mHEALTH:
COCIR RECOMMENDATIONS
FOR AN EFFECTIVE DEPLOYMENT

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COCIR, the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

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INTRODUCTION

In its 2018 Communication on the digital transformation of health and care,[1] the European Commission set out to deliver citizen's secure access to, and sharing of, health data across borders. This will provide better data for advancing research, prevention and personalised care and for creating digital tools that empower citizens and provide person-centred care. Deploying mHealth can help make the digital transformation of health and care a reality, and will support the Commission in delivering on its ambitions.

The ubiquitous availability and use of mobile devices, such as smartphones and connected personal health devices, can accelerate patient-centred care. However, standards-based interoperability will be essential in deploying mHealth to the maximum effect.

To allow mHealth to truly deliver genuine clinical value and support a patient-centred care model, the core applications must be able to communicate with the full range of systems used in day-to-day medical practice.

The importance of interoperability of Electronic Health Records (EHRs) was clearly acknowledged by the European Commission in its Communication, where it proposed to use open exchange formats to drive this as a priority.

This document sets out industry recommendations for ensuring and advancing mHealth interoperability. However, mHealth addresses the "last mile" to the patients and the health professionals. Its successful implementation depends on a well-established eHealth infrastructure. This will ensure that the information flows freely between the various participants in the patient care pathway and that it is available to the mHealth applications. Therefore, a number of the recommendations made in earlier COCIR publications remain relevant for the implementation of mHealth.[2]

> *"Standards-based interoperability will be essential deploying mHealth to the maximum effect."*

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1. Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society
2. We are all in this together: Advancing eHealth Interoperability

EXECUTIVE SUMMARY

Mobile devices and applications in health – mHealth - have an increasingly important impact in the growing trend towards digitising various aspects of healthcare. mHealth offers a channel for reaching out to the citizen or the patient during their day-to-day lives. It can provide access to both personal and generic health-related information, engaging the citizen and soliciting responses, or encouraging changes that will contribute to a better health.

mHealth also has an increasingly important role in exchanging data between different stakeholders. It provides rapid access to real-world data, reports on outcomes and allows patients to take active control of their health data and share it with others as they see fit.

We first reviewed the most common approaches to interoperability and took stock of the existing challenges and opportunities, which identified the need for a more strategic approach. We also analysed what has been learned in eHealth over the last 20 years.

We make several industry recommendations that are specific to the topic of interoperability for mHealth. These, COCIR believes, will accelerate deployment of mHealth-centric projects by reducing the risks and costs generated by uncoordinated approaches to interoperability.

These recommendations take into account the fact that various stakeholders are already engaged in deployment projects. In particular, they recognise that the policy maker perspective may have assumed – possibly prematurely - that health-centric applications differed little from existing consumer applications.

COCIR RECOMMENDS THAT THE EUROPEAN COMMISSION, MEMBER STATES AND OTHER KEY STAKEHOLDERS:

1. **Collaborate** with each other, and with local stakeholders, on steering mHealth interoperability in individual Member States or at EU level.

2. **Set** stakeholder engagement rules by fostering a use case-based approach to interoperability.

3. **Define**, for each use case, a brief interoperability specification referencing open, international interoperability profiles that can be recommended for use in tendering and procurement.

4. **Educate** stakeholders, such as mHealth architects, project leaders, manufacturers, start-ups and care providers.

5. **Identify**, based upon high-priority use cases, the organisational and policy changes needed to effectively deploy and foster implementation of mHealth.

1. THE CURRENT mHEALTH DEPLOYMENT STATE

When assessing the maturity of mHealth deployment, many mobile-based services have been introduced in silos. These have often adopted limited pilot deployments that, in many cases, have not seen subsequent broader deployment.

The European Commission published a Green Paper on mHealth[3] in 2014. This forecast rapid adoption, stating that:

"As for mHealth revenues, a joint analysis by GSMA and PwC projects that the global mHealth market will reach the equivalent of US$ 23 billion in 2017, with Europe accounting for US$ 6.9 and Asia-Pacific for US$ 6.8 billion, ahead of the North American market of US$ 6.5 billion. According to that report, remote monitoring treatment solutions constitute almost 60% of the total mHealth deployments in Europe. Solutions that increase the efficiency of healthcare workforce and systems make up nearly 15% of overall deployments, alongside health and wellbeing apps."

Subsequently, it has become clear that although there has been some progress, it did not proceed at the predicted rate.

The three areas that saw the greatest growth were:

· Personal wellbeing apps on smartphones, which allow users to self-monitor specific vital signs and assist patients in managing a specific condition or disease. Here, uptake has expanded rapidly.

· Health professional mobile apps that extend existing health IT systems (hospital medical records, RIS/PACS), or that make mobile phone-based diagnosis devices, such as ultrasound scanners, available.

· Patient access to hospital or regional portals through smartphone browsers, or via mobile phone apps provided by the portal or EMR vendor.

The barriers to further growth were clearly identified in the European Commission's 2014 mHealth Green Paper. It is now worthwhile reconsidering these barriers and assessing those that remain:

ENSURING DATA PROTECTION, including the security of health data, in the light of an unclear EU legal framework.
· The implementation of the General Data Protection Regulation (GDPR) has provided some clarity. Applied consistently across EU Member States, it is reasonable to say that this barrier has been lowered. However, considerable technical and organisational challenges to compliance remain, some of which call for standardised / interoperable solutions.

LIABILITY, PATIENT SAFETY AND TRANSPARENCY OF INFORMATION
· With the Medical Device Regulation (MDR) entering into force on 26 May 2021, the new requirements for medical device software will provide tangible progress.

mHEALTH ROLE IN HEALTHCARE SYSTEMS AND EQUAL ACCESS
· This is one of the areas that has seen little progress, except for some national initiatives (e.g. in Germany, where a new legislative framework was created for digital health applications). This demonstrates that integration of mHealth and patient-centred care still present a major organisational challenge.

REIMBURSEMENT MODELS
· There have been a number of local initiatives piloting new reimbursement models, however, most insurance systems have taken a cautious approach.

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3. *European Commission - Green Paper on mobile Health ("mHealth")*

INTEROPERABILITY

· The interoperability of the various mHealth and eHealth applications is essential for the broad deployment of mHealth. Unfortunately, in practice this continues to present a substantial challenge, despite the existence of applicable standards and profiles / guidelines. These challenges, along with a series of recommendations to address them, will be addressed in greater detail in the following chapter.

· The European Commission should lead concerted efforts on a recommendation for a European EHR exchange format,[4] a common semantic strategy[5] and investment guidelines.[6] If adopted by the eHealth Network, this will allow national eHealth infrastructures to improve their interoperability in the future.

· One area that has seen significant progress is in developing standards that are more mobile platform-friendly, such as HL7 FHIR and DICOMweb. However, many challenges remain to their broad, uniform deployment.

4. *Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format*
5. *https://ec.europa.eu/health/ehealth/events/ev_20191128_en*
6. *eHealth Network Guidelines to the EU Member States and the European Commission on an interoperable eco-system for digital health and investment programmes for a new/updated generation of digital infrastructure in Europe*

2. CHALLENGES AND OPPORTUNITIES FOR INTEROPERABILITY IN mHEALTH

2.1 CHALLENGES

COCIR has identified the following interoperability challenges facing mHealth deployment:

- Despite the existence of appropriate standards, care providers are finding it hard to define their interoperability requirements in their tenders, in terms of selecting appropriate standards and demanding compliance to them. In addition, in the event that buyers do articulate their needs, these can be highly diverse, as currently there is no effective mechanism for coordination. As a result, vendors have few incentives to actually adopt interoperability standards.

- The corpus of healthcare IT interoperability standards is continuously evolving, as the underlying ICT technology develops and needs of the care provision sector change. This increases the difficulty for care providers to articulate their requirements in their specifications.

- Deployment projects predominantly focus on mobile applications that are presented to users. This poses problems when addressing the level of interoperability required to integrate these with healthcare IT systems in such a way that the associated health services can access and liberate the data. This results in unproductive systems that in turn lead to a low return on investment and frequent rejection by health professionals.

- Interoperability standards coming from traditional healthcare IT fields are not well understood by most entrepreneurs active in mHealth. They often lack the experience required to allow mHealth interoperability in health systems.

- Mobile applications, and the service they connect to, are designed as closed systems (no standard APIs), which means that:

  1. Buyers are deprived of healthy, competition-driven innovation, as the introduction of apps or devices from alternative suppliers - which could potentially offer better services for patients – are blocked.

  2. They are difficult – or impossible - to integrate with multiple health services, an also make it difficult for patients to switching between them.

  3. Care organisations need to invest in specific integrations for each application, which is costly and complex and leads to high ICT maintenance costs. As mobile applications and services mostly use non-standard APIs, health providers relying on a range of offerings will have to interface their health IT with each different API. This requires a huge effort and investment and also poses a risk to the integrity and security of the health providers' IT infrastructure.

- If the popular apps used by patients do not build on a commonly agreed set of interoperability standards, it will make it more complicated for those health record-sharing platforms that want to offer access via mHealth applications.

These issues outlined above demonstrate how bespoke systems act as a brake on the independent procurement and evolution of mobile health apps, software platforms and healthcare IT systems. The lack of standardised interfaces causes unnecessary complexities, which in turn erects barriers to establishing the best mHealth ecosystem. for their needs.

2.2 OPPORTUNITIES

What opportunities could make interoperability a visible priority for technology providers and deployment architects in the mHealth market?

· **CREATE** a strong and homogeneous demand pull for solid interoperability solutions as an integral part of vendor mHealth offerings. This can be done by aligning and clearly articulating the needs of providers, payers, project architects and patients.

· **EDUCATE** those companies entering the mHealth market from outside the sector on existing interoperability standards / profiles used in the health domain. This will avoid creating proprietary mHealth interfaces.

· **ENCOURAGE** mHealth companies and mHealth users to become active within the healthcare standard and profiling bodies (IHE, PCHA, DICOM, HL7, etc.). This can be used to develop IHE and Continua profiles suitable for mHealth.

· **INCENTIVISE** these companies to participate in collaborative interoperability test events in mHealth, such as plugathons, Plugfest and IHE Connectathon[7].

[7.] See Annex B

3. RECOMMENDATIONS FOR EFFECTIVE DEPLOYMENT OF mHEALTH

COCIR has actively promoted interoperability in eHealth, where the focus is on allowing health data created by health professionals to follow the patient as they move through health systems. In addition, the patient has access to their health data. As previously discussed, eHealth is essential for patient-centred care; when extended with mHealth, it offers the potential for patients and other care givers (e.g. family and friends) to engage in their care more directly.

COCIR believes that the effective eHealth approaches developed over the past 20 years can also be applied to mHealth, particularly as there must be seamless integration of mHealth and eHealth from an interoperability perspective. The six-step approach widely used in eHealth is remains a valuable resource for mHealth projects architects (See Annex A). COCIR stresses that interoperability in mHealth must rely on open standards. Otherwise, proprietary approaches will lock buyers in and thus restrict competition, stifling innovation and making it difficult to reduce costs. Indeed, there is already an immense range and number of sources and users of health data and a huge array of different IT systems and platforms, such as mobile apps and devices. Each of these has been designed and procured by different health related organisations or the patient.

The relevance of profiling, as discussed in the COCIR document entitled, 'We are all in this together: advancing eHealth interoperability",[8] also applies to mHealth interoperability. It also stresses the importance of adopting standards facilitators such as IHE and PCHA.

Large-scale interoperability needs an adoption and testing ecosystem capable of rapidly delivering the robustness and quality needed to allow users and healthcare professionals to build trust in eHealth technology.

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8. We are all in this together: advancing eHealth interoperability

COCIR THEREFORE RECOMMENDS THAT THE EUROPEAN COMMISSION, MEMBER STATES AND KEY STAKEHOLDERS SHOULD:

1. **Collaborate**, with each other and with local stakeholders, on steering mHealth interoperability in individual Member States or at EU level.
   This was the case for eHealth in sharing health records in recent years.

2. **Set** the stakeholder engagement rules by fostering a use case-based approach to interoperability.

   - The EU Commission should engage the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA) reference networks in developing a consensus on two or three initial use cases. This should be coordinated by the IHE and PCHA, both of which are experienced[9] in this type of process and in selecting supporting Profiles and Standards.

   - Member States could further leverage the outcome of this European-level process, bringing the benefits of a shared approach to interoperability in mHealth throughout the Digital Single Market for the most common use cases.

   - Care providers, payers and patient representation organisations should be encouraged to be part of this process.

3. **Define**, for each use case, a brief specification[10][11] that references open, international interoperability profiles (or standards when profiles are not available) that can be recommended for use in tendering and procurement. These should have been aligned at national, and preferably European, levels.

4. **Educate** stakeholders such as mHealth architects, project leaders, manufacturers, start-ups and care providers. They should understand where and how to find and use existing interoperability specifications and, where necessary, how to define such specifications themselves.

5. **Identify**, based upon high-priority use cases, the organisational and policy changes required to address roadblocks to effectively deploy and foster the implementation of mHealth.

9. *We are all in this together: Advancing eHealth Interoperability*
10. *COCIR eHealth Toolkit 2013 (chapter on mHealth)*
11. *COCIR eHealth Toolkit 2015 (chapter on Interoperability)*

ANNEX A
COCIR'S SIX-STEP APPROACH TO INTEROPERABILITY IN A DEPLOYMENT PROJECT

COCIR has previously developed guidance on how to incorporate interoperability, which has already proved effective, for example in Austria and Switzerland[12].

COCIR defines six steps to achieving interoperability:

1. **Identify use cases**
Describe the proposed functionality in medical terms, avoiding any technical language.

2. **Select profiles and standards**
Identify existing profiles and standards that may support the use case.

3. **Refine data content**
Design the messages and data structure required in the use cases.

4. **Write the interoperability specifications**
Assemble the components and scenarios, building on existing standards.

5. **Organise testing**
Prepare test cases and an environment for implementers to demonstrate component interoperability in scenarios with multiple implementers.

6. **Educate end-users on interoperability**
Develop communication materials that help end-users become familiar with the benefits and impact of interoperability.

ANNEX B
INTEROPERABILITY STANDARDS TO SUPPORT mHEALTH

Interoperability will be key to the success of mHealth applications. This can best be achieved by using internationally defined, open and freely available interoperability standards that represent a consensus between the medical community and those vendors providing the applications. This will ensure true interoperability, a broad selection of potential vendors and a better coverage for the needs of the medical community.

Various groups have already created such profiles and standards for mHealth, and are working relentlessly to expand their coverage and adoption.

B.1 IHE

Integrating the Healthcare Enterprise (IHE)[13] is an initiative by healthcare professionals and industry designed to improve how computer systems in healthcare share information. Communication standards such as HL7, DICOM, IETF, OASIS, SNOMED and LOINC usually provide a number of options for achieving a specific clinical goal, particularly where they need to be used in combination. IHE therefore creates detailed specifications, the so-called 'IHE Profiles',[14] setting out how to use the standards in a coordinated way to reach these goals. Vendors can verify their implementation of IHE profiles at Connectathons, which are annual face-to-face interoperability-testing events organised by IHE.

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12. *We are all in this together: advancing eHealth interoperability*
13. https://www.ihe.net/
14. https://wiki.ihe.net/index.php/Profiles

IHE has created, and continues to create, profiles that specifically address mHealth scenarios, including Mobile Access to Health Documents (MHD), Patient Demographics Query for Mobile (PDQm), patient Identifier Cross-referencing (PIXm), mobile Cross-enterprise Document data-element Extraction (mXDE), Query for Existing Data for mobile (QEDm), Device Enterprise Communication (DEC), Internet User Authorisation (IUA), Web-based Image Access (WIA), mobile Care Services Discovery (mCSD) and Mobile Health Document Sharing (MHDS).[15]

IHE has developed a testing methodology for interoperability with tools and processes:
- "IHE Plugathon"[16] and PCHA Plugfest,[17] a hackathon dedicated to interoperability of Apps and APIs;

- "Connectathons",[18] where testing is planned at the profile level;

- "Projectathons", where end-to-end testing of the various scenarios covered by the use case, in the regional or national deployment context, are covered.

IHE offers and maintains an interoperability test platform, "Gazelle" (http://gazelle.ihe.net), to support and automate each of these testing phases.
This methodology has already proven highly effective in rapid, large-scale deployment, without major problems, in several European countries as well as around the world. It currently covers more than 200 million patients.

B.2 PCH Alliance

The Personal Connected Health Alliance[19] is a non-profit organisation formed by HIMSS. The Alliance publishes and promotes the adoption of the Continua Design Guidelines. These guidelines are recognised by the International Telecommunication Union (ITU) as the international standard for safe, secure, and reliable exchange of data to and from personal health devices.

B.3 DICOM

DICOM (Digital Imaging and Communications in Medicine)[20] is the international standard for transmitting, storing, retrieving, printing, processing and displaying medical imaging information. It is supported by virtually all medical imaging devices. DICOM is published by the US National Electrical Manufacturers Association (NEMA) in close collaboration of manufacturers and clinical community.

In order to make medical images more easily accessible for mobile devices, DICOM has standardised an additional, lightweight transfer mechanism: DICOMweb. Similar to FHIR from HL7, DICOMweb uses RESTful[21] services that can be effortlessly integrated into today's development environments for mobile applications.

B.4 HL7

Health Level Seven International (HL7)[22] is a non-profit, ANSI-accredited standard developing organisation providing standards for exchanging, integrating, sharing, and retrieving electronic health information (with the exception of medical images, which are covered by DICOM). All stakeholder groups involved in the electronic processing of health information are contributing to creating HL7 standards. To make health information more easily accessible, HL7 has begun to create Fast Healthcare Interoperability Resources (FHIR).[23]
FHIR Resources represent granular clinical concepts that can be accessed via RESTful services, thus lending themselves to processing on mobile devices.
HL7 standardised the first FHIR Resources with the release of R4 in 2019. It will continue to add further as they mature.

15. https://wiki.ihe.net/index.php/Category:FHIR
16. https://connectathon.ihe-europe.net/plugathon
17. https://www.pchalliance.org/value-and-benefits-plugfest
18. https://connectathon.ihe-europe.net/
19. https://www.pchalliance.org/
20. https://www.dicomstandard.org/
21. https://restfulapi.net/
22. https://www.hl7.org/
23. https://hl7.org/fhir/

GENERAL INFORMATION ABOUT COCIR

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries.

Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries.

Our focus is to open markets for COCIR members in Europe and beyond. We provide a range of services in the areas of regulatory, technical, market intelligence, environmental, standardisation, international and legal affairs.

COCIR is also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (www.globalditta.org).

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