

mHealth subgroup suggestions for future work

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1. Introduction

The eHealth Network formed the mHealth sub-group in November 2015 and it presented a [report on national mHealth strategies](#) to the 10th eHealth Network meeting on 21 November 2016. The report includes an overview on the mHealth developments in Member States as well as suggestions on the areas for future collaboration.

At the 10th eHealth Network meeting the mandate of the mHealth sub-group was extended and the group was tasked to come up with proposals for concrete actions in the field of mHealth.

The current report outlines a comprehensive set of actions that the mHealth subgroup considered necessary to support **mHealth as an engine for health system transformation through empowered citizens**.

The main effects of mHealth are the changes in work processes with increased disentanglement of care interactions from care institutions and related data processing outside of ICT networks controlled by care facilities. Both health systems and health information systems need to adapt to this new context and meet the specific requirements. Given the rapid developments in the area and potential need for coordinated approaches, it is important to follow closely the deployment of mHealth solutions in healthcare and reinforce the cooperation among Member States in this field.

The report further specifies and focuses on actions that should be taken forward by the eHealth Network via its Multiannual Work Programme 2018-2021 and the Third Joint Action supporting the eHealth Network. Support from the European Commission, the Member States and many other stakeholders is necessary for the implementation of these activities and for the development and promotion of mHealth to support health policy objectives.

2. Proposed actions for collaboration

The mHealth subgroup carried out a mapping of possible actions and related existing initiatives. The overview of the mapping is in Annex 1. Some of the actions that are specific to mHealth could be included in the new eHealth Network Multiannual Work Programme 2018-2021 and implemented via the 3rd Joint Action supporting the eHealth Network. Other actions, where other initiatives already exist or are planned, should be taken forward by other mechanisms in order to avoid overlapping or duplication of effort.

2.1 Actions for the Multiannual Work Programme 2018-2021 and the 3rd Joint Action supporting the eHealth Network

Common assessment framework for coordinated mHealth app endorsement

In several countries, initiatives are underway to set up schemes for mHealth app assessment in order to provide guidance to the professionals and general public on “good apps” or to integrate them into the mainstream health care provision by linking them to the public health platforms.

The benefit of developing a common assessment framework would be to harmonise the practices in different Member States as much as possible, in order to reduce market fragmentation and the administrative burden for both the MS competent authorities and the app developers. This framework could for example include the main aspects or quality criteria considered by the MS competent authorities in the assessment (e.g privacy, interoperability etc) and a minimum common dataset as regards the information and evidence required from the app developers. Bearing in mind that setting up such schemes and how the assessment is carried out (content, organization, outcome etc) is an exclusive competence of each MS, the framework needs to be flexible enough to be adaptable to concrete local contexts. For example, the outcome of the assessment could be quality labelling, a positive list of endorsed apps or linking apps to the public health platform, depending on the local decisions. A common baseline could facilitate the assessments and avoid duplication of effort, e.g in case an app has been already assessed in one of the MS, a lighter procedure could be foreseen. The framework would also assist those MS, which do not yet have a system in place and are only starting the process in their country.

Other initiatives such as the Privacy Code of Conduct for app developers and the EU eHealth Interoperability Framework could feed into and be linked to the assessment framework.

A collaboration platform for coordination and knowledge exchange

In addition, a support action for system-level capacity building and coordination could be foreseen in the 3rd Joint Action to support best practice dissemination and information exchange among Member State national and regional bodies.

This could include knowledge exchange supporting **best-practice dissemination on** personal data and consumer protection in mHealth, including technical solutions for authentication and authorisation, data governance etc. Such platform could also serve as monitoring tool for real-life implementation and impact of mHealth on modernizing of health systems. If a health app has been assessed in accordance with a common framework by one country – a common platform for publicizing that assessment for the benefit of all other countries (and their citizens) could be useful.

Following topics could be covered under the platform:

- Regular assessment survey of mHealth uptake & impact assessment
- Practices and implementation of interoperability framework and standards

- Implementation of regulatory frameworks related to the medical devices and protection of personal data
- Data governance practices (including authentication and authorisation)
- Facilitating the creation of quality guidelines for health apps, orientation and training programmes by and for health professionals and health professional scientific communities in their respective specialities

The collaboration platform is therefore to evolve also towards providing value for the medical specialists, professionals, health organisations and scientific societies to exchange knowledge develop guidelines or assessments in their specific domains and to support the integration of mHealth tools in clinical guidelines.

JAsEHN and the European Commission could be given the task for elaborating a concrete concept for such a platform including an analysis of the practicability as well as cost analysis of such a platform.

Interoperability and standards development

mHealth specific considerations related to interoperability and standardisation should be covered in the eHealth Network MWP 2018-2021 under the actions related to interoperability and standardisation which is a horizontal topic. There was interest among members to do a mapping of existing standards (HL7 FHIR, ISO, PAS) to facilitate their use and to exchange information among Member States on important developments and best practices to facilitate the interoperability of the mobile devices and mobile health apps.

In addition, the implementation of standards and interoperability framework could be facilitated by support of collaboration between active Member States.

2.2 Other actions

Training, education and awareness raising

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.

As digital skills is a topic that is related to eHealth adoption in general and several initiatives already exist at the EU level, no specific action is suggested for mHealth related training and awareness raising in the eHealth Network MWP. However, exchange of experiences on training programmes could be foreseen under the collaboration platform.

Health system outcome monitoring

A systematic overview of existing **evidence on the cost-benefits of mHealth** is important to support uptake. Further actions should be considered in the light of the existing initiatives and EU projects, for example those funded under H2020, and the prospective WHO-ITU mHealth hub¹, being set up under H2020 with the aim to support evidence gathering.

A mapping and exchange of experiences related to the **use of patient generated data** in the clinical setting and linking the data to EHR could be foreseen under the collaboration platform.

Funding instruments to support system-wide implementation

While exchange of knowledge on funding instruments and reimbursement models that support system-wide implementation is considered important, no specific action is proposed for the new MWP. As this topic is closely related to the evidence generation on cost-benefits of mHealth and the implementation of national mHealth strategies, evidence generation and knowledge exchange could be supported by the future WHO/ITU mHealth hub.

¹ For further details please refer to the Deliverable D8.1.2 : « Information paper on WHO eHealth Initiatives and programmes »

Annex 1 Mapping of possible actions and related initiatives

	Possible actions	Implementation	Related initiatives/ Comments
1. Coordination activities			
1.1 Common assessment framework for coordinated mHealth app endorsement			
Common framework for the assessment/ endorsement of health apps	3 rd Action	Joint	<p>Validity and reliability guidelines facilitated by DG CONNECT</p> <p>Privacy Code of Conduct for app developers facilitated by DG CONNECT</p> <p>Regional/National existing certification/ accreditation schemes</p>
Collaboration platform to exchange knowledge and coordinate approaches to mHealth assessment and capacity building	3 rd Action	Joint	<p>A platform for exchange for those organisations assessing apps to exchange knowledge and practical experiences related to app assessment and endorsement. Possible online platform, meetings, twinnings etc</p> <p>Other topics possibly to be covered:</p> <ul style="list-style-type: none"> • Interoperability and standards • Training programmes for health professionals • Regulatory issues related to the medical devices, data protection • Authentication and authorisation

<p>Collaboration platform for health professionals to exchange knowledge and develop guidelines or assessments on the use of mobile health apps</p>	<p>3rd Joint Action (H2020 CSA ?)</p>	<p>Cooperation among medical specialists, health organisations or scientific societies to promote exchange of knowledge and the development of guidelines and to introduce mHealth in respective clinical guidelines.</p>
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1.2 Interoperability and standardisation

<p>Mapping of existing standards relevant for mHealth and identifying standardization needs</p> <p>Recommendations on the EU and MS level actions to facilitate interoperability (e.g. to introduce interoperability requirements in public procurement)</p> <p>Proposals for updating the EU eHealth Interoperability Framework and the Rolling Plan for ICT standardisation</p>	<p>3rd Joint Action</p>	<p>Commission Communication “ICT Standardisation Priorities for the DSM” (“The Commission will encourage actions to promote the security, safety and interoperability of mHealth apps”)</p> <p>EU eHealth Interoperability framework</p> <p>EC Rolling Plan for ICT standardisation</p> <p>European standard on quality criteria for the development of health and wellness apps (based on PAS:277) – work in process by CEN</p> <p>International Standard IEC 82304-1:2016 (safety and security of health software products)</p> <p>IHE Profiles for referencing in public procurement</p> <p>Continua Design Guidelines for personal connected health devices and systems</p> <p>GSMA report “Digital Healthcare interoperability” (Oct 2016)</p> <p>SANTE study on telemedicine (results expected by the end of 2017)</p>
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2. Awareness-raising and capacity building		
2.1 Training and education of general public, health professionals, technology experts and decision-makers		
Mapping of existing training activities and needs related to digital skills as part of continuous professional development in the MS	Exchange of knowledge under action 1.1	Action plan for EU health workforce Working group on European workforce for health European Health Parliament report on Digital skills for health professionals Study concerning the review and mapping of continuous professional development and lifelong learning for health professionals in the EU
Develop common tools for the training of health professionals and awareness campaigns for the general public	Exchange of knowledge under action 1.1	Digital skills as part of continuous professional development (CPD) and life-long learning (LLL) Training programmes on the benefits and use of digital tools (e.g MOOCs)
2.2 Knowledge exchange supporting best-practice dissemination on personal data and consumer protection in mHealth (including technical solutions for authentication and authorisation, data governance etc)		
Monitoring and exchange of information on regulatory issues related to medical devices	Exchange of knowledge under action 1.1	MDEG Software Group facilitated by DG GROW Facilitating collaboration and information exchange between health authorities and authorities responsible for market surveillance (for example, medical devices, consumer protection, data protection)
Exchange of information on the practices related to data protection , to monitor systematically the practical roll-out of General Data Protection Regulation in Member	Exchange of knowledge under action 1.1	Privacy Code of Conduct for app developers facilitated by DG CONNECT Art 29 WP guidelines on data portability

States		ENISA guidelines for SME-s on the security of personal data processing
<p>A mapping of existing technical solutions and issues related to digital authentication and authorisation (specific to mobile devices)</p> <p>Recommendations on mHealth specific considerations related to authentication and authorization</p>	Exchange of knowledge under action 1.1	<p>eSENS JAseHN task 5.2.1 (eID specific framework for eHealth)</p> <p>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.</p>
2.3 Health system outcome monitoring (including cost-benefit analysis and maturity assessment)		
A study mapping the available evidence and the existing methodologies and tools for outcome monitoring	WHO/ITU mHealth hub	<p>H2020 projects (a list of mHealth projects to be provided by DG CONNECT)</p> <p>WHO/ITU mHealth Hub</p> <p>JAseHN Deliverable D8.1.2 : « Information paper on WHO eHealth Initiatives and programmes »</p> <p>SANTE study on telemedicine (economic benefits)</p>
Recommendations to the MS for monitoring and measuring the outcome of the mHealth initiatives	WHO/ITU mHealth hub	<p>Existing monitoring frameworks:</p> <p>WHO mERA checklist for mobile health evidence reporting and assessment of mHealth interventions</p> <p>JAseHN Deliverable D8.1.2 : « Information paper on WHO eHealth Initiatives and programmes »</p> <p>MAFEIP – Monitoring and Assessment Framework for the European Innovation Partnership on AHA</p>

		<p>MAST - Model for Assessment of Telemedicine</p> <p>Nordic Council of Ministers report “Nordic eHealth Benchmarking”</p> <p>OECD Patient Reported Indicators Survey (PaRIS)</p>
Mapping the existing practices in the MS on the use of patient generated digital data	Study	The study could, for example, explore practices related to linking patient generated digital data (from wearables, apps, remote monitoring devices etc) to the EHR, use of PHR systems, personal information management services and other available tools. Also perceptions and expectations of different actors (professionals, patients etc) could be further explored.
Recommendations on the best practices related to the use of patient generated digital data in healthcare		<p>This could cover linking patient generated data to the EHR and use in the clinical setting</p> <p>Deliverables of the JAseHN on Patient access to EHR and health data portability (task 7.5)</p>
3. Investment and financial support measures for innovation and uptake		
3.1 Funding instruments to support system-wide implementation of mHealth		
Collect evidence and exchange information on possible reimbursement models and frameworks to support system-wide implementation	WHO/ITU mHealth hub	<p>This action could be included in the support measures provided by the WHO/ITU mHealth hub in relation to the implementation of national strategies</p> <p>JAseHN Deliverable D8.1.2 : « Information paper on WHO eHealth Initiatives and programmes »</p>
3.2 Information exchange on innovation programs and gateways for app developers		

<p>Mapping of MS initiatives related to the innovation support measures</p> <p>Recommendations on best practices related to innovation support measures</p>		<p><u>Blueprint on Digital Transformation of Health and Care for the Ageing Society</u></p> <p>Innovation support in broader terms, not only funding but also e.g third party access to data (APIs, open data etc), communication of public health needs and priorities to the technology developers, support cooperation between health care providers and innovator/technology developers</p>
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