E-health Standards and Interoperability

ITU-T Technology Watch Report
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E-health systems can potentially transform healthcare through mobile health delivery, personalized medicine, and social media e-health applications. Reaching the potential for advancements in e-health will only be achieved through information and communication technology standards efforts that facilitate interoperability among systems and devices, provide unqualified privacy and security, address the unique needs of the developing world, and leverage existing ubiquitous technologies such as social media applications and mobile devices.
The rapid evolution of the telecommunication/information and communication technology (ICT) environment requires related technology foresight and immediate action in order to propose ITU-T standardization activities as early as possible.

ITU-T Technology Watch surveys the ICT landscape to capture new topics for standardization activities. Technology Watch Reports assess new technologies with regard to existing standards inside and outside ITU-T and their likely impact on future standardization.

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This report was prepared by Dr. Laura DeNardis of American University in Washington, DC. Dr. DeNardis is a globally recognized expert on Internet governance and ICT standards. Her books include Opening Standards: The Global Politics of Interoperability (MIT Press 2011), Protocol Politics: The Globalization of Internet Governance (MIT Press 2009); and Information Technology in Theory (Thompson 2007 with Pelin Aksoy). The opinions expressed in this report are those of the author and do not necessarily reflect the views of the International Telecommunication Union or its membership.

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1 Introduction: Standards at the Core of E-health

Until quite recently in history, the delivery of professional health care services required a patient to be physically collocated with a medical provider. Patients living in regions with inadequate health services had to either travel long distances for care or accept substandard medical services. Those seeking access to medical literature and educational health resources were relegated to visiting specialized medical libraries, if they could access these resources at all. Patient data stored in the files of a primary care physician were not readily accessible by specialists, pharmacies, insurance companies, hospitals or labs. Each healthcare provider housed individual data and imaging snapshots of patients. There were physical, economic, and knowledge barriers to receiving optimal healthcare services.

The advent of digital information and communication technologies (ICTs) did not automatically solve these problems. Patients living in remote areas still lacked direct access to medical professionals, and medical devices could not be electronically connected from remote locations to advanced medical facilities. Patient records, when stored electronically in one medical office, could not necessarily be accessed from a hospital or pharmacy. Each healthcare provider – hospitals, administrative entities such as government agencies or insurance companies, pharmaceutical services, or primary care physicians or medical specialists – all had their own installed base of proprietary systems, technologies, and information systems which lacked interoperability with the systems used by other providers.

Solving these deficiencies can only be accomplished with e-health standards, the specifications that enable interoperability among healthcare-related information and communication technologies and systems made by different providers. Standards represent information in common formats, encrypt or compress information, perform functions like error detection and correction, or provide common addressing or security structures. All of these functions, taken together, are what enable the reliable and interoperable sharing of information over communication networks and between devices which agree to adhere to these common standards. ICT standards enable not only e-health but the Internet, mobile systems, the traditional phone system, and systems that deliver digital music, movies, video, and images. Standards are not software or hardware but are the blueprints that technology developers use to create products that will inherently be compatible with other products adhering to these same standards.

This report explains how rapid advancements in the development of e-health standards must accompany three trends in electronic healthcare in the coming decade: 1. Advancements in healthcare delivery via mobile and wireless e-health technologies; 2. Personalized medicine, including personal health records, medical diagnostic devices, and biometric records; and 3. Interactive healthcare via social media and Web 2.0 applications. The report also provides an introduction to some of the institutions working to develop standards in the capacious area of e-health, including CEN/TC 251, DICOM, HL7, ISO/TC 215, ISO/IEEE 11073 and, in particular, the work ITU-T is doing in e-health standards areas such as telecommunications and mobile infrastructure, multimedia e-health applications, and emergency and disaster response. The report concludes by suggesting five standards prerequisites necessary for achieving the promise of e-health: emphasizing greater interoperability, increasing coordination over global e-health standardization, ensuring privacy and
security, reducing the standardization gap in the developing world, and leveraging existing technologies like mobile devices and social media applications.

2 Emerging Trends in Electronic Health Care

The January 2011 ITU-T Technology Watch Report on “Standards and e-Health” described some specific trends in e-health, including the rise of genomic medicine, standardized electronic health records, remote healthcare and diagnostics, and aggregated public health data. One year later, these trends still embody the global promise of e-health as do three other trends – further emphasis on mobile health, personalized medicine, and health 2.0 social media applications.

Genomic medicine, the use of personal genetic markers in DNA to assist in disease prevention, diagnosis, and treatment decisions, has continued to progress. Advancements in computational power over the past year have increased the ability of scientists to sequence genetic information and perform the computationally intensive data manipulation tasks inherent in genomic medicine. The area of electronic health records is still a central focus of standards organizations, national e-health policies, and strategies within health systems. This is also an area that continues to raise concerns about data security and privacy. As the use of massive distributed computing resources to assist development of disease diagnostic and prevention progresses, such as the EU outGRID Project, increased calls are heard for standards that provide for robust infrastructure, deployment models and interfaces.

The trend that has made perhaps the most progress over the past year is remote healthcare and diagnostics, the use of telecommunications networks and information technology for healthcare services such as remote clinical care, diagnostics, and electronic patient monitoring. This progress is being driven by the pervasiveness of ICTs generally, by wireless capability, and by the relative affordability of devices. It is also being driven by standardization efforts and also pilot projects, including many in the developing world. Developments in this area include advancements in remote clinical care technologies that enable doctors to provide medical assessments and treatments from a remote location away from the patient via real time multimedia interactions with a patient such as a video feed transmitted over a telecommunications network. This type of e-health service is expected to be significantly advanced by the further introduction of remote diagnostic processing capabilities that acquire medical information via diagnostic technologies such as Magnetic Resonance Imaging (MRI) or ultrasound and transmit this information to the remotely located medical provider for diagnosis. This is both cost effective in general and specifically vital for patients in remote areas without access to specialist medical doctors.

Recent studies have indicated that remote electronic patient monitoring systems have great potential to improve patient care for those in rural and remote regions. These systems, such as blood glucose monitors, blood pressure devices, pulse oximetry devices, or heart monitors, enable medical providers to electronically observe a patient remotely using these devices and telecommunications networks, and are a cost effective and patient-friendly way to monitor elderly patients and those with chronic medical conditions or recovering from a

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medical procedure. The exchange of information among these various remote devices is sometimes referred to as machine-to-machine communications (M2M).

As identified in the 2011 Technology Watch report on "Standards and e-Health", the other major trend in e-health, this one at a public health rather than individual level, is aggregated public health data. The availability of standardized digital patient data is presenting unprecedented opportunities for the aggregation and mining of this data. Enormous collections of aggregated health data are often described colloquially as “big data” – a term of art describing information stores in the terabyte to petabyte range and so large it is not able to be manipulated by routine database management tools. Genomic information stores are also usually considered “big data” stores. The presumption in aggregated public health data is that this data is stripped of personal identifiers to protect individual privacy. Questions remain about what constitutes adequate anonymization of digital data to protect individual privacy, as well as whether this information can be used to carry out discriminatory practices in insurance coverage or employment. Furthermore, if the source of data was for an administrative or insurance purpose rather than a clinical function, this raises concerns about the accuracy and quality of data. Nevertheless, aggregated health data can provide a number of public health advancements such as aiding health research, assessing the efficacy of pharmaceutical products, providing data for patients interested in certain treatments, or helping governments monitor overall public health conditions and determine where to allot scarce resources.

The following sections both further highlight the innovations described above and call attention to three related trends in electronic healthcare expected in the coming decade: advancements in healthcare delivery via mobile and wireless e-health technologies, personalized medicine, and interactive healthcare via social media applications.

mHealth: Healthcare via Wireless and Mobile E-health Technologies

ITU statistics suggest that almost 6 billion people have mobile phone subscriptions⁴. The 21st century reality is that the majority of the world’s population, nearly 90% of the world, is plugged in via cellular telephony. Not surprisingly, there is considerable enthusiasm for the potential of capitalizing on this ubiquitous mobile technology infrastructure for improving both healthcare delivery and access to health information, particularly in low and middle-income countries which have limited access to the Internet via broadband fixed access and limited ICT infrastructure other than cellular phone networks. Certainly, mobile phone systems are encroaching upon and supplementing health-related services traditionally provisioned via land-line telephone networks. These types of traditional voice services include emergency dispatch services, health information lines and call centers, appointment systems, and pharmacy ordering systems.

The transformational potential of mobile e-health services extend well beyond traditional voice services to include more sophisticated health delivery such as remote clinical care, electronic patient monitoring, remote diagnostics, and access to (and input into) public health information. To date, mobile health has not lived up to this full potential. A World Health Organization (WHO) global survey on e-health found that “the dominant form of mHealth today is characterized by small-scale pilot projects that address single issues in

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information sharing and access”. Nevertheless, there are several specific applications gaining traction for mobile phone-based health issues:

**Public Communication during Natural Disasters or Public Health Pandemic.** During the 2011 Japanese earthquake and associated tsunami, cell phone service sustained less damage than the traditional landline public switched telephone service. One potential use of cellular telephone networks in such an environment is a public alert system in which government agencies can send alerts to citizens about evacuation procedures, impeding aftershocks, relief efforts, and notifications about health hazards such as radiation or disease outbreaks.

**Patient Self Education about Healthcare.** Many patients without access to the Internet via a broadband network have access via their intelligent handheld devices connected to cell phone networks. Patients use their cell phones to research medical information, drug side effects, or treatment options or search for health care providers in their area.

**Remote Patient-to-Physician Communication via a Mobile Device.** Routine communications over mobile phones already occur among patients and physicians, particularly as follow up calls after a procedure or test. New applications, coupled with remote diagnostic equipment, will increasingly rely upon mobile calls for diagnosis and treatment intervention strategies.

**Mobile Apps for the Detection of Counterfeit Drugs.** Counterfeit drug products can have fatal or debilitating effects and often target populations in impoverished regions. Mobile apps like mPedigree allow patients to text-message a unique product code found on prescription medicine and receive back a text indicating whether it is a valid or counterfeit prescription.

**Gathering Public Health Data.** Non-governmental agencies, government agencies, and health systems are increasingly viewing mobile phones as an effective and ubiquitous means of assessing general health conditions and requesting specific health data on a voluntary basis from citizens.

Country-specific examples of mobile e-health initiatives are described in the recent ITU-D Study Group 2 report “Mobile e-health Solutions for Developing Countries”, Question 14-2. ITU-T’s earlier “Roadmap for Telemedicine” also outlines mobile e-health applications and barriers. Challenges to emerging mHealth applications are numerous, including how to ensure the accuracy of medical information obtained by patients via mobile devices, how to secure patient-to-provider communications over mobile networks, and how to guarantee adequate service reliability for remote monitoring functions.

**Personalized Medicine**

Advances in computing and genomic technologies are expected to provide unprecedented innovations in personalized medicine. The National Cancer Institute of the National Institutes of Health in the United States defines personalized medicine as:

“A form of medicine that uses information about a person’s genes, proteins, and environment to prevent, diagnose, and treat disease.”

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6 See [http://mpedigree.net/](http://mpedigree.net/)


The National Human Genome Research Institute suggests that personalized medicine will “transform healthcare” because of its potential for early diagnosis of diseases, highly tailored treatment remedies, and the ability to foresee and avoid adverse drug side effects. The human genome contains the entirety of a person’s genes and DNA. This field of science is beginning to identify correlations between gene mutations and markers with inherited diseases, such as the BRCA 1 and BRCA 2 genes indicating a heightened risk of breast cancer.

This area of cutting edge science is also an area of e-health, because of the computationally intensive digital computing resources necessary to decode and calculate personalized medical records from biological samples, the information and communication technologies necessary to store and transmit this information, and the standard formats in which to encode and usefully share personalized and biologically derived information. As such, personalized medicine will be technically dependent on the Electronic Health Record (EHR). Sometimes called “personally controlled Electronic Health Records”, standardized data collected via information systems used by health providers, pharmacies, clinical laboratories, and hospitals creates a detailed and accessible record of a patient’s medical history. Standardization efforts around EHRs are the lynchpin of enabling such digital collection, storage, and retrieval of this type of data. At present, the reality is that legacy systems developed by different manufacturers use proprietary formats that are not mutually interoperable, sometimes even within a single healthcare system. If this lack of interoperability is overcome, even at the national level in various countries, by standardization advancements, personalized electronic health records will eventually become standard practice.

These records would contain a patient’s entire medical history from birth, including biometric and genetically derived information, immunization records, doctor and hospital visits, clinical observations, diagnoses and treatments, records of procedures performed, diagnostic images, allergies, drugs administered, and other medical information. It would also contain personal and administrative information about the patient such as insurance coverage, legal permissions, next of kin, and contact information. Not surprisingly, the greatest concern about this type of permanent, biometric, and possibly ubiquitous digital record is the question of how to protect individual privacy and under what conditions to grant access to such information and to whom. Other questions address where the data should be stored and whether governments should ever have access to this personal information and under what conditions. Such a personalized record, in addition to producing healthcare cost efficiencies and highly personalized and tailored medical treatments, would be advantageous to patients in other practical ways. With fragmented and non-interoperable patient records, it can be difficult for patients to keep track of medical histories and difficult to recount these histories every time they visit a new medical provider. Having immediate access to this information in an understandable format would presumably enable more informed medical choices.

Social Media and Health 2.0 Technologies

A significant question in e-health standardization discussions is how the now pervasive social media applications and web 2.0 technologies will transform healthcare. What should standards organizations and e-health providers be thinking about now to prepare for the emerging relationship between electronic health and these new media? The use of web 2.0 technologies is pervasive among those with any form of Internet access. The so-
called web 2.0 moniker describes Internet applications that are either geared toward interactive, participatory communications (e.g. social media applications) or user generated content such as blogs, wikis, content hosting sites, podcasts, and customized web search tools.

**Web 2.0 Managing Electronic Health Data.** One nascent trend is the emergence of technology companies providing a platform for patients to manage their own personal health data online, or health data for elderly parents or children (e.g. CareZone\(^\text{10}\)). A *New England Journal of Medicine* article contends that the these platforms would be “a disruptive innovation that inverts the current approach to medical records in that they are created by and reside with patients who grant permission for their use to institutions, clinicians, researchers, public health agencies, and other users of medical information”\(^\text{11}\). Citizens are accustomed to controlling their own information online and some will increasingly turn to new online health data portals to control and access medical data.

**Online Reputation Systems and Healthcare.** The use of online reputation systems – whether Yelp, Amazon reviews, or Reddit, are a daily way of life for those members of the younger generation with online access. These systems allow citizens to rate businesses, news, videos, services, and restaurants. Online reputation systems are also beginning to be used to rate medical services, and this trend is expected to only increase\(^\text{12}\).

**Social Media Patient Support Communities.** Patients consult medical information online, and they also turn to online social media communities for peer-to-peer support and information gathering. Many of these social networking sites promote positive health-related activities such as providing peer group support for those suffering from the same disease or are devoted to the overall promotion of health, fitness, and environmental safety. In other cases, the social media health sites provide a space for patients to ask and answer questions about diagnoses, etiology, and treatment, questions which are answered by laypersons rather than medical doctors. This raises serious concerns about the preponderance of inaccurate and unprofessional medical advice online as well as the possibility that someone might substitute this advice for consulting a doctor.

**Gamification of Health.** Gamification describes “the broad trend of employing gameplay elements to non-game environments such as customer retention, marketing, innovation, training, health and social change”\(^\text{13}\). Video games have a profound and pervasive effect on young people. Health-related, interactive video games are emerging in several areas: those geared toward the promotion of healthy lifestyles and wellness; video games designed for prevention, such as the prevention of HIV in teens; and video games designed to provide health information for those being treated for specific diseases such as cancer.

**Social Media-Based Health Services.** Communication between healthcare providers and patients is a foundation of healthcare services. The ways in which people communicate with each other has changed with the advent of social media applications, begging the question of how patient-provider communication will (or should) change to encompass social media\(^\text{14}\). In developing parts of the world with insufficient healthcare services, social media applications may be another avenue for providing direct remote healthcare services to patients. Social media applications are also a prime delivery tool for communicating crisis information during a natural or human-made disaster.

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\(^\text{10}\) See [https://carezone.com/](https://carezone.com/)


\(^\text{14}\) Carleen Hawn, “Take Two Aspirin and Tweet Me in the Morning: How Twitter, Facebook, and Other Social Media are Reshaping Healthcare”, *Health Affairs*, 28 (2) 2009: 361-365.
The idea of using social media for remote clinical care raises similar questions as any type of technology delivering this type of service about the legal liability of such healthcare delivery, and the technical and social steps necessary for preserving patient confidentiality and insuring adequate security and reliability of information transmitting over the Internet via social media applications.

3 E-health Standards Institutions

One of the challenges and opportunities of e-health standardization is the proliferation of multitudinous e-health standards developed by numerous standards-setting institutions. One historical challenge is that many of these e-health standards are not interoperable with each other or directly coordinated with each other at an institutional level. This is not universally the case, however. Because e-health standardization occurs at all layers of standardization – the physical layer, the data link layer, the network layer, the transport layer, the session layer, the presentation layer, and the application layer – there are also technically specific efforts at these various levels. It is the extent to which these efforts interoperate between layers, as well as competition in specific areas of standardization, that will determine the future of e-health, as discussed in the conclusion of this report.

This section provides an introduction to the primary standards bodies doing specific work in e-health standards. This is not at all an exhaustive list of standards organizations doing work in various e-health areas, but is meant to provide a selection of some of the most high-profile organizations doing work in the capacious area of e-health as well as some emerging e-health standards organizations. This collection of standards organizations was also selected because it provides an excellent cross section of the complexity and variety of types of standards necessary to enable e-health services. ITU work in this area, as well as coordination work associated with the World Health Organization, will specifically be described in Section IV.

The following table lists the websites of the organizations and initiatives presented in Sections III and IV, for further reading.

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<thead>
<tr>
<th>Name</th>
<th>Website</th>
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<td>Continua Health Alliance</td>
<td><a href="http://www.continuaalliance.org/">www.continuaalliance.org/</a></td>
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<tr>
<td>epSOS: European Patients Smart Open Services</td>
<td><a href="http://www.epsos.eu/">www.epsos.eu/</a></td>
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<td>GS1 Healthcare</td>
<td><a href="http://www.gs1.org/healthcare">www.gs1.org/healthcare</a></td>
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<td>DICOM: Digital Imaging and Communications in Medicine</td>
<td><a href="http://medical.nema.org/">http://medical.nema.org/</a></td>
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<tr>
<td>HL7: Electronic Health Information Systems</td>
<td><a href="http://www.hl7.org/">www.hl7.org/</a></td>
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CEN/TC 251 – Health Informatics

CEN/TC 251 is the health informatics technical committee of Comité Européen de Normalisation, the European Committee for Standardization (CEN). CEN primarily publishes standards that address application and content layer issues in e-health such as CEN/TS 15699:2009 “Health informatics – clinical knowledge resources – Metadata” and CEN/TS 15212:2006 “Health informatics – Vocabulary – Maintenance procedure for a web-based terms and concepts database”. Most of the committee’s standards address aspects of information representation, message standards, electronic health records, and some areas of communication specifications between medical devices. Part of the committee’s charge is to address the European Commission’s health interoperability mandate – Mandate 403.15

Continua Health Alliance

Continua Health Alliance is a non-profit organization with more than 240 member companies seeking to promote interoperability among personal e-health devices and systems. The Alliance was formed in recognition of the transformation of healthcare from primarily institutional environments to patient homes and other more distributed health delivery environments. Interoperability of personal health and fitness devices is a primary focus of this organization. Some of the technology and healthcare companies included among founding members of this group include Cisco Systems, GE Healthcare, IBM, Intel, Kaiser Permanente, Motorola, and others. One of the objectives of this organization is to develop “design guidelines that will enable vendors to build interoperability sensors, home networks, telehealth platforms, and health and wellness services”.16 Although it does write guidelines, Continua Health Alliance does not consider itself a standards body but rather an alliance that works to identify gaps in interoperability that prevent interconnection among diverse health products and devices.

This organization focuses on three areas of e-health. The first area encompasses technologies geared toward health and wellness, particularly for managing weight and preventing the diseases associated with obesity. Interoperability in this area focuses on weight scales, Internet fitness coaching, pedometers, fitness equipment, and related wellness systems. The second area focuses on chronic disease management and health care delivery. The third area encompasses technologies geared toward medical devices, particularly for enabling interoperability among medical devices, information technologies, and health care delivery systems. Interoperability in this area focuses on clinical information exchange, information technology, and medical devices.


particularly health monitoring and diagnostic systems. The third focus area addresses the aging world population and devices geared toward assisted living for the elderly. Continua has also launched a certificate program in which products certified and containing the Continua logo can be expected to be interoperable with other products with the Continua logo certification.

epSOS

Another emerging e-health standardization initiative is epSOS, or EuropeanPatientsSmartOpenServices. This relatively young pilot initiative, funded partially by the European Commission Competitiveness and Innovation Programme, involves 23 European countries and seeks to create an interoperable electronic health record system across Europe. The objective is a cross-border e-health system whereby patient records, prescriptions and insurance information could be accessed electronically regardless of where the patient was being treated in Europe. Europeans traveling as tourists, working in another country, or visiting another country as an exchange student would benefit from this interoperability and electronic health data access. Industry leaders from healthcare and information technology are involved and include IBM, Oracle, CareCom, MediciCognos, Microsoft and others. The initiative is adopting a general policy to employ already developed international standards whenever possible, including standards from HL7, WHO, ISO, and others.

GS1 Healthcare

GS1 is a global non-profit standards association comprised of member institutions from a host of countries. The focus of GS1's standardization effort is primarily supply and demand chains. GS1 Healthcare develops global standards to “help healthcare companies improve the accuracy, speed, and efficiency of the supply chain and care delivery”\(^7\). The association has been involved in supply chain data standardization in a number of industries but more recently expanded into the healthcare area. Examples of its working groups, primarily comprised of industry participants, are addressing product identification from manufacturer to point-of-care; location identification for tracking product progress through the supply chain, and hospital implementation issues related to ensuring product safety and supply chain optimization.

National Electrical Manufacturers Association – DICOM Standards for Medical Images

DICOM, short for Digital Imaging and Communications in Medicine, is a set of specifications dedicated to the standardization of medical images. The U.S. NationalElectricalManufacturersAssociation(NEMA) is responsible for the DICOM standards, originally developed by a joint committee formed by NEMA and the American College of Radiology. DICOM standards specify image file formats, storage protocols, and the processing and transmission of medical images. DICOM standards originated out of a “need for a standard method for transferring images and associated information between devices manufactured by various vendors”\(^8\). Some of the types of medical imaging standards encompassed by DICOM include: network protocols standardizing communications among devices adhering to DICOM standards; syntactical and semantic information necessary for exchanging medical images; media storage specifications; and file formats for medical images.

The DICOM standards are widely adopted in equipment and information systems used in hospitals, imaging centers, and in providers’ offices to produce, display, store, or exchange medical images. To give a more specific flavor of the types of standards within DICOM, certain specifications deal with information object definitions, data structures and encoding, message exchange, media storage and file format for media interchange, grayscale standards display function, security and system management profiles, application hosting, and transformation of DICOM to and from HL7, meaning the mapping and conversion of imaging system information from DICOM into HL7 clinical information systems, discussed next.

\(^7\) “Healthcare Standards and Initiatives” described on GS1 Healthcare website. URL (last accessed 11 March 2012) www.gs1us.org/industries/healthcare/standards-and-initiatives.

HL7 – Electronic Health Information Systems

Health Level Seven International (HL7) is a standards organization specifically devoted to the practice of developing standards related to the exchange, storage, and use of electronic health information such as clinical data and administrative information. In this regard, HL7 provides application-layer standards and the “7” in this organization’s name correspondingly refers to the application layer, or layer 7, of the ISO/ITU Open Systems Interconnection (OSI) reference model for describing technical standards. HL7 typically refers to both the standards organization and the HL7 family of standards. HL7 dates back to the mid-1980s, when it was formed to develop a standard for hospital information systems. It is a not-for-profit standards development organization involved in all aspects of standardization related to health information systems, electronic health records, and the communication, storage, and retrieval of this information. The scope of HL7’s standards activities is quite large. Like many other standards organizations, HL7 is organized into Work Groups chaired by two or more co-chairs and responsible for defining some area of HL7 standards. Some of HL7’s many Work Groups include: Electronic Health Record Work Group; Clinical Decision Support Work Group; Security Work Group; Patient Care Work Group; Structured Documents Work Group; Pharmacy Work Group; Regulated Clinical Research Information Management; Clinical Interoperability Council; Public Health and Emergency Response Work Group, and more.

HL7’s stated vision is “to create the best and most widely used standards in healthcare”. HL7 includes thousands of members including most companies involved in the provisioning of health information systems and products and companies involved in health delivery or technology. Some of the organizational members of HL7 include technology companies (e.g. IBM, Microsoft, Oracle); health providers (Quest Diagnostics, Kaiser Permanente); and pharmaceutical companies (e.g. Novartis, GlaxoSmithKline).

ISO/TC 215 – Electronic Health Records

The International Organization for Standardization (ISO) establishes e-health standards through its Technical Committee 215, “Health Informatics”. TC 215 has a wide scope which includes “Standardization in the field of information for health, and Health Information and Communications Technology (ICT) to promote interoperability between independent systems, to enable compatibility and consistency for health information and data, as well as to reduce duplication of effort and redundancies”. ISO’s 93 standards in “Health Informatics” address healthcare delivery, clinical research, public health, and prevention and wellness. To help convey the types of protocols ISO sets in this area, the following are the names of some of ISO’s 93 published health information standards: Electronic reporting of adverse drug reactions; Archetype interchange specification; Security; and Interface specification. Part of ISO’s activity in e-health involves the rebranding of specifications developed in other standards-setting institutions such as HL7 or DICOM. For example, ISO 12052:2006 is “Digital Imaging and Communication in Medicine (DICOM)”.

ISO/IEEE 11073 – Medical Device Communication Standards

Medical device interoperability and communications are critical components of remote care and citizen-centric electronic health environments. ISO/IEEE 11073 Medical/Health Device Communication Standards are a set of joint ISO, IEEE, and CEN standards for medical device interoperability. Examples of medical devices addressed under this standard include primarily personal, or end user, health devices such as blood glucose monitors, blood pressure monitors, thermometers, independent living activity hub, weighing scale, pulse oximeters, etc. As evident by this list, the personal health device communication standards are geared toward enabling communications from devices that patients can use in their own homes or other end points to monitor existing medical conditions.

20 From “About HL7” at URL (last accessed 14 February 2012) www.hl7.org/about/index.cfm?ref=nav
E-health initiatives, whether mobile health applications or remote multimedia diagnostics, are foundationally based and dependent upon core telecommunications services and infrastructures. These core telecommunications architectures are, in turn, dependent upon the standards that address the specific requirements – such as interoperability, security, mobility, and reliability – necessary for supporting advanced e-health applications. ITU-T Recommendations address these standards requirements in two ways. The first category of relevant ITU-T standards efforts are those specifications that support and enable e-health initiatives but are not specific to e-health applications.

The following are a few selected examples of broadly applied ITU-T standards initiatives that are not specifically designed to address e-health communications but nevertheless serve as vital information and communication technology underpinnings supporting the type of e-health networks and services described in this report:

- **(x)DSL – Digital Subscriber Line**  
  A family of standards enabling broadband Internet access over traditional twisted pair telephone networks (e.g. serves as a key access technology for the transmission of remote diagnostic applications.).

- **Digital Video Compression Standards**  
  ITU-T and ISO/IEC JTC1 jointly developed video compression specifications such as ITU-T H.262, or MPEG-2 video, and ITU-T H.264, also known as Advanced Video Coding (AVC) or MPEG-4 AVC (e.g. standards necessary for compressing and encoding video, including DVDs and other video formats delivering remote multimedia medical applications to remote areas).

- **Digital Image Compression Standards**  
  ITU-T and ISO/IEC JTC1 jointly developed compression specifications such as ITU-T T.81, also known as JPEG, or ITU-T T.800 JPEG-2000 (e.g. standards necessary for compressing still images, including digital cameras and other imaging devices used for medical applications, such as DICOM).

- **Information Security Standards**  
  ITU-T telecommunication security standards such as the X.800-X.849 Recommendations, the X.1000-X.1099 information and network security standards, including telebiometrics, the X.1120-X.1139 mobile security standards, and many more (e.g. for securing the transmission of personal health information over mobile networks and other transmission systems).

- **Quality of Service Standards**  
  ITU-T Recommendations geared toward standardizing performance and reliability of information transmission on a variety of networks, including home grid network standards such as ITU Recommendation G.9960 and Recommendation G.9961 (e.g. standards necessary for ensuring high reliability and quality of medical information transmitted to and from home environments).

- **Voice over the Internet**  
  ITU-T standards such as Recommendation H.323, a signaling protocol for transmitting audio (and visual) information over the Internet. H.323 is part of the broader Voice over

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22 See, for example, ITU-T Recommendation G.993.1, “Very High Data Rate Digital Subscriber Line (VDSL)”, available at URL (last accessed 14 February 2012) [http://itu.int/rec/T-REC-G.993.1](http://itu.int/rec/T-REC-G.993.1).


Internet (VoIP) family of standards. (e.g. necessary for supporting provider-patient voice communication over the Internet.)

These are a few examples of specific standards having a direct bearing on e-health systems. Consequently, many ITU Study Groups address issues supporting e-health, such as quality of service (Study Group 12), mobile telecommunications networks (Study Group 13), multimedia coding and systems (Study Group 16), security issues (Study Group 17), and others.

The new ITU-T Focus Group on M2M service layer will initially focus on e-health applications and services, performing a gap analysis in the M2M health area, identifying requirements, and analyzing the extent to which existing protocols meet these requirements. The group is expected to identify future ITU-T standards work in the M2M area\(^{28}\).

In addition to general areas supporting e-health networks, other ITU-T Recommendations and initiatives are directly related to the unique requirements and characteristics of global e-health technologies. The following section describes four of these specific initiatives: multimedia framework for e-health applications, emergency services standardization, global standards for the Internet of Things, and specific coordination efforts working with other standards institutions involved in e-health.

**ITU-T Multimedia Framework for E-health Applications**

Multimedia-specific e-health standardization efforts in ITU-T are addressed by Question 28/16, “Multimedia Framework for e-health Applications”\(^{29}\). Study Group 16 is the lead group addressing this question but, as indicated above, e-health questions traverse the standardization efforts of numerous ITU-T Study Groups. Study items under Question 28/16 are fourfold: to develop a multimedia framework for e-health applications (and telemedicine in particular); to develop a roadmap for e-health standards; to construct a general architecture for e-health applications; and to identify particular characteristics and requirements for e-health applications including video and still picture coding, audio coding, security, and directory architecture\(^{30}\). As described verbatim in the study question, the particular tasks of this initiative include the following:

- Inventory of existing e-health / Telemedicine standards
- Roadmap for e-health / Telemedicine standards, compiling and analyzing standardization requirements from e-health stakeholders and identifying standardization items with priorities
- Involvement within the E-health Standardization Coordination Group (eHSCG)
- Provide inputs for extension and improvement of existing Recommendations on MM-Systems (e.g. H.323, H.264, V.18)
- Develop new Recommendations if necessary\(^{31}\)

The impetus behind the formation of Q28/16 was the understanding of the critical and growing requirement for global interoperability among fragmented e-health systems based on various standards and the need for coordination among major global players such as medical institutions, governments, intergovernmental organizations, non-profit groups, and private industry.

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\(^{28}\) For more information, see the Terms of Reference document for ITU-T Focus Group on “M2M service layer”. URL (last accessed 11 March 2012) [http://itu.int/en/ITU-T/focusgroups/m2m](http://itu.int/en/ITU-T/focusgroups/m2m).


ITU-T Study Group 13 is currently developing a Recommendation (provisionally called Y.EHM-reqts) that will define a methodology to classify and describe the features of e-health monitoring services, as well define requirements and service capabilities from a network perspective.

ITU-T Study Group 17 has a focal Question 9/17 on telebiometrics that developed the ITU-T X.1081 series of Recommendations on telebiometrics and is working on ITU-T X.1080.x sub-series for secure telecommunication of e-health data between caregivers, patients and insurers (third party payment identification).

**ITU-T Emergency E-health Services Standardization**

A critical component of public health policy involves public communications, disaster relief, and the effective delivery of medical services during a public emergency. ITU-T is involved in standardization of electronic health-related communication during a public health emergency such as a natural disaster or health crisis. After the 2004 Indian Ocean tsunami and a spate of other natural and human-made disasters, the need became apparent for greater standardization and interoperability among telecommunications devices used in disaster coordination, response, and victim assistance. A related requirement is for techniques that prioritize emergency communications during a public health disaster.

Disaster communication problems in recent years have drawn greater attention to ITU-T’s emerging work in this area, particularly standardization efforts for telecommunications services for disaster relief and early warning to the public in advance of an imminent natural disaster such as a tsunami. Some specific standards efforts include ITU-T standards activities for telecommunications prioritization systems for the public switched telephone network during disasters and associated damage and congestion of telecommunications systems, and also Internet protocol based preferential communications systems over packet switched systems like the Internet. These efforts take place in ITU-T Study Group 2, which is responsible for a number of standards related to critical telecommunication resources such as numbers, names and addresses. It is also specifically responsible for work on standards supporting telecommunications for disaster relief, such as Recommendation ITU-T E.106, International Emergency Preference Scheme for disaster relief operations. Study Group 2 is also responsible for activities seeking to standardize broadcast alert systems designed to notify the public of an imminent public health disaster via telecommunications devices.

In addition to the activity of Study Group 2 in this area, a number of other Study Groups are addressing telecommunication standardization areas related to emergency and disaster relief systems. For example, Study Group 5 is working on improvements to network resiliency during disasters; Study Group 13 addresses emergency telecommunications in next generation networks; Study Group 15 advances work related to network recovery and resiliency; Study Group 17 has developed a Recommendation (ITU-T X.1303) for a Common Alerting Protocol (CAP) that standardizes formats for the transmission of emergency alerts and warnings over various networks.

Most recently, the ITU-T Telecommunication Standardization Advisory Group (TSAG) meeting in January 2012 in Geneva established a Focus Group on Disaster Relief Systems, Network Resilience and Recovery. The focus group is tasked with identifying additional future standards work that should be done in the area of disaster relief systems, encouraging standards collaboration among various groups doing work in this ar-

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ea, and addressing areas not yet addressed such as “(1) disaster relief for individuals (to notify the damage situation from victims to their relatives, friends, or employers) and (2) disaster relief guidance (to show victims the routes to evacuation shelters, home, etc.)”\textsuperscript{37}.

These telecommunications standardization efforts all involve the use of electronic networks to improve public health responses and survival prior to, during, and in the aftermath of large scale public disasters. Disaster alert systems and emergency telecommunication services are particularly vital in developing areas of the world that have limited communication technology infrastructures or are remote or small island states which become extremely isolated and vulnerable to health crises in the wake of natural disasters.

**Global Standards for the Internet of Things**

One of the most challenging aspects of e-health standardization is the need to enable interoperability among countless devices, often mobile and always distributed in location. ITU-T’s Internet of Things Global Standards Initiative (IoT-GSI) was formed with the vision of this type of interconnectivity among these devices or “things”. The Internet of Things effort is not only relevant to e-health systems but also other environments requiring distributed connectivity among a wide range of devices such as in remote sensing environments and in applications such as climate change mitigation and geo-information systems. In addition to health-related devices, the “things” in the Internet of Things can be cars, sensors, televisions, doors, or kitchen appliances and general consumer devices. Interoperability and standardization in these environments require standardized systems of device identification, data capture, privacy and security, and information exchange with other devices.

Some of ITU-T’s Recommendations related to the Internet of Things effort include: Recommendations for tag-based identification (e.g. ITU-T Y.2213); Requirements for ubiquitous sensor networks (e.g. ITU-T Y.2221); Requirements for SNMP-based sensor network management (e.g. ITU-T H.641); Requirements for personally identifiable information in tag-based ID systems (e.g. ITU-T X.1171); and Requirements for securing ubiquitous sensor networks (e.g. ITU-T X.1311 | ISO/IEC 29180). These are a few examples of ITU-T Recommendations related to the Internet of Things Initiative. IoT Recommendations related to identification, management, security, and information exchange of remote distributed devices are generalizable to a number of remote diagnostic networks, of which one specific application genre is e-health.

**Coordination with other e-health Standards Bodies**

ITU, along with WHO, seeks to coordinate and convene global workshops about the still extant need for a comprehensive and coordinated approach to global e-health standards development that ensures interoperability and sustainability. An example of efforts to promote such a dialog was the convening of a joint ITU-WHO Workshop on e-health Standards and Interoperability in Geneva, Switzerland, in April 2012.

ITU, along with the World Health Organization previously established an e-health Standardization Coordination Group (eHSCG) to serve as an overarching coordination group in the area of e-health standardization. The charter of the group laid out certain parameters for its activities, such as serving primarily as a technical, rather than regulatory group, to help promote cooperation among various standards development groups doing work in e-health, to discourage duplicative standards efforts, and to provide a repository of information identifying current e-health standards and work. In addition to ITU, member organizations of eHSCG include the WHO, the ISO Health Informatics technical committee (ISO TC 215), the Health Informatics Committee of Comité Européen de Normalisation (CEN), the IEEE 11073 medical device committee, Health Level 7, DICOM, OASIS International Health Consortium, and GSI. One of the tasks of ITU-T Study Group 16 is to participate in eHSCG.

5 Conclusion: Five Prerequisites for Transforming Healthcare with ICT Standards

The 21st century reality is that most citizens in the world do not have sufficient and affordable access to healthcare. e-health technologies hold the potential to help fill this gap in the coming decade. e-health services can lower healthcare costs through efficiencies in information sharing and health information delivery. They can reach underserved and remote areas. They can offer innovations that improve public and individual health through personalized medicine and aggregated health data.

From a standards perspective, e-health is one of the most complicated and challenging areas of standardization. There are several reasons for the difficulties inherent in e-health standardization efforts. First, the healthcare industry has an enormous installed base of legacy systems based on proprietary technologies. Second, e-health systems inherently involve “big data”, massive quantities of data, including multimedia diagnostic images, patient codes, test results, research samples, insurance identifiers, financial codes, and nearly countless other types of data. Third, e-health standards do not address one unified area of technology but hundreds upon hundreds of areas. Some involve standardization at the content level, such as patient data, diagnostic images, and medical research. Other areas of standardization must address a wide range of devices, software systems such as mobile apps, database management systems, and process management. Another enormous area involves e-health infrastructure and network management such as telecommunications systems, security, and identification and authentication. Finally, the e-health standards arena is difficult because it involves, to a certain extent, competing or at least overlapping standards initiatives taking place in different institutions. Many of these initiatives have traditions of charging fees for accessing or implementing standards in products, a phenomenon which can drive up the cost of e-health products or, in some cases, discourage innovation based on e-health standards.

The e-health advancements examined in this and previous e-health and Standards reports, as well as manifested in the promises of global e-health investments, will simply not occur without concomitant advancements in interoperability, coordination, privacy and security, attention to emerging markets, and willingness to leverage pervasive technologies like social media and mobile phones that are already in the hands of many citizens around the globe. Institutions directly involved in e-health standardization efforts should explicitly address strategies for meeting each of these requirements.

1. Emphasizing Greater Interoperability

Interoperability is not a given in electronic healthcare. Lack of interoperability is one of the greatest threats to achieving the improvements to healthcare and cost efficiency promised by emerging e-health systems. This barrier is not only a technical barrier but a market-driven barrier arising from the economic competition inherently occurring among companies seeking to profit in emerging and extremely lucrative e-health industries, and the lack of incentives among healthcare delivery systems to adopt standards. Unless a critical mass of healthcare technology providers adheres to the same standards for electronic health records, the system will not provide the anticipated cost efficiencies and healthcare quality improvements. The same requirement holds for aggregated public health data and mobile systems. As long as electronic health records are fragmented technically without adequate standardization among providers and vendors, meaningful system federation / public aggregation or remote clinical care will be difficult to achieve.

2. Increasing Coordination over e-health Standardization

Many standards in the area of electronic health are collaborations or endorsements of standards developed by other organizations such as ISO, ITU, HL7, or IEEE. For example, consider ISO/HL7 27931:2009, “Data Exchange Standards – Health Level Seven Version 2.5” which establishes an application protocol for electronic
data exchange in healthcare environments. But there is still a critical need for a top-level view of standardization efforts that, at a minimum, tracks and itemizes various e-health standards and identifies when there are competing specifications that could detract from interoperability goals. This tracking and coordination function is a technical function. But there are also economic and political rationales for greater coordination. The standards landscape is institutionally heterogeneous. Economically, medical providers and healthcare administrative entities will not be willing to invest in new systems based on e-health standards unless they have some assurance that the implemented standards have expected longevity in the future. Globally (or at least regionally/nationally) agreed-upon standards can provide the necessary stability to economically incentivize new investments. Politically, and to an even greater extent than most types of technical standards, the design decisions underlying e-health standards have public interest effects in areas such as individual privacy, non-discriminatory access to healthcare, and the overall public good. These decisions should be made with some type of global public accountability, whether developed in a multistakeholder fashion or at least openly available to the public for oversight.

3. Ensuring Privacy, Security and Safety

One of the most significant issues complicating the standards landscape for e-health is the inherently sensitive nature of the information, requiring a high degree of privacy protections, quality assurance, and security. Furthermore, health practitioners can be inherently risk adverse and reluctant to adopt new technologies. The health sector is also heavily regulated by national authorities. Standards efforts in any health area have to weigh the requirements (legal and social) for protecting the individual privacy of patients and patient data. They have to address patient safety and reliability concerns e.g. about the consequences of errors or degradation in the transmission of medical data over various types of networks. They also have to build in highest levels of security in areas such as data integrity, access controls, and authentication of users.

4. Reducing the Standardization Gap in the Developing World

Perhaps the greatest potential of e-health systems is the prospect of improving healthcare delivery in the developing world. There are many factors preventing developing countries from reaching advanced capability in standardization. The research conducted as part of the ITU-T Bridging the Standardization Gap program has identified six primary standards gaps in the developing world, many of them interrelated:

- Lack of understanding of the national importance of standards
- Relatively less private industry involvement in standards
- Inadequate funding of standardization
- Insufficient standardization human resources
- Insufficient involvement in international standards development processes
- Inadequate technical infrastructure for standards participation

Efforts such as the ITU-T Bridging the Standardization Gap program and the ITU-D Study Group 2 (Question 14-2) “Mobile eHealth solutions for Developing Countries”, were well targeted in this regard but much more work is necessary.

5. **Leveraging existing ICTs like Mobile Devices and Social Media**

Several e-health and health support areas do not entail the development of completely new e-health standards and systems *ex ante* but rely upon other existing technologies and infrastructures already standardized. One of these areas is the underlying telecommunications and packet switched infrastructure upon which health information is exchanged. The second area involves social media and web 2.0 tools that can be adapted in various ways to support access to health information, promote health initiatives, provide peer support networks, and create new communication alternatives for those in the developing world seeking medical advice not immediately available to them. The third area is mobile telephony, as described in Section II of this report. The basic requirement is to meet patients in the ICT infrastructures in which they reside, not just for cost savings but for usability and the reality that these infrastructures may be their only alternative for accessing e-health.
<table>
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<tr>
<th>Acronym</th>
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<tr>
<td>CDA</td>
<td>Clinical Document Architecture</td>
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<td>CEN</td>
<td>Comité Européen de Normalisation</td>
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<tr>
<td>DICOM</td>
<td>Digital Imaging and Communications in Medicine</td>
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<td>DNA</td>
<td>DeoxyriboNucleic Acid</td>
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<td>E-health</td>
<td>Electronic Health</td>
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<td>eHSCG</td>
<td>E-health Standardization Coordination Group</td>
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<td>epSOS</td>
<td>European Patients Smart Open Services</td>
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<tr>
<td>ETSI</td>
<td>European Telecommunications Standards Institute</td>
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<td>ICT</td>
<td>Information and Communication Technology</td>
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<td>International Electrotechnical Commission</td>
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<td>International Organization for Standardization</td>
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<td>ITU</td>
<td>International Telecommunication Union</td>
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<td>ITU Telecommunication Standardization Sector</td>
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<td>M2M</td>
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<td>mHealth</td>
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<td>NEMA</td>
<td>National Electrical Manufacturers Association</td>
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<td>NGO</td>
<td>Non-Governmental Organization</td>
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<td>SDO</td>
<td>Standards Development Organization</td>
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<td>SG</td>
<td>Study Group</td>
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<td>SNMP</td>
<td>Simple Network Management Protocol</td>
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<td>TC</td>
<td>Technical Committee</td>
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<td>Working Group</td>
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<td>WHO</td>
<td>World Health Organization</td>
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The rapid evolution of the telecommunication/information and communication technology (ICT) environment requires related technology foresight and immediate action in order to propose ITU-T standardization activities as early as possible.

ITU-T Technology Watch surveys the ICT landscape to capture new topics for standardization activities. Technology Watch Reports assess new technologies with regard to existing standards inside and outside ITU-T and their likely impact on future standardization.

Acknowledgements

This report was prepared by Dr. Laura DeNardis of American University in Washington, DC. Dr. DeNardis is a globally recognized expert on Internet governance and ICT standards. Her books include Opening Standards: The Global Politics of Interoperability (MIT Press 2011), Protocol Politics: The Globalization of Internet Governance (MIT Press 2009); and Information Technology in Theory (Thompson 2007 with Pelin Aksoy). The opinions expressed in this report are those of the author and do not necessarily reflect the views of the International Telecommunication Union or its membership.

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E-health Standards and Interoperability

ITU-T Technology Watch Report
April 2012

E-health systems can potentially transform healthcare through mobile health delivery, personalized medicine, and social media e-health applications. Reaching the potential for advancements in e-health will only be achieved through information and communication technology standards efforts that facilitate interoperability among systems and devices, provide unqualified privacy and security, address the unique needs of the developing world, and leverage existing ubiquitous technologies such as social media applications and mobile devices.