Connected Living

DIGITAL HEALTHCARE INTEROPERABILITY

Assessment of existing standards and how they apply to mobile operator services, in order to provide global recommendations to increase their adoption

October 2016

TABLE OF CONTENTS

Executive Summary

1 Digital Health solutions to address major healthcare challenges 4
2 Interoperability in Digital Health 7
3 Existing interoperability standards & organisations 11
4 Mapping of interoperability standards 16
5 Mobile operator service examples 18
6 Experiences from real world implementations 26
7 Findings & recommendations 31

Glossary

Executive Summary

Digital Health solutions can support healthcare professionals to deliver high quality, consistent and efficient healthcare. They can empower individuals to manage their own health more proactively and effectively. They can assist governments and healthcare providers in increasing access or managing epidemics. Reports by PwC[1] estimate Digital Health could save €99 billion in healthcare costs to the EU, or $14 billion USD in Brazil and $3.8 billion USD in Mexico, if it reaches scale. Lack of interoperability is often cited as one of the barriers to achieving this.

To realise these projected healthcare benefits of Digital Health solutions, interoperability is required at foundational, structural and, most importantly, semantic levels. This enables the secure, reliable and consistent exchange of data between devices, applications and platforms. It also facilitates the seamless design and integration of services, for ease of use by the patient, the clinician and the consumer. Semantic interoperability is an essential requirement, making sure that any data exchanged across devices and systems is understood, interpreted and acted upon in the correct manner.

This document, authored by the GSMA, with input from mobile operators from around the world, assesses existing global standards, and provides recommendations as to how interoperability can be realised when implementing Digital Health services.

A review of a broad range of mobile operator service examples and use cases finds that, by and large, existing standards are sufficient to achieve semantic interoperability. However, there are instances where existing standards are overlapping, or are not backwards compatible. Furthermore, a review of real-world implementations identified challenges during the development and implementation of Digital Health services. These factors are currently inhibiting the wide-spread adoption of standards.

For example:

- Many existing solutions use proprietary elements, i.e. they are not using the free-to-license standards that are available. This limits scale by preventing integration with other services and Electronic Health Records.
- Awareness and experience of interoperability is varied among procurers and in the clinical community. To address this, a growing number of EU governments are now demanding[2] application of interoperability standards in services.
- Simply using a standard does not guarantee interoperability. Significant expertise is required in the definition, design and implementation of systems and services.

[1] Realising the benefits of mobile enabled IoT solutions http://www.gsma.com/connectedliving/pwc-report-realising-the-benefits-of-mobile-iot-solutions/
http://www.gsma.com/connectedliving/socio-economic-impact-of-mhealth-an-assessment-report-for-brazil-and-mexico/
[2] Austria, Catalunya, Denmark, Finland, Norway & Sweden see http://www.pchalliance.org/sites/pchalliance.org/files/nodecontent/ehealth-network-letter.pdf

In summary, the limited interoperability of Digital Health services is not driven by a lack of standards. Rather, the main challenge to realising semantic interoperability is the adoption and consistent use of existing open standards.

Thankfully there are ways to overcome these challenges, and a broad range of stakeholders are already assisting in that endeavour.

First, anyone looking to implement Digital Health services is recommended to engage with standards and industry organisations like the Personal Connected Health Alliance (PCHA) and Integrating the Healthcare Enterprise (IHE), who work on the development and promulgation of standards for healthcare and give guidance on their use.

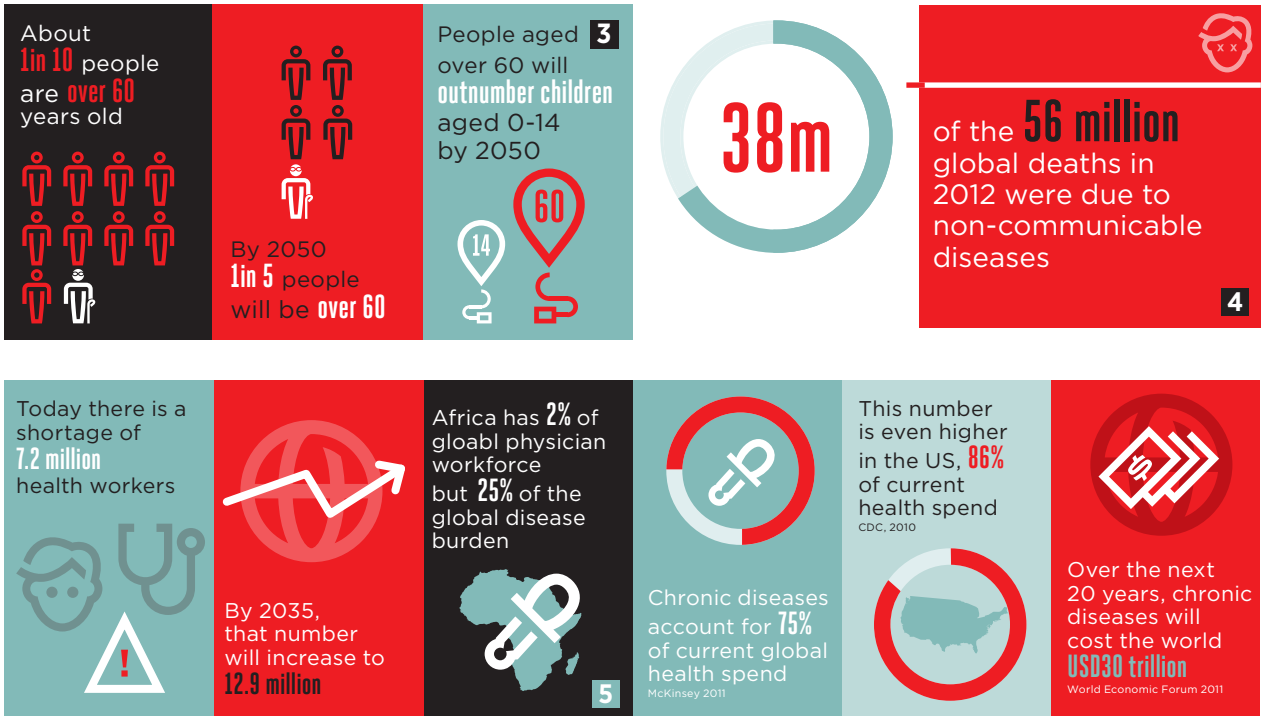
Second, healthcare providers and the clinical community, medical device and pharmaceutical companies, governments and mobile industry can all play a role to help further the adoption of standards that deliver semantic interoperability. In particular:

- **Healthcare providers and the clinical community can help educate users on the use of data and standards that maximise the interoperability of systems and serve to assist in the delivery of improved patient centred care;**
- **Medical device and pharmaceutical companies should aim to adopt open standards and interoperability in their design processes and final product solutions;**
- **Governments can help drive adoption by encouraging procurers to specify open standards in their medical device and healthcare ICT system acquisitions, and;**
- **The mobile industry can help by advising on the application of standards and by working with their healthcare industry partners to deliver services based on the principle of semantic interoperability.**

It is only through the collective actions of these stakeholders that the Digital Health opportunity can be realised at scale, in turn delivering the promised socio-economic benefits to citizens, healthcare providers and industry.

1. Digital Health solutions to address major healthcare challenges

The pressures on healthcare systems have never been greater. This is due to factors including rising expectations, ageing populations and, particularly in emerging economies, the combined challenges of infectious disease and the increasing incidence of chronic illness.



[3] Help Age International: http://www.helpage.org/resources/ageing-data/global-ageing-statistics/
[4] WHO Global Health Observatory http://www.who.int/gho/ncd/en/
[5] A Universal Truth: No Health Without a Workforce http://www.who.int/workforcealliance/knowledge/resources/hrhreport2013/en/

Given the wide reach of mobile networks and services that are becoming increasingly intelligent, there is a unique opportunity to develop new and innovative models for collaborative and integrated care systems that put the patient at the centre. This convergence of digital services with the delivery of healthcare (as well as the current genomic revolution emanating from the human genome project) help bring about this personalisation and patient centeredness. This is commonly referred to as Digital Health.

This is particularly important as established healthcare systems seek a shift to preventative techniques that promote healthy living and provide wider access (through the use of sensors and measurement devices in the home) to reduce the requirement for GP and hospital visits. In developing markets, mobile solutions can help bridge the burden of care in areas where the number of healthcare professionals are insufficient for the range of healthcare specialties required. In addition, Digital Health solutions also provide access, for those who wouldn't otherwise be able to receive healthcare services given limited infrastructure and resources, and there are valuable applications in epidemiology, to address challenges such as the recent Ebola and Zika virus outbreaks.

A 2015 report[6] by PwC, commissioned by the GSMA, estimates that Digital Health could save €99 billion in healthcare costs to the EU GDP, if its adoption is encouraged. The same report indicates that Digital Health could enable 11.2 million people with chronic conditions and 6.9 million people at risk of developing chronic conditions to extend their professional lives and improve their productivity. This would add €93 billion to the EU GDP. A separate PwC study concluded Digital Health could enable an additional 28.4 million people access to the healthcare system in Brazil, and an additional 15.5 million to the same in Mexico, without having to add a doctor. Total healthcare spend (public and private) could be reduced by $14 billion USD in Brazil and $3.8 billion USD in Mexico while providing the same care impact[7]. Despite this potential to realise significant healthcare savings and to provide benefits to so many citizens, the widespread deployment of Digital Health services are still limited.

Structures for provision of healthcare can vary around the world. A typical model of provision is a combination of Primary, Secondary and Tertiary Care services.

- Primary Care: Usually the first point of contact for a patient, and generally the 'gateway' to receiving more specialist care. Primary Care typically refers to contact with a General Practitioner (GP), Dentist, Optician or Pharmacist.
- Secondary Care: Contact in Secondary Care typically occurs after referral from Primary Care, to receive care from a more specialised expert. This usually, but not always, takes place in a hospital or clinic with specialist facilities.
- Tertiary Care: Refers to the provision of specialised care similar to that in Secondary Care. With referral from Primary or Secondary Care, to a facility with advanced medical investigation and treatment capabilities.

As Digital Health progresses, patient centric care may completely alter this structure. With the

> *"there are valuable applications in epidemiology, to address challenges such as the recent Ebola and Zika virus outbreaks."*

[6] http://www.gsma.com/connectedliving/pwc-report-realising-the-benefits-of-mobile-iot-solutions/
[7] http://www.gsma.com/connectedliving/socio-economic-impact-of-mhealth-an-assessment-report-for-brazil-and-mexico/

possible exception of accessing very specialist care, as with other industries, information and communications technology (ICT) will move the point of care to the patient, rather than the patient having to move to gain access.

Data security, identity management and interoperability are regularly cited among the Digital Health community as key factors still to be addressed. The focus for this paper is interoperability, specifically the components that will serve to enable interoperability between services, devices and existing healthcare systems to support delivery of scale for Digital Health. Written primarily for the mobile industry, this report also has relevance and provides supporting recommendations for healthcare providers / clinical community, medical device vendors / pharmaceutical industry and governments.

In order to holistically assess the challenge of providing interoperability to achieve scale, this report begins by explaining interoperability in the context of Digital Health, and its main benefits. It then moves to review existing standards and relevant organisations that are currently facilitating interoperability in this space. Service examples are then developed to evaluate the use of existing standards specifically for the mobile industry, and guidance provided on potential enhancement of these services using the latest interoperable standards. To conclude the analysis, real world implementations are reviewed where interoperability was a key consideration, with the learnings from these summarised. Based on these four areas of analysis, a summary of the key findings and recommendations to key stakeholders are then developed and provided.

2. Interoperability in Digital Health

In 2013, the Health Information and Management Systems Society (HIMSS) provided a definition for healthcare interoperability as "the ability of different information technology systems and software applications to communicate, exchange data, and use the information that has been exchanged."[8] Data exchange schema and standards should permit data to be shared across clinicians, lab, hospital, pharmacy and patient regardless of the application or application vendor[9]. "Interoperability means the ability of health information systems to work together within and across organisational boundaries in order to advance the health status of, and the effective delivery of healthcare for, individuals and communities."[10]

> ***"Interoperability means the ability of health information systems to work together within and across organisational boundaries in order to advance the health status of, and the effective delivery of healthcare for, individuals and communities.[10]"***

[8] HIMSS Dictionary of Healthcare Information Technology Terms, Acronyms and Organisations, 2nd Edition, 2010, Appendix B, p190, original source: Wikipedia.
[9] American Academy of Family Physicians (AAFP), Center for Health IT, 2013
[10] HIMSS Dictionary of Healthcare Information Technology Terms, Acronyms and Organizations, 3rd Edition, 2013, p. 75

HIMSS goes further and defines interoperability at three levels, Foundational, Structural and Semantic.[11] All three are required to deliver full interoperability for Digital Health:

1. Foundational interoperability;

allows data exchange from one information technology system to be received by another and does not require the ability for the receiving information technology system to interpret the data.

For example: the ability of a smartphone to connect to a mobile network.

2. Structural interoperability;

is an intermediate level that defines the structure or format of data exchange (i.e. the message format standards) where there is uniform movement of health data from one system to another such that the clinical or operational purpose and meaning of the data is preserved and unaltered. Structural interoperability defines the syntax of the data exchange. It ensures that data exchanges between information technology systems can be interpreted at the data field level.

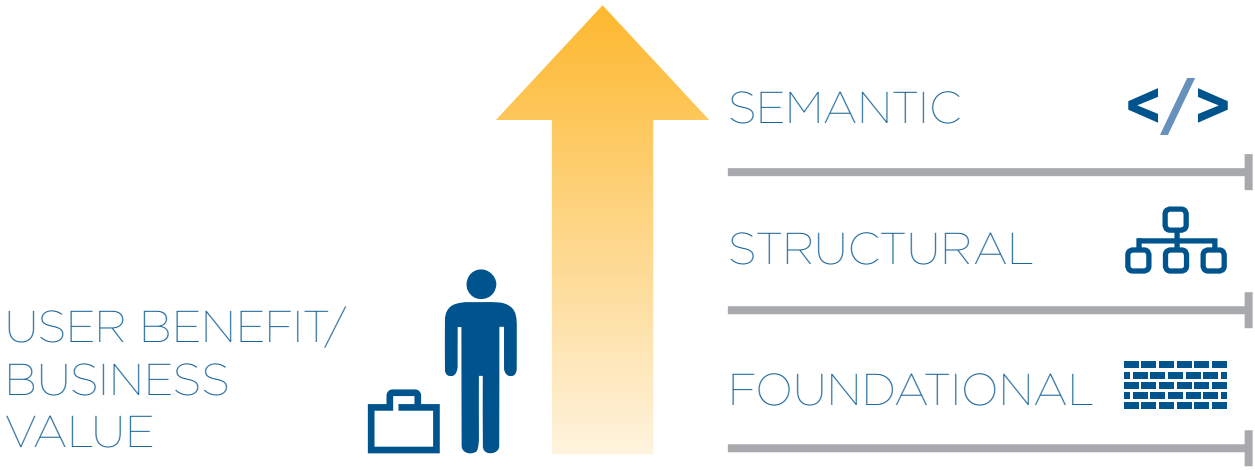
For example: The ability of a remote monitoring system to send information to an electronic medical record system and have the electronic health record (EHR) system recognise it. (e.g. body temperature sensor measures and sends a value of 37.)

3. Semantic interoperability; </>

provides interoperability at the highest level, which is the ability of two or more systems or elements to exchange information and to use the information that has been exchanged.[12] Semantic interoperability takes advantage of both the structuring of the data exchange and the codification of the data including vocabulary so that the receiving information technology systems can interpret the data.
This level of interoperability supports the electronic exchange of health-related financial data, patient-created wellness data, and patient summary information among caregivers and other authorised parties. This level of interoperability is possible via potentially disparate EHR systems, business-related information systems, medical devices, mobile technologies, and other systems to improve wellness, as well as the quality, safety, cost-effectiveness, and access to healthcare delivery.[13]

For example: The ability for a receiving EHR system to understand, interpret and place the information received in the proper area, regardless of the origin of the measurement (e.g. the body temperature sensor sends the name of the measure, the value and the units).

[11] http://www.himss.org/library/interoperability-standards/what-is-interoperability
[12] Institute of Electrical and Electronics Engineers. IEEE Standard Computer Dictionary: A Compilation of IEEE Standard Computer Glossaries. New York, NY: 1990.
[13] HIMSS Dictionary of Healthcare Information Technology Terms, Acronyms and Organizations, 2nd Edition, 2010, Appendix B, p190, original source: HIMSS Electronic Health Record Association.



In order to attain a truly interoperable system and to fully realise the benefits of Digital Health to healthcare systems, achieving the semantic level of interoperability is essential. Foundational and structural without semantic interoperability will allow services to operate, but only in isolation or within a closed proprietary system.

A further dimension to interoperability which should not be overlooked is integration of the digital service with the existing clinical workflow. Many Digital Health services, rather than being stand alone, are designed to support delivery of existing clinical services that will already have an established workflow in place. The integration of a Digital Health element should be designed in such a way that it doesn't add burden to the clinical workflow. Rather, the new technology should enhance the clinical workflow. Therefore, the underlying 'technical' interoperability should bring about better 'clinical' interoperability.

BENEFITS OF INTEROPERABILITY

For Digital Health to reach its full potential, healthcare system architectures will need to open up and become semantically interoperable. There is a need for common interfaces supporting 'plug and play' devices to integrate information into healthcare systems and a standard interoperable interface to exchange data between backend solutions.

Widespread semantic interoperability will deliver four main areas of benefit:[14]

1. Easier and faster access to patients' information
2. Opportunities for better diagnosis, quality of treatment and patient safety
3. Improved cost effectiveness
4. Increased consumer choice and enhanced competition

> *"In order to attain a truly interoperable system and to fully realise the benefits of Digital Health to healthcare systems, achieving the semantic level of interoperability is essential"*

[14] eHealth Stakeholder Group report, Perspectives and Recommendations on Interoperability, March 2014

Easier and faster access to patient information

Interoperable systems can permit data to be shared and retained automatically, eliminating the need to re-enter data into the system each time. This leaves healthcare professionals more time to focus on patient care. This applies to the many different types of data used in healthcare.

This can lead to:

- Better access to information and communication, including Internet and mobile access
- Reduction in data (re)capture errors
- Reduction in duplicated effort
- Reduction in administrative workload
- Improved coordination of care across personal, primary, secondary and tertiary pathways
- Promotion of continuity of care
- Increased involvement of patients in their own care

Opportunities for better diagnosis, quality of treatment and patient safety

Faster access to patient data records enables the potential for a more accurate diagnosis, better quality treatment and care delivery, as well as potential for improved patient safety through:

- Improved knowledge of the patient's health, social status, family and personal history
- Improved care coordination between multiple healthcare professionals
- Increased and higher quality communication between healthcare professionals and patients
- Avoidance of medication interactions and errors, including prescribing and medication administration errors

Improved cost effectiveness

System interoperability can reduce administrative costs arising from reductions in manual data capture, and remove duplication of effort for both clinical and administrative staff.

Implementation costs relating to new IT systems can be lower when they are built using open access technologies that are easier to integrate. Hospitals and primary care centres may benefit from lower costs of maintenance and technical support from vendors. Also, new solutions can be adopted into the system in the future at a faster rate due to less 'brittle' interfaces allowing changes on either side of an interface to cause minimal system disruption.

It may also support the introduction of new business models that promote improved healthcare and wellness, where, for example, the user pays directly for a service.

Increased consumer choice and enhanced competition

Greater interoperability of systems promotes competition and opens up opportunities for new vendors to enter the market. This can result in increased choice for consumers and healthcare providers, and also amplifies the rate of innovation, stimulating development of new services and supporting technologies. A good example of this is the evolution of the mobile industry since the introduction of standards for network interoperability.

3. Existing interoperability standards and organisations

This section details the established and emerging global standards which are currently enabling interoperability in Digital Health, as well as the organisations working to define and align them.

STANDARDS

IEEE

The Institute of Electrical and Electronic Engineers (IEEE) is technical professional organisation that is also a Standards Development Organisation (SDO) that focuses on electrical and electronic technical issues.

The main IEEE standards relevant for Digital Health are the IEEE 11073 Personal Health Devices (PHD) standards. These enable communication between medical, health care and wellness devices with external computer systems. Developed to specifically address the interoperability of personal health devices (e.g. thermometer, blood pressure monitor) with an emphasis on personal use and a more simple communication model. This family of standards ensures that the user of the data knows exactly what was measured where and how, and that the information is not lost when transported to/from the sensor, to a gateway, and then to the EHR.[15]

The Continua Health Alliance (now the Personal Connected Health Alliance, see below) has made considerable progress towards aligning the 11073 standard to modern health services and provides certification routes for adoption of this standard in collaboration with the IHE.

More information is available at: www.11073.org

DICOM

DICOM (Digital Imaging and Communications in Medicine) is a standard for handling, storing, printing, and transmitting information in medical imaging. DICOM files can be exchanged between two entities that are capable of receiving image and patient data in DICOM format. The standard has been defined by the National Electrical Manufacturers Association (NEMA). DICOM is known as NEMA standard PS3, and as ISO standard 12052:2006 "Health informatics – Digital imaging and communication in medicine (DICOM) including workflow and data management".

DICOM enables the integration of scanners, servers, workstations, printers, and network hardware from multiple manufacturers into a picture archiving and communication system (PACS). Devices come with DICOM conformance statements which clearly

[15] For more information see section 4 of the PCHA White Paper, "Fundamentals of Data Exchange", Sept 2015 http://www.continuaalliance.org/node/456

state the DICOM classes they support. DICOM has been widely adopted by hospitals and is making inroads in smaller healthcare facilities, such as dentists' and doctors' offices.

The DICOM standard has achieved a near universal level of acceptance amongst medical imaging equipment vendors and healthcare IT organisations, however the standard has its limitations. It is a standard directed at addressing technical interoperability issues in medical imaging, not a framework for achieving a useful clinical workflow.

More information available at: www.nema.org

LOINC

Initiated in 1994, at the Regenstrief Institute, the Logical Observation Identifiers Names and Codes (LOINC) committee was organised to develop a common terminology for laboratory and clinical observations, to support the growing trend of sending clinical data electronically.

Most laboratories and clinical services use HL7 to send their results electronically from their reporting systems to their care systems. However, the tests in these messages are identified by means of their internal, idiosyncratic code values. As a result, receiving care systems cannot fully "understand" and properly file the results they receive unless they either adopt the producer's test codes (which is impossible if they receive results from multiple sources), or invest in the work to map each result producer's code system to their internal code system.

LOINC is a rich catalog of measurements, including laboratory tests, clinical measures like vital signs and anthropomorphic measures, standardised survey instruments, and more. Enabling the exchange and aggregation of clinical results for care delivery, outcomes management, and research by providing a set of universal codes and structured names to unambiguously identify things that can be measured or observed[16].

LOINC provides a common language for interoperable data exchange, and it has been recognised as the preferred standard for coding testing and observations in HL7.

More information available at: www.loinc.org

SNOMED CT

Owned and distributed around the world by the International Health Terminology Standards Development Organisation (IHTSDO). Systemised Nomenclature for Medicine Clinical Terms (SNOMED CT) is a systematically organised computer processable collection of medical terms providing codes, terms, synonyms and definitions used in clinical documentation and reporting.

The primary purpose of SNOMED CT is to encode the meanings used in health information and to support the effective clinical recording of data with the aim of improving patient care. It provides the core general terminology for, and enables consistent processable representation of clinical content in EHRs. SNOMED CT coverage includes: clinical findings, symptoms, diagnoses, procedures, body structures, organisms and other etiologies, substances, pharmaceuticals, devices and specimens.[17]

More information available at: http://www.ihtsdo.org/snomed-ct

[16] http://loinc.org/background
[17] https://en.wikipedia.org/wiki/SNOMED_CT

HL7

Health Level 7 International (HL7) is a not-for-profit, American National Standards Institute (ANSI)-accredited standards developing organisation. They are dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing and retrieval of electronic health information. This supports clinical practice and the management, delivery and evaluation of health services. HL7 is supported by more than 1,600 members from over 50 countries, including 500+ corporate members representing healthcare providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms. The HL7 mission states "HL7 empowers global health data interoperability by developing standards and enabling their adoption and implementation."[18] Since April 2013, HL7 has licensed its standards and other intellectual property free of charge.[19]

The HL7 standards have been revised over time. Variation in use between v2.0 & v3.0 in systems can potentially cause complications if it is not clear which version of the HL7 standards are being used as the interfaces can be significantly different. Moreover, the current preponderance of systems use HL7 v2.x, however, this is slowly evolving to HL7 v3.0 and FHIR. HL7 is one of the most widespread, health-based open messaging standards available. As such, it is still the most likely mechanism for achieving widespread standards adoption at this level of communication.

More information is available at: www.HL7.org

FHIR

More recently, HL7 is responsible for the emerging standard Fast Healthcare Interoperability Resources (FHIR). Currently published as a draft standard for trial use (DSTU)[20], meaning that the specification is still in active development. FHIR addresses around 80% of use cases, with extensions covering the remainder. This is a tenet of FHIR; the developers have not tried to build a standards framework to cover all potential use cases. This approach was selected to aid development of the standard and support quicker adoption. FHIR combines features of the HL7 v2.x[21], HL7 v3.0[22] and CDA[23] product lines and leverages the latest web standards with a focus on implementation as well as attempting to overcome the incompatibility issues between HL7 v2.x and HL7 v3.0.

A standard for exchanging healthcare information electronically, FHIR defines a set of "Resources" that represent granular clinical concepts. The resources can be managed in isolation, or aggregated into complex documents. Technically, FHIR is designed for the web; the resources are based on simple eXtensible Markup Language (XML) or Java Script Object Notations (JSON) structures, with a hypertext transfer protocol (http)-based (Representational State Transfer) RESTful protocol where each resource has predictable uniform resource locater (URL). REST is an architectural style for networked hypermedia applications and underlies most web based services. Additionally, where possible, open internet standards are used for data representation.[24]

[18] http://www.hl7.org/about/index.cfm?ref=common
[19] http://www.hl7.org/documentcenter/public_temp_6BB98D33-1C23-BA17-0CE99E0B99F496B4/HL7/HL7%20AR%202014%20FINAL%20DRAFT.pdf Page 4.
[20] http://www.hl7.org/fhir/overview.html
[21] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=185
[22] https://www.hl7.org/implement/standards/product_brief.cfm?product_id=186
[23] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
[24] http://wiki.hl7.org/index.php?title=FHIR

Stakeholders across the Health Information Technology ecosystem are actively exploring, experimenting with and testing FHIR. Being based on a modern web services approach makes it easier for systems to exchange very specific items of information, rather than entire documents. e.g. Patient Gender. The alternative which is commonly used to date is Consolidated Clinical Document Architecture (C-CDA) which is designed to transfer entire documents, not a single data point or short list. The benefit of FHIR then, is that it can make exchange of health information faster and more efficient. While still maintaining a proper context for the data as it is exchanged between systems.

In this context FHIR may enable improved patient engagement as it could permit developers to produce applications using specific personal health care information, for example, medication reminders.

More information is available at: www.HL7.org/fhir

ORGANISATIONS

IHE

Integrating the Healthcare Enterprise (IHE) is a global initiative by care providers and vendors to improve the way information systems communicate to support patient care. They have created common frameworks for passing health information seamlessly across multiple healthcare enterprises from application to application, system to system, and setting to setting.

IHE does not create new standards, but rather drives the adoption of existing standards to address specific clinical needs by defining IHE integration profiles specifying exactly how standards are to be used to address these needs. They eliminate ambiguities, reduce configuration and interfacing costs which ensure a higher level of interoperability.

IHE has defined profiles of clinical use cases which identify actors and their interfaces and then specify standards for interaction across those interfaces. IHE Profiles organise and leverage the integration capabilities that can be achieved by coordinated implementation of communication standards, such as DICOM, HL7, W3C and security standards. They provide precise definitions of how standards can be implemented to meet specific clinical needs.[25]

IHE is organised across a growing number of clinical and operational domains. Each domain produces its own set of Technical Framework documents, in close coordination with other IHE domains. Committees in each domain review and republish these documents annually, often expanding with supplements that define new profiles. Initially each profile is published for public comment. After the comments received are addressed, the revised profile is republished for trial implementation: that is, for use in the IHE implementation testing process. If criteria for successful testing are achieved, the profile is published as final Framework Supplement. One example of these profile framework supplements which is directly applicable to mobile health is the Mobile access to Health Document (MHD).[26]

More information available at: www.ihe.net

PCHA

The Personal Connected Health Alliance (PCHA), formerly Continua Health Alliance[27], advocates for global technology standards to enable interoperable solutions for personal connected health. It publishes the Continua Design Guidelines, which provide a flexible implementation framework for 'plug-and-play' or seamless interoperability of

[25] http://www.ihe.net/Profiles/
[26] http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_MHD.pdf
[27] In 2014 the Continua Health Alliance merged with other entities to form the Personal Connected Health Alliance (PCHA). With that merger the Continua Health Alliance ceased to exist as a formal entity, but the technical and policy work for interoperability lives on under the umbrella of the PCHA.

personal connected health devices and systems. It is developed by members from technology, medical device, health care industry, consumer electronics, healthcare service and life science companies as well as government agencies. The Continua Design Guidelines are based on open standards developed by recognised industry groups and standards development organisations. They define interface and standards at those interfaces along with constraints within those standards that enable the secure flow of medical data among sensors, gateways and end services. They remove ambiguity in underlying healthcare standards and ensure consistent implementation through product certification.

Continua's guidelines encapsulate a set of standards (IEEE's 11073 Personal Health Device Standards, IHE Patient Care Device PCD-01 Transaction, and the HL7 Personal Health Monitoring Report (PHMR). They have established a reference architecture and a product certification program that uses a recognisable logo to signify that the product is interoperable with other Continua-certified products.

Within this architecture, they define a set of system interfaces that support the end-to-end delivery of healthcare services.

A. Personal Health Devices Interface
B. Services Interface
C. Health Information Service Interface

Continua has built on the work completed by IHE by providing guidance on the specific use of data within configurable fields in the IHE profile. The implementation of these Continua interfaces enables a full 'plug and play' solution. The interfaces and standards applied are indicated in the illustration in the next chapter (Figure 1).

In December 2013, Continua's Design Guidelines gained the status of an International Standard for personal health systems through International Telecoms Union Telecommunications Sector (ITU-T), the standards setting body within the United Nations.[28]

More information available www.pchalliance.org

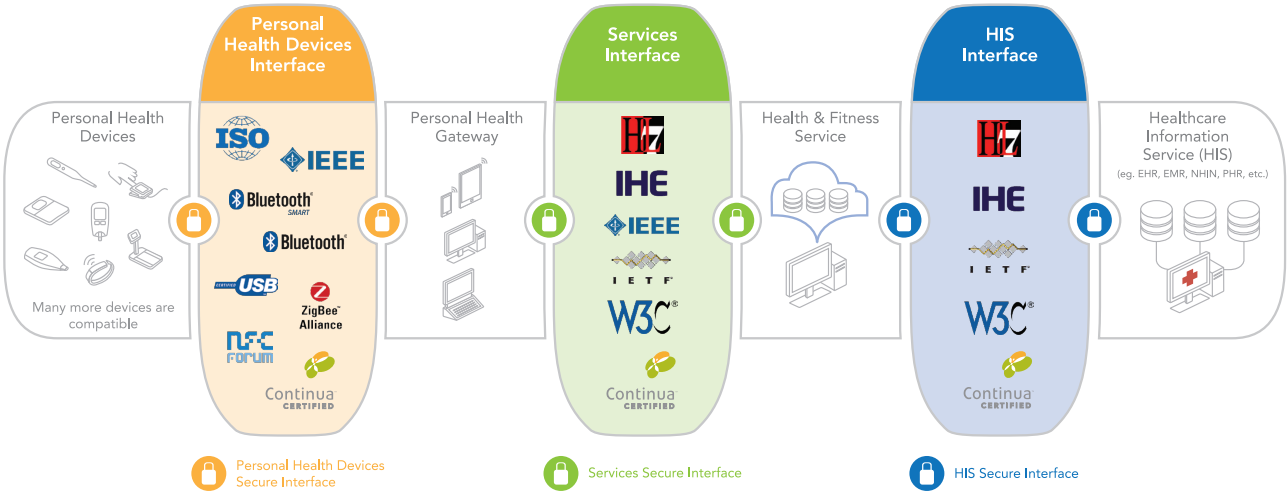
[28] http://www.itu.int/net/pressoffice/press_releases/2013/75.aspx#.V4OmufkrKHs

4. Mapping of interoperability standards

Digital Health architectures in the market today must make use of a wide range of technical components, each with potentially overlapping or missing standards. As seen from the previous chapter there are a number of organisations involved in defining and delivering different aspects required to achieve semantic interoperability.

Organisations, such as PCHA with its Continua Design Guidelines and the Integrating the Healthcare Enterprise (IHE), are addressing the issue of overlapping by providing interoperability guidelines that group standards together into profiles; combining standards for data, security, messaging and transport together into a single certifiable solution.

Figure 1: Continua Design Guidelines Illustration[29]



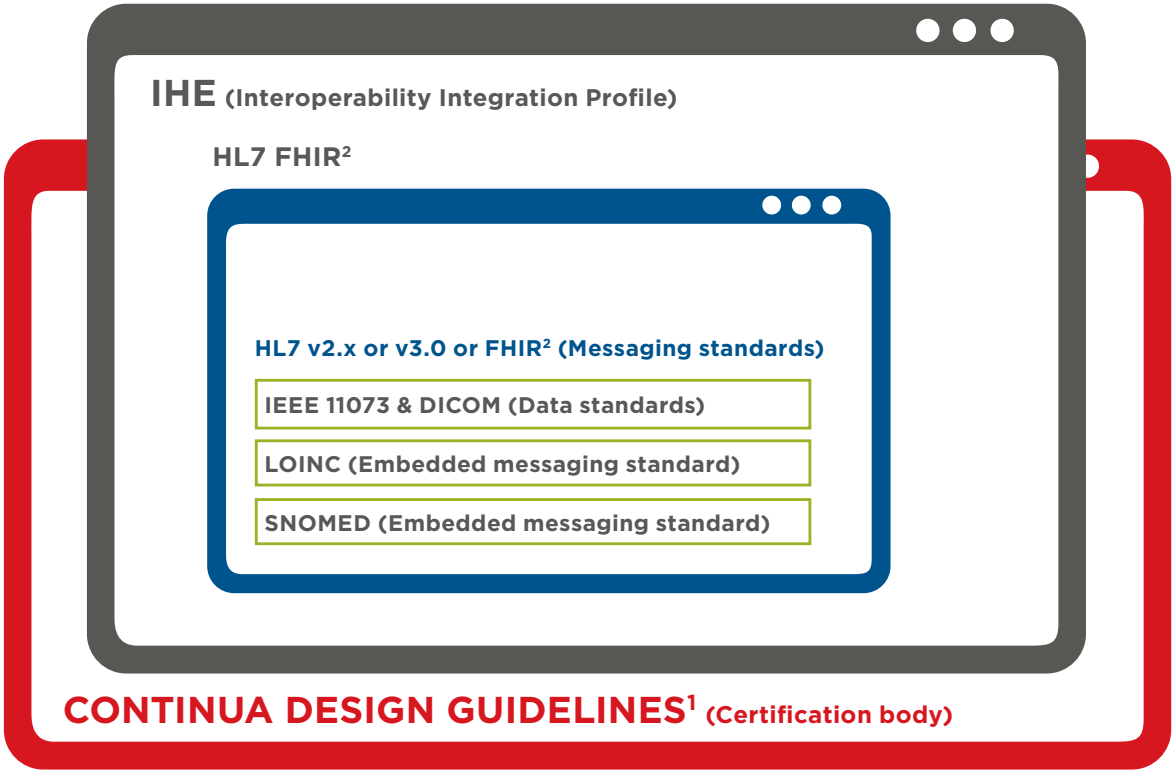
Source: PCHAlliance

[29] Source: PCHA flyer 2016

For example, the International Standards Organisation (ISO) has developed standards (IEEE 11073) for the transmission of blood pressure in a basic binary data format between two low level devices. To enable this blood pressure reading to be transferred into a human-readable format, a set of health messages, such as HL7 using an XML data format containing individual SNOMED clinical codes to define the type of data captured, could be used.

Some of the healthcare messaging standards (HL7) and device data standards (IEEE 11073) can be quite comprehensive and may add an overhead burden for mobile based services. Moreover, some standards may dictate transport mechanisms which are not those adopted by the mobile industry. Some of the standards development and promulgation organisations are aware of these limitations and have been developing mobile transmission and service specific instances to cover these inconsistencies. PCHA has helped develop IEEE personal health device standards as well as developed or refined their guidelines to take into account mobile and web technologies. Moreover, as a basis for transmission HL7 FHIR has the underlying web and computer service standards which lend themselves to mobile services quite well.

The below diagram illustrates how the architectural components, standards and profiles overlap and are not mutually exclusive.



[1]HL7 FHIR, whilst not in the current published Continua Design Guidelines, PCHA is actively working with HL7 FHIR and will be in the next iteration, expected in 2017

[2]FHIR could currently serve as a translation between HL7 v2.x and HL7 v3.0. However, it is migrating to become a standalone messaging standard in its own right

Source: GSMA

In summary, there is no single organisation that covers all the standards needed for Digital Health. However, standards can be combined to provide a fully interoperable Digital Health service. In existing mobile health services, IEEE 11073, HL7 and DICOM seem to be the most prevalent. As such, when looking to develop new Digital Health services, a recommended approach would be to engage with the PCHA and utilise the Continua Design Guidelines as a framework. This will ensure a semantically interoperable service is realised, using appropriate standards for data exchange.

A good example of application of the Continua Design Guidelines was the mHealth Grand Tour in 2015. In this initiative, the guidelines informed the design of an innovative mHealth monitoring and medical coaching service, designed and built to support riders with diabetes[30].

> *"when looking to develop new Digital Health services, a recommended approach would be to engage with the PCHA and utilise the Continua Design Guidelines as a framework"*

[30] http://www.gsma.com/connectedliving/epic-tour-tests-mobile-health-report/

5. Mobile operator service examples

To further understand the unique requirements for mobile operators to achieve semantic interoperability, the GSMA has interviewed members from different regions of the world to identify the key categories of services they are currently offering. For each category, a generic use case has been developed, together with an assessment of relevant existing standards. Based on this it was possible to evaluate the extent to which existing standards are sufficient or whether, from a mobile operator perspective, further work is required. Commentary is also provided on how these existing services could be enhanced.

SERVICE CATEGORIES

Based on the interviews, it was identified that mobile operators are moving towards a more holistic multi-platform, multi-network approach[31]. Specifically, mobile operators are working with healthcare partners to deliver value-added Digital Health services in five main areas:

DATA HOSTING, MANAGEMENT AND SUPPORT; CLOUD SERVICES

Solutions where multiple connected wellness or health devices take key readings, the data is centrally stored, often in a cloud based EHR, and presented back to create insight for patients and healthcare professionals

HOSPITAL INFORMATION & COMMUNICATION SYSTEMS

Systems that help medical professionals to access their patients' Digital Health record wherever they are in the hospital

PATIENT RELATIONSHIP MANAGEMENT & CUSTOMER CARE

Services can range from SMS appointment reminders to call centres, to assist healthcare providers engage with patients

CONTENT SERVICES, HEALTH ACCESS AND MONITORING SOLUTIONS

Providing information to individuals for the prevention or self-management of their condition(s)

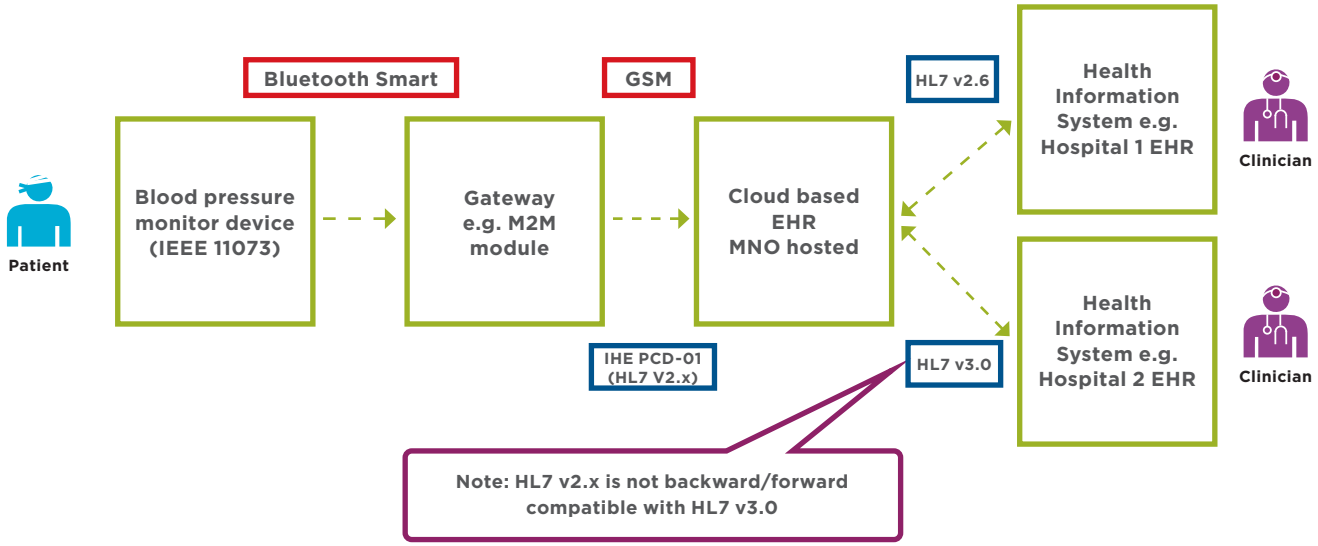
CONSUMER DEVICE MANAGEMENT & SUPPLY, INCLUDING WEARABLES

Delivering mobile packages that can include fitness devices or smart watches, enabling individuals to manage their own health and wellness

[31] http://www.gsma.com/connectedliving/webinar-digital-health-is-it-mobile/ for more information

DATA HOSTING, MANAGEMENT AND SUPPORT; CLOUD SERVICES

Service example: Remote Blood Pressure Monitoring Service



KEY Enhancement with EHR/interoperability | Method of data transmission | Messaging communication standard

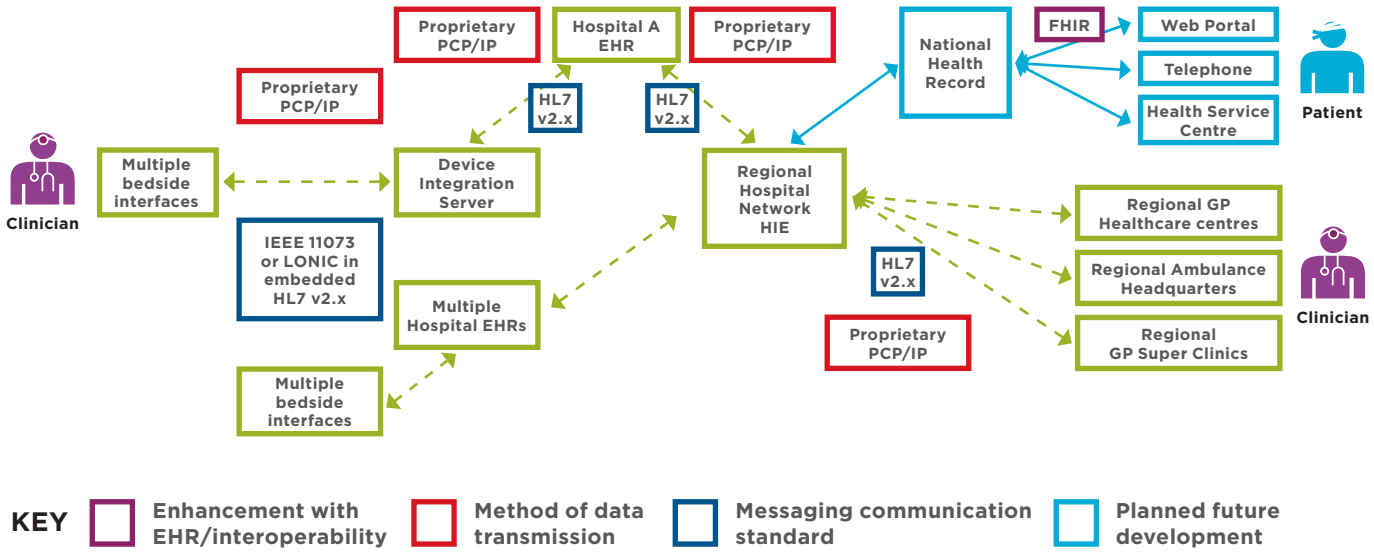
Description of service: A remote monitoring service for recording and transmission of blood pressure readings from a patient at home, with clinicians managing treatments at two hospitals. A blood pressure monitor device using IEEE 11073 captures the patient blood pressure reading. This is connected to a gateway - in this case a Machine to Machine (M2M) module using Bluetooth smart. The M2M module transmits data to the operator hosted cloud-based EHR. From there the data is also shared with two separate hospital EHRs, which provide access to measurements for clinicians in the hospital setting.

Level of interoperability achieved: Semantic

Commentary & insights: This service shows a patient receiving treatment at two hospitals, with each hospital having distinct EHR systems. The hospital EHRs were implemented at different times. Consequently they were designed around different versions of the HL7 messaging communication standard. Hospital 1 using HL7 v2.x and Hospital 2 HL7 v3.0. Therefore, the mobile operator service provider has to provide bespoke data translation for information exchange to occur between the two EHRs as HL7 v3.0 is not backwards compatible with v2.x. This adds a layer of complexity which can lead to potential errors. Another impact is that this may increase the cost of service provision, and this cost will typically be borne by the healthcare provider utilising the service. The version incompatibility occurs as HL7 v2.x is based on a large flat file data format to be sent, whereas HL7 v3.0 requires that the database be reconstructed to react to queries in a very specific manner. Also of note is the IHE PCD-01 profile, shown at the M2M Gateway and service provider interface. IHE-PCD-01 is a specific set of standards which supports data transfer to/from medical devices to systems requesting medical device information. HL7 and IEEE 11073 are specified in the profile. The Continua Guidelines could also inform this interface and those guidelines specify IHE PCD-01 at this wide area network interface as well.

HOSPITAL INFORMATION AND COMMUNICATION SYSTEMS

Service example: Hospital based patient record administration system



KEY Enhancement with EHR/interoperability | Method of data transmission | Messaging communication standard | Planned future development

Description of service: The service shows an EHR system that is designed to be accessible across a regional healthcare network. This permits data to follow the patient as they move between locations, improving the continuity of care the patient receives. Enabled through a shared Regional Hospital Network Health Information Exchange (HIE), it provides access to patient information when required in multiple care locations in the region; i.e. Hospitals, GP clinics and by the Regional Ambulance Headquarters.

At the individual hospital level, Hospital A in this example, the EHR is linked to multiple bedside device interfaces via a device integration server. The device integration server aggregates and provides a buffer for bedside device data as well as functions as an interface broker for this data to flow to the EHR. When clinicians are charting patient information in a hospital, they validate bedside device information from the device integration server and transfer it to the EHR database and application. Clinicians can then, either real-time or retrospectively, use EHR to gain access to patient records, the input of notes, recording of medications administered and other patient health metrics.

Data exchange between the Bedside Interface and the Device Integration Server is supported using IEEE 11073, the coding standard for defining medical device readings, and LOINC (Logical Observation Identifiers Names and Codes) the coding standard for defining medical laboratory observations and results. This standardised data is embedded within a HL7 v2.x message, and is used throughout the system, thereby providing a consistent data and messaging format to transfer to the EHR, the Regional Hospital Network HIE and beyond.

A Proprietary PCP/IP allows applications to create mappings from an external IP address, protocol, and port to an internal IP address, protocol, and port. These mappings are required for successful inbound communications destined to machines located behind a NAT or a firewall.

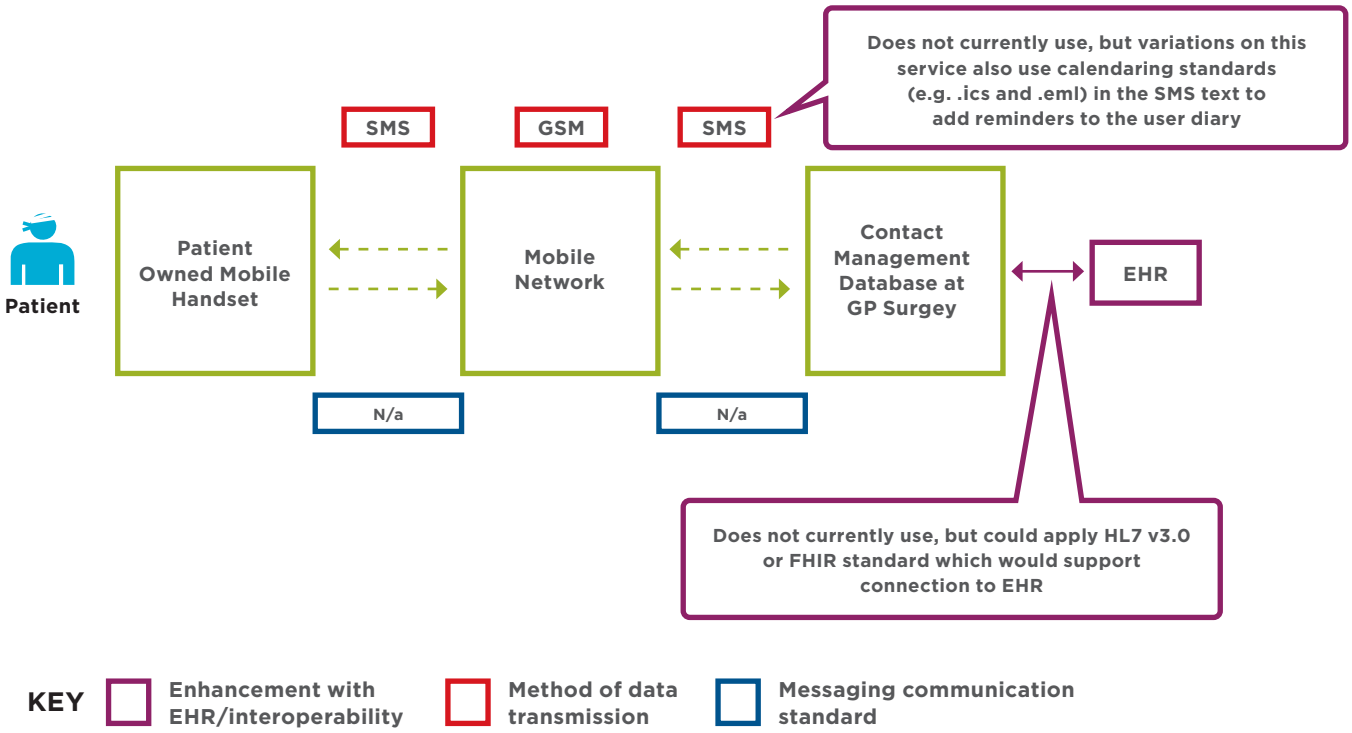
Level of interoperability achieved: Semantic

Commentary & insights: This Hospital Information System and EHR application enables many of the claimed benefits arising from use of Digital Health solutions to be realised. However the service diagram demonstrates the complexity involved in design and implementation of an EHR supported by a Hospital Information System that is fully interoperable and integrated, enabling semantic exchange of information with locations outside of a single Hospital. Design of these services required that clinical workflows be evaluated, understood and in some cases redesigned to enable the features of the different system interfaces be defined appropriately to replace existing paper based or electronically siloed workflows. The intention of this integration is to ensure clinicians in the hospitals are supported by the new systems, rather than impeded in the delivery of their core function as providers of care.

Assuming local regulations allow, the application of standards in the development of this system present the possibility to link the data contained within the Regional Hospital Network HIE to a National Health Record system to extend the service and provide wider coverage. This could also provide access for patients to their own health information through a web portal, alongside the more traditional points of access i.e. by telephone with a trained call center operator or in person at a Health Service Centre. The emerging FHIR standard may be preferable in provision of access via a web portal as FHIR is designed to be more suitable for web based applications.

PATIENT RELATIONSHIP MANAGEMENT AND CUSTOMER CARE

Service example: SMS appointment reminder (Primary Care)



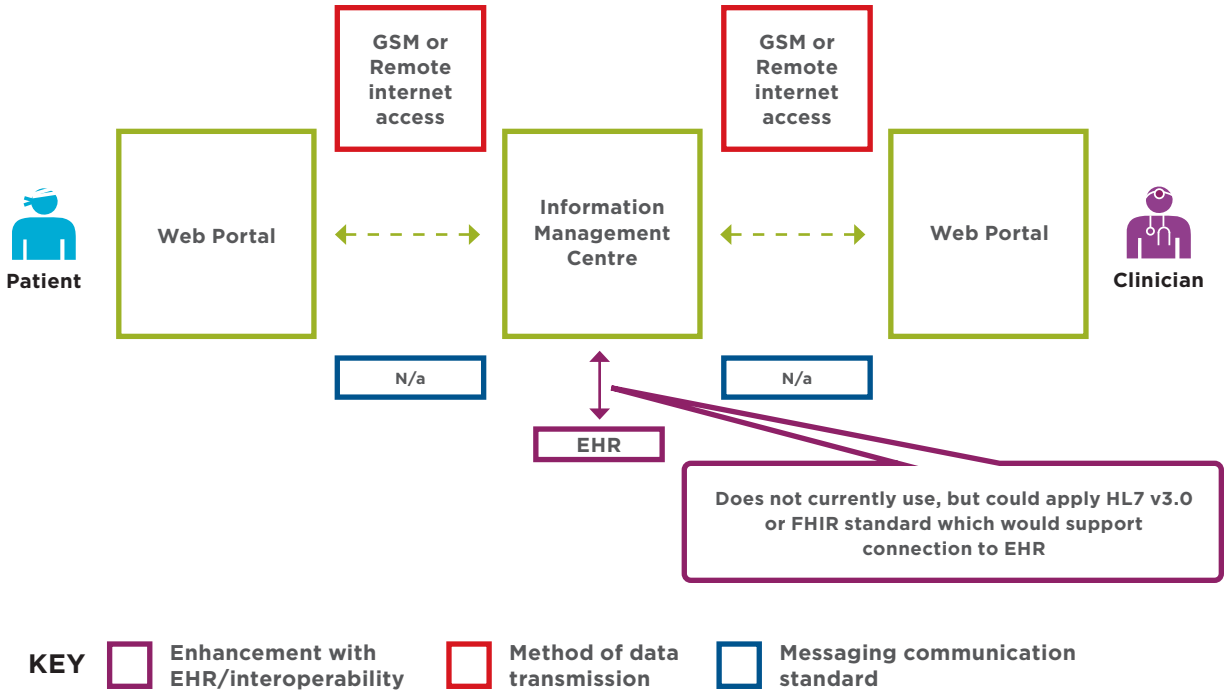
Description of service: A two way, SMS based patient appointment reminder service, linked to a Primary Care (GP) records system. The Contact Management Database is linked to automated system to send a SMS notification via the operator network to patients for pre-booked appointments. The patient has the option to reply 'CANCEL' to the received SMS if the appointment is no longer required.

Level of interoperability achieved: Not applicable, as no device data or health data is currently shared.

Commentary & insights: To supplement this service, standards for calendaring of appointments could be integrated within the SMS text such as .ics or .eml, this would allow the recipient to seamlessly include the appointment in their personal calendar. This service could be further enhanced, by using HL7 v3.0 to link to an EHR containing the patient history. With this facility the Primary Care surgery could automate services such as setting regular check-up appointments for managing patients with chronic conditions and automate appointments for review of medication etc.

CONTENT SERVICES, HEALTH ACCESS AND MONITORING SOLUTIONS

Service example: Internet based doctor Q&A service



Description of service: Citizens are able to use a smartphone or tablet to access an online platform to ask questions of healthcare professionals. Functionality is also available to request follow up appointments with GPs, which are scheduled through a database controlled at the Information Management Center (IMC).

Level of interoperability achieved: Not applicable, as no device data or health data is currently shared.

Commentary and insights: As currently delivered, interoperability standards do not apply to this service. Access is through a standard web portal interface with a facility to ask questions using free text box and no record of the correspondence is shared outside of the current closed system.

The service could be enhanced by linking to an EHR at the IMC to provide a higher level of integrated care for the patient. For example, contact records could be stored and shared in the EHR (with patient permission). Historical patient records could also be accessed using the HL7 v3.0 standard, or emerging FHIR standard (again with patient permission).

This would likely improve ongoing care management for individuals and provide an alternative channel to engage citizens / patients outside of the traditional face to face Primary & Secondary Care settings. Further services could also be integrated, such as the Remote Monitoring service above. This reflects the evolution of services seen in the mobile industry, where the initial service baseline has new services layered on it. Mobile began with voice and SMS services, but then evolved to include other services such as email, cameras were integrated into handsets and the current wave of application based services.

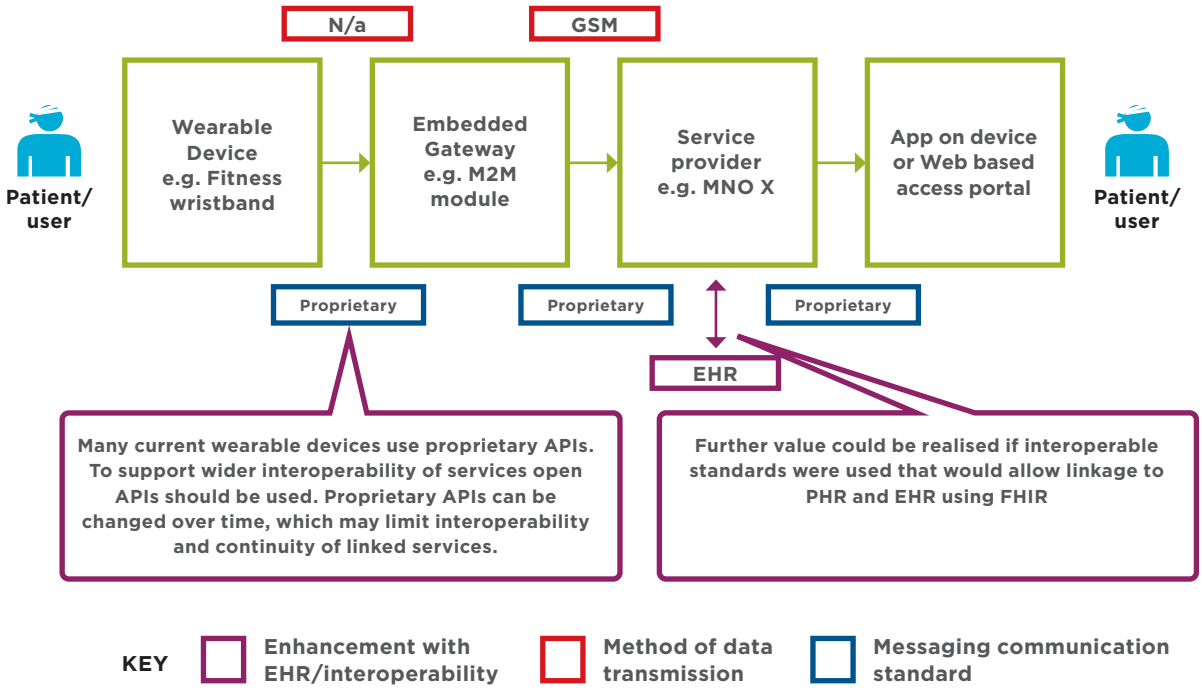
If a patient has a personal health record (PHR), they could share it with their clinician. Their PHR would contain aggregated EHR information from different hospital encounters and any other clinic or personal system (e.g. health and wellness or fitness systems) information.

Even in the current format this is a valuable service for many, as it can provide access to information / a medical professional in a flexible format. This is useful when the user may not be able to have a face to face interaction, or may want advice in a non-emergency context. This is especially relevant for areas where there is limited access to healthcare for large segments of the population.

> *"Citizens are able to use a smartphone or tablet to access an online platform to ask questions of healthcare professionals."*

CONSUMER DEVICE MANAGEMENT AND SUPPLY, INCLUDING WEARABLES

Service example: Wearable fitness tracking with smartphone app



Description of service: A two way, SMS based patient appointment reminder service, linked to a Primary Care (GP) records system. The Contact Management Database is linked to automated system to send a SMS notification via the operator network to patients for pre-booked appointments. The patient has the option to reply 'CANCEL' to the received SMS if the appointment is no longer required.

Level of interoperability achieved:
Structural only, as data not currently shared outside of proprietary platform.

Commentary & insights: As described in the internet based Q&A service, a robust PHR which provides not only health, wellness and fitness tracking information but also information from all healthcare interactions along with role based access and security is the ultimate file or record. It is patient-centric and patient controlled. Mobile operators are uniquely positioned to help reach this vision; they have one-on-one relationships with their mobile customers and they provide access to platforms and applications that can integrate this data from disparate systems. However, as shown in this example, many app and device APIs are proprietary so may be subject to change by the original equipment manufacturer (OEM). This can present issues if linked to an EHR / PHR as changes to APIs can be made by the OEM which can cause aggregating solutions to fail unexpectedly.

Another significant barrier to the scaling and adoption of Digital Health services is that many measurement devices are supplied with an associated proprietary cloud service. This reduces the likelihood of achieving a uniform integrated PHR in the future, and could result in the market being saturated with proprietary, non-interoperable, measurement devices. To address this medical device vendors should consider adopting open standards in their design processes and final product solutions to support integration of the measured data into an integrated, semantically interoperable PHR.

6. Experiences from real world implementations

In addition to the operator service examples, feedback was gathered from individuals and organisations involved in the implementation of a variety of 'real world' solutions where interoperability was a key consideration. The goal of this exercise was to provide a broader view on implementations and share insights from those closest to the projects.

The examples are taken from well documented European Projects. Nevertheless the learnings are relevant for solutions deployed in any region of the world. References are provided, detailing further information on the initiatives discussed.

United4Health

United4Health (U4H) was a European project, co-funded by the European Commission, to deploy and assess the impact of innovative telehealth services for the remote monitoring of patients with chronic conditions. It ran between 2013 and 2015 across nineteen deployment sites in fourteen regions across ten European countries.[32] Each country introduced telemonitoring technologies into their normal delivery of healthcare relating to four chronic conditions: diabetes, congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), and hypertension.

To facilitate input and advice from industry, the U4H project set up an Industry Advisory Team (IAT), and invited three industry associations to join the consortium: Continua Health Alliance[33] (CHA), European Coordination Committee of the Radiological Electromedical and Healthcare IT Industry[34] (COCIR) and GSMA[35].

The IAT supported the project with input and advice from industry, with a particular focus on technology, interoperability and regulatory matters. Contributions included;

- Guidance for the deployment sites' procurements, including
  - a procurement workshop to assist the pilots in their acquisition of appropriate telehealth systems;
  - a checklist for buyers to help them evaluate vendor offerings regarding their compliance with interoperability and regulatory requirements; and
  - a vendor showcase where ten companies exhibited their solutions at a United4health meeting in Slovenia.

[32] Participating countries included; Czech Republic, Finland, France, Germany, Greece, Italy, Norway, Slovenia, Spain & United Kingdom.
[33] www.continuaalliance.org now Personal Connected Health Alliance
[34] www.cocir.org
[35] www.gsma.com

- Two technical reports documenting the pilots' use of technology and assessing their potential for scale;
- A pilot site assessment of procurement practices and technologies;
- A regulatory environment report of telemedicine in Europe
- Several workshops with the deployment sites to review the adoption of interoperable technology, the impact of regulations, and the status of interoperability; and
- Two "shop talk" events at telehealth conferences (May 2014 at mHealth Summit in Berlin and October 2015 at European Telemedicine Conference in Odense, Denmark) to demonstrate the use of telemedicine technology solutions in U4H.

The pilot site assessment presented an excellent opportunity to observe and understand experiences from the deployment sites. Interviews were held with members of clinical staff who knew the content and organisation of the telemedicine intervention, along with the site project leaders and people involved in the procurement process.

The following are key observations and commentary from the Pilot Site Assessment[36] relating to interoperability:

Scalability and sustainability

Most sites took a short-term view when choosing their technical solutions, and focused on shorter term project goals, rather than executing a service that would be scalable and sustained over a longer time. In part this was due to the particular vendor engagement/procurement process that was used. E.g. some sites did not implement a new procurement process as they already had pre-existing framework agreements for provision of technology. Where these frameworks were already established, functionality to achieve interoperability may be lacking in the specifications. Therefore sites may end up with less scalable and less sustainable devices and systems for the future.

Vendor responses on procurement

Some sites encountered vendors who were willing to provide free software and sensor devices. Whilst offering budget savings, this often resulted in systems that required significant manual handling of data. Other regions opted for a bring-your-own-device solution. Both of these experiences raised questions of data veracity and data quality, as the likelihood of errors was considered to be increased. This could have broader implications for the future integration of remote monitoring services and personal health device use in clinical settings. In U4H this was discussed and consensus reached that in order for readings to be broadly accepted and used by the clinical community, data veracity had to be managed. This could be achieved by providing the clinician using the data information relating to its origin. For example, a flag to indicate the data was patient generated versus recorded by a HCP in a clinical setting. The clinician may then use their professional judgement to apply a weighting to the data, and make informed decisions on the appropriate course of action.

Of those regions who did specify standards based solutions, vendors often stated prices would be higher or the solutions were not available locally. Those regions then procured solutions without standards, limiting interoperability. This highlights the importance of clarity when engaging with vendors. The procurer should specify standards in their requests for proposal and cost should be a consideration but not the only factor in the procurement decision.

[36] http://united4health.eu/wp-content/uploads/2016/02/D5.6-Annex-1-v1.0-U4H-Pilot-site-assessment-report.pdf

Knowledge sharing

Levels of understanding of telehealth and the experience in implementation varied across deployment sites. Some regions had been working in this area in previous EC projects such as Renewing Health[37], whilst for others this was their first foray into telehealth deployments. Some pilot site assessment visits were cited as the first occasion for the regions that all participating staff sat and talked together. Prior to this, feedback indicated that meetings took place but these tended to be function based, and within professional siloes e.g. diabetes clinicians and COPD clinicians meeting separately. Time and resource constraints limited regional implementation team interactions, but feedback indicated the multi-disciplinary gatherings were appreciated and needed to ease the implementation process.

Clinical protocols

Clinical protocols were required to ensure a common framework for management of patients for each disease state. These were a requirement included in procurement specifications. The scientific community took some time to reach agreement on clinical protocols, due to their complex nature and the requirement for negotiation between participating sites. Common medical protocols were also a key condition for scalability and interoperability. Consensus on clinical protocols was achieved despite individual site differences. If similar agreement would have been sought for a standardised technical interoperable solution, this could have improved procurement outcomes through a larger scale RFP for the market to respond to.

At the project outset the IAT emphasised the importance of interoperability in solutions, to deliver replicability and scalability, and included a checklist for discussions with vendors. The execution of the project objective to reach a target of more than 10,000 patients for clinical study may have overridden this ambition. Despite this, the observations above give further insight to the complexities of developing Digital Health services.

Lastly, nearly all of the pilot sites have since incorporated their remote monitoring service models into their standard of care (securing local funding and clinical resource allocation) and looked at ways to scale those services. This signals that the procurers of these types of systems are adding capability to their healthcare delivery models outside of their traditional controlled enterprise environments. They are beginning to embrace services that move the point of care closer to the patient while using the underlying information and communication technology infrastructure to support that care. Mobile technologies and infrastructure are one of the key components of this evolution. Moreover, the U4H pilot sites realised as a lesson learned that procurements with a lack of at least data standards at the interfaces did not lend well to scaling or future integration with their existing databases or applications.

More information on the United4Health initiative and its outcomes can be found at www.united4health.eu

> *“Common medical protocols were also a key condition for scalability and interoperability”*

[37] http://www.renewinghealth.eu/en/

SmartCare

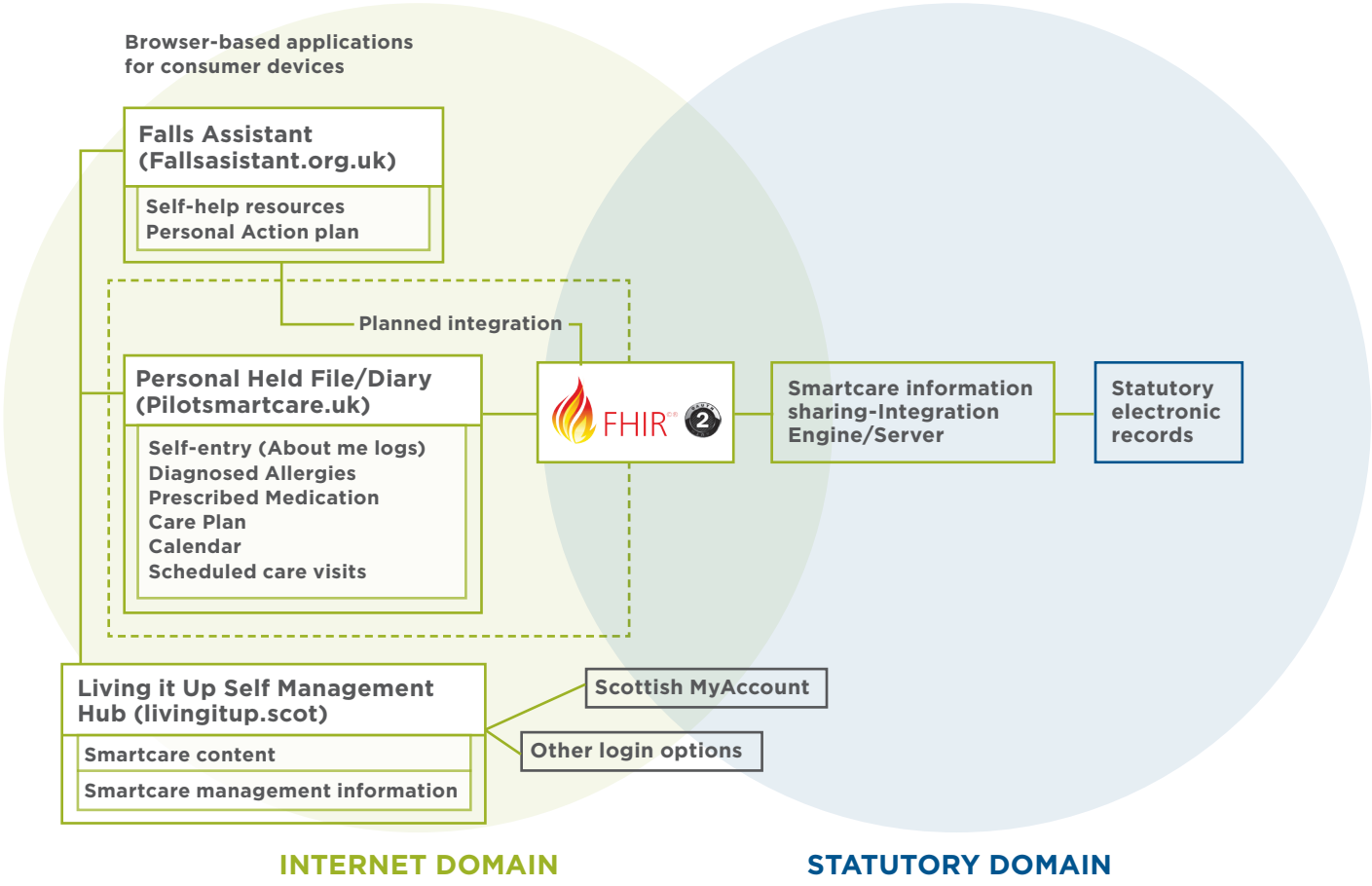
SmartCare was a European project, where 10 deployment regions endeavoured to build and provide at scale, integrated platforms to enable integrated care services. One of the 'first wave' deployment regions was NHS24 in Scotland. They used SmartCare to develop a 'Falls' program to support patients who had fallen, or were at risk of falling, and guide them to services on self-management and prevention. The below summarises the NHS24 experience of developing an architecture using HL7 FHIR, to integrate patient generated data into a person held file (PHR) and share this with the statutory electronic record (EHR).

Operating in a framework of strict security and data privacy regulations, NHS24 used SmartCare as an opportunity to create a baseline architecture for the inclusion of patient generated data into its centrally managed healthcare information systems. They created a person held file (PHF), another term for PHR, as a data repository, where the ownership of patient generated data resides with the patient.

The PHF was developed using the FHIR application programming interface (API), so that web based applications can connect to the PHF and enable movement of data in and out. FHIR (Specifically FHIR DSTU 2) was chosen after review with a pool of vendors, on the basis that it would be the easiest and best option long-term for industry, as the API and data structure specification. It is worth noting, as data travels from the statutory domain (EHR) to the PHF the ownership of the data shifts to the patient, and is retained by the patient unless the data travels back to the statutory domain.

A technical architecture for the implementation is shown below:

General Architecture for NHS24 use of FHIR Interface and SmartCar Transition with HL7 FHIR server and 2nd generation hub



Source: http://medicalconnectivity.com/2016/06/22/fhir-in-action-how-well-does-it-work/

The implementation has two domains, internet and statutory, with the FHIR API sitting between them. The statutory domain contains data gathered by healthcare professionals in the statutory electronic record (EHR). This can be moved into a national database if required. In the future plans for the solution, select elements from the internet domain data in the PHF (PHR) could be moved to the statutory domain (EHR).

Lessons learned from using FHIR in this context:

- FHIR is open, so a lack of access control to the PHF was cited. Access control was required to meet data privacy and security requirements, so NHS24 opted to use oAuth2 for access control. This means when a request is made to access data in the PHF, the requestor is checked against an approved list. If listed, approval is granted and a token issued for access. In the current version this access control list is maintained by NHS24. The vision for the future is that this function migrates to the PHF owner i.e. the patient. In this scenario the patient may also grant access on a case by case basis if a request is sent from a user not listed. Therefore accommodating new services to be included in the future.
- This implementation has an open source code base, so dealing with bugs and other issues was difficult due to differing levels of support and tool maturity. However, as previously stated FHIR is currently a draft standard for trial use, so this should be expected to be less challenging as the standard matures.

Using the FHIR standard as their API, NHS24 is positioning itself for integration of personally generated health data from external data sources into its EHR system as well as presenting opportunities for further complementary services to be developed and integrated.

More information on the SmartCare initiative and its outcomes can be found at http://www.pilotsmart-care.eu

7. Findings & recommendations

KEY FINDINGS FROM RESEARCH

The following is a summary of the key findings of this report. Including key insights from the review of standards, bodies coordinating their practical application, as well as learnings from operator service examples and real world implementations.

Achieving Semantic interoperability is the key to enabling Digital Health to scale

Services should use an open standard data format at the sensor interface (i.e. at data measurement/capture) along with contextual information (i.e. who, where, what, why as well as the data that was measured). This will enable systems to exchange and interpret data, also to integrate new devices/services as they become available.

No specific gaps in provision of interoperable standards exist, the core issue is a lack of adoption/use of standards

Operator service examples and broader real world experience show that open interoperable standards are not regularly used in existing services or where they are those tend to be intermittently, and not from the sensor/point of data capture. Also, many current services use proprietary standards, however there are viable non-proprietary standards available which could be applied.

Awareness of the importance of interoperability is generally low, often due to a lack of experience

There is a need for education to increase awareness among all stakeholder groups on interoperable standards and the potential benefits arising from their use. This includes mobile industry, healthcare providers, medical device/pharma industry and governments.

Digital Health services should not be designed in isolation, instead there is a need to encourage involvement of all relevant stakeholders in their design, development and implementation. As shown in U4H, working in partnership with industry can assist in to addressing the challenges.

Interoperable systems are complex to implement

Significant expertise is required in the definition, design and implementation of systems and services. Systems need to be designed to support the underlying clinical workflow, not just deliver information from one location to another. Simply using a standard does not guarantee interoperability, as shown by the absence of backward compatibility between HL7 v2.x & v3.0. A level of optionality is built in to HL7 v3.0, therefore depending on how this is configured one HL7 v3.0 system may not simply align with another HL7 v3.0 system. Personal Connected Health Alliance has worked to remove this ambiguity in their Continua Design Guidelines by specifying exact parameters for these variable elements

EHR usage is still not broad enough/consistently implemented

EHRs are an important component in the management of patient data in the clinical environment. Where applied most successfully they can enable rapid, secure access to the patients' clinical information and enhance continuity of care. Service examples show proprietary systems are commonplace among early adopters of EHRs, which will only serve to limit interoperability and limit future scaling of Digital Health if this trend continues.

New standards and technologies are emerging which bring new opportunities/challenges

HL7 v2.x is currently the most commonly used standard in existing solutions, and HL7 v3.0 has not yet been widely implemented.
FHIR is a draft standard for trial use so is still developing, however among the service developers and industry experts that were interviewed there is growing consensus that FHIR will probably overtake HL7 v3.0 due to easier implementation, particularly in web based applications. Still caution is needed, as while FHIR can transfer granular items of information, there is a need to ensure context for the data is not lost. A system may be able to use the data it receives using FHIR, but without the appropriate context it may draw the wrong conclusion.

The increased use of personal connected devices, and greater levels of self-monitoring means more patient/user held data, but this often sits in Personal Health Record (PHR) silos. Further value could be realised by linking PHR data with EHRs to enhance clinical decision making. This would also serve to accommodate more 'Bring your own device' scenarios which could further enable services and increase options for consumers.

Adoption challenges remain within the clinical community

Experience from United4Health supports the view many system users are ignorant of standards available until required to work with them, and to date there has been a tendency to think short term in their use. This problem is exacerbated by clinicians typically working in very specific areas of health care, who are typically only familiar with the workflows associated with their own specialist area, and consequently coordinated EHR systems are not prioritised.

Some clinicians are beginning to come around to the use of standards, however as the application of standards are only one aspect of implementation, at times they do not receive the emphasis needed.

There is still a need to convince some in the clinical community to adopt use of and accept the readings from Digital Health devices & services. Particularly data captured outside of the traditional, closed, clinical setting (e.g. data from remote monitoring, wearables and integration of data from PHRs). Hence, Digital Health solutions that directly address the question of data veracity are required to overcome this barrier.

Historically there has been low market demand for interoperable solutions

Real world implementation experience suggests if interoperable standards are not specified in requirement documents (RFPs) then it is unlikely the market will provide them as there is no/low incentive present to deliver. Commercial drivers may influence vendor behaviour, with vendors charging more for openly interoperable solutions versus those using proprietary standards. Procurers should be cognisant of this when vendors position proprietary solutions as less

expensive in response to RFPs, and should prioritise the long term benefits of semantic interoperability versus the short term cost savings of a proprietary alternative.

To address these challenges, some Governments are now moving to demand interoperability & standards in services

Within the EU, Austria, Catalunya (Spain), Denmark, Finland, Norway and Sweden have committed to Continua Guidelines for open and interoperable personal connected health.[38] Also, the International Telecoms Union approved the standard – Recommendation ITU-T H.810 – which contains reference to PCHA's Continua Design Guidelines for providing "Interoperability design guidelines for personal health systems". Focussing on the Personal Health Device Interface between device and gateway, Services Interface between gateway and service provider and the Health Information Service Interface between service provider and the Health Record Network (EHR, PHR etc.)

[38] http://www.pchalliance.org/sites/pchalliance.org/files/nodecontent/ehealth-network-letter.pdf page

RECOMMENDATIONS TO STAKEHOLDERS:

Key to unlocking the digital health opportunity is the realisation of Semantic Interoperability. To achieve this, stakeholders are recommended to consider the following:

MOBILE INDUSTRY

- **RAISE AWARENESS OF THE IMPORTANCE OF INTEROPERABILITY STANDARDS,** and a plug-and-play experience. For example, share learnings and best practice examples of interoperable Digital Health deployments, and the goals they help to achieve, in terms of:
  - Easier and faster access to patient information
  - Opportunities for better diagnosis, quality of treatment and patient safety
  - Improved cost effectiveness
  - Increased consumer choice and enhanced competition.

- **ADVISE ON THE APPLICATION OF STANDARDS** and work with the healthcare industry to deliver Digital Health services based on the principle of semantic interoperability.

- **PROMOTE INTEROPERABILITY END-TO-END.** In developing services, adopt open interoperable data standards at the sensor interface i.e. upon data measurement and/or capture, rather than at a later stage along the transmission path. Using an open standard format from the outset, along with contextual information (i.e. who, where, what, why, as well as the data that was measured) will serve to ensure interoperability runs through the entire service.

- **ENSURE INTEROPERABILITY WITH THE EXISTING CLINICAL WORKFLOWS.** When designing a new service for use in a clinical environment, it is important to review and align with the existing clinical workflow. The Digital Health element should be easy to integrate and adopt so it enhances, rather than hinders, the existing clinical workflow. Failure to deliver this risks low adoption rates for new services.

- **CONSIDER THE FUTURE INTEGRATION OF CONSUMER-ORIENTED SOLUTIONS WITH ELECTRONIC HEALTH RECORDS.** When designing these services, use interoperable standards and provide appropriate security/access control rights for the Personal Health Record owner to control who else may access and use their data.

- **CONSIDER ADOPTION OF THE EMERGING HL7 FHIR STANDARD,** currently at draft standard for trial use status. FHIR may be better suited to support delivery of new mobile based applications due to lower bandwidth requirements, and also a possible solution to HL7 v2.x & v3.0 version incompatibility.

HEALTHCARE PROVIDERS/CLINICAL COMMUNITY

- **SUPPORT EDUCATION FOR THE CLINICAL COMMUNITY IN THE USE OF DATA AND STANDARDS.** Promote adoption of interoperability and standards, and a plug-and-play experience across the healthcare system to maximise the interoperability of systems that serve to assist in the delivery of improved patient centered care.

- **SPECIFY ADHERENCE TO OPEN AND RECOGNISED MESSAGING AND DATA STANDARDS IN PROCUREMENT TENDERS.** Use technical specifications which make health data easily available and interoperable e.g. HL7 and IEEE11073 and/or the Continua Guidelines and IHE profiles. This will make systems easier to integrate, scale and adapt.

- **DEVELOP A TESTING ENVIRONMENT,** or insist upon testing vendor claims, to verify and validate that standards are being used as per specifications and are effectively interoperable with existing workflows. This should help obtain interoperability when deploying a new service or solution.

- **ENSURE INTEGRATION** of new services and the new data sets into existing healthcare systems workflows. This is a lever for change.

MEDICAL DEVICE VENDORS/PHARMACEUTICAL INDUSTRY

- **ADOPT OPEN STANDARDS AND INTEROPERABILITY IN DESIGN PROCESSES AND FINAL PRODUCT SOLUTIONS** to meet increased market demand for interoperable solutions.

- **RESPOND TO REQUEST FOR PROPOSALS WITH INTEROPERABLE SOLUTIONS.** See interoperability as an opportunity, not a threat to business models.

GOVERNMENTS

- **IDENTIFY BEST PRACTICE.** Learn from effective leadership provided by pioneering countries moving forward with implementations of interoperable systems/solutions e.g. Denmark and Norway

- **CONSIDER ADOPTING FRAMEWORKS FOR INTEROPERABLE DIGITAL HEALTH STANDARDS** such as those put forward by Personal Connected Health Alliance in the Continua Design Guidelines.

All stakeholders can benefit from engaging with standards and industry organisations like the Personal Connected Health Alliance & Integrating the Healthcare Enterprise, who work on the development and promulgation of standards for healthcare and give guidance on their use.

Glossary

CDA - Clinical Document Architecture (CDA) is a popular, flexible markup standard developed by Health Level 7 International (HL7) that defines the structure of certain medical records, such as discharge summaries and progress notes, as a way to better exchange this information between providers and patients.

Clinical Workflow – At its simplest is the movement of documents and / or tasks through a work process. More specifically, workflow is the operational aspect of a work procedure: how tasks are structured, who performs them, what their relative order is, how they are synchronised, how information flows to support the tasks and how tasks are being tracked.

Continuity of Care - Continuity of care is concerned with the quality of care a patient receives over time. There are two important perspectives on this. Traditionally, continuity of care is idealised in the patient's experience of a 'continuous caring relationship' with an identified health care professional. In the context of Digital Health, and providers of vertically integrated systems of care, the contrasting ideal is the delivery of a 'seamless service' through integration, coordination and the sharing of information between different providers. As patients' health care needs are now only rarely met by a single healthcare professional, multidimensional models of continuity have had to be developed to accommodate the possibility of achieving both ideals simultaneously.

DICOM – Digital Imaging and Communications in Medicine; a standard for storing, printing, and transmitting information in medical imaging.

EDIFACT – Electronic Data Interchange for Administration, Commerce and Transport; a messaging standard.

EHR – Electronic Health Record; a term used to describe a health record stored electronically often managed by a healthcare organisation or medical professional.

FHIR – Fast Healthcare Interoperability Resources, is a draft standard describing data formats and elements ("resources") and an Application Programming Interface (API) for exchanging Electronic health records. The standard was created by the Health Level Seven International (HL7) health-care standards organisation.

HL7 – Health Level 7; a standards body that defines interoperability and messaging standards for the health industry.

IEEE – Institute of Electrical and Electronics Engineers.

IEEE 11073 – Is the standard that has been defined by IEEE to support medical devices, it is a coding standard for defining medical device readings.

IHE – Integrating the Healthcare Enterprise.

ISO – International Standards Organisation.

JSON - JavaScript Object Notation is a lightweight data-interchange format. It is easy for humans to read and write. It is easy for machines to parse and generate. It is based on a subset of the JavaScript Programming Language, Standard ECMA-262 3rd Edition - December 1999.

PCHA – The Personal Connected Health Alliance (PCHA), a division of HIMSS, works collaboratively with health, technology and life sciences, public policy, research and advocacy groups to achieve personal connected health for all. PCHA hosts the annual Connected Health Conference (formerly the mHealth Summit) and publishes the Continua Design Guidelines, the international standard for interoperability of personal connected health devices and systems.

LOINC – Logical Observation Identifiers Names and Codes; a coding standard for defining medical laboratory observations and results.

NAT – Network Address Translation, is a method of remapping one IP address space into another by modifying network address information in Internet Protocol (IP) datagram packet headers while they are in transit across a traffic routing device.

OSI – Open Systems Interconnection model; a model for representing layers of communications between systems.

PHR – Personal Health Record; a term used to describe a health record managed directly by the patient.

Primary Care - Usually the first point of contact for a patient, and generally the 'gateway' to receiving more specialist care. Primary Care typically refers to contact with a General Practitioner (GP), Dentist, Optician or Pharmacist. (Note: Structures for provision of healthcare can vary by geography).

RESTful web services - Representational State Transfer (REST) is an architectural style for designing network applications that specifies constraints, such as the uniform interface, that if applied to a web service induce desirable properties, such as performance, scalability, and modifiability. In the REST architectural style, data and functionality are considered "resources" and are accessed using Uniform Resource Identifiers (URIs), typically links on the Web. The resources are acted upon by using a set of simple, well-defined operations. The REST architectural style constrains an architecture to a client/server architecture and is designed to use a stateless and cacheable communication protocol, typically HTTP. In the REST architecture style, clients and servers exchange representations of resources by using a standardised interface and protocol.

SDO – Standards Development Organisation is an organisation whose primary activities are developing, coordinating, promulgating, revising, amending, reissuing, interpreting, or otherwise producing technical standards that are intended to address the needs of some relatively wide base of affected adopters.

Secondary Care - Contact in Secondary Care typically occurs after referral from Primary Care, to receive care from a more specialised expert. This usually, but does not always, takes place in a hospital or clinic with specialist facilities. (Note: Structures for provision of healthcare can vary by geography).

SMS – Short Message Service; a short text based messaging system available within the GSM communication standards.

SNOMED CT (SNOMED Clinical Terms) – Systemised Nomenclature for Medicine; a coding standard for defining clinical concepts.

Tertiary Care - Refers to the provision of specialised care similar to that in Secondary Care. With referral from Primary or Secondary Care, to a facility with advanced medical investigation and treatment capabilities. (Note: Structures for provision of healthcare can vary by geography).

W3C - The World Wide Web Consortium (W3C) is an international community where Member organisations, a full-time staff, and the public work together to develop Web standards.

XML - Extensible Markup Language (XML) is a markup language that defines a set of rules for encoding documents in a format that is both human-readable and machine-readable.

Connected Living

GSMA HEAD OFFICE

Floor 2
The Walbrook Building
25 Walbrook
London EC4N 8AF
United Kingdom

Tel: +44 (0)20 7356 0600

www.gsma.com/connectedliving
connectedliving@gsma.com