mHealth sub-group
Report on national mHealth strategies

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Contents

Summary

World Health Organization (WHO) defines mHealth (mobile health) as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices". As the European Commission is recognizing both the potential of as well as the issues arising from the growth of mHealth, several mHealth-specific initiatives have been launched.

The eHealth Network at its meeting on 23 November 2015 established a subgroup on mHealth, which aims to "collect experiences on approaches in dealing with mobile health apps, to identify common challenges and recommend possibilities for future collaboration among Member States".

This report is based on the responses received to the survey conducted among the sub-group members to compose an overview of the existing strategies, activities and perspectives on mHealth in the Member States. The questionnaire yielded 14 responses, and the results show that mHealth is considered a strategic area in most of the participating countries/regions. Usually mHealth is covered by broader strategic documents, mainly eHealth strategies. The focus of and level of detail for national approaches vary, but the most common foci are patient-orientation, market development, quality and security, and increase of mobility.

When it comes to existing and prospective mHealth activities, over half of the respondents said they are either already linking patient generated data to the electronic health records/personal health records, or are about to initialise such projects. The existing activities are implemented in small scale for either particular conditions or for certain regions.

Five respondents stated that reimbursement is applied to mHealth services in their countries. While no mHealth-specific reimbursement schemes have been implemented, Germany, Denmark and Finland reimburse mHealth in the framework of general health financing. The flexibility of the Dutch healthcare system allows agreements for reimbursing mHealth, and in France specific initiatives are covered.

Not a lot of training and educating activities are currently conducted for health professionals or general public. However, several countries are planning their activities, mainly with health professionals as the target group. Guidelines and/or recommendations have been published in 6 participating countries/regions and these are mainly targeted at developers. Generally, the

initiative for such guidelines comes from the public sector. Certification/endorsement systems are in place for mHealth apps in four countries/regions, and four more are currently in the process of development.

So far little evidence-gathering has been done regarding on the cost benefits, cost effectiveness and other related aspects of mHealth. Some case studies have been conducted, and a few more projects are on the way.

The implementation of mHealth applications in public health programmes, primary care and hospitals varies greatly between the countries/regions. In countries where mHealth is utilized it is either for prevention and informational services, or for assisting health professionals

In the scope of next 3 years, almost all respondents plan to conduct mHealth related activities, including development of strategic and action plans), composing guidelines, focusing on compatibility between mHealth applications and personal/electronic health records, and conducting specific projects.

Looking at horizontal domains, most countries do not have mHealth specific legislation implemented. In some cases, the wider legislation framework is applied to mHealth. When it comes to market surveillance initiatives the situation is similar- most countries have not set up such mechanisms, but do understand the need for it.

The majority of respondents see the need to address data protection issues, specifically in the context of mHealth, and have outlined different aspects that should be considered. Six respondents already have a digital authentication/access solution in place. Most cases it is an eCitizen/eID solution, however only one respondent stated they are also using it for health applications. 6 respondents stated they see a need to address mHealth specific authentication and authorization, and outlined different issues that have to be taken into account.

Countries participating in the subgroup are open to future collaboration, especially to exchange knowledge and experiences in this fast developing field. Market surveillance initiatives, cooperation in certification/endorsement of mHealth apps and data protection were seen as areas for cooperation with most added-value according to the survey. The subgroup also found that systematic monitoring of practical roll-out of General Data Protection Regulation in Member States would facilitate more coherent implementation of mHealth in Europe. Most respondents would prefer to collaborate in the framework of the eHealth

Network and the Joint Action supporting the eHealth Network (JAseHN), but also wish to conduct specific projects within the Horizon 2020 Framework Program.

1. Background

1.1 Mobile Health

World Health Organization defines mHealth (mobile health) as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices"[1]. The same definition has been adopted by the European Commission, additionally including applications (apps), such as "lifestyle and wellbeing apps that may connect to medical devices or sensors (e.g. bracelets or watches) as well as personal guidance systems, health information and medication reminders provided by SMS and telemedicine provided wirelessly"[2]. According to the definition by the U.S. Department of Health and Human Services telemedicine and mHealth are both part of a larger field of telehealth and "telemedicine" has usually "been used to refer specifically to bilateral interactive health communications with clinicians on both "ends" of the exchange" [3]. As several investigations have been conducted in the field of the regulation and application of telemedicine in Europe[4,5] the current report concentrates only on mHealth, namely on the broader use of mHealth applications by the general public for monitoring their lifestyle and health or managing a chronic condition.

The Green Paper published by the European Commission in 2014 sees mHealth as one of the tools for tackling the healthcare challenges Europe is facing. mHealth has potential to increase prevention and improve quality of life, contribute to a more efficient and sustainable healthcare, and empower patients by giving them a participatory role.[6]

At the same time, the rapid evolution of mHealth raises a multitude of issues. The Green Paper identifies issues such as data protection and security of health data, big data, legal

[1] World Health Organization „mHealth. New horizons for health through mobile technologies. Global Observatory for eHealth series, Volume 3", 2011. Retrieved from http://www.who.int/goe/publications/goe_mhealth_web.pdf

[2] European Commission „Green Paper on Mobile Health", 2014. Retrieved from https://ec.europa.eu/digital-single-market/en/news/green-paper-mobile-health-mhealth

[3] U.S. Department of Health and Human Services „Report to Congress. E-health and Telemedicine", 2016. Retrieved from https://aspe.hhs.gov/sites/default/files/pdf/206751/TelemedicineE-HealthReport.pdf

[4] Commission of the European Communities "Communication from the Commission to the European Parliament, the Council, The European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society", 2008. Retrieved from http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0689:FIN:EN:PDF

[5] European Commission „Commission Staff Working Document on the applicability of the existing EU legal framework to telemedicine services", 2012. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012SC0414&from=en

[6] European Commission „Green Paper on Mobile Health", 2014. Retrieved from https://ec.europa.eu/digital-single-market/en/news/green-paper-mobile-health-mhealth

framework, patient safety and transparency of information, mHealth role in healthcare systems and equal access, interoperability, reimbursement, liability, research and innovation, international cooperation and market access[7].

In 2015 a subgroup on mHealth was established as part of the eHealth Network[8]. The purpose of the subgroup is to "collect experiences on approaches in dealing with mobile health apps, to identify common challenges and recommend possibilities for future collaboration among Member States".

The subgroup had two face-to-face meetings in 2016 (on 5 April and on 15 September). Estonia was appointed as the new Chair of the subgroup at the first meeting. At the meetings Portugal, Finland, Denmark, Catalonia and Andalusia presented their national and regional initiatives. To compose an overview of the existing strategies, activities and perspectives on mHealth, a questionnaire was sent out in July 2016 to the members of the subgroup. The questionnaire concentrated on national strategies and action plans, use of mHealth in the care pathways, mHealth-related activities in the horizontal domain, and areas for collaboration. The full list of questions can be found in Annex 1. The questionnaire yielded 14 responses. The list of respondents can be found in Annex 2.

The draft report was discussed at the meeting of the sub-group on mHealth on 15th September 2016. Input from that meeting and following contributions have also been included in this report.

1.2 EU Policy Actions

As follow-up to the Green Paper, stemming out of the results to the public consultation, the European Commission has initiated several activities like an industry-led Code of Conduct on privacy of mHealth apps and mHealth assessment guidelines on data validity and reliability[9] but also is still conducting some others.

1. ***Privacy Code of Conduct on mobile health apps***

[7] European Commission „Green Paper on Mobile Health", 2014. Retrieved from https://ec.europa.eu/digital-single-market/en/news/green-paper-mobile-health-mhealth

[8] eHealth Network „The establishment of a sub-group on mHealth", 2015. Retrieved from http://ec.europa.eu/health/ehealth/docs/ev_20151123_co04_en.pdf

[9] European Commission. „Current initiatives to unlock the potential of mobile health in Europe", 2016. Retrieved from https://ec.europa.eu/digital-single-market/en/news/current-initiatives-unlock-potential-mobile-health-europe

The European Commission is facilitating a code of conduct on mobile health apps which covers data privacy and data security. A drafting team consisting of industry representatives was set up in March 2015. The draft has been consulted with other stakeholders online and at open meetings. In June 2015 it the Code was submitted to the Article 29 Working Party (composed of all Member States data protection authorities under the Data Protection Directive) for their opinion.

The code of conduct aims to make it easier for mHealth app developers to comply with data protection requirements and provide a competitive advantage for those who are signatory to the code and will finally increase citizens' trust in mHealth apps. The code of conduct contains practical guidelines to follow for app developers. For instance: data can be collected only for specific purposes; the user needs to give his consent before data processing can take place; the app developer must provide the user with some information on the data collected; security measures should be put in place; provisions on the secondary use of data. The code of conduct aims at making the language as simple as possible, so it can be understood easily by people without legal expertise.

2. Guidelines on assessing validity and reliability of mHealth apps data

In February 2016 the Commission set up a working group to develop guidelines for assessing data validity and reliability of mHealth apps. 20 organisations representing civil society, research institutions and industry were selected as members based on a public call for expression of interest (the call closed 4 December 2015). Member State public authorities were invited to join the group. Other stakeholders will be able to contribute to the draft guidelines via online consultations and open stakeholder meetings. The guidelines are expected to be drafted by the end of 2016.

3. European standard on quality criteria for the development of health and wellness apps

In order to enhance the quality of health and wellness apps, the Commission has proposed in the 2016 Rolling Plan for ICT standardisation a European standard on quality criteria for the development of health and wellness apps (e.g functionality, usability, reliability).

The British Standards Institution (BSI) has developed a publicly available standard "PAS 277:2015 Health and wellness apps – Quality criteria across the life cycle – Code of practice"

which has been suggested as the basis for the European standard. BSI will be in lead for this standardisation action which will be taken forward in CEN (Technical Committee 251 Health Informatics).

4. Public consultation on the safety of apps and other non-embedded software

Under the Digital Single Market Strategy, the Commission is exploring ways to adjust the existing EU legislative framework on general product safety, consumer rights and e-commerce to appropriately cover safety and liability issues related to the digital products in general, including health apps.

The Commission launched a public consultation on the safety of apps and other non-embedded software in June to gather views on possible EU tools to support safety and avoid adverse impacts of non-embedded software. The public consultation closed on 15 September. The Commission received 78 replies to the consultation from which approximately 50% belong to individuals while the rest come from businesses, organisations, public authorities and academia. The results of this consultation are currently being analysed.

5. Supporting research under Horizon 2020

Actions in the Horizon2020 Work Programme 2016-2017 related to mHealth include funding of research and innovation in the field of big data, digital security for healthcare, empowering patients/citizens and improving digital health literacy.

eHealth/mHealth have been identified as one of the key priorities in the report on H2020 2018-2020 Work Programme from the Advisory Group on Societal Challenge.[10]

2. National Level Strategic Approaches to mHealth

mHealth is considered as a strategic area in most of the countries/regions that responded to the questionnaire. Usually, mHealth is covered by broader strategic documents, such as the eHealth strategies in Ireland, Finland, Croatia, Estonia, Germany, Netherlands and UK. The only existing mHealth-specific strategy is the Catalan Master Plan on mHealth, approved by the Catalan Government in 2015. The Master Plan aims to bring health and social assistance

[10] https://ec.europa.eu/research/health/pdf/ag_advice_report_2018-2020.pdf

closer to citizens, and to advance towards a more integrated care process through the use of mobile technologies.

Malta stated that they are about to start developing a mHealth-specific strategy document. In Greece, mHealth is not considered as an "immediate priority", however they do intend to take up mHealth related activities before the beginning of 2017.

The focus and level of detail of national approaches to mHealth vary from having "no clear goals or implementation plans" in Croatia to Germany's three-step plan that consists of an independent and in-depth study of the *status quo*, opportunities and risks of mHealth; a structured dialogue with all stakeholders and an activity plan to be set up (covering development of guidelines; improving market access and regulatory environment; and analyses of the use of mHealth applications). In many cases the strategic documents don't differentiate between either mHealth and eHealth, or between mHealth and telemedicine.

Most common foci of the national approaches to mHealth include:

- ***Patient-orientation*** (empowering patients by supporting the self-management of chronical diseases and reaching persons who are conventionally hard to reach in Germany; emphasizing patients' role in their wellness and health in Finland; improving the literacy regarding health services in Portugal).

- ***Market development*** (promoting the use of mHealth and Internet of Things (IoT) applications in France; stimulating the apps' market with advice and guidance for suppliers and purchasers in UK).

- ***Quality and security*** (developing an accreditation model in Catalonia; delivering a label of data quality and security in France).

- ***Increase of mobility*** (developing a health platform of mobility in Catalonia; making the electronic health records portable in Portugal).

Other aspects mentioned are the improvement of quality and cost savings (Germany), enabling services outside healthcare delivery facilities (Croatia). In the Netherlands the following principles of the eHealth policies are also applied to mHealth development: agreeing on information standards, norms and guidelines; reducing barriers that slow the

adoption of new technologies; knowledge-sharing and raising awareness. The Netherlands also emphasised the importance of including all stakeholders when developing policies.

3. Existing and Prospective mHealth Activities

3.1 Linking Patient Generated Data to Electronic Health Records

8 respondents said that they are either already linking patient generated data to the electronic health records/personal health records, or are about to initialise such projects. The existing activities are implemented in small scale, for either particular conditions (for example renal conditions in UK) or for certain regions (for example The Pascaline Project from the Rhône-Alpes region in France, and several local/regional "patient portals of platforms that have been developed in the Netherlands). Croatia is developing a platform of applications for disease management for asthma, chronic obstructive pulmonary disease, hypertension and diabetes, to be used by field nurses and to be integrated within the national eHealth system. Catalonia, Finland and Estonia also stated they are about to initialise such projects.

MEDMIJ is a multi-stakeholder program, launched under the framework of the National Information Council [in this council the following stakeholders are represented: general practitioners, social care, hospitals, care for disability, paramedics, patients, health care insurers, municipalities, government, IT-developers and Nictiz] and led by the Dutch Patient Federation. This program aims to create a set of demands, specifications, and agreements for a reliable and safe way to exchange data between systems of patients (personal health records and apps) and systems of health care providers (registries of electronic health records). MEDMIJ will create a national information model and additional agreements on security, legal issues and compliance for IT-developers and patient portal holders, which will help different portals and eHealth-solutions with personal health data connect with each other. For more information (in Dutch), see http://www.medmij.nl/

3.2 Reimbursement of mHealth as Part of Service Provision

Five respondents stated that reimbursement is currently applied to mHealth services in their countries. Germany has no mHealth-specific reimbursement tools, but mHealth can be included in current treatment or service reimbursement schemes. The conditions differ if it is

for ambulatory or stationary care purposes. mHealth applications could also be listed at the Registry of Therapeutic Appliances and Aid at the Association of Statutory Health Insurance Funds. In order to have mHealth applications to be part of the catalogue of services of all statutory health insurance funds, in general more evidence needs to be provided, whereas decisions are made within the self-administrative structures of the health system. In Germany mHealth reimbursement takes place at the moment through single health funds, that arises from the opportunity of selective agreements between single health funds and mHealth providers.

Denmark does not have mHealth-specific reimbursement rules either, but mHealth is considered as a part of the general health system. Finland stated that if mHealth applications are part of a reimbursable treatment, they can be covered. The Dutch healthcare system uses integrated tariffs to pay the providers, which allows the insurer and healthcare provider agree on reimbursing mHealth services. In France there are currently three specific cases, within which mHealth reimbursement takes place: monitoring patients' breathing problems at night; a diabetes surveillance application called Diabeo, and a lung cancer metastases' avoiding process.

In UK there is ongoing discussion about reimbursement, but no decisions have been made yet.

3.3 Training and Education of Health Professionals and/or General Public

Seven respondents said there are training and education activities conducted, however three of them (UK, Catalonia, Croatia) specified that implementation is still in the planning phase. The main target group for training is health professionals, for example in France IT education and training on computerised systems is an obligatory part of medical education. In Croatia field nurses will be educated on using the mobile application for disease management.

In the Netherlands and in Germany training and education are part of the eHealth strategy. Currently, in the Netherlands, eHealth-related training is provided by medical organisations and educational institutions. However, participation is voluntary. When it comes to raising public awareness, the Federal Centre for Health Education in Germany may use mHealth technologies like apps, but no particular mHealth-awareness-programmes are set up. In Denmark, educating the general public on mHealth issues is part of the general education on digitization.

There are some activities already at the EU level addressing health workforce skills as part of the Action Plan for the EU Health Workforce[11] and the Joint Action on Health Workforce[12]. Guidelines have been produced by the EU project ENS4CARE[13] to share good nursing and social work practices in eHealth services (telehealth and telecare).

3.4 Guidelines or Recommendations to Users or Developers

Guidelines or recommendations have been published in 6 participating countries/regions, mainly aimed at developers. Generally, the development of such guidelines is initiated by the public sector, for example Finland has set the certification criteria for mHealth apps to connect to healthcare services. In Germany the Federal Institute for Drugs and Medical Devices has published a guidance on medical apps, helping developers determine if their application is a medical device or a lifestyle product. Denmark has an existing reference architecture regarding security and collection of data in patients' homes.

The German Federal Institute for Drugs and Medical Devices has published an informative guidance for differentiation between lifestyle applications and medical devices, and the subsequent risk classification. It includes the following sections:

1. *Differentiation/Qualification*
2. *Risk classification*
3. *Examples of qualification/differentiation*
4. *Further information and guidance*

For more information see
http://www.bfarm.de/EN/MedicalDevices/differentiation/medical_apps/_node.html

In the Netherlands the collaborative development of guidelines is facilitated by the National Health Care Institute, and the Expert Group on Quality Standards and the Advisory Commission on Quality agreed to include specific instructions in regards to eHealth.

France has guidelines issued by both public and private sector. An independent public body Haute Autorité de Santé has issued guidelines on the request from the Ministry of Health, and

[11] http://ec.europa.eu/health/workforce/docs/staff_working_doc_healthcare_workforce_en.pdf
[12] EU Joint Action on Health Workforce Planning & Forecasting http://healthworkforce.eu/
[13] The aim of the ENS4CARE project is to compose „evidence-basedguidelines for the deployment of eHealth services at EU level based on the identified best practices that have achieved major benefits in cost-effectiveness and better self-management of care". http://www.ens4care.eu/

the organisation is an active participant of the respective European working group on mHealth assessment guidelines. There are also two private SMEs (Medappcare and DMD) that have developed methodologies and criteria for the assessment of mHealth apps.

MEDAPPCARE is a private initiative to assess mHealth apps. The focus of the assessment is on confidentiality and up-to-date regulation, and the process consists of both technical and medical evaluation. Based on the evaluation score and developer's interest, higher-ranked apps get included in a database accessible by industry professionals. For more information see https://www.medappcare.com/en/

3.5 Certification/Endorsement of mHealth Applications

Four respondents stated that they have certification/endorsement systems for mHealth apps in place. Catalonia and Denmark are following larger frameworks, the CE marking framework and the Continua framework respectively. There is also a certification/endorsement system implemented in UK, however they did express caution on how it will be managed.

The AppSalut website was created within the Catalan Master Plan on mHealth. It is a portal showcasing health and social care oriented applications, facilitating access to mobility tools, and encouraging citizens to take a more active role in managing their health. All apps showcased on the AppSalut Website are required to pass an accreditation process, which is based in 120 different criteria in the fields of usability, security, technical and clinical issues.

After accreditation, professionals can recommend the use of certified apps to patients. When downloading an app the patient is asked to accept a legal disclaimer specifically integrated in the app to agree to share their data with the Catalan Health Department. The health professional will then be able to access the data generated by the patient and to integrate it into the patient's medical record, using an innovative Digital Health Platform.

For more information see https://appsalut.gencat.cat/

Certification systems are in preparation in France, Finland and Croatia. Croatia sees the existing eHealth certification programs as potential base for developing mHealth certification. France has initiated an inter-ministerial working group to develop certification process for IoT and mHealth.

Andalusian Agency for Healthcare quality has implemented a labelling system for mHealth apps, which assesses the apps from the following aspects[14]*:*

- *Design and appropriateness (including accessibility, design and usability)*
- *Quality and safety of information (suitability for the audience, transparency and authorship, information update, content and information sources, risk management)*
- *Provision of services (technical support, e-commerce, bandwidth and advertising)*
- *Confidentiality and privacy.*

For more information, see http://www.calidadappsalud.com/en/

Several bodies have set up their certification/endorsement systems for mHealth apps in the Netherlands, however these are not supported by the national government. Examples include:

- GGD app store (www.ggdappstore.nl), a cooperative initiative between all local public health authorities to assess apps they find useful.

- The Dutch Portal for Health Promotion and Prevention (www.loketgezondleven.nl), developed by the Centre for Healthy Living provides information concerning public health interventions, including the eHealth and mHealth possibilities;

- The "Online Help Label" (www.onlinehulpstempel.nl), a certification for eHealth interventions in the field of mental health, including apps for psychic disorders. The label is offered by the Dutch Trimbos Insititute.

- The Medical App Checker provided by the Royal Dutch Medical Association provides frameworks for assessing the quality of medical apps and seeks to encourage the responsible use by physicians, patients and caregivers. It helps with targeted searches for suitable apps, to assess the reliability and quality of the app prior to downloading, and to assess the protection of personal data after downloading the app. The Medical App Checker focuses on apps that act as a medical device, tracking, tracing and monitoring apps, and also communication apps used for health purposes.

[14] Overview is based on Javier Ferrero Àlvarez-Rementeria's presentation „The Andalusian mHealth strategy" to the mHealth subgroup on 15th September 2016.

3.6 Evidence on mHealth

Even though the participating countries agree that generating evidence is important for uptake, reimbursement etc., little evidence has been generated on the cost benefits, cost effectiveness and other related aspects of mHealth. A CHARISMHA study has been carried out in Germany on the benefits and risks of mHealth apps. Several research programs exist in the Netherlands, the largest being managed by the Organisation for Health Research and Development. Some case studies have been conducted in France and UK, for example the latter has looked into the mobile working for community nursing staff.

CHARISMHA Chances and Risks of Mobile Health Apps is a research published by Hannover Medical School in 2016. The study looks into data protection and security, practical and regulatory hurdles, and ethical implications. It also provides an outline of possible ways to support different stakeholder groups (patients, medical professionals, developers).

For more information see http://www.bmg.bund.de/fileadmin/dateien/Downloads/A/App-Studie/charismha_abr_v.01.1e-20160606.pdf

France, Finland, and Croatia are planning to conduct such researches in the future. Finland's approach is to keep the threshold low for innovation to allow adoption, that in turn allows creating real-life evidence. In France evidence-gathering will be conducted in the framework of the eHealth strategy. Croatia is participating in an EU CIP project „CareWell"[15], which includes a cost-benefit analysis to be performed.

A number of projects funded by the Horizon 2020 are looking into opportunities of using mHealth for supporting active and healthy ageing (www.frailsafe-project.eu , www.preventit.eu, www.reach2020.eu, www.activeageing.unito.it, www.i-prognosis.eu , http://www.city4ageproject.eu/); supporting patient empowerment (http://nohow.eu/) and focus on transforming healthcare via procurement of mobile health solutions ((www.decipherpcp.eu , www.unwiredhealth.eu).

[15] http://www.carewell-project.eu/home.html

3.7 mHealth in Public Health Programmes, Primary Care and Hospitals

The implementation of mHealth applications in public health programmes, primary care and hospitals varies greatly between the respondents. For example, in Croatia mHealth is not used in public health programs as the national regulation on data security is still lacking.

Germany is utilizing several mHealth applications, mainly for prevention and informational services. The applications are financed by the single health funds, and include areas such as allergies, nutrition counselling, and dental recommendations. In the field of therapy and diagnosis there are less applications used, but some prominent examples include „Tinnitracks“, a treatment for Tinnitus patients; and „Caterna“, an app used for therapy of patients with amblyopia. mHealth technologies are also used in the treatment of diabetes patients.

Tinnitracks is an app that allows patients to filter their music to use for tinnitus therapy. It can be used for specific types of tinnitus diagnoses, and requires the patient's tinnitus frequency. The effectiveness of the therapy has been approved in clinical studies. For more information, see http://www.tinnitracks.com/en

The Netherlands are about to launch a pilot for iMediSense, a proactive monitoring of heart failure patients. An app in combination with various sensors has been developed in cooperation between Thales Netherlands, Hospital group Twente and University of Twente, assisted by Vodafone and health insurer Menzis.

Caterna is an online therapy platform for amblyopia, specially developed for children. It provides 90 days of daily vision training with configuration according to medical development, and it is a certified medical product. For more information, see http://caterna.de/en/

mHealth technologies are used by health professionals also in UK, Catalonia and Malta. In UK the mobile technologies are used to access guidelines, assist with risk calculating and measuring fluid balance. In Catalonia mHealth technologies are used to recommend adherence programs. Maltese health professionals use mHealth applications on their own discretion, to explore the compatibility of medicines.

Mobile devices are used by health workers in Denmark and Finland. However, in Finland currently the mobile devices still use web interface, and the connection point is to be built in the future. Portugal is putting more emphasis on patients – they work to facilitate introduction and improve the interactions of the National ePrescription Initiative with the patients, and they aim to create a country-wide notification system for public health situations.

The private sector has also taken up mHealth applications, for example in Ireland and France. In France, the bigger insurance companies (MGEN, AG2R, Malakoff-Mederic, Axa) are experimenting with and implementing the technologies. Initiative has also been taken by SMEs that have proposed innovative projects in the Future Investment Programme.

3.8 Projected Future Activities

Majority of the respondents are planning to implement mHealth related activities over the next 3 years, but the countries differ both in scope and scale. Ireland considered themselves to be at an early stage of developing eHealth and mHealth activities, so they could not confirm their future plans yet.

Several countries are making plans on the strategic level. For example, the aim set by Catalonia is to promote the concept of health transformation trough mHealth. Malta, Croatia, Germany and Estonia are about to develop ***strategic and/or action plans for mHealth***, although Malta and Germany stated it is still unknown to which extent and when the action plans will be developed and implemented.

France, UK and Portugal are concentrating on the development of ***classification and guidelines***. French Haute Autorité de Santé is working towards creating a label for mHealth applications and publishing guidelines based on evidence of medical benefit. UK intends to produce a toolkit for healthcare providers to assist with investment decisions. Portugal plans to build a database for mHealth applications with clear classification.

Finland and Portugal are focusing on the ***interoperability*** between mHealth applications and personal/electronic health records. The Danish citizens' health portal Sundhed.dk is commencing a mobile strategy. Denmark is also running a small proof-of-concept project regarding mobile apps for rendering prescription information to the citizens.

4. Activities in the Member States in the Horizontal Domains Related to mHealth

4.1. Governance, Legal Framework, Market Surveillance

Most countries do not have mHealth specific legislation implemented. Some countries consider that the wider legislation framework applies to mHealth, for example the general rules regarding health, product liability and data protection in Denmark; consumer protection, safety and liability in Germany; and legal obligations linked to the health data hosting in France. Maltese government has published a Mobile Government Green Paper, which also mentions mHealth.

Countries/regions that do have legislative and governance framework covering mHealth are UK, Catalonia and Finland. UK has set up an Information Governance toolkit, a code of practice for application developers. Catalonia also has an accreditation application model in place, and similarly, Finland has set certification criteria for mHealth applications.

When it comes to market surveillance initiatives the situation is similar- most countries have not set up such mechanisms. Generally, conducting surveillance would be the task of authorities working with medical devices, but adding extra tasks to them must be carefully planned. There are some existing activities in France, UK and Catalonia. The French Data Protection Authority is collaborating with the National Agency for Medicines and Health Products to conduct market surveillance for mHealth and IoT. UK runs a register for applications, with crowd-sourcing assessment and validation. Catalonia's accreditation model also includes functional and medical validations.

4.2 Data Protection

The majority of respondents see the need to address data protection issues specifically in the context of mHealth. Only two countries suggested that it is not necessary: Denmark stated that mHealth is „covered by the risk assessment and security by design within the regulation" and that they do not „see a need for specific legislation", and in Estonia the issues are covered by existing data protection regulations. Germany sees the current legal system, both on the European level (EU Data Protection Directive, General Data Protection Regulation) as well as on the national level to be sufficient, but they see the need to add actions to facilitate compliance. The Netherlands emphasized the necessity of developing a European-level federated data policy, as divergent and often conflicting policies artificially fragment the market and hinder innovation and economic development.

What needs to be defined are security levels, access, sharing and consent management (Croatia), and the use of mHealth-generated data for public research (Netherlands). The reasons for additional regulation development include the necessity to have a common understanding of the legislation (Catalonia), to reduce the risk of attacks (UK, Catalonia), and to align the applications on the private market with European data protection standards (Germany). It is also important to look into the terms and conditions for using and stopping the use of apps (Croatia).

Special data considerations should be applied to cases where mHealth devices are used as medical devices (Finland), or where the information shared can identify the patient (Portugal). France suggested developing a label that would address the data protection, as well as the medical aspects, while Germany feels that drafting the Code of Conduct by the European Commission is a good start to regulation development.

4.3. Digital Authentication and Authorization

When it comes to solutions for digital authentication (verifying the identity), and granting access, six respondents are already implementing some type of system. In most cases it is an eCitizen/eID solution (Croatia, Portugal, Malta, Finland, Denmark, Estonia). UK is currently looking into implementing an eID solution. Finland's digital authentication system includes health apps. In the Netherlands the authentication and authorization issues of mHealth are addressed within the other health information activities.

Portugal and Croatia are considering adapting the eCitizen/eID systems for mHealth applications, but additional work must be done to implement the solutions in mHealth. For example, Croatia's main concern is the lack of security regulation on health data access from mobile services. Also, Denmark feels that their current solution would not suit mHealth and „new standardized solutions supporting native mobile apps and Representational State Transfer (REST) services are needed". Estonia is currently not planning a dedicated solution for mHealth, but instead relies on universal mID, which is based on national eID - almost 10% of the population is using mID for identification and the number is growing fast.

Ireland is in the process of implementing an „individual health identifier", which would be a „key enabler for all eHealth and mHealth rollouts in the future". France has started with some experiments (for example with the dematerialisation of the European Insurance card), and is foreseeing solutions which would compose of a legal framework for defining obligations and

requirement, a multi-level repository. In Germany particular health identifiers are set for patients and health professionals. Developing a single identifier "for all domains would be highly critical under German law", and currently they are exploring if the current card-based special health identifier could be used with mHealth.

6 respondents stated they see a need to address mHealth specific authentication and authorization, as „health data is one of the most sensitive data and therefore the authentication and authorization standards have to correspond at a highest level" (Germany). The aspects that countries/regions want to see development are improvement of usability (Portugal), validation of different models of easy accessibility (Catalonia), eliminating possibility of abuse of technologies while keeping usability in mind (Germany). Malta emphasized that mHealth specific authentication and authorization are especially important in cases when the information that can identify the patient is shared. UK's expectation is to have a unified approach to the development of systems.

The HEART Working Group intends to harmonize and develop a set of privacy and security specifications that enable an individual to control the authorization of access to RESTful health-related data sharing APIs, and to facilitate the development of interoperable implementations of these specifications by others. For more information see http://openid.net/wg/heart/

In more detail, Denmark suggested utilizing the possession of a mobile phone or its SIM card for authorization. They also recommend considering the use of OpenID Connect, OAuth2 protocol and User-Managed Access protocol. France suggests adding the necessary role recognition of the health professional on top of generic eID. Work in this field is done within the eSENS project[16] and JAseHN work package on eID.

5. Areas for Collaboration

Based on the outcomes of the survey, the subgroup members see developing market surveillance initiatives as the most added-value area (6 respondents) for collaboration. This is

[16] The aim of "e-SENS is to facilitate the deployment of cross-border digital public services through generic and re-usable technical components, based on the building blocks of the Large Scale Pilots. The consolidated technical solutions, with a strong focus on e-ID, e-Documents, e-Delivery, Semantics and e-Signatures, aim to provide the foundation for a platform of "core services" for the eGovernment cross-border digital infrastructure foreseen in the regulation for implementing the Connecting Europe Facility". Retrieved from http://www.esens.eu/

followed by cooperation in the following fields: data protection (4), linking patient-generated data to electronic health records (4), certification/endorsement of mHealth apps (3), national strategies and action plans (3), generating evidence on mHealth (3), developing guidelines for developers (3), and legal and organisational framework (3). Also mentioned were developing guidelines or recommendations to users, digital authentication and authorization. Croatia explained that they are most interested in the experience of countries that already offer mHealth services and have set up the administrative, legal and service framework for it. As their potential contribution they see piloting and implementation of services.

Most respondents would prefer to conduct collaboration in the abovementioned fields in the framework of eHealth Network/JAseHN (8 responses). UK specified that even though mHealth cooperation would take place within JAseHN, it should be aligned with the eHealth Network. Second preferred cooperation option was within the H2020 program (5 responses). Croatia specified that H2020 projects could be suitable for analysing actual needs and expectations, and experiences in different countries. EU Health Programme[17] was mentioned 4 times.

The subgroup suggests the following areas to be further considered for future collaboration:

1. Promoting quality and supporting the use of mHealth in the health service provision

Since systems for **certification and endorsement** of health apps are in place or under preparation in several countries, the subgroup agreed that collaboration in this area is necessary to address market fragmentation. Although creating a harmonized certification system would be difficult, a mutual recognition could be envisaged in the future. The EU guidelines for assessing validity and reliability of mHealth apps, expected to be finalized by the beginning of 2017, could be a good base for future actions in this area. In the future, collaboration could also be considered for addressing the global market, for example under the EU-US Roadmap activities.

In addition, **training and education of health professionals and the general public** is important to raise awareness about the benefits of mHealth, to improve digital skills and digital health literacy. The sub-group suggests that a mapping of existing educational and training activities could be conducted and collaboration could be considered to create

[17] http://ec.europa.eu/health/programme/policy/2014-2020/index_en.htm

common training programmes for the health professionals. Also, bringing together health professionals to exchange knowledge and to come up with the guidelines or assessments on the use of mobile health apps within their area of expertise/specialty could be further explored.

Use of patient generated data in healthcare and linking data to the electronic health records is another topic of interest for exchanging information and experiences.

Best practices and approaches to facilitate the **interoperability** of the mobile devices and mobile health apps should be further considered as well.

The sub-group concluded that an overview of existing **evidence on the cost-benefits** of mHealth is needed to support uptake. Further actions could be discussed in the light of the existing initiatives and EU projects, for example those funded under H2020, and the prospective WHO-ITU mHealth hub, being set up under H2020 with the aim to support evidence gathering.

2. Governance, legal framework, market surveillance

As part of public sector governance role, there is interest to continue exchanging information on the issues related to the **legal frameworks** and **market surveillance or monitoring initiatives**. More specifically, collaboration and information exchange between health authorities and authorities responsible for market surveillance (for example, medical devices, consumer protection, data protection) could be facilitated.

In relation to data protection, the sub-group concluded that the General Data Protection Regulation framework is sufficient and mainly compliance issues need to be addressed. The Code of Conduct on privacy for health apps is useful and a follow up on its implementation is needed. Exchange of information on the practices related to data protection would be useful to monitor systematically the practical roll-out of General Data Protection Regulation in Member States in facilitating a coherent implementation of mHealth in Europe.

Digital authentication and authorisation is vitally important in mHealth and must meet the highest standards in view of the sensitive nature of health data. Where eCitizen/eID solutions meet the highest criteria they could also be considered appropriate. A follow up on the work within the eSENS project and the JAseHN work package on eID would be necessary, so that mHealth specific considerations would be taken into account.

In addition to regulatory approaches, information could be exchanged and further collaboration considered in relation to **innovation support** (innovation programs, gateways to app developers risk-capital funds,innovation funds) .

6. Next steps

The eHealth Network is invited to take note of the report and to decide to extend the mandate of the subgroup:

- to exchange knowledge and share information on the ongoing and prospective initiatives in the Member States
- to follow up on the ongoing actions at the EU level related to mHealth
- to further discuss the areas for collaboration to come up with specific recommendations or actions in certain areas with the view to add concrete actions in the next eHealth Network multiannual work plan and to be taken up by the Joint Action supporting the eHealth Network in the next phase.

Annex 1. Questionnaire to the Member States on mHealth strategies

Responses to this questionnaire will be used as an input for the report on national mHealth strategies to be produced for the 10th meeting of the eHealth Network (Nov 2016)

1. National strategies and action plans

Do you have a national strategy or action plan covering mHealth? *YES/NO*

1.1. If yes, please give a brief overview of the main focus, priorities or activities in relation to mHealth.

1.2. If no, please elaborate, if and why you plan (or not) to develop a strategy or action plan addressing mHealth.

2. Use of mHealth in the care pathways (prevention and treatment processes)

2.1. What kind of initiatives/solutions have you IMPLEMENTED (and to what extent) on:

a. Linking patient generated data (e.g health apps) to the electronic health records/personal health records *YES/NO, Please give further information*

b. Reimbursement of mHealth as part of service provision *YES/NO, Please give further information*

c. Training and education of health professional and/or general public *YES/NO, Please give further information*

d. Guidelines or recommendations to users (professionals, patient groups, general public) or developers *YES/NO, Please give further information*

e. Certification/endorsement of mHealth apps e.g to be recommended by health professionals, to be included in the clinical guidelines, for reimbursement purposes etc *YES/NO, Please give further information*

f. Generating evidence on mHealth e.g analysing cost-benefit, cost-effectiveness etc *YES/NO, Please give further information*

2.2. Please provide examples on how mHealth is used in your public health programmes or in the healthcare system in primary care and hospitals?

2.3. Please summarise briefly projected future activities over the next 3 years in the abovementioned domains.

3. Activities in the Member States in the horizontal domains related to mHealth

3.1. What kind of initiatives/solutions have you IMPLEMENTED (and to what extent) on:

a. Legal and organisational (governance) framework e.g covering consumer protection, safety and liability issues relating to health apps

Please give a brief description

b. Market surveillance initiatives, e.g for health apps which come under medical devices regulations

Please give a brief description

3.2. Do you see a need to address data protection issues specifically in the context of mHealth - are there any specific considerations that need to be taken into account in the framework of the General Data Protection Regulation? *YES/NO*

Please explain what specific actions are needed

3.3. What are the solutions in place (or under development) for digital authentication (=verifying the identity) and authorization (=granting access) and how feasible are these in the context of mHealth?

Please give a brief description

3.4. Do you see a need to address authentication and authorization specifically in the context of mHealth? *YES/NO*

Please explain what specific actions are needed

4. Areas for collaboration

4.1. In which areas do you see most added-value for collaboration between Member States (exchange of best practices, cooperation projects etc)?

a. National strategies and action plans
b. Linking patient generated data (e.g health apps) to the electronic health records/personal health records
c. Reimbursement of mHealth as part of service provision
d. Training and education of health professional and/or general public
e. Guidelines or recommendations to users (professionals, patient groups, general public)
f. Guidelines for developers
g. Certification/endorsement of mHealth apps
h. Generating evidence on mHealth

i. Legal and organisational (governance) framework
j. Market surveillance initiatives
k. data protection issues
l. digital authentication and authorization
m. other

Further comments on collaboration areas

4.2. In what format could this collaboration be taken forward (e.g under the EU Health Programme, H2020, other funding instruments etc)?
   a. eHealth Network/ JAseHN
   b. EU Health Programme
   c. H2020
   d. other

Further comments on the format of collaboration

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Definition of mobile health[18]

Mobile health (hereafter "mHealth") covers "*medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices"*.

It also includes applications (hereafter "apps") such as lifestyle and wellbeing apps that may connect to medical devices or sensors (e.g. bracelets or watches) as well as personal guidance systems, health information and medication reminders provided by sms and telemedicine provided wirelessly.

[18] *European Commission Green Paper on mHealth*
https://ec.europa.eu/digital-single-market/en/news/green-paper-mobile-health-mhealth

Annex 2. List of Respondents

1. Croatia: Ana Vrancic-Mikic, Croatian Health Insurance Fund-HZZO
2. Denmark: Thomas Rieneck, National Health Data Agency
3. Estonia: Indrek Jakobson, Ministry of Social Affairs
4. Finland: Teemupekka Virtanen, Ministry of Social Affairs and Health
5. France: Michele Thonnet, France
6. Germany: Niklas Kramer, Federal Ministry of Health
7. Greece: Athanasios Kelepouris, Ministry of Health
8. Ireland: Kevin Conlon, Department of Health
9. Malta: Euchar Sultana, Ministry for Health
10. Netherlands: Erwin Eisinger, Dutch Ministry of Health, Welfare and Sport
11. Portugal: Tome Vardasca, SPMS - Serviços Partilhados do Ministério da Saúde
12. Spain/Catalonia: Francesc Garcia Guyas, TicSalut Fundatión
13. Spain/Andalusia: Javier Ferrero Alvarez-Rementeria, Andalusian Agency for Healthcare quality
14. United Kingdom: Jeremy Thorp, Health and Social Care Information Centre

Annex 3. Country Profiles

Croatia

National strategy/action plan	No. mHealth is mentioned in the Strategic Plan for eHealth Development, but no clear goals or implementation plans.
Use of mHealth in care pathways	
Linking data to electronic health records	Yes, planning a platform for various applications to connect to the electronic healthcare records.
Reimbursement of mHealth	No
Training and education	No, but training will be conducted when the platform is ready for use.
Guidelines and recommendations	No
Certification and/or endorsement	No, but the certification infrastructure for eHealth could be re-used.
Generating evidence	No, but is gathered during EU CIP project "CareWell".
Examples of mHealth use	None, due to undefined regulation on data security.
Planned activities	No concrete plans, but to establish a working group to define mHealth goals and an action plan.
Horizontal activities	
Legal and organisational framework	None
Market surveillance	None
Data protection issues	Need to define what data can be accessed with which security level, which data can be sharedand how to develop effective consent management. Also data protection in cases of theft, breach of security on device, and terms and conditions for using and ceasing to use the apps.
Authentication and authorization	eCitizens program could be re-used for mHealth purposes. Need to address lack of security regulation.
Collaboration	
Areas for collaboration	National strategies and action plans. Legal, data protections, authorization and authentication, organizational and certification.
Framework for collaboration	eHealth Network/JAseHN EU Health Programme H2020

Denmark

National strategy/action plan	No, as the national strategy mainly focuses on telemedicine
Use of mHealth in care pathways	
Linking data to electronic health records	No
Reimbursement of mHealth	No mHealth specific reimbursement, mHealth considered part of general health system.
Training and education	Yes, general education to public regarding digitization.
Guidelines and recommendations	Yes, a reference architecture regarding security and collection of data in patients' homes.
Certification and/or endorsement	General decision to use the Continua framework
Generating evidence	Individual analysis of business cases
Examples of mHealth use	Mobile devices used by health workers in primary care and in hospitals.
Planned activities	Small proof-of-concept project on mobile app for prescription information. Mobile strategy for citizens' health portal Sundhed.dk
Horizontal activities	
Legal and organisational framework	mHealth covered by the general rules regarding health, product liability and data protection.
Market surveillance	No initiatives
Data protection issues	mHealth covered by the risk assessment and security by design within the regulation, no need for mHealth specific legislation.
Authentication and authorization	Current solutions not well suited for mHealth, new standardized solutions supporting mobile apps and REST services needed. Using mobile phone or SIM card as an authentication factor and use of OpenID Connect, Oauth2 & UMA should be considered.
Collaboration	
Areas for collaboration	Guidelines for developers Governance and legal framework Market surveillance Data protection Digital authentication and authorization
Framework for collaboration	eHealth Network/JAseHN H2020

Estonia

National strategy/action plan	No, but part of eHealth Strategy.
Use of mHealth in care pathways	
Linking data to electronic health records	No, but work in progress.
Reimbursement of mHealth	No
Training and education	Yes, going on continuously.
Guidelines and recommendations	No
Certification and/or endorsement	No
Generating evidence	No
Examples of mHealth use	None
Planned activities	Creating an mHealth programme and activity plan
Horizontal activities	
Legal and organisational framework	None
Market surveillance	None
Data protection issues	Covered by the general data protection regulation.
Authentication and authorization	None
Collaboration	
Areas for collaboration	Linking patient-generated data to electronic health records
Framework for collaboration	EU Health Programme

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France

National strategy/action plan	Yes, objective to promote the use of mHealth and IoT and tools that haveproved to have medical benefits.
Use of mHealth in care pathways	
Linking data to electronic health records	Yes, several projects on local or regional level
Reimbursement of mHealth	Yes, for specific cases (monitoring breathing problems, surveillance of diabetes, lung cancer metastases)
Training and education	Yes, legal obligation to include IT an computerise systems into medical training.
Guidelines and recommendations	Yes, being developed by *Haute Autorité de Santé* Also private initiatives (Medappcare, DMD).
Certification and/or endorsement	Yes, ongoing work for non-mandatory certification.
Generating evidence	Planned, as part of the eHealth strategy
Examples of mHealth use	Currently implemented by and/or experimented with insurance companies.
Planned activities	Plan to issue a label, and publish guidelines/best practices based on evidence of medical benefit.
Horizontal activities	
Legal and organisational framework	Legal obligations for health data hosting for storing health data outside the premises of healthcare providers. Planning a certification process to follow the national health information system security framework.
Market surveillance	Responsibility of the French Data Protection Authority and the national Public Agency for Market Surveillance and Medical Devices.
Data protection issues	Interest in developing a label to address data protection and medical/care.
Authentication and authorization	Proposing a set of instruments consisting of a legal framework defining obligations and requirements, and a multi-level repository. Need to add role recognition of health professionals on top of eIDAS generic eID.
Collaboration	
Areas for collaboration	National strategies and action plans Guidelines or recommendations for users Guidelines for developers Certification/endorsement Generating evidence

	Governance and legal framework Market surveillance
Framework for collaboration	eHealth Network/ JAseHN H2020

Finland

National strategy/action plan	Yes. Emphasizing people's role in wellness and health, mobile devices are essential to that development.
Use of mHealth in care pathways	
Linking data to electronic health records	No, but in implementation phase.
Reimbursement of mHealth	Yes, if considered part of a reimbursable treatment.
Training and education	No
Guidelines and recommendations	Yes, certification criteria for mHealth to be connected to healthcare services.
Certification and/or endorsement	No, but in preparation.
Generating evidence	No, but in preparation.
Examples of mHealth use	Currently mobile devices use web interface, a connection point for external mHealth services is being built.
Planned activities	Connection point for mHealth applications.
Horizontal activities	
Legal and organisational framework	Certification criteria for mHealth apps
Market surveillance	
Data protection issues	Need to address mHealth devices that are used as medical devices.
Authentication and authorization	National digital authentication system being used in healthcare apps.
Collaboration	
Areas for collaboration	Certification/endorsement
Framework for collaboration	eHealth Network/ JAseHN

Germany

National strategy/action plan	Yes, part of strategy to digitialize the health care system. Focus on empowering patients, quality improvement and cost saving.
Use of mHealth in care pathways	
Linking data to electronic health records	The German eHealth competence centre is currently analysing options for compatibility commercial smart phones with data security standards of the infrastructure.
Reimbursement of mHealth	Several options, decided within the self-administrative structures within the health care system.
Training and education	Part of eHealth strategy, conducted by a range of organisations.
Guidelines and recommendations	Yes. The Federal Institute for Drugs and Medical Devices is to become the first contact point for developers to guide them through the law on medical devices.
Certification and/or endorsement	No
Generating evidence	No, but an extensive study on chances and risks of mobile applications has been conducted.
Examples of mHealth use	Variety of apps used for prevention and informing: nutrition counselling, dental care, allergies. “Tinnitrack”-App for Tinnitus patients, “Caterna” for patients with amblyopia. Solutions for diabetes patients.
Planned activities	Development of the action plan formHealth.
Horizontal activities	
Legal and organisational framework	Included in general regulation of consumer protection, safety and liability issues.
Market surveillance	Conducted by regional states.
Data protection issues	Need to address the compatibility with European data protection standards and rules of the German health system.
Authentication and authorization	Currently there are particular health identifiers for patients and health professionals. The German eHealth competence centre is currently looking into if and how to use the current card-based health identifier with mHealth technologies.
Collaboration	
Areas for collaboration	National strategies and action plans

	Generating evidence Market surveillance Data protection
Framework for collaboration	eHealth network/ JAseHN EU Health Programme H2020

Greece

National strategy/action plan	No. mHealth currently not a priority, but will be taken up later.
Use of mHealth in care pathways	
Linking data to electronic health records	No
Reimbursement of mHealth	No
Training and education	No
Guidelines and recommendations	No
Certification and/or endorsement	No
Generating evidence	No
Examples of mHealth use	
Planned activities	
Horizontal activities	
Legal and organisational framework	
Market surveillance	
Data protection issues	
Authentication and authorization	
Collaboration	
Areas for collaboration	Linking patient-generated data to electronic health records.
Framework for collaboration	eHealth Network/ JAseHN

Ireland

National strategy/action plan	No, but incorporated in the eHealth Strategy.
Use of mHealth in care pathways	
Linking data to electronic health records	No
Reimbursement of mHealth	No
Training and education	No
Guidelines and recommendations	No
Certification and/or endorsement	No
Generating evidence	No
Examples of mHealth use	No coordinated central approach, but some activities in the non-public health area.
Planned activities	Currently too early stage of development for significant projects.
Horizontal activities	
Legal and organisational framework	
Market surveillance	
Data protection issues	Need for significant development of legislation with the advent of the EU Data Protection Regulation.
Authentication and authorization	Currently implementing an individual health identifier for patients.
Collaboration	
Areas for collaboration	Data protection
Framework for collaboration	eHealth Network/ JAseHN

Malta

National strategy/action plan	No, but about to start developing a national mHealth strategy.
Use of mHealth in care pathways	
Linking data to electronic health records	No
Reimbursement of mHealth	No
Training and education	No
Guidelines and recommendations	No
Certification and/or endorsement	No
Generating evidence	No
Examples of mHealth use	Doctors using apps to identify compatibility of prescription medicines at their own discretion.
Planned activities	To develop, publish and implement the mHealth strategy.
Horizontal activities	
Legal and organisational framework	A Mobile Government Green Paper
Market surveillance	None
Data protection issues	Need to address the issue of identifying the patient by the information shared.
Authentication and authorization	e-ID authentication. Need to address the issue of identifying the patient by the information shared.
Collaboration	
Areas for collaboration	Certification/endorsement of apps
Framework for collaboration	EU Health Programme

Netherlands

National strategy/action plan	Yes, but there is no differentiation between mHealth and eHealth. Focusing on information standards, reducing financing barriers, sharing knowledge and increasing awareness.
Use of mHealth in care pathways	
Linking data to electronic health records	Few local/regional patient portals and platforms that link to generated data. Launched the MEDMIJ program to create an interoperable environment.
Reimbursement of mHealth	Flexible financing, so mHealth can become part of reimbursement if agreed between insurer and provider. Also experimenting with new financing mechanisms.
Training and education	eHealth training is voluntary. Advisory on educating health and care workforce about to be published.
Guidelines and recommendations	Some, developed by professional bodies and multi-stakeholder programs. For example "Guideline for the development of quality guidelines in health care" contains eHealth.
Certification and/or endorsement	Not nationally supported, but a variety of systems (GGD app store, loketgezondleven.nl, online help for e-interventions in mental health, the Medical App Checker)
Generating evidence	Several research programs.
Examples of mHealth use	"The Box" – a home monitoring equipment for cardiac rehabilitation. iMediSense – an app in combination with various sensors for heart failure patients. A "Living Lab" for caregivers to experiment with apps, Fitbits, e-coaching modules etc.
Planned activities	To increase role of personal health records and integrate them with professional systems.
Horizontal activities	
Legal and organisational framework	None
Market surveillance	The Dutch Health Inspectorate conducts scans and local inspections
Data protection issues	Need for a federated European data policy. Need to provide patients/consumers with more information about re-using their data for research purposes.
Authentication and	Addressed in the framework of other health information

authorization	activities
Collaboration	
Areas for collaboration	National strategies and action plans Linking patient-generated data to electronic health records Guidelines for developers Generating evidence Legal framework and governance Market surveillance Data protection
Framework for collaboration	eHealth Networks/ JAseHN H2020

Portugal

National strategy/action plan	Yes, focus on portability of the electronic health record and improving the patients' literacy using health services.
Use of mHealth in care pathways	
Linking data to electronic health records	Yes
Reimbursement of mHealth	Yes
Training and education	Yes
Guidelines and recommendations	Yes
Certification and/or endorsement	Yes
Generating evidence	Yes
Examples of mHealth use	Facilitating introduction and interactions of the National ePrescription Initiative with the patients. Creating a country-wide notification system for public health.
Planned activities	To provide classification and a database for mHealth apps. To provide apps a way to export data to electronicealth records. To develop a study on the influence of medical notifications on public health.
Horizontal activities	
Legal and organisational framework	None
Market surveillance	None
Data protection issues	Need to address data protection issues.
Authentication and authorization	Using national eID infrastructure. Providing a custom identity service based on assumptions that give "almost" the same assumption as the eID infrastructure.
Collaboration	
Areas for collaboration	Market surveillance
Framework for collaboration	H2020

Spain/Andalusia

National strategy/action plan	YES, strategy for quality and safety for health apps was launched in 2012. In 2013 the quality labelling system, Appsaludable distinctive was released. In 2014 these regulation initiatives were complemented with integration and personalization mHealth projects, conforming the Andalusian mHealth strategy, focused on the creation of a corporate mHealth service hub, open to third party services aimed to be integrated with the eHR in Andalusia.
Use of mHealth in care pathways	
Linking data to electronic health records	NO, currently piloting diverse projects (drug management, surgery verification lists, blood donation, etc). Full scale deployments are envisaged for early 2017
Reimbursement of mHealth	YES, a part of the business processes defined to create the corporate mHealth repository, the reimbursement models are tackled through commercialisation agreements with third parties.
Training and education	NO, currently launching some mHealth surveys to be aware of the status of citizens' and healthcare professionals' mHealth literacy.
Guidelines and recommendations	YES, published since 2012 at www.calidadappsalud.com (translated to English). They are aimed at all stakeholders (healthcare professionals, app developers and citizens).
Certification and/or endorsement	YES, with our own App catalogue, published under www.calidadappsalud.com
Generating evidence	No
Examples of mHealth use	
Planned activities	As a result of the full-scale integration project that will be delivered in early 2017, business models will be tried and deployed within all the territory.
Horizontal activities	
Legal and organisational framework	A governance model covering several aspects: Quality and safety certification; Integration issues; Personalisation of services to citizens etc
Market surveillance	Under the certification scheme, those apps under the medical device legislation will be reviewed, requiring compliance with current regulation plus several criteria not included in MD legislation.
Data protection issues	compliance with current and future regulation would be enough. There is a clear need of market surveillance, because there are no mechanisms (apart from those from market owners) to ban apps.
Authentication and authorization	Currently deploying authentication solutions based on: Digital certificates in mobility; Spanish Id card 3.0 (DNI 3.0), using NFC technology; Two factor authentication (Cl@ve), a centralised initiative from the Spanish Central

	Health Ministry This is a key point, not solved at all at the moment. There is no strong authentication standard easy to deploy for the majority of the population.
Collaboration	
Areas for collaboration	National strategies and action plans Reimbursement of mHealth as part of service provision Training and education of health professional and/or general public Certification/endorsement of mHealth apps Generating evidence on mHealth Legal and organisational (governance) framework Market surveillance initiatives
Framework for collaboration	eHealth Network/ JAseHN EU Health Programme H2020

Spain/Catalonia

National strategy/action plan	Yes, part of Master eStrategic Plan Aim to develop a market place with an accreditation model and a Health Platform of mobility
Use of mHealth in care pathways	
Linking data to electronic health records	Yes, about to initialize such projects
Reimbursement of mHealth	No
Training and education	Yes, about to initialize mHealth courses through professional associations
Guidelines and recommendations	Yes
Certification and/or endorsement	Yes, a model of accreditation under the CE Commission framework
Generating evidence	No
Examples of mHealth use	Recommending adherence programs
Planned activities	Introduce the culture of Health transformation using mHealth
Horizontal activities	
Legal and organisational framework	Accreditation APP model based in legal rules
Market surveillance	The accreditation model includes functional/medical validations
Data protection issues	Need to set a legal vision and address interpretations of different laws
Authentication and authorization	Currently using digital authentication Need to validate different models of easy accessibility
Collaboration	
Areas for collaboration	Linking patient-generated data to electronic records
Framework for collaboration	EU Health Programme

United Kingdom

National strategy/action plan	Yes, part of plan for eHealth Includes stimulating the apps' market, advice and guidance for suppliers and purchasers
Use of mHealth in care pathways	
Linking data to electronic health records	Yes, on small scale for particular conditions
Reimbursement of mHealth	Discussion, no decision yet
Training and education	Planned, starting with health professionals
Guidelines and recommendations	Yes, for professionals and suppliers
Certification and/or endorsement	Yes, but there is caution about how it will be managed
Generating evidence	Yes, some case studies
Examples of mHealth use	Access to guidelines, risk calculation, fluid balance
Planned activities	A toolkit for healthcare providers for investment decisions
Horizontal activities	
Legal and organisational framework	Information Governance toolkit, code of practice for app developers
Market surveillance	Register of apps, with crowd-sourcing assessment and validation
Data protection issues	Need to address insufficient security measures
Authentication and authorization	Looking at implementing citizen ID
Collaboration	
Areas for collaboration	Market surveillance
Framework for collaboration	eHealth Network/ JAseHN