International Telecommunication Union

ITU-T

TELECOMMUNICATION
STANDARDIZATION SECTOR
OF ITU

FG M2M

D0.2 – Version 1.0
(04/2014)

ITU-T Focus Group on M2M Service Layer

M2M enabled ecosystems: e-health

Focus Group Technical Report

FOREWORD

The International Telecommunication Union (ITU) is the United Nations specialized agency in the field of telecommunications, information and communication technologies (ICTs). The ITU Telecommunication Standardization Sector (ITU-T) is a permanent organ of ITU. ITU-T is responsible for studying technical, operating and tariff questions and issuing Recommendations on them with a view to standardizing telecommunications on a worldwide basis.

The procedures for establishment of focus groups are defined in Recommendation ITU-T A.7. The ITU-T Focus Group on the M2M service layer (FG M2M) was established further to ITU-T TSAG agreement at its meeting in Geneva, 10-13 January 2012. ITU-T Study Group 11 is the parent group of FG M2M.

Deliverables of focus groups can take the form of technical reports, specifications, etc. and aim to provide material for consideration by the parent group in its standardization activities. Deliverables of focus groups are not ITU-T Recommendations.

SERIES OF FG M2M TECHNICAL REPORTS

Deliverable 0.1: M2M standardization activities and gap analysis: e-health

Deliverable 0.2: M2M enabled ecosystems: e-health

Deliverable 1.1: M2M use cases: e-health

Deliverable 2.1: M2M service layer: requirements and architectural framework

Deliverable 3.1: M2M service layer: APIs and protocols overview

Deliverable D0.2 “M2M enabled ecosystems: e-health”

CONTENTS

M2M enabled ecosystems: e-health

1 Scope

This deliverable provides an overview of e-health ecosystems enabled by M2M. The main objectives of this deliverable are to provide an introduction to e-health, to describe high level requirements of e-health applications and services making usage of M2M capabilities and to present a high level view of e-health ecosystems incorporating M2M capabilities.

2 References

[1] World Health Organization (2005), *"WHA resolution WHA58.28 eHealth"*, http://apps.who.int/iris/bitstream/10665/20378/1/WHA58_28-en.pdf

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[8] Mitchell (1999), *"From telehealth to e-health: the unstoppable rise of e-health", Department of Communications, Information Technology and the Arts*

[9] ITU-T Recommendation Y.2060 (2012), *"Overview of the Internet of Things"*

[10] ITU-T FG M2M Deliverable D1.1, *"M2M use cases: e-health"*

3 Definitions

3.1 Terms defined elsewhere

This deliverable uses the following terms defined elsewhere:

3.1.1 e-health [1]:

The cost-effective and secure use of information and communications technologies in support of health and health-related fields, including healthcare services, health surveillance, health literature, and health education, knowledge and research.

NOTE 1 - e-health can be seen as an umbrella term introduced in [2] to define "an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology."

NOTE 2 - Relevant examples of e-health applications and services include electronic health records, electronic medical records, personal health records, health information including health knowledge management and e-learning for healthcare professionals, clinical decision support systems and remote patient monitoring and management [3].

3.1.2 EHR [4]:

A longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports. The EHR automates and streamlines the clinician's workflow. It has the ability to generate a complete record of a clinical patient encounter – as well as supporting other care-related activities directly or indirectly via an interface – including evidence-based decision support, quality management, and outcomes reporting.

3.1.3 PHR [4]:

A record controlled and managed by the citizen. It is a universally accessible, layperson comprehensible, lifelong tool for managing relevant health information, promoting health maintenance and assisting with chronic disease management via an interactive, common data set of electronic health information and eHealth tools. The PHR is owned, managed, and shared by the individual or his or her legal proxy(s) and must be secure to protect the privacy and confidentiality of the health information it contains. It is not a legal record unless so defined and is subject to various legal limitations.

3.1.4 m-health [5]:

Mobile computing, medical sensor and communications technologies for healthcare.

3.1.5 Telehealth [6]:

Remote monitoring by health professionals of a patient's physiological data for diagnosis and disease management.

3.1.6 Telemedicine [7]:

The delivery of healthcare services, where distance is a critical factor, by all healthcare professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of healthcare providers, all in the interests of advancing the health of individuals and their communities.

NOTE - [6] defines telemedicine as the use of communications to exchange medical diagnostic and therapeutic information, usually between a doctor and a patient who are in different places.

3.2 Terms defined in this deliverable

This deliverable defines the following terms:

3.2.1 Remote patient monitoring/assisted living (RPM/AL)

e-health applications and services providing medical treatments or healthcare feedbacks, such as post operative monitoring, chronic diseases management, preventive medicine, and wellness/fitness programs, to monitor people based on vital signs and environmental data utilizing Machine to Machine (M2M) technologies. NOTE - Assisted living is mainly for elderly people who need to maintain their health and functional capabilities, and expect medical or healthcare feedbacks based on vital signs or environmental data using M2M technologies.

4 Abbreviations and acronyms

This deliverable uses the following abbreviations and acronyms:

3G	Third Generation
BAN	Body Area Network
DSL	Digital Subscriber Line
ECG	Electrocardiography
EHR	Electronic Health Record
ICT	Information and Communication Technology
IoT	Internet of Things
LAN	Local Area Network
LTE	Long Term Evolution
M2M	Machine to Machine
NFC	Near Field Communication
NGN	Next Generation Network
PC	Personal Computer
PHR	Personal Health Record
POTS	Plain Old Telephone Service
PSTN	Public Switched Telephone Network
QoS	Quality of Service
RPM/AL	Remote patient monitoring/assisted living
USB	Universal Serial Bus

5 Conventions

None

6 Introduction

The period 1998-1999 was the era of a significant rise in e-commerce and ”e-health” was introduced at that time as a new term to describe the combined use of information and communication technologies (ICT) in the health sector and a subset of e-commerce [8]. Along with the progress of ICT, e-health has been characterized not only by health-related technical developments, but also by the development of solutions to improve healthcare locally, regionally, and worldwide by the usage of ICT [2].

E-health provides substantial benefits to both personal health and public health. It empowers individuals in self-monitoring, chronic disease management and access to trusted health knowledge

sources. It also improves the abilities to support surveillance and management of public health interventions and to analyse and report on population health outcomes [3].

An e-health ecosystem involves different roles impacting the ecosystem stakeholders, such as citizens, research professionals, hospitals, health-related business actors and governments.

6.1 Basic concepts of e-health

E-health is an emerging field in the intersection of medical informatics, health and business, referring to health services and information delivered through, or enhanced by, ICT.

E-health is concerned with improving the flow of information to support the delivery of various health services and the management of systems for health.

E-health deals with both personal health and public health: personal health focuses on personalized healthcare, while public health manages diseases and risk factor trends in populations.

6.2 Overview of e-health system

An e-health system contains the infrastructure for providing e-health services to users. Figure 1 provides an overview of e-health system, including examples of e-health system and their deployment environments.

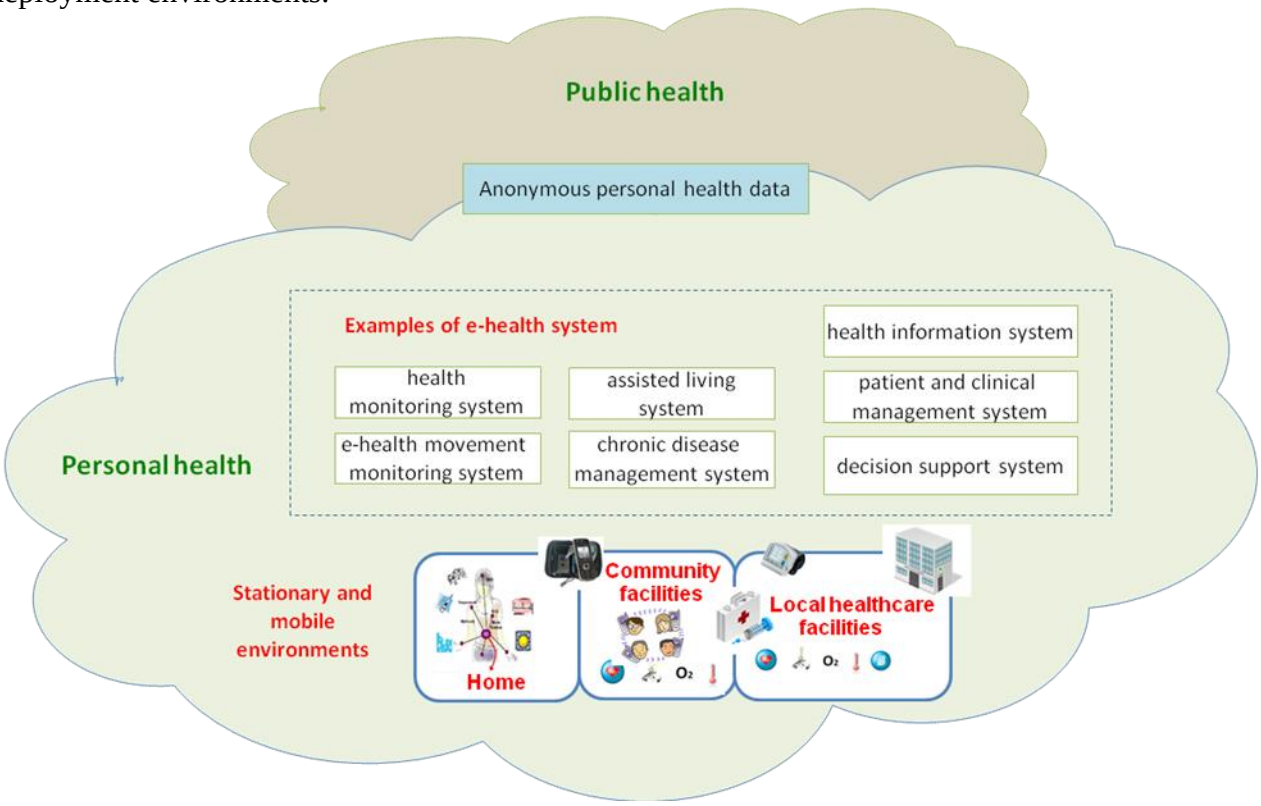

Figure 1 – e-health system overview

Examples of e-health system include health monitoring system, e-health movement monitoring system, chronic disease management system, assisted living system, decision support system, health information system, patient and clinical management system, as well as other systems assisting disease prevention, diagnosis, treatment and lifestyle management. These systems may be deployed in stationary and mobile environments, such as home, local healthcare facilities and community facilities.

NOTE 1 - The local healthcare facilities are patient-care points of first intervention and may include clinics, hospitals, ambulances, regional health sites and primary health care centers [4].

NOTE 2 – The community facilities provide social welfare and community services, typically in, but not limited to, rural and remote areas. It is expected that basic and enhanced health services for communities be not limited to those provided at home and in local healthcare facilities.

In the personal health domain, an e-health system is used by professionals to provide medical services, and also used to provide healthcare service such as movement and health monitoring for individuals.

In the public health domain, an e-health system is used by public health organizations to provide public health services, utilizing anonymous personal health data retrieved from personal health domain in order to make analysis and take decisions.

6.3 E-health ecosystem

An e-health ecosystem needs to be developed to sustain the expected e-health services and this implies the implementation of the required functional features using ICT, the so-built infrastructure constituting an e-health system. The ecosystem also needs to be flexible enough to evolve in line with the development of new information and communication technologies or services.

E-health is aimed at supporting both personal health and public health. Each of these two health domains has its own ecosystem. The personal health domain benefits from an ecosystem mainly from a business model flexibility viewpoint, whereas the public health domain benefits from it also from a governmental viewpoint, as well as from the perspective of not only individual nations but also of global health.

The ecosystem for personal health is characterized by integrated services provided by the actors of the ecosystem. Figure 2 shows a high level view of the ecosystem for personal health with the involvement of « User », « Healthcare provider » and « ICT provider » as the key actors. In the ecosystem, these key actors interact with other actors, including those from the economic and legal environments, such as insurance companies, regulation entities and legal entities.

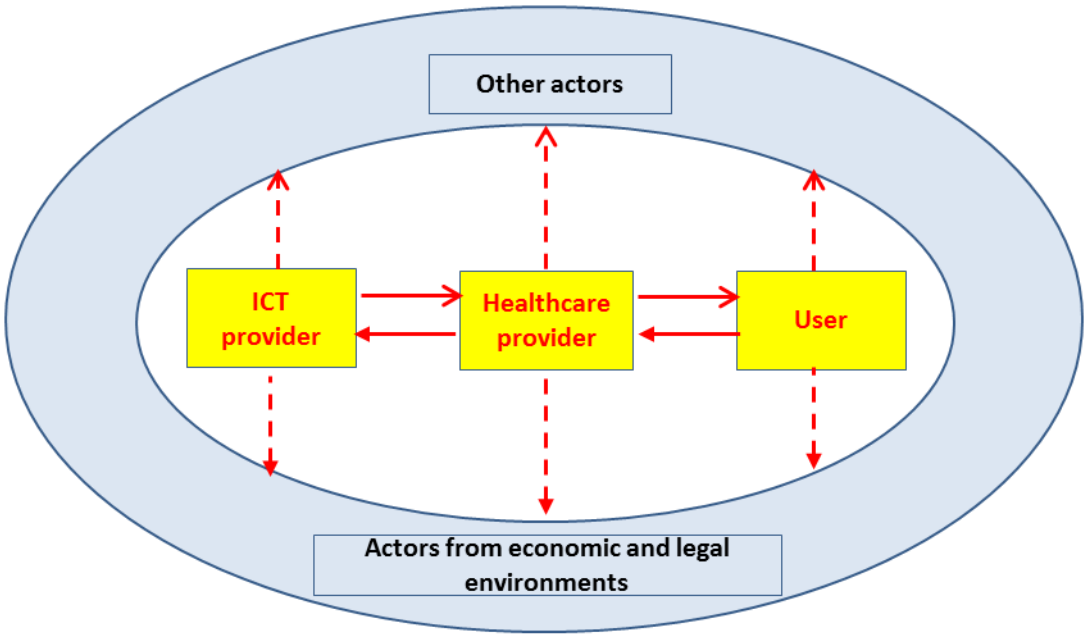

Figure 2 – High level view of the e-health ecosystem for personal health with its actors

The three key actors of the e-health ecosystem for personal health are characterized as follows:

- ICT provider: It offers ICT facilities that store, retrieve, process, transmit or receive information electronically.
- Healthcare provider: It implements and offers e-health services to be used by the User.
- User: It uses e-health services.

The ecosystem for public health is more complex than the ecosystem for personal health, and encompasses all aspects of the society: it is characterized by a multiplicity of interactions among the numerous actors of the ecosystem, including healthcare institutions, social services, educational institutions, urban planning agencies, public health agencies and so on. The large diffusion of the ecosystem for personal health and the large aggregation of data operated by the e-health services may benefit the ecosystem for public health, e.g. for a global health surveillance service, through the use of anonymous personal health data.

7 e-health applications and services with M2M

This document deals with "e-health applications and services with Machine to Machine (M2M)": these are e-health applications and services characterized by the usage of the so-called "e-health M2M framework" feature. The usage of this feature indicates that the e-health application or service under consideration uses at least a capability per layer of the capabilities located in each of the four layers identified in the Internet of Things (IoT) reference model [9]: "Application layer", "Service support and Application support layer", "Network layer" and "Device layer".

The following is a typical example of information flow related to an e-health application or service with M2M. E-health data are automatically collected from an e-health device residing on the user side and transferred to the remote side (automatic data collection). The data generated by the analysis and evaluation of the received data are then automatically transferred from the remote side to the user side in order to prompt an intervention (automatic data transfer in feedback loop). The data transfer to the user side can be performed manually in the case that a notification is generated based on the analysis and evaluation of the received data. In such case, the notification alerts the caregiver(s) and prompts an intervention which may lead to the actuation of an e-health device (manual data transfer in feedback loop).

The usage of M2M capabilities enhances e-health applications and services in various aspects by integrating and managing the capabilities of advanced technologies in data sensing (e.g. sensing of vital and environmental data), data analysis, area networking and wired/wireless communication. Enhancements of e-health applications and services include efficiency gains in health service delivery (e.g. enhanced health workers' productivity such as acquisition of patient information and medical record keeping), empowerment of individuals (e.g. improved participation of individuals in self-monitoring and chronic disease management) and quality and safety of care (e.g. medication compliance monitoring).

The following sub-clauses describe categories and high level requirements of e-health applications and services with M2M.

7.1 Categories of e-health applications and services with M2M

NOTE - Except for the remote patient monitoring/assisted living category, all other e-health application and service categories are not analysed in detail in this document.

7.1.1 Remote patient monitoring/assisted living

One of the categories of e-health applications and services with M2M is "remote patient monitoring/assisted living" (RPM/AL), which - as defined in clause 3 - has the purpose of supporting personal healthcare. Some use case examples of this category include mass medical examination services, personal healthcare services and e-health monitoring services, remote health counselling and health data management (see [10], clause 7).

The applications and services of RPM/AL involve the following key functional components: sensor(s), local area network(s) or body area network(s), gateway(s), medical information system, front end tools, application and service customers (patient(s) and caregiver(s)). An overview of the key functional components in the e-health ecosystem for RPM/AL is shown in figure 3.

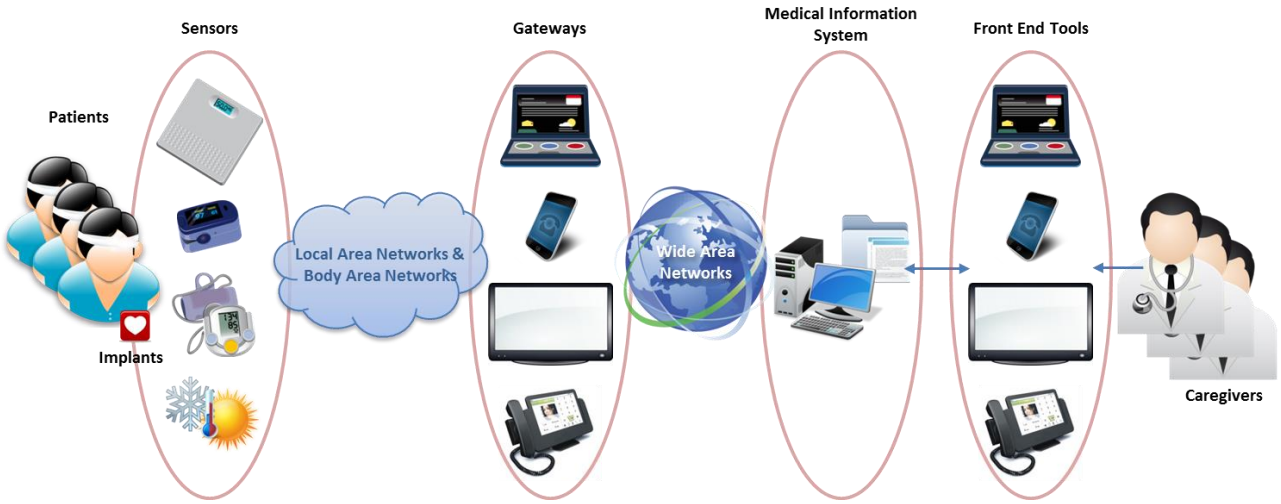

Figure 3 – Overview of the key functional components in the e-health ecosystem for RPM/AL

In RPM/AL applications and services, the information flows from the patient's side (usually in his/her home) to a caregiver. Data are transferred from sensors linked to the patient to a gateway that manages the sensors. Data transfer in a local area network (LAN) or body area network (BAN) is continuous or at one time depending on sensor types and data retrieval time-ordering among sensors. Gathered data are stored in a gateway or uploaded to a medical information system located in a wide area network. In the gateway, gathered data are linked to the patient and put into the patient's personal information. Caregivers, such as medical doctors, access the patient's personal information in accordance with privacy and security requirements.

The following provides some details about the key functional components in the e-health ecosystem for RPM/AL:

A Patient is a person who is monitored by caregivers and receives feedback by them upon his/her request.

Sensors are composed of non-invasive devices (e.g. pulse oximeter, sphygmomanometer, electronic scale, environmental temperature) and/or invasive medical devices (e.g. glucose meter, pacemakers, cardiac defibrillators, insulin pumps). A sensor retrieves data from a patient or his/her environment and sends them to the gateway which manages the sensor via a LAN or BAN. Sensor locations can be fixed or mobile depending on the use pattern.

A Local Area Network (LAN) provides wired/wireless communications for sensors to exchange data with a gateway at a location such as a building, facility and campus (e.g. WiFi).

A Body Area Network (BAN) offers either a wired communication or short range radio communication capability for sensors to exchange data with a gateway around a person's body (e.g.

USB [b-USB], Bluetooth [b-Bluetooth], ZigBee [b-Zigbee], Medical BAN [b-IEEE802.15.6], NFC [b-NFC]). A BAN is not limited to the space around a person, but depends on the distance reachable by cables and radios in an environment with power constraints.

A Gateway collects vital and environmental data from sensors in a LAN or BAN, and structures the collected data with the personal data of the patient as a medical/healthcare record. Prior to structuring, it analyses the data continuously received from environmental measurements. It compiles them as personal information and uploads the information to a medical information system via a WAN.

A Wide Area Network (WAN) offers either a wired or wireless communication capability (e.g. cellular (3G, LTE), PSTN/POTS, DSL/Ethernet) for gateways to upload data to a medical information system.

A Medical Information System manages the patient's information uploaded from gateways and stores it, in accordance with security and privacy requirements, in the system (e.g. in a backend server of a remote monitoring service provider) as individual electronic health information (e.g. EHR, PHR). It manages access to the stored information from caregivers and patients according to the service policy.

A Front End Tool interrogates and displays individual electronic health information from a medical information system upon a caregiver's request (e.g. a PC, tablet or a smart phone). It helps a caregiver to identify remedies and give a feedback in therapy or for wellness. It is also used to modify the information upon a caregiver's request.

A Caregiver retrieves and modifies individual electronic health information stored in a medical information system via a frontend tool and gives a feedback to the patient (e.g. nurse, paramedic, medical doctor or non-licensed health worker).

7.2 High level requirements

The following high level requirements of e-health applications and services with M2M are described - where applicable - by referencing to the Internet of Things high level requirements classification (and associated content) used in ITU-T Y.2060 [9].

Security: Trustworthy services are recommended to be provided, and threats to them are recommended to be avoided. Provided solutions shall follow regulation requirements. Personal health information such as medical records is required to be securely protected.

NOTE 1- The guidelines to deal with personal health information depend on the policies, laws and regulations in each country and/or region.

Privacy protection: Sensitive personal health information is recommended to be managed via established security mechanisms in compliance with regulation and laws, and all means are required to be put in place to guard against privacy breaches. In multi-user environment, when an e-health device for monitoring is shared among persons, the link between aggregated personal health information from the device and the person is recommended to be ensured.

NOTE 2 - Sensitive personal health information may include personal data such as name, address, age, gender, medical history, family etc. and medical records including any health related data associated with the person's identification provided by a patient to the caregiver.

Qualified data retrieval from human body: The quality of sensed data retrieved from human body is recommended to be associated with the e-health device's measurement environment, such as via unique production number of the e-health device or other method. Continuous and large amount of data received from e-health devices are recommended to be handled.

NOTE 3 - According to regulation, a medical device is required to provide reliable measurement results with high accuracy and stability.

NOTE 4 - E-health devices and gateways in area networks dealing with health related data and environmental data are recommended to follow international standards applicable to e-health applications and services, such as IEEE 802.15.6 [b-IEEE802.15.6], NFC [b-NFC], Zigbee [b-Zigbee] and Bluetooth [b-Bluetooth].

NOTE 5 - Automatic data transfer without human intervention from e-health devices and gateways is recommended to be supported.

Device identification: E-health devices are recommended to be identifiable by their unique identifier, such as production serial number. E-health device property information on healthcare applicability (e.g. measured data reliability) is recommended to be retrieved based on identification.

NOTE 6 - Various wired or wireless communications as well as various types and large numbers of e-health devices are expected.

Configurability: E-health device and gateway self-configurability may be optionally supported for caregivers and patients to avoid misuse and failure in healthcare treatments.

Interoperability: Interoperability is recommended to be ensured among heterogeneous and distributed systems for provision and consumption of a variety of information and services, including interoperability among e-health devices, gateways, medical information systems and services themselves.

Quality of Service: Usage of the Quality of Service (QoS) capabilities provided by the underlying networks is recommended to be enabled so that e-health applications or service capabilities may use the QoS capabilities of the underlying networks as appropriate in order to satisfy their end-to- end QoS requirements. Quality of Service (QoS) is a very broad area with numerous attributes, with reliability and latency being the most vital requirements for the support of a large number of e-health applications and services.

NOTE 7 - The Internet of Things high level requirements contained in [9] include support of other relevant features, such as **Identification-based connectivity, Plug and play**, **Autonomic networking**, **Manageability**, **Location-based capabilities** and **Autonomic services provisioning**. These features, although they may improve the quality of the e-health applications and services, are not specific requirements for these applications and services.

8 M2M enabled e-health ecosystem

As shown in figure 2, an e-health ecosystem involves various types of actors depending on the expected services and their environments.

An M2M enabled e-health ecosystem has the complexity derived by the combination of the roles involved in the provisioning of M2M services and the actors of an e-health ecosystem.

The provisioning of M2M services involves multiple roles and these roles are also required to be supported by the actors of an M2M enabled e-health ecosystem.

The M2M technologies are key enablers for the Internet of Things (IoT) and, as such, the IoT ecosystem concepts are at the basis of an M2M enabled e-health ecosystem.

NOTE - The IoT ecosystem is discussed in appendix of ITU-T Y.2060 [9]. The following roles are involved in an IoT ecosystem: Device provider, Network provider, Platform provider, Application provider and Application customer.

8.1 High level view of an M2M enabled e-health ecosystem

A variety of actors are involved in an M2M enabled e-health ecosystem. Each actor plays at least one role, but more roles are possible.

It is assumed that the key actors of an M2M enabled e-health ecosystem (for personal health) are the same as those of an e-health ecosystem (for personal health) as described in clause 6.

An M2M enabled e-health ecosystem, as shown in figure 4, can be seen as an implementation of the IoT ecosystem in the e-health domain.

Figure 4 shows an M2M enabled e-health ecosystem (for personal health) via its key business roles and their interactions. The key business roles are: Device provider, Network provider, Platform provider, Application provider and Application customer (this last one actually consisting in two distinct roles, Caregiver and Patient).

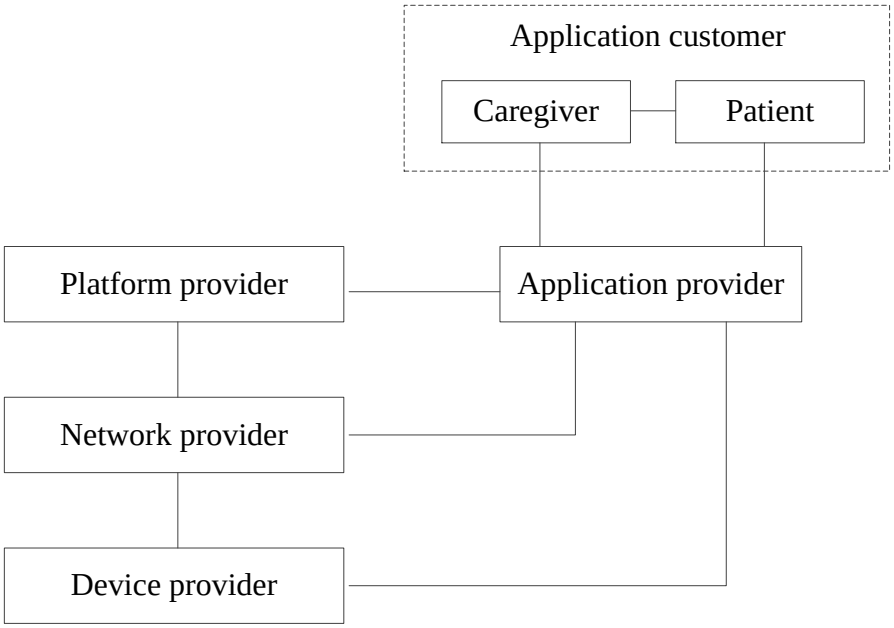

Figure 4 – M2M enabled e-health ecosystem

The **Device provider** is responsible for devices (with or without M2M capabilities) which provide health related data and other data to the network provider and the application provider. The device provider deals with a potentially huge number of devices used by the application customer.

The **Network provider** performs the following main functions:

- Support and control of the network infrastructure;
- Exposure of network capabilities to other providers.

The **Platform provider** provides application support capabilities and open interfaces. The capabilities include typical integration capabilities, as well as data storage, data processing and device management. Support for different application domains is also possible.

The **Application provider** utilizes the capabilities or resources provided by the network provider, device provider and platform provider depending on the application requirements, such as security and privacy policies, in order to provide applications to the application customer.

The **Application customer** uses the application(s) provided by the application provider. The application customer consists of two distinct roles, caregiver and patient, whose involvement in a given business deployment depends on the specific application requirements, including regulation

aspects. The patient may directly consult the caregiver by using information provided by the application provider.

NOTE 1 – The identified business roles and their relationships as described in figure 4 do not represent all possible relevant roles and relationships which can be found across M2M enabled e-health business deployments.

NOTE 2 – A typical example of business deployment involves the "User" actor playing the role of application customer, the "Healthcare provider" actor playing the role of application provider, and the "ICT provider" actor playing the roles of platform provider, network provider and device provider. Depending on the business model as well as the economic and legal environments, the mapping between actors and roles may be various.

In an M2M enabled e-health ecosystem, interactions between application provider and application customer are expected. It is also expected that the M2M devices are provided by the device provider and associated with the application. The application provider may utilize the M2M capabilities of the devices supplied by the device provider, in order to provide e-health application to the application customer, directly and/or indirectly (via the network provider and platform provider).

As shown in figure 4, the interactions between application provider and patient may occur with or without caregiver's intervention, depending on the regulation related to the services. In these interactions, the information and instructions are usually sent to the patient from the caregiver by using analyzed data provided by the application provider. In some cases, the information and instructions may be sent directly from the application provider to the patient without intervention of a caregiver. Thus, by reducing the needs of direct communications between caregiver and patient, the M2M technologies increase the scalability of an e-health ecosystem and, potentially, may increase the number of supported patients in the ecosystem.

9 Regulatory considerations for e-health with M2M

For further study.

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Printed in Switzerland
Geneva, 2014