathway. But a digital culture must be established, to allow everybody to achieve a significant independence in using the new technologies quickly and simply.

ASL Umbria would like, in the near future, to extend the possibilities given by RIS system to departments which use modalities that are not purely radiological, such as: gynaecology (US), cardiology (US and EKG), dermatology and ophtalmology.

References https://www.youtube.com/watch?v=AHxrvFfH6zY

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

Interview summary

Interviewee: Lorenzo Gios, Autonomous Province of Trento

mHealth Practice:

TreC Diabetes

Interviewers: Marzia Lucianer, Journalist, Head of Media Relations and Digital Communication at TrentinoSalute4.0

Date of interview: 1/12/2020

Summary of main interview ideas:

- TreC Diabetes aims at implementing a new organizational asset to manage patients with diabetes type 1 and type 2, supported by new technologies.
- The core target are mainly pregnant women affected by diabetes, including Gestational Diabetes Mellitus (GDM).
- TreC Diabetes has been piloted and fine-tuned from 2015 to 2018.
- The systems (App for patients and dashboard for healthcare staff) is used as part of the standard service delivery.
- The App includes a messaging system to facilitate communication with healthcare staff.
- The App includes an AI component enabling a virtual coach system to support healthy lifestyles and behaviour changes.
- Healthcare staff members (nurses and doctors) can monitor patients through the online medical dashboard.
- The dashboard was conceived as an easy-to-use console, allowing proper management of clinical and non/clinical information collected through different sources (medical history, personal data, laboratory data, self-reported information) and allowing to keep the healthcare staff and the patients in touch (chat).
- The communication between patients and health care staff was significantly improved, as well as the quality of both monitoring and management of the patients.
- Associations/NGO have been involved in the App design and piloting.
- The platform is used as part of the standard care for specific segments of the target population.

Description

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

TreC Diabetes is a project developed by the joint laboratory APSS/FBK/PAT of TrentinoSalute4.0 (partners: Autonomous Province of Trento – PAT, Provincial Healthcare Trust of Trentino - APSS, the Bruno Kessler Foundation – FBK). Based on previous experiences gained through TreC and TreC_FSE projects, this initiative aims at implementing a new organizational asset to manage patients with diabetes type 1 and type 2, supported by new technologies. The core target of TreC Diabetes is mainly pregnant women affected by diabetes, including Gestational Diabetes Mellitus (GDM).

The project was launched in 2014 with a preliminary piloting. Particularly in the case of GDM, the management of diabetes during pregnancy is a sensitive issue, and the impact on the (perceived) quality, acceptability and easiness of the service delivery is a vital aspect of any potential innovation. TreC Diabetes has been piloted and fine-tuned from 2015 to 2018: currently, the systems (App for patients and dashboard for healthcare staff) is used as part of the standard service delivery.

The first step was to conduct a formative research (including sociological assessment) to identify and to structure requirements and procedures to develop a technological asset supporting both patients with diabetes and healthcare staff. Following this phase, the TreC Diabetes platform has been developed including (i) a mobile app for patients and (ii) a web dashboard for health care staff. The TreC Diabetes App is an application designed to incorporate medical and lifestyle recommendation, as well as allowing the patient to record in a mobile diary disease and health-related information. The App includes also a messaging system to facilitate communication with healthcare staff, as well as an AI component enabling a virtual coach system to support healthy lifestyles and behaviour changes.

Healthcare staff members (nurses and doctors) can monitor patients through the online medical dashboard. The dashboard was conceived as an easy-to-use console, allowing proper management of clinical and non/clinical information collected through different sources (medical history, personal data, laboratory data, self-reported information) and allowing to keep the healthcare staff and the patients in touch (chat). An intuitive menu allows doctors to set up specific triggering patterns to collect specific data and to activate reminders, where settings and limits can be personalized in light of the specific patients' conditions.

The project constructively brings together both technological innovations and organizational aspects, to promote healthy lifestyles in and efficient management of patients with diabetes. Through the project and the related app/dashboard, the communication between patients and health care staff was significantly improved, as well as the quality of both monitoring and management of the patients. From a citizens' perspective, this has enabled patients to easily access health documents and to manage their contacts with the health care staff. From a health care team viewpoint, this technology has promoted prompt and smooth management of patients (so far, pregnant women with diabetes).

Considering weaknesses of the platform, the core one is related to the scalability and exportability of the model to other types of patients with diabetes. This is also due to missed integration of the platform with automated devices currently in use by the patients (e.g. glucometers). Specific studies have been implemented over the years to assess the platform usability, confirming that TreC Diabetes platform could be an effective tool when used to support patients's self-management and patients monitoring (Osmani 2017) (Miele 2015) (Eccher 2020).

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Additional strength is related to the active involvement of NGO/patient associations at province level. Associations have been involved in the App design and piloting. They were invited by the Provincial Healthcare Trust of Trentino – APSS / Governance. Proper qualitative research has been conducted also to collect needs and requirements from the main stakeholders, namely, patients and MD/nurses.

APSS supervised the contents related, FBK developed the technology to support the initiative. Associations provided inputs for app development. The core stakeholders, namely, patients and MD/nurses, provided inputs for the system development, and contributed to the piloting. FBK was also responsible of the sociological/qualitative assessment of the initiative.

A digitally enabled, patient-centred approach adopted since the beginning of the project and an active involvement of all the stakeholders were key success factors within this initiative. The engagement of patients and the support of self-monitoring/self-management appeared to be a key factor in improving patients' health and the perception of the quality of the service received, particularly during pregnancy.

More than 100 patients per year have been enrolled using this platform (mainly pregnant women with diabetes). mHealth technologies have been shown to have an increasing level of acceptance, both from patients' and healthcare staff's side. The perceived quality of the patients has been assessed through qualitative analysis and it has been reported as very high.

The platform has been piloted and tested in the past years. Currently, the platform is used as part of the standard care for specific segments of the target population, whereas other functionalities (advanced functionalities) are still under development and piloting.

As described above, the core issue is related to the scalability and exportability of the model itself to other types of patients with diabetes, and the lack of integration with patient automated devices. Contacts and agreement with the private companies and related integration could have been an action to pursue adopting different approach.

Future plans are to further assess the use and efficacy of the platform through specific evaluation project (clinical trial). In addition, further studies are under elaboration with the view of: piloting advanced functionalities/tools (particularly for monitoring specific steps of the patients' journey, as example: first diagnosis, change of therapeutic plan); scaling up of the platform for patients with diabetes 1 and 2 within specific phases of the patients' journey.

References: Project website https://smks.fbk.eu/en/results/app-diabete/ Project video https://www.youtube.com/watch?v=OoIsqaGdHng&t=2s

To find out more about **TreC Diabetes**, please watch this video from our 6th Hub Talk on patient centric approaches in mHealth (from 19:40 to 31:20)

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

Interview summary

Interviewee: Marco Frassoni (Autonomous Province of Trento)

mHealth Practice:

TreC_FSE

Interviewers: Marzia Lucianer

Date of interview: 2020-12-10

Topics

TreC_FSE has a successful approach on the following topics:

- Execution > Interoperability models
- Execution > Data security - legal framework
- Monitoring and evaluation > Monitoring and evaluation

Summary of main interview ideas

- The official launch of TreC_FSE took place in April 2018
- The app is fully integrated with all the healthcare services
- It allows to access to all data uploaded into the EHR starting from 2007
- It enables e-prescriptions
- It has been developed following a privacy and security by design approach
- The use of apps by elderly people is a false problem and reduces the digital divide
- The app is fully operational and available for the whole population of Trentino
- After Covid-19 pandemic outbreak, the following services were made available through the app: booking blood tests, booking medical examinations, booking tampons, availability of an embedded calendar with all the appointments, possibility to change family doctor, possibility to access another EHR through a delegation, booking appointments with the counter operators of the Provincial Healthcare Trust
- In March 2021 a completely renewed version will be released both web and app who will integrate additional services such as remote monitoring of patients with diabetes and heart disease

Description of the mHealth Practice

TreC (from the Italian acronym three “C” which stands for “Cartella Clinica del Cittadino”, i.e. citizen’s medical record) is the digital health ecosystem implemented in the Autonomous Province of Trento (PAT) since 2010. TreC is accessible via web portal and represents for the citizens a single point of access to all the services provided by the provincial healthcare system. Furthermore, it enables citizens to access, supplement, manage and share their health and wellbeing information.

Thanks to a co-creation process which involved about 30.000 people in Trentino through focus groups, surveys and online interviews, it emerged the need for a mobile version of TreC, since almost every citizen has a smartphone, but not a PC, especially among the elderly who represent the main users of the health service.

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This evidence laid the foundations to TreC_FSE (where the Italian acronym "FSE" corresponds to the Anglo-Saxon EHR).

The decision to implement TreC_FSE was taken in 2017. The development of the app was carried on thanks to a system approach coordinated by TrentinoSalute4.0, the competence centre for digital health formally established in 2016 which involves PAT in the role of decision maker, the Provincial Healthcare Trust (APSS) in the role of provider of services and the Bruno Kessler Foundation (FBK) as research institute. The official launch of TreC_FSE took place in April 2018, during the 2nd edition of Trento Smart City Week, an annual informational event aimed to promote the knowledge of and the advantages brought by the digital services available in Trento.

After the demand analysis detected the need for a mobile version of TreC, namely TreC_FSE, the team of TrentinoSalute4.0 started working to development of prototypes that were tested thanks to the active involvement of experimenter citizens following a co-creation process who made it possible to arrive at the final version of the app.

The main ***strength*** is that the initiative was endorsed by the institutional side and delivered by the public service. The app was implemented in the framework of TrentinoSalute4.0, which also provide for integration with the Provincial Healthcare System and release in the stores.

The initiative TreC_FSE was formally approved through the Resolution of the Provincial Council of Trentino no. 596 of 9th April 2018, which, among other contents, identified the timeline from the testing phase to its definitive release.

The ***strengths*** are that the app is fully integrated with all the healthcare services; it allows to access to all data uploaded into the EHR starting from 2007; it enables e-prescriptions; it has been developed following a privacy and security by design approach.

Security is a strength, but the strong authentication required by law can even represent a weakness as far as it affects the readiness of use. In fact, after installing the app, it is necessary to go to a counter, where an operator will identify the citizen and provide him with a QR code that will allow him to activate the app and start using it.

The shared governance already put in place through TrentinoSalute4.0 allowed to quickly engage PAT as decision maker, APSS as provider of services and FBK as research institute.

TrentinoSalute4.0 and the information system service of the APSS were institutionally involved.

The University of Trento gave support to TrentinoSalute4.0 in preparing about 35.000 surveys to citizens in Trentino who were engaged in a co-creation process

The main ***obstacle*** was of a technical and organisational nature and it was related to the strong authentication required by the digital public administration code (CAD from its Italian acronym which stands for "Codice dell'Amministrazione Digitale"), that is the legal act in force in Italy from 2005. This act indicates that online public services can be accessed by citizens only through the Electronic Identity Card, the Health Card or the credentials to access to the Public System of Digital Identity. This obstacle has been overcome by means of a specific communication campaign towards the citizens, through the counter operators throughout the provincial territory who were trained to communicate to citizens how to access the service and through the creation of a devoted helpdesk to support citizens in case of need.

The use of apps by elderly people is a false problem and reduces the digital divide, making it simpler and more immediate than using a portal through a PC; services must be useful in

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responding to needs; the solution is part of the public service and for this reason the citizen is reassured about its use. The figure of the first two years of availability of the solution tells that 26.000 citizens are using it.

The app is fully operational and available for the whole population of Trentino. Since the app is natively integrated with the Provincial Healthcare System, it can be rapidly enriched with additional features. For example, after Covid-19 pandemic outbreak, in order to meet the needs of physical distancing and decreasing the overcrowding of clinics, the following services were made available through the app: booking blood tests, booking medical examinations, booking tampons, availability of an embedded calendar with all the appointments, possibility to change family doctor, possibility to access another EHR through a delegation, booking appointments with the counter operators of the Provincial Healthcare Trust.

The training paths of operators in support of citizens and the promotion of the app with initiatives better calibrated on the territory are two aspects that could be improved.

The goal is to reach all Trentino citizens through a single access point to the Provincial Healthcare Service, allowing them to access their PHRs, to access all the available services and to interact with health professionals for telemedicine services. In November 2020 the teleconsulting function was released which will allow specialists and family doctors to guarantee assistance even remotely. In March 2021 a completely renewed version will be released both web and app who will integrate additional services such as remote monitoring of patients with diabetes and heart disease. This new version, called TreC+ will be launch through an information campaign that will exploit all media and social channels.

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Interview summary

Interviewee: Riccardo Farina, PhD, MSc, Policy Officer at the Department of Health and Social Policies of the Autonomous Province of Trento, Project Manager of Trentino Salute+

mHealth Practice:

Trentino Salute+

Interviewers: Marzia Lucianer, Journalist, Head of Media Relations and Digital Communication at TrentinoSalute4.0

Date of interview: 2020-12-01

Topics

Trentino Salute+ has a successful approach to the following topics:

- Execution
  - **Interoperability models**
  - **Data security – legal framework**
- Monitoring and Evaluation
  - **Monitoring and evaluation**

Summary

- An app explicitly developed for promoting healthy lifestyles.
- A privacy and security by design approach in the development of the solution.
- Innovative incentive system for the user based on two levels: personal and social.
- Designed to be a “serious game” in the health sector.
- Using the app and participating in “health challenges”, the user gets offers and discounts from associated partners (like gyms, swimming-pools, healthy food shops, etc.)
- The first operational phase of the solution which will end on 31st December 2020.
- The app currently available is still in a pilot phase.
- The official launch will be in spring 2021.
- The new app will propose new health targets to encourage behavioural change.
- The new app will link the promotion of health with the promotion of the territory, by providing hints to local healthy food products and walks and excursions in Trentino.

Scope of the mHealth Practice

Trentino Salute+ is an app explicitly developed for promoting healthy lifestyles in accordance with the first macro-thematic objective of the 2015-2025 Trentino Health Plan: "More years of healthy

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life". The promotion of healthy lifestyles triggers a dialogue between different entities: citizens, provincial government, social cooperatives, associations and commercial partners, following the paradigm “the healthier your behaviour, the greater your help to others” and fostering the creation of a virtuous community.

The project idea was born following the public discussion which took place during the Trento Festival of Economics in 2017, focused on "Unequal Health", between the Councilor for Health and Social Policies of the Autonomous Province of Trento (PAT), a representative of the World Health Organization (WHO) and a representative of the National Agency for Regional Health Services (AGENAS). The app was officially launched during the 2018 edition of the Trento Festival of Economics and then made available to download in June.

Some months after the aforementioned public discussion, an interinstitutional working group was created in order to define the contents of the Project. The group was coordinated by representatives of the Department of Health and Social Policies, and involved the Provincial Healthcare Trust of Trentino (APSS) and the Bruno Kessler Foundation (FBK), following the framework of the competence centre for digital health TrentinoSalute4.0 in which the same subjects collaborate.

The main **strength** is that the initiative was strongly endorsed by the institutional side, which sped up its implementation; the formal approval of the initiative through a provincial act guarantees its reliability to all the stakeholders involved: citizens, social cooperatives, associations and commercial partners. On the other hand, a leading formal act implies that any modification to the initially foreseen plan has to undergo to the modification of the act itself, which can sometimes lengthen the time for a quick provision of the service.

The initiative Trentino Salute+ was formally approved through the Resolution of the Provincial Council of Trentino no. 535 of 29th March 2018, which, among other contents, identified the timeline to follow for its implementation for about three years, from the first semester of 2018 until the 31st December 2020.

The first *strength* is a privacy and security by design approach in the development of the solution. The second *strength* is the implementation of an innovative incentive system for the user based on two levels: personal and social. Using the app and participating in “health challenges”, the user gets offers and discounts from associated partners (like gyms, swimming-pools, healthy food shops, etc.) and earns “social points” with which he can support the social initiatives selected by the project Steering Committee. When a social initiative reaches a prefixed threshold, it can be financed up to 5.000 € through a dedicated fund allocated by the Provincial Government. The third strength is that Trentino Salute+ has been designed to be a “serious game” in the health sector.

On the other hand, the main **weaknesses** are: the current release of the solution implements a virtual coach which is too basic; the food diary that the user is asked to keep to evaluate the overcoming of the “health challenges” is not much user-friendly; the lack of integration of a pedometer for monitoring physical activity which instead must be entered manually by the user.

The shared governance already put in place through TrentinoSalute4.0 allowed to quickly engage PAT as decision maker, APSS as provider of services and FBK as research institute. Some institutional meetings took place to reach particular categories of stakeholders like General Practitioners, Pharmacists, voluntary associations related to particular pathologies and active citizenship. Commercial partners were identified inside the areas of interest for the project and then contacted directly. Citizens were involved through voluntary associations and through an information campaign that exploited all media and social channels.

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The main **obstacles** were of a technical and organisational nature and they were related to the easy access to discounts through the app. In the case of large retailers, there was the difficulty of integrating the app with their proprietary authentication systems. In the case of small retailers there was indeed the difficulty of automating the process by which the user claims and the retailer applies the discount so that the app keeps track of it. These obstacles have not yet been fully overcome.

A major obstacle has been represented by Covid-19 pandemic outbreak which prevented the engagement of a wider number of stakeholders and citizens on the territory initially foreseen to release a fully operational version of the app in May 2020. Anyway, this unexpected stop gave TrentinoSalute4.0 time to work on the technological side of the project, by taking into account all the feedbacks received from citizens and associations collected until then and laid the foundation for the new release of the app in December 2020.

The holistic approach to the promotion of health and healthy lifestyles by following the paradigm "the healthier your behaviour, the greater your help to others" can trigger horizontal synergies among different stakeholders of the territory and reinforce vertical relations between the territory and the institutions. A virtuous community that is attentive and committed to promoting health and healthy lifestyles can be then also the key for a sound economics and a social commitment on the territory.

A digitally enabled, person-centred holistic approach to healthy life-style and well-being where citizens and components of civil society are engaged through a co-creation process to improve themselves and the community in which they live is the key to bring public services closer to people.

The figures of the first operational phase of the solution which will end on 31st December 2020 are: 3.500 citizens involved, 20 selected social initiatives, 15 of which funded, and 10 commercial partners.

The app currently available is still in a pilot phase. The release of the fully operational version, initially planned in May 2020, was prevented by Covid-19 pandemic outbreak, and it is now foreseen in December 2020, while the official launch will be in spring 2021, after a promotional campaign on the territory. The new app, among other additional features, will propose new health targets to encourage behavioural change and will link the promotion of health with the promotion of the territory, by providing hints to local healthy food products and walks and excursions in Trentino. (To learn more: https://www.trentinosalute.net/Aree-tematiche/Promozione-della-salute/Trentinosalute)

Watch the **video** about this initiative here (access to playlist)

Interview summary

Interviewees: Wenche Tangene (Project Manager, Sørlandet Hospital Trust), Inger-Alice Naley Ås (Project Assistant Sørlandet Hospital Trust) and Rune Fensli (Technical Project Manager, University of Agder), Southern Norway

mHealth Practice:

United4Health, Southern Norway

Interviewers: Berglind Smaradottir and Santiago Martinez (University of Agder, Norway)

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

Date of interviews: 2020-11-24 and 2020-11-26

Topics

United4Health, Southern Norway has a successful approach to the following topics:

- Planning
  - **User centered design considerations**
- Execution
  - **Solutions testing and validation**

It also promoted learnings about **regional collaboration across organisational boundaries.**

Summary

- EU FP7 Project (2013-2016) CIP-ICT PSP-2012-3, 20 countries, 20 000 patients.
- Kristiansand municipality and University of Agder design, development and deployment of telemonitoring program for COPD patients.
- Aim: to reduce hospital re-admissions from COPD exacerbations over the following year and pathway is more cost-effective compared to usual care.
- User-centred design: all stakeholders at all times.
- COPD patients and health professionals designing and evaluating together.
- Service deployed into the Norwegian Health Network.
- Triage based on clinical evidence (no standard available at the time).
- International partners with different expertise but tackling the same type of problem.
- Learning objectives: legal, technical and economic issues.
- Benefit realisation takes time: short- versus long-term approach.
- Triage is now part of an algorithm in use at same municipality.
- The Agder region is a Norwegian and European Reference Site (3 star in EU EIP-AHA).

Scope of mHealth Practice

The United4Health was an EU FP7 project (2013-2016) with stakeholders collaborating across organisational and administrative levels (municipal and hospital sectors) in the Region of Southern Norway. A technology solution allowed to telemonitor Chronic Obstructive Pulmonary Disease (COPD) patients at home. The system was deployed into the Norwegian Health Network. A field trial included around 100 patients during the duration of the project.

United4Health had a strong focus on user-centred design during the entire development and deployment processes.

Topic: User-centred design with multiple stakeholders

Scope and timeline of the mHealth good practice implementation

How long did it take for the mHealth practice to be implemented?

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The technology development process took approximately 6 months. The implementation and integration into the National Health Network took another 6 months and created a delay that affected the planned schedule for the project.

What are the key steps that were undertaken?

A project board was established and a project management in charge of the medical and technology aspects, legal contracts between the stakeholders, and a patient organisation was involved. Workshops with key stakeholders allowed for end-user representativeness throughout all the stages of the project. These included user tests and validation test over a test network. A field study was carried out with patients and health professionals in a pre-implementation phase to preliminary analyse the usability of technology in real settings.

What are the strengths and weaknesses of the implementation process?

Strengths:
1) user-involvement in all the stages of the project,
2) implementation in the National Health Network,
3) a detailed protocol for the implementation of the service for patient follow-up.

Weaknesses:
1) lack of integration with the electronic health record due to process time length, which made it became a standalone system,
2) the municipalities were not included as full project partners, although they contributed to the project outcomes,
3) the detailed protocol for the patient follow-up service was a limitation for the municipality who had need for individualising the patient follow-up.

Is there a workplan that can be included as a reference? Is there further documentation about the approach?

There are scientific peer-reviewed publications connected to the project (around 10).

What are the strengths and weaknesses of the solution?

Today, the solution would not have been approved as Medical Device (due to the European General Data Protection Regulation, Quality Assurance ISO 13485 and Medical Device Regulation (EU 2017/746). Standards and quality assurance would have taken a more relevant role in the development of the solution.

Stakeholder involvement

What stakeholders needed to be involved for the good practice to work?

All directly and indirectly involved in the design, development, deployment and evaluation of the solution. This includes hospital, municipalities, research institution, IT provider of hospital and municipal organisations, The Norwegian Data Protection Authority, IT company, patient organisation.

What are the stakeholders' roles and activities/effort?

Municipality: to run the IT-system, HR resources, location/real estate. Hospital: owned the technical equipment/tablets, configuration of technology, teaching of nurses that included patients at hospital before being discharged, user training of patients and advisory function.

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Research institution: responsible for the user-centred design overall approach; development the tablet application to be used by patients. Research and dissemination at regional, national and international level. IT company: development of the backend information system. Patient organisation: to support the recruitment of end-users. The Norwegian Data Protection Authority: advisory role. All stakeholders: providing resources to join user-centred development process workshop/tests.

How was involvement and buy-in of the stakeholders secured?

By legal contracts connected to the project agreement and own contribution from the organisations.

Barriers

The stakeholders were from different organisations and had multiple levels of administration (as a barrier for financial support to project activities and regarding laws, the data storage and data access had to be taken care of). The municipality and hospital had different economy and service models. The technology was not fully integrated with other systems in use, such as electronic health records (hospital and municipality). It was challenging to involve the General Practitioners in the project and operation of the service.

Were there any obstacles you experienced? How were they overcome?

Realisation of benefits: the one who provided new services did not immediately see the benefits. In this case, the municipality had to establish a new service with employees and corresponding costs. The overall benefit was to release patients from hospital knowing they would be followed up and monitored at home.

Success factors

1) Involvement of all stakeholders at all times for the design, development, deployment and evaluation of the technology solution.

2) Technical solution implemented in National Health Network.

3) International and national clinical guidelines for COPD were carefully taken care of and the algorithms that were developed are still in use in other regional projects.

Lessons learnt

Involve organisations as equal partners. Legal and economic issues may arise, and they need to be taken into account when designing the project. Realisation of benefits may take longer time than expected, so it is essential to structure them with short-, middle- and long- term perspectives. Policy/political: long-term view regarding investments, operation and permanent implementations is needed. The focus has to be on the benefits of the patients and not mainly the organisations. It is relevant for the development of the Project to take into account organisational policy and involve politicians, making them aware of the benefits for the region/city/organisations/citizens. Legal resources must be available to assist in new implementation and risk management is relevant to predict any unforeseen circumstances. It was difficult to engage and enrol physicians to the project, and it was experienced that this engagement is important and has to be a priority from top management.

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Outcomes

What were the main outcomes of implementing the mHealth solution?

Establishment of new services connecting stakeholders and organisations. New ways of carrying out services supported by technology. Providing means to improve quality of life, save time and resources. Patient empowerment was a central part of the project where patients learned how to manage their own disease. After the end of the United4Health project, the stakeholders involved are still collaborating closely regarding digital health and remote monitoring in the Agder region.

What is the status?

The project/system was fully operational until 2016, but was discontinued after the end of the project. Due to the Norwegian rules for procurements, another system was later bought for a similar service in the region.

Continuous learning and outlook

What would you have done differently? What can still be improved?

Involve all partners equally. Permanent implementation. Include data protection standards and quality assurance in a systematic way through the project. More available technical support/user support for all user groups (patients and health professionals).

What are the future plans for exploiting the mHealth solution?

The same organisations are still collaborating in other similar mHealth projects, although they are using an off-the-shelf solution for the technology. The Southern Norway Region is a national pilot for testing and running new mHealth services in Norway. In addition, the Agder Region is a reference site for mHealth in EU (Reference site 3-star of the European Innovation Partnership on Active and Healthy Ageing, EU EIP-AHA).

Other elements to be highlighted

1) Strong focus on collaborative work across organisations.

2) A specific application/server solution was developed for this mHealth implementation for patient-generated data.

3) The importance of testing out new technical solutions in a secure network (professional test facilities and National Health Network) and also to make clinical test and evaluation.

To find out more about lessons from Norway on collaborative approaches to user-centred design as enabler for large-scale implementation, please watch this video from our 6th Hub Talk (from 46:15 to 01:03:00)

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

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