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# Health informatics — Provisions for health applications on mobile/smart devices

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TECHNICAL REPORT

**ISO/TR 17522**

First edition
2015-08-01

# Health informatics — Provisions for health applications on mobile/smart devices

*Informatique de santé — Provisions pour les applications de santé sur les dispositifs smart/mobiles*

Reference number
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# Foreword

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The committee responsible for this document is ISO/TC 215, *Health informatics.*

# Introduction

Development and implementation of smart devices are rapidly progressing around world. An appropriate deployment of smart health applications and services on smart device platforms will enhance various aspects of healthcare delivery. Smart devices will also enable health organizations to provide essential care and health information anytime, anywhere through information and telecommunications technologies. This includes a broad spectrum of capabilities including health sensors, devices, manager, server, health information systems, and call centre services of patient information.

Recent development of smart devices such as smart phone, TV, and electronic book where the patients' services are stored and distributed securely whenever necessary (sharing EHR information at point of care) requires a robust architecture to be able to manage the mobile data effectively.

This Technical Report describes the status and requirements of health applications and services on smart devices platforms and suggests the reference architecture for these. The report is not intended to be prescriptive either from a methodological or technological perspective.

# Health informatics — Provisions for health applications on mobile/smart devices

## 1 Scope

This Technical Report is applicable to the developments of smart health applications available anywhere, anytime and supporting new health businesses based on the smart devices. This Technical Report is to investigate the areas of ongoing developments and analyses of emerging interoperability standards for smart mobile devices.

## 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

There are no normative references.

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

**3.1**
**accelerometer**
device that measures proper acceleration

**3.2**
**access**
provision of an opportunity to approach, inspect, review, make use of data, or information

**3.3**
**android**
open source operating system for mobile devices developed by a group of organizations led by Google

**3.4**
**application**
software program or set of related programs that provide some useful healthcare capability or functionality

**3.5**
**Apple iOS**
previously iPhone OS
mobile operating system developed by Apple Inc. and distributed exclusively for Apple hardware

Note 1 to entry: It is the *operating system* (3.12) that powers iPhone, iPad, iPod Touch, and Apple TV.

**3.6**
**BlackBerry**
line of wireless handheld devices and *services* (3.20) designed and marketed by BlackBerry Limited, formerly known as Research In Motion Limited

**3.7**
**bluetooth**
standard for sending information wirelessly over short distances

**3.8**
**healthcare professional**
person entrusted with the direct or indirect provision of defined healthcare services to a subject of care or population of subjects of care

**3.9**
**electronic health record**
health record with data structured and represented in a manner suited to computer calculation and presentation

**3.10**
**medical device**
instrument, apparatus, implant, in vitro reagent, or similar or related article that is used to diagnose, prevent, or treat disease or other conditions and does not achieve its purposes through chemical action within or on the body

**3.11**
**metadata**
"data about data"

Note 1 to entry: The term is ambiguous, as it is used for two fundamentally different concepts.

**3.12**
**operating system**
set of programs that provide basic operating functions for hardware devices

EXAMPLE Starting up the device and running other software applications.

**3.13**
**out-of-the-box functions**
used to describe the functions of a device that run when you first buy it and start it up without the need to purchase or install any additional software or hardware

**3.14**
**patient**
individual person that is a subject of care

**3.15**
**personal health record**
may have contributions from providers of healthcare and the person or their carer/s

Note 1 to entry: The legal rules for a health record still apply to this record.

**3.16**
**picture archiving and communication system**
**PACS**
application system that uses an image server to exchange X-rays, CT scans, and other medical images over a network

**3.17**
**registry**
collection of all the official records relating to something or the place where they are kept

**3.18**
**repository**
place where something is kept safely

**3.19**
**security**
combination of confidentiality, integrity, and availability

**3.20**
**service**
specific behaviour that a communication party in a specific role is responsible for exhibiting

**3.21**
**smartphone**
additional features usually include media player and the ability to run mobile apps

Note 1 to entry: There is no single fixed definition of a smartphone.

**3.22**
**standard**
technical specification which addresses a business requirement, has been implemented in viable commercial products, and, to the extent practical, complies with recognized standards organizations such as ISO

**3.23**
**tablet computer**
mobile computer based around a flat touchscreen operated by finger or stylus

**3.24**
**Windows phone**
**Windows mobile**
proprietary smartphone operating system developed by Microsoft

**3.25**
**data carrier**
all-encompassing term covering the different encoding modalities for machine readable data applied to the product packaging or directly to the product

Note 1 to entry: The possibilities include barcodes both 1 and 2 dimensions and radio frequency identification tags. It is critical to standards based mobile applications that the data is represented in symbol using ISO based standards such as GS1 and industry adopted guidelines.

**3.26**
**vital sign**
clinical information relating to one or more *patients* (3.14) that is measured by or derived from apparatus connected to the patient, or otherwise gathered from the patient

**3.27**
**healthcare provider**
healthcare organization or *healthcare professional* (3.8) responsible for the provision of healthcare to a subject of care or to a population

## 4 Symbols and abbreviated terms

| | |
|---|---|
| **AAC** | Augmentative and Alternative Communication: Communication methods such as use of signs, symbols, or software tools to help people who have problems with the use of speech or written language to express themselves and communicate |
| **API** | Application Programming Interface: An interface that allows one piece of software to interact with another allowing developers to add new functions on top of existing software |
| **BECS** | Blood Establishment Computer Software |
| **CDA** | Clinical Document Architecture |
| **DOC** | Document query |

| | |
|---|---|
| **ebXML** | Electronic Business Extensible Markup Language |
| **ECG** | Electrocardiogram |
| **ECG/EKG** | Electrocardiography is the recording of the electrical activity of the heart |
| **EHR** | Electronic Health Record |
| **FDA** | Food and Drug Administration |
| **FHIR** | Fast Healthcare Interoperability Resources |
| **GS1** | General Specifications and Standards |
| **HL7** | Health Level 7 |
| **HIE** | Health Information Exchange |
| **HTTP** | Hypertext Transfer Protocol |
| **IHE** | Integrating the Healthcare Enterprise |
| **ISO** | International Organization for Standardization |
| **JSON** | JavaScript Object Notation |
| **MHD**[38] | Mobile Access to Health Documents |
| **OASIS** | Organization for the Advancement of Structured Information Standards |
| **OS** | Operating System |
| **PACS** | Picture Archiving and Communication System |
| **PCD** | Patient Care Device |
| **PDQ** | Patient Demographics Query |
| **PHR** | Personal Health Record |
| **PIX**[37] | Patient Identifier Cross Referencing |
| **PMA** | Premarket Approval |
| **QPB** | Query by Parameter/Segment Pattern Response |
| **QRY** | Query, original mode |
| **RHEx** | RESTful Health Exchange |
| **RIM** | Reference Information Model |
| **RS** | Registry Service |
| **RSP** | Segment Pattern Response |
| **RTB** | Tabular Response |
| **SDK** | Software Development Kit: A set of software tools that enable a developer to create applications for a specific operating system or other software environment |

| | |
|---|---|
| **WAI** | Web Accessibility Initiative: A project of workstream of the W3C (see below) that develops guidelines and techniques to make the web more accessible. Website: www.w3.org/WAI |
| **W3C** | World Wide Web Consortium: An open, collaborative international community of technology organizations, academic bodies, and others which creates and maintains the web's core technical standards. Website: www.w3.org |
| **XDS** | Cross Enterprise Document Sharing |
| **XDW**[36] | Cross-Enterprise Document Workflow |
| **XML** | Extensible Markup Language |

## 5 Mobile health applications based on Registry and Repository (Reg/Rep)

The mobile access to health documents (MHD) profile

a) defines a simple HTTP interface to an XDS like environment, and

b) defines transactions to

   1) submit a new document and metadata from the mobile device to a document receiver,

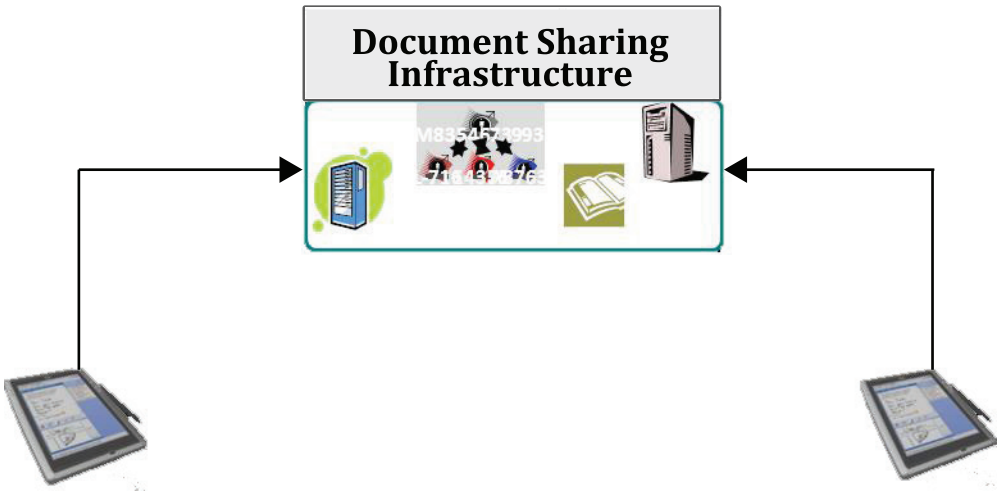
   2) get the metadata for an identified document,

   3) find document entries containing metadata based on query parameters, and

   4) retrieve a copy of a specific document.

The above four transactions leverage the document content and format agnostic metadata concepts from XDS, but simplify them for access by constrained environments such as mobile devices. The MHD profile does not replace XDS. It can be used to allow mobile devices constrained access to an XDS health information exchange.

Figure 1 shows one possible way to implement the MHD with a document sharing environment (that may, but is not necessarily, XDS based).




NOTE From Reference [38], Figure 1.

**Figure 1 — Mobile access to a document sharing environment**

The MHD profile supports a broad set of the XDS use cases and functionality while keeping the technology as simple as possible.

— Medical devices such as those targeted by the Patient Care Devices (PCD) domain or Continua organization submitting data and documents.

— Kiosk used by patient in hospital registration departments where it is anticipated that a hospital staff member will review, edit, and approve the document before it is allowed into the hospital system.

— PHR publishing into a staging area for subsequent import into an EHR or HIE.

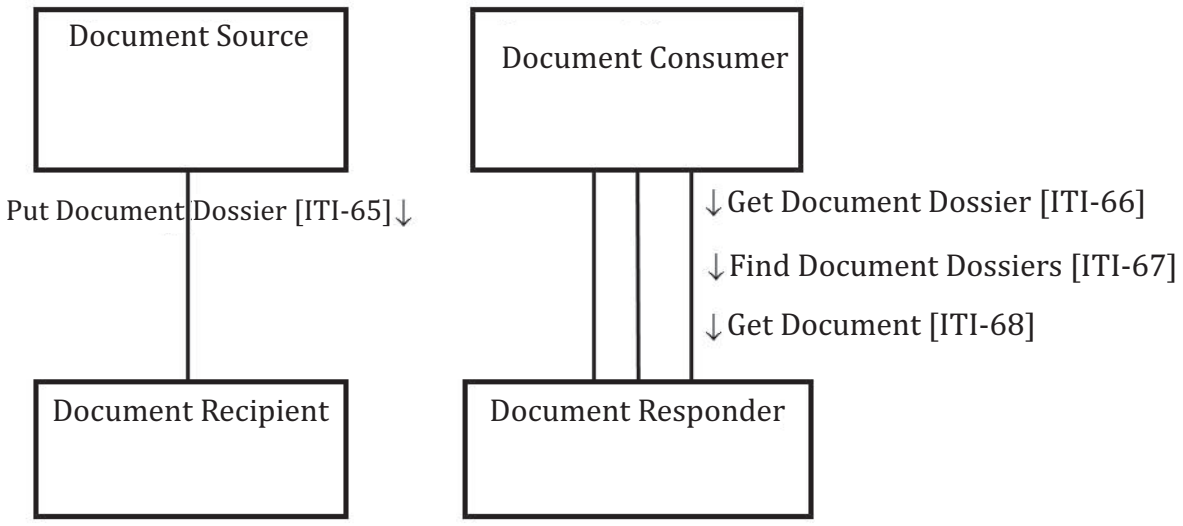
— Patient or provider application that is configured to securely connect to a PHR in order to submit. a medical history document.

— Electronic measurement device participating in an XDW workflow and pulling medical history documents from an HIE.

— A general practitioner physician's office with minimal IT capabilities using a mobile application to connect to an HIE or EHR.

— MHD has defined simple HTTP RESTful transactions using the Document Entry metadata as the object acted upon. Metadata is described in JSON format.

Figure 2 shows the actors directly involved in the MHD Profile and the relevant transactions between them.




NOTE From Reference [38], Figure 33.1-1.

**Figure 2 — MHD actor diagram**

## 5.1 Transportation of emergency patient

— Paramedic looks for hospitals in the emergency hospital list displayed on the device where the patient can be accepted.

— The paramedic sends the patient information using the device to the selected hospital.

— During transportation, the paramedic takes pictures and/or videos of patient and sends them to the hospital, as well as the patient's vital signs.

— The clinician at the hospital observes the data from the ambulance and gives directions and advice to the paramedic.

## 5.2 Manage medication

— Patient reads/scans the data carrier of the medicine and stores the identity of the drug and other associated data into the medication list in the device. Open standards such as GS1 enable globally interoperable solutions.

— When the patient goes to a new clinic, the clinician checks the medication list to avoid contraindication.

## 5.3 Telehealth

— When the healthcare provider communicates with the informal healthcare provider through a voice or computer link, there is no face-to-face contact.

— Informal healthcare provider can provide medical images or bio-signals.

— In tele-dermatology, an image of the skin is the main information exchanged.

— When an informal healthcare provider provides information at a distance, the accredited healthcare provider is available to provide a medical opinion or advice concerning medical images or bio-signals.

## 5.4 Referenced Standards

**Table 1 — Referenced standards of mobile health applications based on Reg/Rep**

| Contents | Standards |
|---|---|
| RESTful interface definition | — IHE MHD(mobile access to healthcare document) profile |
| Document sharing | — IHE XDS.b (cross enterprise document sharing) profile |
| Identity | — IHE ITI Technical Framework Supplement - Patient Identifier Cross-Reference(PIX)/Patient Demographic Query (PDQ) HL7 v3 |
| Communication | — JSON<br>— HL7(Health Level 7) V2 Messaging<br>— ISO/HL 727932:2009 *Data Exchange Standards — HL7 Clinical Document Architecture, Release 2*<br>— ISO/TR 16056-1 *Health informatics — Interoperability of telehealth systems and networks — Part 1: Introduction and definitions*<br>— ISO/TR 16056-2 *Health informatics — Interoperability of telehealth systems and networks — Part 2: Real-time systems* |
| Code | — SNOMED-CT<br>— ICD-10<br>— GS1 |

**Table 1** *(continued)*

| Contents | Standards |
|---|---|
| Security | — ISO/IEC 27001<br>*Information technology — Security techniques — Information security management systems — Requirements*<br>— ISO/TR 27809<br>*Health informatics — Measures for ensuring patient safety of health software*<br>— ISO 27789:2013<br>*Health informatics — Audit trails for electronic health records* |

## 6 Mobile health applications in a health provider

This Clause describes mobile health applications which are utilized for healthcare providers. The use of mobile health applications in healthcare facilities is increasing, so this subclause will explain about it.

### 6.1 Mobile electronic medical record system

— Figure 3 is the representative model of mobile health applications in a health provider. It is for mobile electronic medical record.

— We can manage patient information, vital signs, medication information, laboratory result, and nursing records using smart device.

— If we request required information, mobile server convert to HL7 request message (QRY, QPB) and then it request to healthcare system.

— The healthcare provider converts from request information to HL7 response message (RSP, RTB, DOC) and return to mobile server. Mobile server converts to JSON format that is easy and light to use in smart device.

— RESTful health exchange (RHEx) technology can be used to make health information exchange simple, secure, and standards-based.

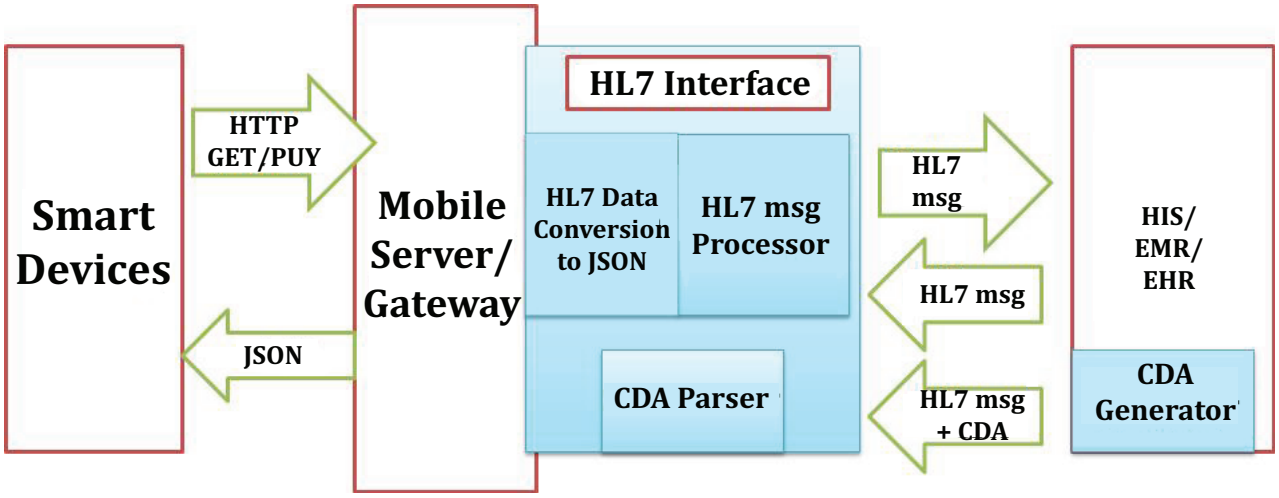



**Figure 3 — Mobile electronic medical record system**

### 6.2 Scheduling medical examination

— Patient makes a reservation medical examination using the smart device (medical appointment).

— The clinician checks the schedule using the smart device.

— The patient checks, changes, and cancels reservation.

### 6.3 Manage chronic diseases patient

— Patient with chronic diseases measures the vital values such as weight, blood pressure, blood sugar level, etc.

— The patient inputs and mails them to the clinician through the device.

— The clinician checks the measurements and mail back clinical comment and/or advice to the patient.

### 6.4 Nursing home

— Nurses share the schedule of visiting patient's home.

— Nurses share the nursing reports of the patients.

— Nurse adds the new nursing report when visiting the patient.

— Nurse asks the doctor an advice by transmitting the images and/or movies of the patient.

— Nurses write and send the nursing summary monthly to the doctors.

### 6.5 Mobile PACS architecture

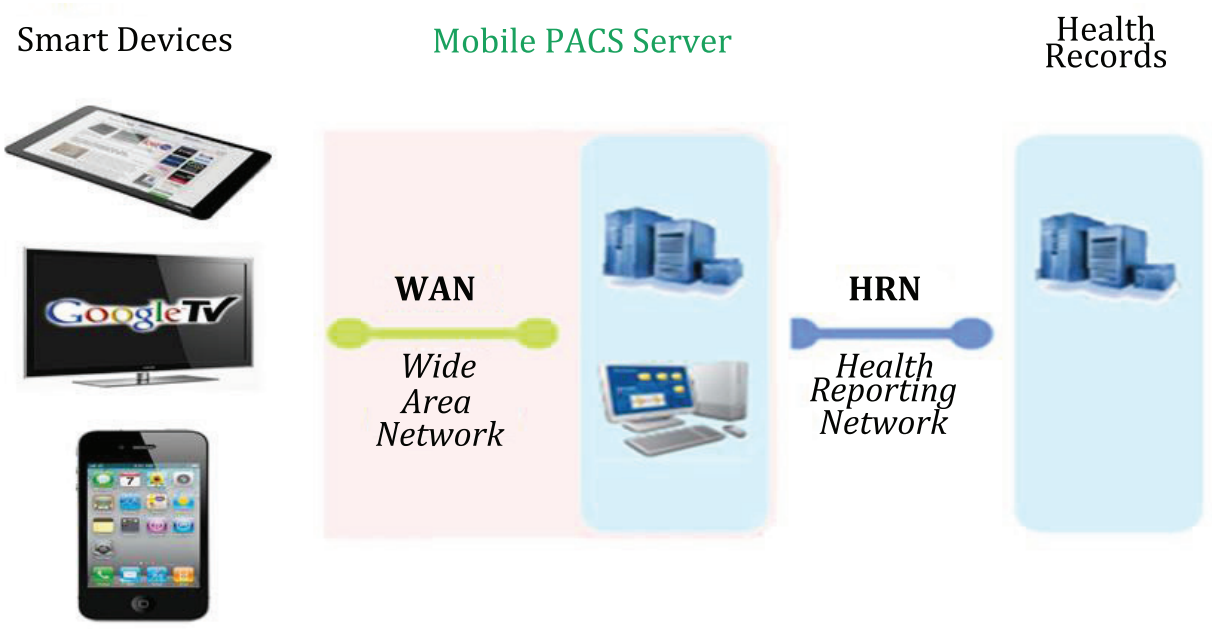



**Figure 4 — Mobile PACS architecture**

— Figure 4 shows the Mobile PACS Architecture. It is the system that supports and allows doctors to better treat patients. The PACS system converts from medical image to digital type and send to physician.

— Mobile PACS certification process is performed in a couple of countries such as United States of America and Republic of Korea.

— US FDA has responsibility for 510(k) premarket notification and its medical device certification process. Medical devices are classified into three levels (Class I, II, and III) and different regulatory level.

— Class I and class II medical device have to obey the 510(k) (premarket notification). Class II medical device has to obey PMA (premarket approval).

— Mobile PACS is class II medical device and it is certified 510(k) by the FDA.

— Regulation number "892.2050" means PACS.

— Mobile PACS can be used for disaster. It should include the use case that the mobile PACS might be applied in the case of disaster, big earthquake, typhoon, or tornado.

  — The big earthquake: Many medical facilities were destroyed.

  — They lost medical records of their patients.

  — They do not have the way to take pictures of patients and to get a diagnosis either.

  — We have mobile modalities, but there are few radiologists who can read MRI/CT images.

  — If images stored at a safe area were accessed remotely, doctors could read images on their mobile devices wherever they are.

### 6.6 Veterans personal electronic health record

— My HealtheVet allows veterans to self-enter their personal health indicators (blood pressure, weight, heart rate), emergency contact information, test results, family health history, military health history, and other health related information.

— My HealtheVet users who receive VA health care services can also refill their prescriptions and view their appointments, allergies, and laboratory results online.

— The Blue Button feature allows veterans to access and download their information into a very simple text file or PDF that can be read, printed, or saved on any computer.

— The download can include all their data or be broken out by data class or by date range.

— Blue Button gives veterans complete control of this information without any special software and enables veterans to share this data with their health care providers, caregivers, or people they trust.

## 7 Mobile medical application

— "Mobile Medical Application" is a mobile application that meets the definition of "device" in section 201(h) of the federal food, drug, and cosmetic act (FD&C Act) and either of the following:

  — used as an accessory to a regulated medical device;

  — transforms a mobile platform into a regulated medical device.

— The intended use of a mobile application determines whether it meets the definition of a "device".

— When the intended use of a mobile application is for the diagnosis of disease or other conditions (or the cure) mitigation, treatment, or prevention of disease.

— When a mobile application is intended to affect the structure or any function of the body of man (the mobile app is a device).

— In South Korea, a guideline for the safety and management of mobile medical application is developed based on the guidance of US FDA.


**Figure 5 — Mobile medical app**

## 7.1 Mobile application for the purpose of processing patient medical device data

— Mobile medical applications that are extensions of regulated medical device for the purpose of displaying, storing, analyzing, or transmitting patient-specific medical device data.

  — Applications that connect to a home use diagnostic medical device such as a blood pressure meter, body composition analyzer, or blood glucose meter to collect historical data or to receive, transmit, store, analyze, and display measurements from connected devices.

  — Applications that analyze, assess, or interpret electrocardiogram or electroencephalogram data.

  — Applications that connect the mobile platform to vital signs monitors, bedside monitors, cardiacmonitors, or other similar devices.

  — Applications that are used as patient screening tools for blood transfusion (extension of blood establishment computer software (BECS) or other biologics.

## 7.2 Mobile application to function as a medical device

— If a mobile application is intended for use in performing a medical device function, it is a medical device regardless of the platform on which it is run.

  — Mobile applications intended to run on smart phones to analyze glucose meter readings would be considered similar to software running on a desktop computer which is regulated under 21 CFR 862.1345 (“glucose test system”).

  — Applications that attach EKG/ECG leads to a mobile platform to collect/analyze/monitor EKG/ECG signals.

  — Applications that use the built-in accelerometer or other similar sensors in a mobile platform to monitor the user’s movement to determine conditions such as sleep apnea, sleep phase, fall detection, or detect motion related to other conditions or diseases or to measure heartrate.

  — Applications that generate sine signals from 125 Hz to 8 kHz (eight steps) to check the user’s hearing.

  — Applications that use a mobile platform in determining blood donor eligibility prior to collection of blood or blood components.

# 8 Analysis of required architectures for mHealth

In Clause 4 to Clause 6, the architectures which can be applied into mobile health are described and the examples of mobile application are additionally explained in detail. In this Clause, we will analyse these three mobile architectures in terms of short description, main contents, and issues and requirements.

## 8.1 IHE MHD

Integrating the healthcare enterprise (IHE) mobile access to health documents (MHD) is a profile that defines a simple HTTP interface for a mobile device to access to cross enterprise document sharing (XDS). The MHD profile has simplified the interactions in ways that are more consistent with a single policy domain use. The MHD profile supports a broad set of the XDS use cases and functionality while keeping the technology as simple as possible. The document to be provided, retrieved, and queried in XDS might be Health Level 7 (HL7) clinical document architecture (CDA) document. HL7 CDA contains clinical information sections such as patient's medication, allergy, and family history information etc. This clinical information can be exchanged in a document type through MHD. So, a mobile device can be more easily integrated into an XDS environment.

Contents of MHD are document metadata and ISO/HL7 27932.

We have issues and requirements as follows: XDS profile designates ebXML OASIS standard for representing a document metadata. ebXML OASIS standard is also specified in ISO/TS 27790 document registry framework to represent a document metadata. For a mobile device, however, a simpler way to represent a document metadata is required. JavaScript object notation (JSON) is chosen to express a document metadata in MHD profile. JSON is a de-facto standard in a mobile development world and JSON is simpler, more lightweight, and easier to process in a mobile device than ebXML. Even though JSON has many advantages, JSON which is defined in MHD profile has some limitations such as it is not enough to express the details of a document metadata. Following is the list of problems when JSON is converted into ebXML which is a required format in XDS environment. Document metadata such as DocumentEntry, SubmissionSet, and Folder is expressed as JSON format in mobile device. When the document metadata in mobile device is converted into ebXML for XDS system, the values of the ID attribute for ebXML elements such as Classification, ExternalIdentifier, and Association are not properly generated. To retrieve a document using GetDocument transaction in MHD profile, it is told that two parameters such as document uuid and patientId are needed. In XDS profile, however, to retrieve a document, parameters such as document uniqueId and repository uniqueId are needed. The parameters are different between MHD and XDS profile.

## 8.2 Mobile EMR

Electronic Medical Record (EMR) is a computerized legal clinical record created in care delivery organizations such as hospitals and physician offices. Mobile EMR is a mobile version of EMR system for clinicians to easily access the clinical information of a patient. Using mobile EMR, clinicians can identify the patient's demographics, medications, medical summary records, vital signs, laboratory results, and other important clinical information wherever they are. They can also have additional time for necessary treatment and they are able to search the latest medical updates very fast so that they can quickly make a decision for treating patients.

Contents of the mobile EMR are patient demographics, medications, medical summary records, vital signs, and surgery information.

We have issues and requirements as follows: to exchange clinical contents, ISO/TC 215 standards can be used. For example, ISO/HL7 27931 can be used for exchanging patient demographics, laboratory results, and vital signs; ISO/HL7 27932 can be used for exchanging medical summary records, medications, and surgery information; ISO/HL7 21731 can be used to exchange the other clinical information.

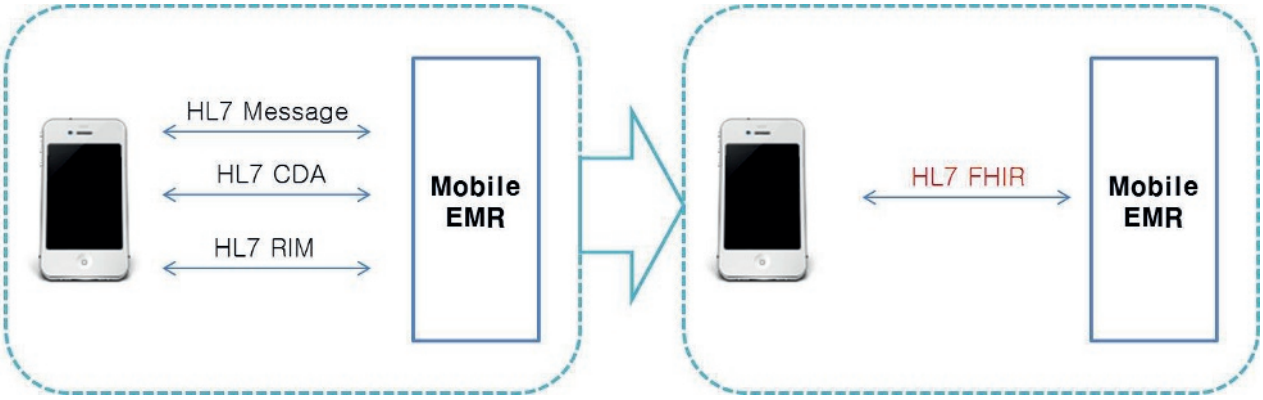



**Figure 6 — After HL7 FHIR style framework is applied for exchanging mobile health data**

In case of mobile EMR, simple and lightweight data representation is necessary to quickly process health information in mobile devices. HL7 derives Fast Healthcare Interoperability Resources (FHIR) standard. The reason why the HL7 FHIR standard gets paid attention is that it focuses on implementers, leverages cross-industry web technology, and supports multiple paradigms such as REST, Documents, Messages, and Services. HL7 FHIR supports message- and document-style data exchanges. The more important thing is that it supports REST-style data exchange mechanism which is already popularized in mobile development world. The requirements for simply representing and lightly exchanging mobile health information are being recognized so HL7 FHIR style framework is best suitable for mobile EMR.

## 8.3 Mobile Medical Application

"Mobile Medical Application" is a mobile application that meets the definition of "device" in section 201(h) of the federal food, drug, and cosmetic act (FD&C Act). It is used as an accessory to a regulated medical device or a transformation of a mobile platform into a regulated medical device. The intended use of a mobile app determines whether it meets the definition of a "device". The intended use of a mobile app is for the diagnosis of disease or other conditions or the cure, mitigation, treatment, or prevention of disease. It aims to affect the structure or any function of the body of a man (the mobile app is a device).

Examples of Mobile Medical Applications are as follows according to its purposes; medical device application, Mobile PACS, monitoring vital signs such as blood pressure, glucose meter, body temperature, ECG/EKG, providing medical information, how to react in an emergency, finding a doctor nearby, providing drug information, for managing wellness information, and recording personal health information such as diet, weight, exercise, nutrition, and exercise mentoring for early childcare.

Contents of Mobile Medical Application are medical information obtained from medical device, medical service information, and wellness management.

We have issues as follows: HL7 message can be used to send health data measured from a mobile device to an external device. Even though HL7 message is good enough to represent health information and exchange it between health information systems, it is not easy for a mobile device to process HL7 message. For a mobile device to process HL7 message, HL7 engine which can parse, build, and validate HL7 message might be needed. It hinders the mobile developers from creating, deploying, and testing a mobile app. For a mobile device, the simpler way to process health data is needed. Resources are represented as a simple format like JSON, XML to be easily processed in a mobile device. HL7 FHIR style framework is an appropriate standard to be used in a mobile device.

We have recommendations as follows: to establish mobile health systems, the following approaches are possible: 1) developing mobile client application as a client of XDS.b, 2) placing proxy server (e.g. mobile server) between the mobile client and exchanging server, 3) suggesting a new resource that can represent existing metadata and a new interface on the existing system, and 4) supporting cloud resources by materializing existing exchange system with the cloud environment.

As shown above, various approaches can be attempted. However, the following problems might occur:

a) different protocol and message format are used by architectures;

b) message contexts and data are different according to architecture;

c) so if a user wants to use a system that is configured with different architectures, they should be used for different applications and translate messages.

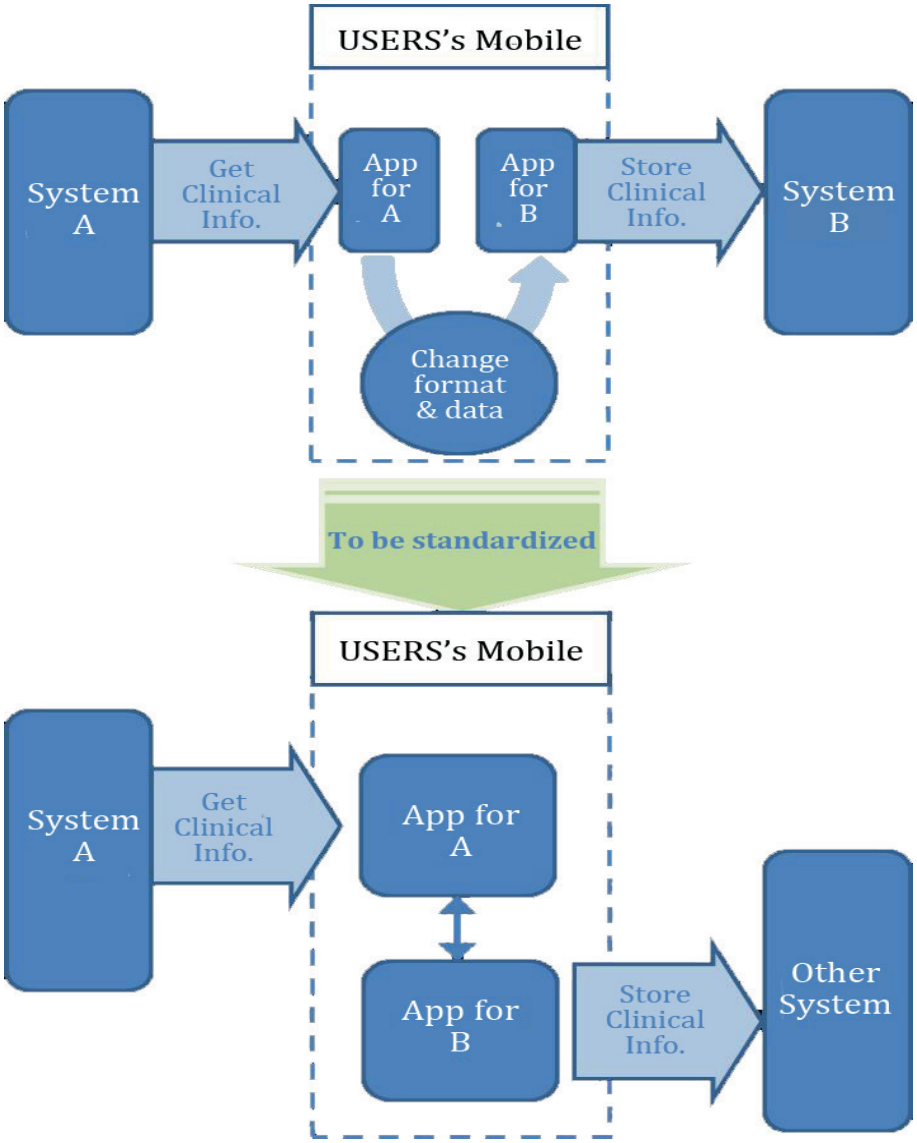



**Figure 7 — Simplification after standardized process**

Figure 7 describes the simplification after health data exchange is standardized. Mobile developer doesn't have to convert one standard to another standard.

When dealing with a variety of medical information in healthcare applications, there are several available approaches in terms of data format and terminology, etc. However, this is a burden of developer and user which develop the mobile health applications because they have to struggle with finding an appropriate way to develop. In other words, in spite of the existence of several methodologies, it is not easy to discover proper methodologies and apply them into the development of mobile health application due to the constraints of developing environmental. As a result, new standards are needed for the purpose of contributing to the development of mobile health application.

Therefore, in order to adopt mobile health into legacy health information system, HL7 standards such as HL7 message, HL7 CDA, and HL7 RIM can be used. However, it is better to use FHIR style framework because they are supporting REST-style data exchange mechanism and data format such as JSON, XML which are already popularized in the mobile development world.

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