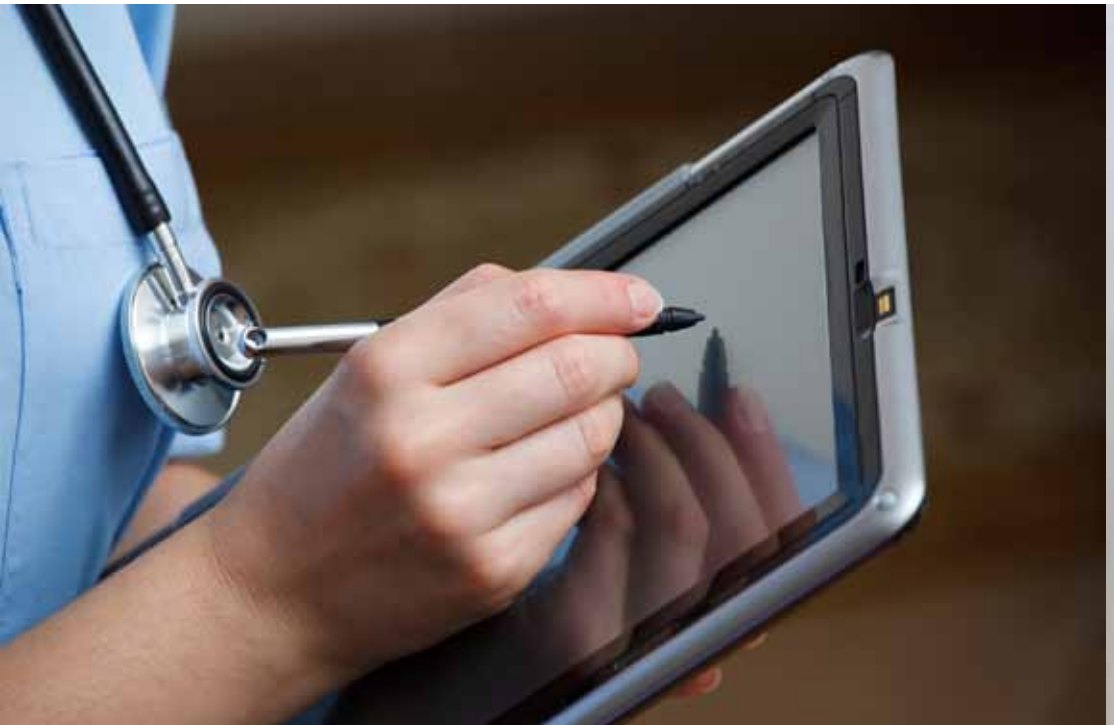
Mobile Health

A High Level Reference Architecture for Mobile Health

This report, aimed primarily at the Mobile industry, sets out to identify the key network architectures and capabilities required to deliver secure and reliable end-to-end mobile health services.



Executive Summary

This report explains the key network architectures and capabilities required to enable secure and reliable end-to-end mobile health services, while identifying significant gaps and potential next steps.

The GSMA believes that realising the full potential of mobile health will require:

- Use of a standards-based approach
- The development of open interoperable systems and devices
- Strong partnerships between mobile operators and healthcare providers.

Mobile health standards

A fragmented approach to solution development is one of the reasons that sustainable commercial models for mobile health have been slow to develop. To become cost-effective and commercially-sustainable for the mass-market, mobile health services will need to be based on standardised, open and interoperable solutions.

There is no single standards organisation that covers the complete needs of mobile health. Some organisations, such as the Continua Health Alliance and the Integrating the Healthcare Enterprise (IHE), are addressing this issue by providing interoperability guidelines that group standards together into profiles, combining data standards, security standards, messaging standards and transports together into a single certifiable solution.

However, there is still some way to go before the mobile health sector has a fully interoperable set of standards that is universally-adopted, and market volumes have yet to justify the sort of equivalent investment that resulted in the mobile industry offering handsets that support roaming across multiple network protocols.

The importance of interoperability

As most mobile health solutions are vertically-integrated, bespoke and closed solutions, it is virtually impossible to integrate devices and products from other providers into the solution. For mobile health to reach its full potential, healthcare system architectures will need to open up and become interoperable, both in terms of getting information into the healthcare systems and to exchange data between back-end solutions.

Until healthcare ICT systems become fully-standardised, mobile operators will need to integrate with a large number of healthcare ecosystem players, all of whom will be using different platforms and systems. One way to enable this integration would be the use of a robust centralised integration engine, or mobile health gateway, which sits between the mobile network and the healthcare systems. This approach would enable the mobile health element of the solution to be standardised - the only configuration required would be for a medical records interface to be integrated into the existing healthcare ICT systems.

New mobile capabilities could add further value

New mobile technologies, such as on-SIM applications, wireless smartcard authentication, NFC and 2D barcode scanning, could be used to enhance mobile health solutions.

The need for partnerships

Mobile operators have developed and optimised robust processes for provisioning and managing millions of devices on their networks. Strong relationships between healthcare providers and mobile operators would enable the full integration of mobile health solutions into the existing mobile networks and systems, paving the way for the delivery of complete end-to-end services throughout the solution's life cycle, encompassing provisioning, set-up, management and billing.

The bottom line

In essence, the GSMA believes that the mobile industry should attempt to replicate the common standards approach that has made GSM so successful in the mobile health arena, both to fuel economies of scale and enable interoperability.

Contents

1. Overview

Ongoing advances in the coverage and capabilities of mobile networks are opening up new opportunities to improve access to healthcare, deliver efficiencies and engage patients directly in the management of their own health and wellness.

Forecasters believe direct spending on healthcare worldwide will reach $4.2 trillion in 2011[1] and predict it will continue to grow faster than GDP. Governments, healthcare providers, payers and patients are looking at mobile health services as one way to control these spiralling costs.

What contribution can the mobile industry make? Will mobile operators choose to be a simple connectivity provider or can their network architectures and data platforms add additional value?

The scope of this report

This report explains the key network architectures and capabilities required to enable secure and reliable end-to-end services, while identifying significant gaps and potential next steps. The report includes:

- A summary of the main architectures that are being adopted in existing mobile health solutions
- A comparison with existing cellular infrastructure
- An analysis of the standardisation of interfaces
- Guidance on direction/gaps/prioritisation.

The report examines the technical architectures of several live mobile health services to help identify the components that are likely to be required to enable the development of scalable, interoperable and user-centred mobile health solutions. However, it stops short of proposing detailed architectural definitions. These will be incorporated into future work streams of the GSMA.

This report is based on interviews with a broad range of stakeholders representing industry bodies, mobile operators, healthcare service providers and healthcare application providers conducted early in 2011. It also drew on publicly-available documentation and published academic materials.

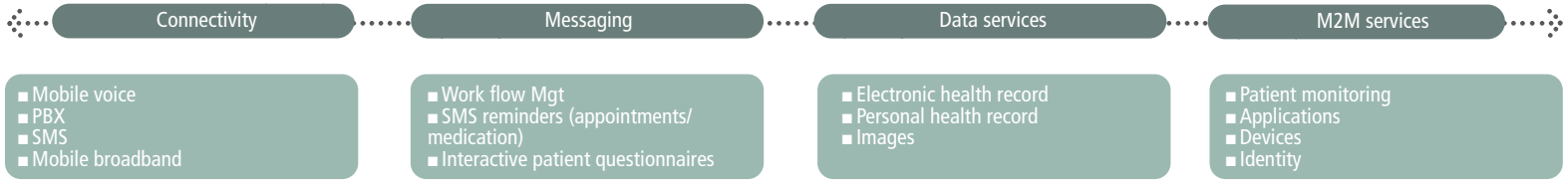
The role of the mobile operator

The more active the role of the mobile operator in the provision of a mobile health solution, the more feature-rich it will become for the end user and the greater the likelihood of the operator developing a sustainable revenue stream.

The diagram below outlines the variety of different products and services that could be categorised as mobile health solutions, ranging from enhancement of current mobile operator capabilities, in the case of SMS reminders and call centres, through to the creation of entirely new capabilities to support clinical transactions.

1 Source: World Health Organisation

What role can the mobile industry play?



Source: GSMA

Using SMS, web browsers and other established technologies, mobile operators and application developers are already offering mobile health reminders and alerts, as well as information on symptoms and treatments and providing remote access to electronic medical records. Some pioneers are now integrating mobile connectivity into medical devices to enable remote monitoring, rapid diagnosis and ongoing management of health and wellness. However, these services have yet to achieve any substantial scale – they are typically a set of discrete solutions to specific problems.

A fragmented approach to solution development is one of the reasons that sustainable commercial models for mobile health have been slow to develop. To become cost-effective and commercially-sustainable for the mass-market, mobile health services will need to be based on standardised, open and interoperable solutions.

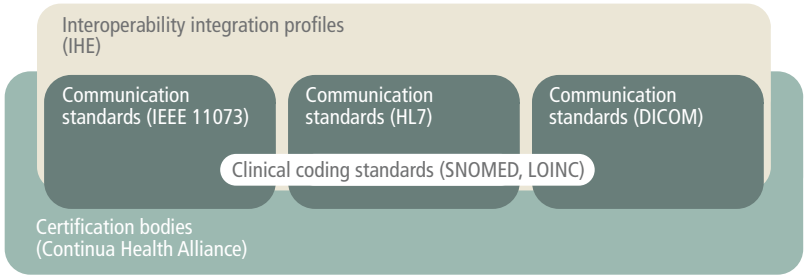
Mobile health standards

There is no single standards organisation that covers the complete needs of mobile health. Mobile health architectures in the market today must make use of a wide range of technical components, each with potentially overlapping or missing standards.

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, which can be transferred into a human-readable format using health messaging standards, such as HL7.

However, HL7 and IEEE 11073 contain transport mechanisms that don't apply to mobile and coding standards that are cumbersome for low-power mobile devices to process. In addition, these existing standards have some gaps within them and interpretations are needed to enable fully-interoperable mobile systems.

Some organisations, such as the Continua Health Alliance and the Integrating the Healthcare Enterprise (IHE), are addressing this issue by providing interoperability guidelines that group standards together into profiles, combining data standards, security standards, messaging standards and transports together into a single certifiable solution (see diagram below).



Source: GSMA

The standards encapsulated within the Continua Alliance guidelines and IHE profiles are of a high technical quality, covering HL7, Bluetooth Health Device Profiles and IEEE 11073 medical device data standards. In addition, they cover much of the wider electronic health functionality, such as security, encryption and authentication, which are key elements of a mobile health solution.

However, there is still some way to go before the mobile health sector has a fully interoperable set of standards that is universally adopted, and market volumes have yet to justify the sort of equivalent investment that resulted in the mobile industry offering handsets that support roaming across multiple network protocols.

Significantly, some of the standards required for mobile health relate to healthcare enterprise integration. These mostly fall outside areas in the direct control of the mobile industry and will involve engagement with other sectors, notably the healthcare applications and ICT infrastructure industries.

Adoption of the existing standards does not preclude upgrading or migrating to more complete standards in the future. But developers adopting the current mobile health standards often run into the following issues:

- Missing or limited functionality: Due to the standards' relative immaturity and the speed at which mobile health is developing, not all use cases are covered
- Low uptake: The success of any standard depends on wide adoption. Many mainstream developers do not wish to be the first to adopt these standards and take the risk that they may not be suitable.

The importance of interoperability

As most mobile health solutions are vertically-integrated, bespoke and closed solutions, it is virtually impossible to integrate devices and products from other providers into the solution.

The adoption of proprietary solutions is partly driven by a desire to control technical complexity and a need to meet privacy requirements and other national regulations. However, this approach has often meant significant local development and integration costs, as few solutions can be deployed across different national boundaries – there is generally limited opportunity for 'reuse' at the service or infrastructure level.

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

Although widespread interoperability will amount to a significant paradigm shift from traditional healthcare ICT solutions, it will enable technology suppliers to generate economies of scale and lower costs.

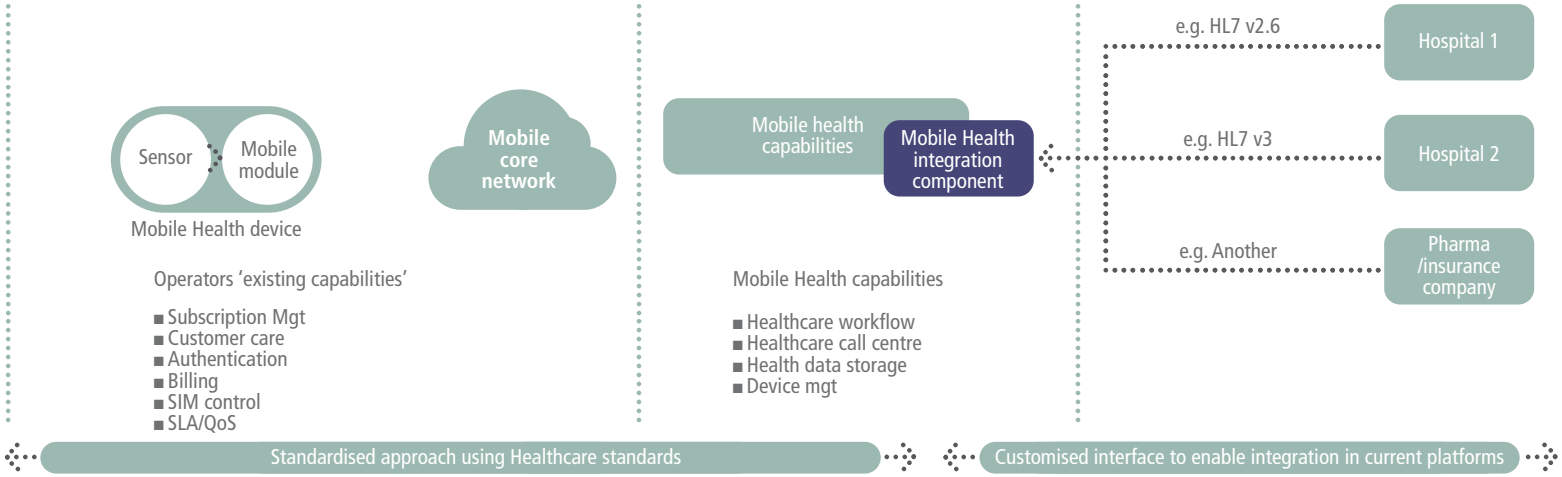
Bridging the gap between mobile and healthcare systems

Until healthcare ICT systems become fully-standardised, mobile operators will need to integrate with a large number of healthcare ecosystem players, all of whom will be using different platforms and systems.

One way to enable this integration would be the use of a robust centralised integration engine, or mobile health gateway, which sits between the mobile network and the healthcare systems (see diagram on the next page). This integration component could take on various forms, but its fundamental role would be to fill the technology gap between healthcare systems and mobile networks and devices.

This approach would enable the mobile health element of the solution to be standardised – the only configuration required would be for a medical records interface to be integrated into the existing healthcare ICT systems.

Standardisation using an integration engine



Source: GSMA

New mobile capabilities could add further value

New mobile technologies being developed outside of the healthcare ecosystem could be used to enhance mobile health solutions. Taking security management as an example, there have been a number of recent advances that could help strengthen authentication and encryption processes in mobile health:

- **On-SIM applications** – applications can be embedded directly on the SIM where they can be managed by the mobile operator without a requirement to upgrade or replace the mobile device
- **Wireless "smartcard" authentication** – wireless smartcard readers can significantly strengthen authentication without having to significantly alter the hardware of the existing mobile devices.

The latest mobile phones are also being equipped with technologies that can be used to support the actual delivery of healthcare. Examples include:

- **Contactless NFC** – Mobile phones are now being equipped with Near Field Communications, a short-range wireless technology, which can support an array of health applications, such as patient check-ins at clinics, identifying the location of staff and the management of patient medication
- **2D barcodes scanning** – Mobile phones with cameras and appropriate software can scan 2D barcodes enabling them to quickly identify medication and then download information on possible side-effects, for example.

The need for partnerships

Mobile operators have developed and optimised robust processes for provisioning and managing millions of devices on their networks. Strong relationships between healthcare providers and mobile operators would enable the full integration of mobile health solutions into the existing mobile networks and systems, paving the way for the delivery of complete end-to-end services throughout the solution's life cycle, encompassing provisioning, set-up, management and billing.

Conclusion

Over the past 20 years, the mobile industry has benefited greatly from a common standards approach, which has fuelled economies of scale and user acceptance. The GSMA believes that the mobile industry should attempt to replicate this approach in the delivery of mobile health services, by advocating a standardised approach for connecting into the mobile health network, supplemented with an integration component enabling connectivity into the fragmented fixed healthcare systems.

2. Mobile health today

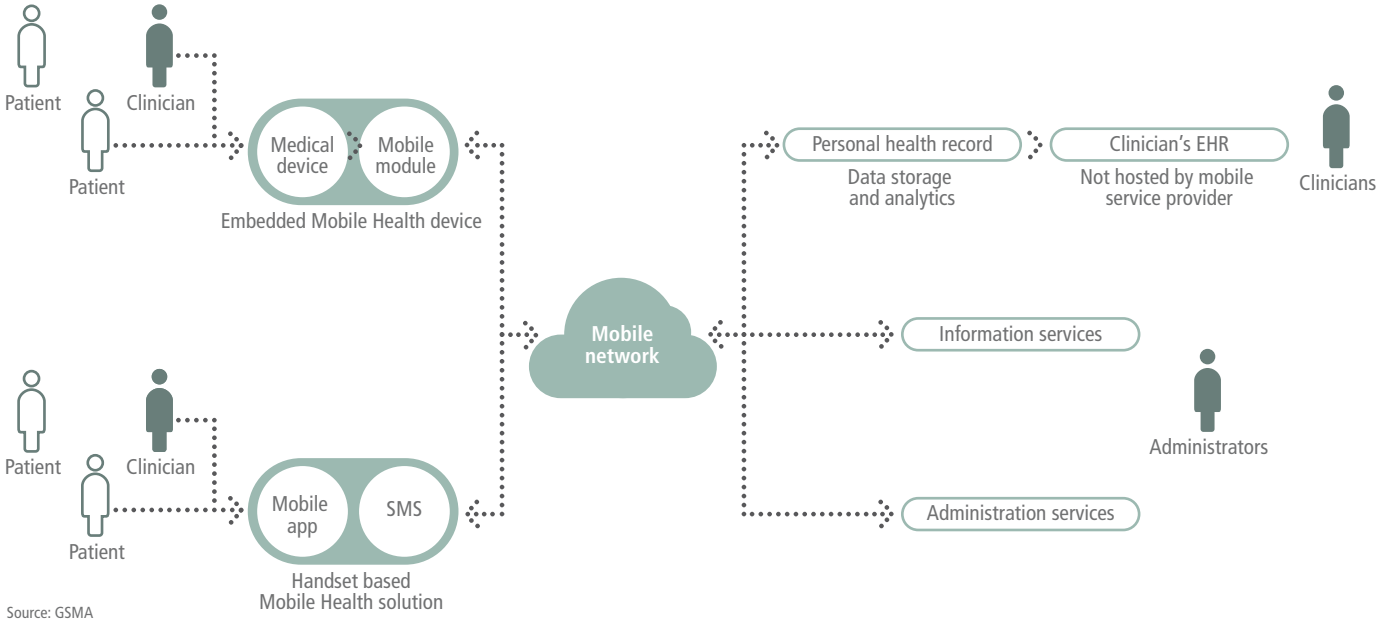
2.1 Mobile has started to make an impact in health

Network operators and application developers are already offering a range of mobile health services, typically focused on providing reminders and alerts through technologies, such as SMS, using web browsers to enable access to information on symptoms and treatments and, in some cases, providing remote access to electronic medical records. Some pioneers are now integrating mobile connectivity into medical devices to enable remote monitoring, and the next generation of services is expected to involve much greater use of connected medical devices by health professionals and patients to support rapid diagnosis and ongoing management of health and wellness. Such services have yet to achieve any substantial scale – they remain a set of discrete solutions to specific problems, and have yet to be generalised. This paper will discuss the potential causes for this lack of scale, and identify some of the main drivers that may encourage wider adoption.

There has been some early progress in developing standards for interoperability for mobile health. Groups, such as the Continua Health Alliance, have established interoperability guidelines for personal health devices, working with standards organisations, such as the IEEE and Health Level 7 (HL7). While the early emphasis of this work has been primarily focused on systems using fixed networks, the generic architecture allows for the use of mobile networks and this work is being applied for mobile health services.

Although some early adopters have established viable business models, a significant proportion of moves into mobile health have been funded as research, as speculative enterprise investments or by philanthropic donor funding. Sustainable commercial models for mobile health have been slow to develop traction. This is particularly the case in markets with an established healthcare infrastructure. In such markets, the challenge has been to bridge the gap between the *beneficiary* of the mobile health service, and the payer for such a service. Often the beneficiary and the *payer* are too far apart to make mobile healthcare business models acceptable. However, a move towards a more consumer-oriented market, supported by open architectures, should enable sustainable growth in mobile health and opportunities for mobile network operators, device manufacturers and application developers.

Figure 1. A range of service offerings are appearing across the mobile health marketplace



Source: GSMA

2.2 There are some significant barriers to wider adoption

As a complex and sensitive business, healthcare has lagged behind comparable industries in adopting information technology. While most healthcare enterprises do use a wide range of information systems, the exchange of information between different organisations is rare. Apart from some specialist disciplines, such as digital x-ray systems, technical standards in this field are relatively immature and adoption is patchy, hampering attempts to join up care electronically. This lack of interoperability will have a significant impact on the scope for mobile health in the short term.

2.2.1 Proprietary end-to-end solutions still dominate

In the absence of robust standards for interoperability, early adopters of mobile health solutions have met privacy requirements and other regulations by fielding proprietary solutions designed to comply with local rules. The deployment of vertically-integrated solutions has allowed operators to avoid complexity – both technical and regulatory. But this approach has often meant significant local development and integration costs, and means that few solutions are marketable across different national boundaries. There is limited opportunity for 'reuse' at the service or infrastructure level.

While there has been positive progress in developing interoperability standards in recent years, actual adoption in the market remains very low. For example, two years after the Continua Health Alliance released guidelines and a certification programme that covers the most commonly-used consumer medical devices, the number of certified devices remains relatively low and the market share of those devices is small compared to the overall market.

2.2.2 Current healthcare policy and regulation limits the scope for further innovation

To date, the successful business architectures for mobile health have reflected the provider-centric way reimbursement mechanisms work in healthcare. Solutions have tended to focus on how healthcare professionals can use mobile to be more effective or efficient. These solutions haven't typically needed to develop the more demanding aspects of the technical architecture that arise when the use of mobile extends beyond the provider organisations' boundaries.

This provider-centric view of mobile healthcare services, with its focus on delivering value by improving efficiency, represents only a small part of the total mobile health opportunity. The power of mobile connectivity to engage patients directly is a significant part of the value proposition, but adoption requires a step change in the development of open architectures.

Regulation,[1] particularly medical device regulation, has also impacted the growth of the mobile health market. Uncertainties about the certification requirements mean that, even where an open standard exists, solution vendors may not use the standard as it would increase risks, and potential liability, in the end-to-end solution. A number of potential players, including mobile network operators and component vendors, are reluctant to enter the market while ambiguity over medical device regulation remains.

2.2.3 There are significant gaps in health information infrastructure

The success of mobile healthcare solutions is highly dependent on a broader infrastructure for sharing health information electronically. While there are some notable initiatives, particularly across the more developed economies, these have often not reached the stage where the supporting infrastructure can be considered to be well-established. A few early adopters have been able to demonstrate benefits from effective enterprise-wide integration, but many mobile health solutions for clinicians have been deployed as silo offerings or as bolt-on solutions which have to work within the limitations of enterprise systems designed for use over fixed local area networks.

The market for personal health records (PHRs) is far less established than that for enterprise solutions.[2] The most widely-used PHRs are portals providing access to enterprise solutions, creating a tie between the consumer and a specific healthcare provider. Patient 'ownership' and 'control' of their medical records is often cited as an objective, but the portability of the information remains limited with implications for the timing and nature of a move towards consumer solutions in mobile health.

1. See 'Policy and regulation for innovation in mobile health' published by GSMA and PA Consulting, February 2011
2. Boehm, Elizabeth " PHRs: Scant Penetration And Lots Of Confusion", Forrester Research, November 4, 2009

2.3 How can the mobile industry achieve a step change in adoption?

The mobile industry has a track record of driving standardisation to enable new markets for innovative technology and service offerings. Fundamental to this success has been both an openness to standardisation, and a recognition, from the outset, of the needs of the end-customers whose interests are not bounded by a single contractual relationship with a network operator.

A step change in the adoption of mobile health services depends on a similar customer-centric perspective for health underpinned by open architectures and interoperability, with an ultimate goal of supporting more diverse relationships between people and their professional care providers.

2.4 What role can the mobile industry play in an end-to-end healthcare solution?

The simplest role that a mobile operator could take within a mobile health solution is to provide the connectivity for a product or service. However, the more active the role of the mobile operator in the provision of the solution, the more feature-rich it will become for the end user, while providing the mobile operator with a better opportunity to develop a sustainable revenue stream.

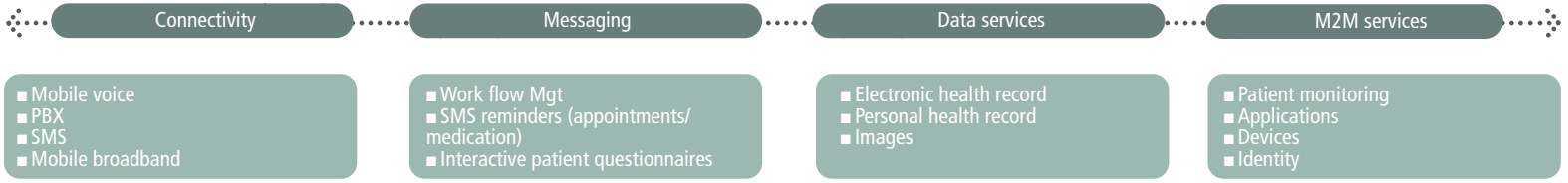
The diagram below (figure 2) highlights the variety of different products and services that could be categorised as mobile health solutions. These products and services vary greatly, from an enhancement of current mobile operator capabilities in the case of SMS reminders and call centres, through to the creation of entirely new capabilities to enable the support of clinical transactions.

Mobile operators need to make a business decision around the level of ownership that they would like to take of the end-to-end product or service. The greater the ownership of the end-to-end solution, the greater the associated risk in its delivery, but also the reward for delivering it.

The following chapters of this report will:

- Explore current service offerings and their approaches to complexity
- Map out the complexity involved in delivering truly open solutions
- Assess the maturity of current standards in this space
- Identify where the opportunities lie for achieving rapid impact
- Provide a high level reference architecture for future mobile health solutions and a route map for achieving new value for mobile health suppliers.

Figure 2. What role can the mobile industry play?



Source: GSMA

3. Current mobile health offerings

In seeking to establish a foothold in mobile health, operators have had to adopt strategies that circumvent or accommodate the restrictions imposed by current technologies and regulations. While these services cover a full range of potential service offerings, there tends to be a split between enterprise and consumer solutions.

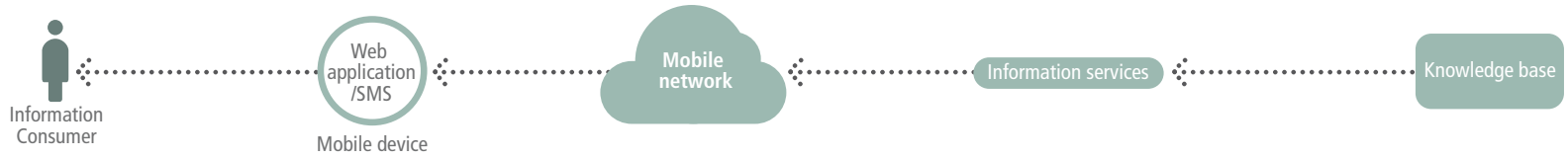
Enterprise solutions, that include technologies for remote patient monitoring and patient coaching, can avoid or control complexity by retaining control of the end-to-end architecture. However, consumer solutions, particularly those targeted at the wellness end of the market, typically do not have the capability for exchanging data with clinical systems.

The following sections highlight the features of some of the current service offerings and draw out the implications for technical architectures. They cover three main types of service:

- Health information and content provision
- Healthcare management/scheduling management
- Interactive healthcare provision.

Most of these business architectures are developed in isolation and are vertically-integrated only within a single operator or service provider, allowing them to avoid many of the more complex technical challenges. This section attempts to highlight the hidden complexity within each of the service types identified.

Figure 3. Basic one-way information flow of health information services



Source: GSMA

Table 1: Example systems for healthcare information services

Example system	Location	Primary business functions
Clickatell	UK	Distribute health information to patients via SMS text message
WebMD Mobile	US	Distribute health reference information to patients and clinicians
Tata Docomo – "Sparsh"	India	Distribute sexual and reproductive health information

3.1 Health information/content services

Health information or health content service providers do not provide comprehensive clinical diagnoses. They provide medical knowledge based on the requests made by their customers. These services are normally one-way information flows, on a request or response model from the patient to a non-clinical backend service. The key point of these services is that they do not link to any patient records or operational healthcare systems; they only connect to healthcare knowledge-bases (see figure 3 and table 1 for examples).

These services provide valuable information, providing preventative and proactive health advice to populations that may not have easy or efficient access to physical health services or high speed, fixed-line Internet connections. The recipient could be a patient, or a clinician at a patient's side.

By providing a one-way information flow, the service provider is able to avoid a substantial number of the more complex technical issues that arise in two-way mobile health solutions. The service does not need to recognise the identity of the patient nor handle any security or consent issues around the clinicians near the patient – there is no personalisation required. Mobile operators are acting only as a data pipe and the service providers are pushing the service management responsibilities of connectivity and support down to the customer.

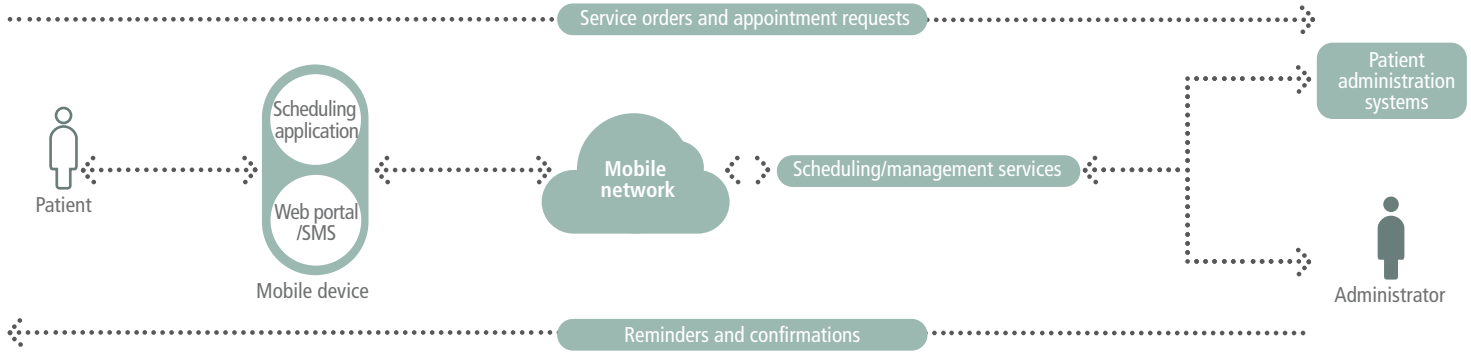
3.2 Healthcare management/scheduling management

Healthcare management or scheduling management solutions within a mobile health ecosystem are designed to provide remote access to the operational elements of healthcare provision. These services are often linked to patient administration systems or hospital information systems and are used to increase the efficiency of healthcare services through:

- Improving patient attendance
- Improving patient awareness of operational processes
- Automating repetitive ordering processes.

Significantly, these services do not need to access sensitive clinical information or the patient's clinical records, and therefore avoid the complex issues that are faced around consent management and patient authentication.

Figure 4. Bidirectional scheduling management, without clinical involvement



Source: GSMA

These types of services are not exclusive to healthcare. However, they are an important element of providing a comprehensive mobile healthcare offering.

Examples of these solutions include:

- Appointment reminders
- Medication reminders.

In the cases where there is no integration into patient or clinical records then this architecture could be used to support the following types of services:

- Medication ordering
- Symptom recording.

A number of these systems are being marketed to health organisations and end consumers. Table 2 below shows a selection of these types of solutions.

Table 2: Example systems within the healthcare scheduling and management

Example system	Location	Primary business functions
The pill phone	USA	Medication reminder
Maternity management	Turkey	Maternity management
iPlato	UK	Appointment scheduling

From a technical perspective, healthcare management and scheduling management services are more complex than one-way information systems. Identity, security and confidentiality start to become an issue as it is important to ensure the reminders or orders are generated for, and received by, the correct patients.

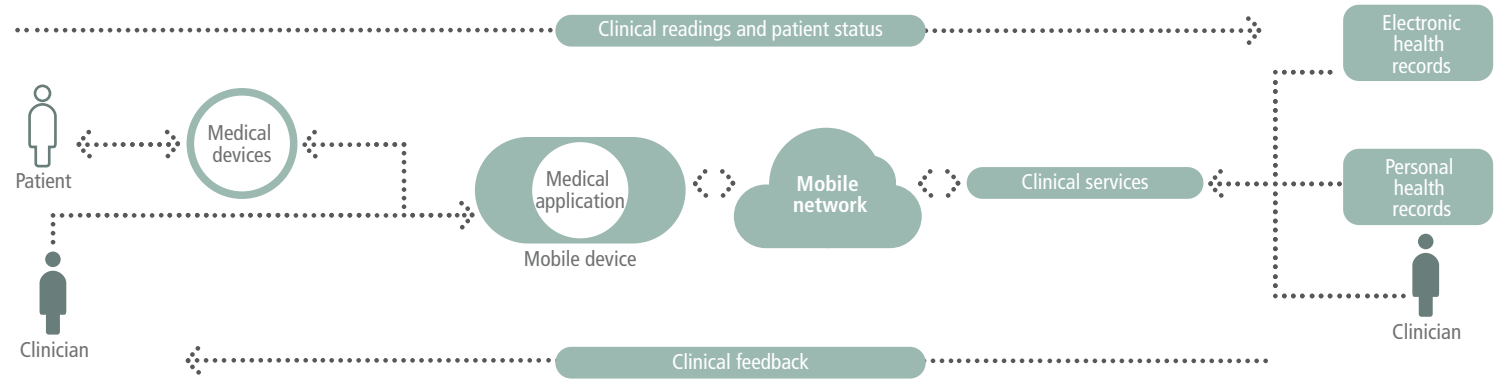
However, these management services work with the prior explicit consent of the patient, which reduces some of the complexities. While individual service offerings typically use their own distinctive solutions to address consent, security and identity, they have all simplified the issue by providing a direct point-to-point, closed system with proprietary identity and security management.

Healthcare management and scheduling management services generally do not contain clinical information that is required for clinical decision making, simplifying the technical solutions involved. These services are used solely for reminders and administrative tasks; the information gathered through these tools and systems increases the reliability of clinical and administrative processes, but does not necessarily alter them in any fundamental way. Therefore these solutions don't require specialised clinical coding or highly accurate and trusted clinical messaging and integration with clinical backend systems, requiring higher standards of detail. However these services types will be subject to Data Protection regulation associated with the storage of data.

3.3 Interactive healthcare provision

Where other services are only designed for information exchange, interactive healthcare services offer a more integrated clinical experience, often with clinical expertise actively involved during certain stages of the process. These services also connect directly to clinical systems and normally have read and write access to a patient's clinical history or patient record.

Figure 5. Bidirectional interactive healthcare services, with direct clinical involvement



Source: GSMA

Table 3: Further example systems within the healthcare scheduling and management

Example system	Location	Primary business functions
AT&T MedApps	USA	Home monitoring, medical measurements, chronic condition management
Ericsson mobily	Saudi Arabia	Remote vital signs monitoring
Telecom Italia MyDoctor@Home	Italy	Home monitoring, medical measurements, chronic condition management

Basic interactive services involve the exchange of information between a mobile device and a remote clinical service provider. In some cases, the services involve connectivity embedded within a mobile device.

Fully interactive healthcare solutions could involve significant technical complexity. Most of the factors creating this complexity are covered later within this document. However, in most of the solutions observed in this research, the technical complexity has been limited by design, providing a closed solution involving end-to-end systems from consumer devices through to backend systems.

3.4 The need for standardisation

The GSMA's research has found that most mobile health solutions are vertically-integrated. This approach is common in traditional healthcare ICT systems and has led to the deployment of bespoke, closed solutions in which the healthcare providers supply and then own the end-to-end service. This closed approach means that it is virtually impossible to integrate devices and products from other providers into the solution.

For mobile health to reach its full potential, healthcare system architectures will need to open up and become interoperable, with common interfaces supporting 'plug and play' devices to get information into the healthcare systems and a standard interoperable interface to exchange data between backend solutions. This will be a significant paradigm shift from the way that traditional healthcare solutions are currently being developed. There is also a need to standardise the systems currently being used in healthcare ICT, pharmaceutical and insurance systems, but the mobile industry should focus on the areas within its control.

Over the past 20 years, the mobile industry has benefited greatly from a common standards approach, which has fuelled economies of scale and user acceptance. The GSMA believes that the mobile industry should attempt to replicate this approach in the delivery of mobile health services, by advocating a standardised approach for connecting into the mobile health network, supplemented with an integration component enabling connectivity into the fragmented fixed healthcare systems.

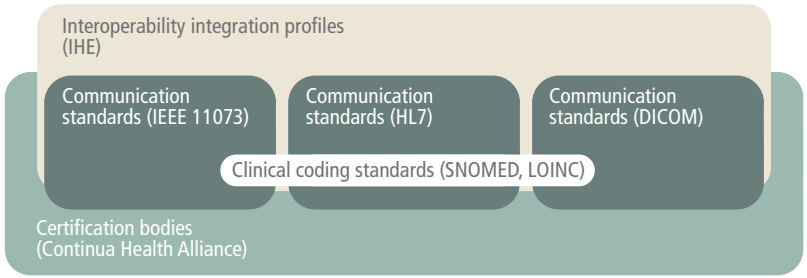
4. Understanding healthcare messaging

There is no single standards organisation that covers the complete needs of mobile health. Mobile health architectures in the market today must make use of a wide range of technical components, each with potentially overlapping or missing standards.

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 could involve 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.

However, HL7 and IEEE 11073 contain a range of additional elements that are not applicable to mobile health. For example, transport mechanisms do not apply to mobile and coding standards are cumbersome for low-power mobile devices to process. In addition, these existing standards have some gaps in the interpretations needed to enable fully interoperable mobile systems.

Figure 6. Architectural components, standards and profiles often overlap and are not mutually exclusive



Some organisations, such as the Continua Health Alliance and the Integrating the Healthcare Enterprise (IHE), are addressing this issue by providing interoperability guidelines that group standards together into profiles, combining data standards, security standards, messaging standards and transports together into a single certifiable solution. However, there is still some way to go to provide a fully interoperable set of standards that is universally-adopted and market volumes have yet to justify the sort of equivalent investment that resulted in the mobile industry offering handsets that support roaming across multiple network protocols.

Significantly, some of the standards required for mobile health relate to healthcare enterprise integration. These mostly fall outside areas in the direct control of the mobile industry and will involve engagement with other sectors, notably the healthcare applications and ICT infrastructure industries.

4.1 Healthcare messaging standards

Although there is a growing consensus around a common set of communication standards for mobile health solutions, there is little take up and use of these standards in physical devices, reflecting he immaturity of the market, and the hesitancy of major players to embrace the opportunities.

Notwithstanding this hesitancy, strong communications standards will give suppliers and operators a clear way to start to interoperate the world over – something that will be increasingly important as mobile health seeks to embrace the patient directly, rather than adopting a more traditional physician-centric view of health.

Figure 7 shows some of the standards bodies covered in our research. These standards vary across the different technologies that are used and different disease types that are being supported.

In existing mobile health services, IEEE 11073, HL7 and DICOM seem to be the most prevalent standards in use. The sections below describe these standards in a little more detail. However, the use of these standards doesn't automatically enable interoperability due to the inflexible way they have been defined.

4.1.1 IEEE 11073

The IEEE 11073 standard is primarily concerned with the transmission of measurement data from medical devices. It is designed to be flexible, with different sub-standards developed to cover each type of medical device (for example, blood pressure, blood oxygen, etc.), without the need to alter the core offering.

This IEEE standard is not, however, exhaustive. It doesn't yet cover some key medical measurements, such as electro cardiograms, and devices, such as the mobile stethoscope. The Continua Health Alliance 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.

Future adoption of this standard will depend on the standards groups committing to the fast and efficient development of new medical measurement sub-standards as new device types become available.

More information is available at: **www.11073.org**

4.1.2 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). The different devices come with DICOM conformance statements which clearly 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.

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

More information available at: **www.nema.org**

4.1.3 HL7

HL7 standards are living standards and as such have developed a considerable revision history. Moreover, the major version numbers, version 2 and version 3 are not backward-compatible with other major versions. This can lead to a disconnect between two systems that claim compliance with HL7, but, in reality, have significantly different interfaces. HL7 also provides minor version numbers, which are theoretically backward-compatible, but may present significant challenges when attempting to interface with them.

However, 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 available at: **www.hl7.org**

4.2 Healthcare systems interoperability

The healthcare industry is taking steps to address the current lack of interoperability between ICT systems and has created two global organisations focused on resolving these problems.

IHE (Integrating the Healthcare Enterprise) and Continua Health Alliance have been established as not-for-profit organisations by healthcare ICT companies. IHE's primary focus is on large complex medical devices and systems, whereas Continua's focus is on the development of guidelines for personal connected healthcare devices.

4.2.1 IHE (Integrating the Healthcare Enterprise)

A global initiative, IHE is designed to create common frameworks for passing vital health information seamlessly from application to application, system to system, and setting to setting across multiple healthcare enterprises. IHE brings together healthcare stakeholders to develop a framework for interoperability.

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, eliminating ambiguities, reducing configuration and interfacing costs, and ensuring a higher level of practical interoperability.

Although these integration profiles have led to an improvement in the levels of interoperability, they have not resolved the issue fully as there are a number of configurable fields that require definition before systems can become fully interoperable.

More information available at: **www.ihe.net**

4.2.2 Continua Health Alliance

The Continua Health Alliance aims to establish a system of personal connected healthcare solutions to promote independence, empowering individuals and providing the opportunity for truly personalised health and wellness management. The Alliance is working toward establishing systems of interoperable telehealth devices and services in three major categories: chronic disease management, aging independently, and health and physical fitness. Continua has encapsulated a set of standards (IEEE 11073, HL7 using IHE DEC PCD-01) into a set of guidelines, along with establishing 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, the Alliance has defined a set of system interfaces that support the end-to-end delivery of healthcare services:

- **PAN** – Personal Area Network
- **LAN** – Local Area Network
- **WAN** – Wide Area Network
- **HRN** – Health Record Network.

In addition, they are in the process of defining two further interfaces to support new interactions in mobile health:

- **TAN** – Touch Area Network
- **EAN** – Embedded Area Network.

Continua has built on the work completed by IHE by providing guidance on the specific use of the data within configurable fields in the IHE profile. The implementation of these Continua interfaces is designed to enable a full 'plug and play' solution.

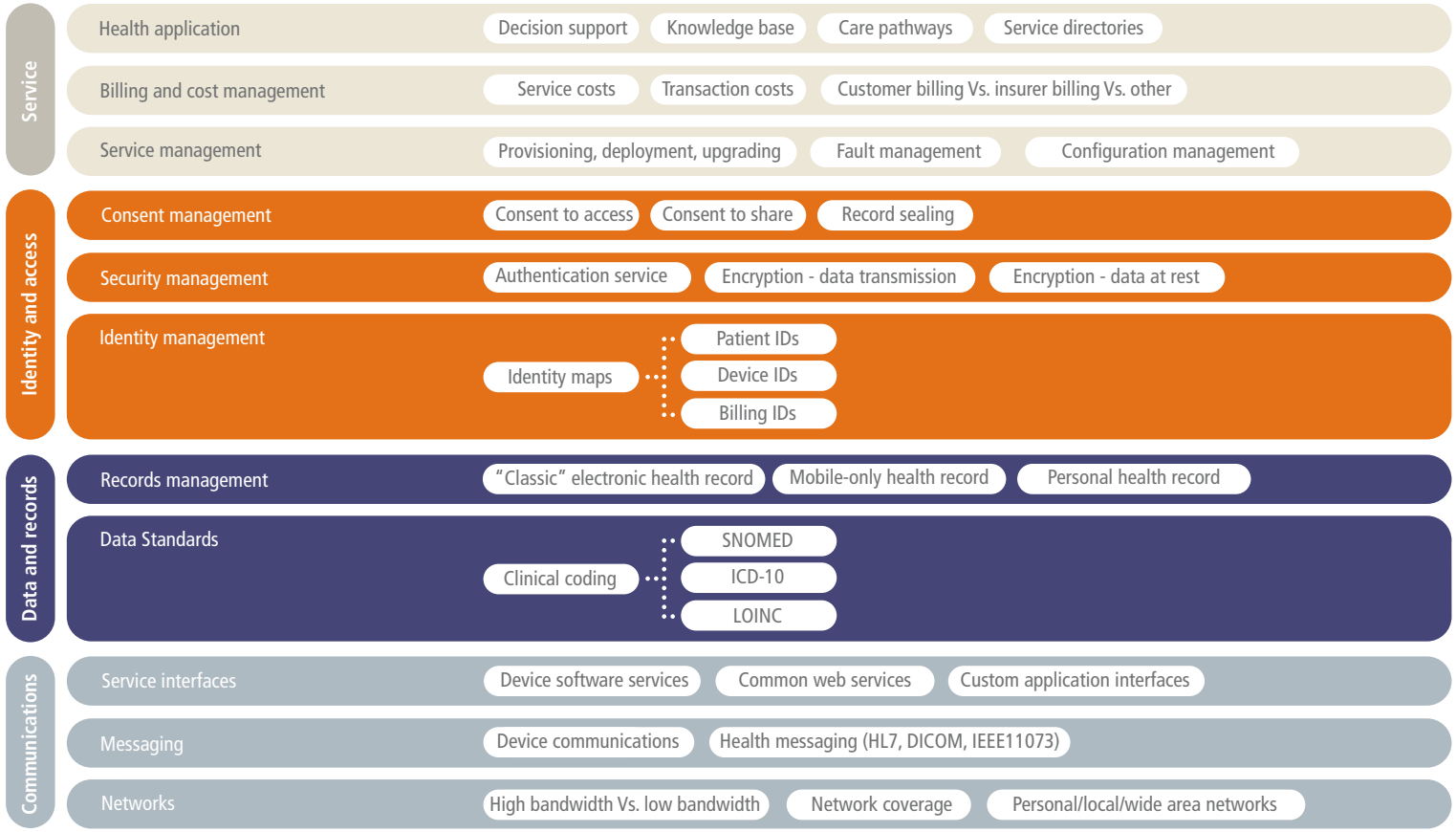
More information available at: **www.continuaalliance.org**

5. Building an open architecture

This section identifies the components that are likely to be required for scalable and user centred mobile health solutions. It draws on details of the technical architectures in use, including how they interoperate, to propose a set of elements common to all mobile health architectures. The diagram below shows these common components and groups them into four broad functional areas:

- Communications; consisting of the raw communications protocols and services
- Data and Records; consisting of the data, information and record storage, and the standards that the data conforms to
- Identity and Access; consisting of the non-functional components around patient identity, patient confidentiality and consent, and security around the solutions
- Service and Application; consisting of the functional healthcare specific application components that interface with existing systems and business functions.

Figure 7. Architectural components of a mobile health solution



This diagram is not designed to be exhaustive, but gives an impression of the building blocks necessary to develop a fully integrated, end-to-end mobile health solution. The following sections explore the components in more detail.

5.1 Service and application

5.1.1 Health application

Health applications, which mobile health solutions can connect into, require programming and service interfaces to operate correctly.

The complexity of these application interfaces varies depending on the application type:

- **Decision support** Decision support offerings are clinical systems that are designed to replace or augment a task that a clinical specialist may perform, such as automatic analysis of trends in a remote patient monitoring solution. These applications offer some of the biggest benefits, but come with the biggest clinical risk of incorrect results and guidance and are therefore subject to more stringent regulatory approvals. To manage this risk, most applications involve tight control of the data flows. The GSMA's research found that decision support systems are generally highly-customised to specific clinical scenarios
- **Knowledge bases** Simply providing access to health knowledge is typically intended to improve the speed or accuracy of local diagnoses or local care. The solutions identified in this paper are relatively simple in terms of technology. Much of the complexity lies in developing and maintaining relevant content, some of which will be determined by local protocols or information about local care providers. Knowledge base applications are accessed normally using search-like functions, which can range from sending an SMS with the specific question up to enabling browser-based searches. There are some technical challenges balancing provision of information with device displays
- **Care pathways** Care pathway applications are workflow management applications designed to support standardised referral and treatment regimes, typically tracking progress and adherence to defined standards. Typically, care pathways are embedded into individual EHR solutions. For example, a system used in the UK enables midwives to record the results of home visits, schedule follow-ups and make referrals. Care pathway integration may be complicated by significant variations in local practices and procedures, requiring operators to work closely with enterprise customers to configure and deploy a solution
- **Health planning and booking systems** Administrative applications are increasingly popular. These include SMS reminder services for appointments as well as medication management and maternity management solutions, which are designed to provide order and scheduling, rather than direct clinical information or EHRs.

There may also be a requirement for mobile health solutions to connect with service directories being provided by healthcare organisations or central communications hubs delivering services for healthcare providers.

Future adoption of mobile health solutions will require health applications and services with standardised, open interfaces. By opening up these healthcare services and applications, entire healthcare workflows can be moved out of the clinical settings and onto mobile devices, providing considerable healthcare benefits in remote areas.

5.1.2 Billing and cost management

The billing and cost management options, with respect to mobile health, are extremely varied. The GSMA's research has identified a number of different billing options worldwide:

- Transaction-based; where each service transaction is charged at a set rate
- Message-based; where each service transaction is not necessarily charged, but the mobile transaction costs are charged to the consumer or patient
- Service-based; normally an annual or monthly subscription rate charged by the service provider to either the end patient or the healthcare provider on behalf of their patients.

Effective billing management and general cost modelling is dependent on clarity about the discrete transaction costs of each layer of the service being provided. There may be costs arising from data transfers by the network carrier and costs arising from the healthcare providers. Any effective billing solution will need to have clear and close monitoring of the transactions being used and be able to collect the data in a consistent way across the different transaction providers.

Healthcare's distinctive processes and reimbursement models mean that mobile health solutions will require new and innovative financial models to fully meet the needs of healthcare providers and payers. Network operators can currently share wholesale billing records with third party organisations. However, in order to realise more direct benefit from mobile health, network operators will need to assume more financial risk by repackaging their network costs into healthcare transactions for the patient rather than data transactions for the device.

This paper is focused on technical architectures, rather than financial models. However, it is important to recognise that innovative financial models may require more granular reporting and tracking of system transactions, possibly across multiple organisations, in order to fully capture the health transaction.

A good example from an adjacent industry is the new charging model used by the Amazon Kindle, in which the transmission costs are encapsulated within a business transaction and the consumer is not aware of these charges that are incurred during the delivery of the content. Widespread adoption of consumer mobile health devices will depend on the introduction of similarly innovative charging mechanisms.

5.1.3 Service management

Service management is of increasing importance as software and applications become more involved and more heavily integrated into the end-to-end service offering. Important elements to be considered include:

- **Provisioning, deploying and upgrading applications** – in particular, applications that are embedded on to mobile handsets or other mobile devices need to have mechanisms to enable quick software upgrades or initial deployment
- **Managing faults** – in a healthcare environment, fault management is absolutely critical and must be treated carefully to prevent unnecessary health risks
- **Configuration management** – it is rare that software can be deployed and be fit for purpose for every patient. Significant configuration will likely be required to make any solution effective.

The GSMA's research has found that the current generation of mobile health solutions often rely on existing service management infrastructures to maintain active and updated platforms. In most cases, these services are managed using either the existing mobile network providers or via specially-commissioned service management desks by health application providers.

For example, a number of mobile operators already provide dedicated help desks and single-point support for their entire mobile health offering, covering issues with handsets, devices, services availability and application help. However, in this model all device faults and upgrades are managed through existing 2nd line fault and defect fixing capabilities within the organisation.

The mobile health solutions examined for this study each take different approaches to service management. Mobile health solution providers generally provide their own defect logging services, but their customers are demanding single-point support numbers, requiring the solution providers to also cater for support and fault management for the full end-to-end solution. There is an opportunity for mobile operators to offer service management capabilities beyond device and subscription management as part of a full end-to-end support solution.

There is a public perception within Europe that mobile health services and applications will change from being managed and distributed by mobile network operators and handset manufacturers to more traditional healthcare providers.[3]

3. 'Mobile Health Market Report 2010-2015 – The Impact of Smartphone Applications', research2guidance, 2010

5.2 Identity and access management

5.2.1 Consent management

The concept of consent within electronic health systems and patient records in the developed world is extremely complex, reflecting both regulation and patient concern. The implementation of appropriate controls for consent has a significant bearing on the complexity of technical solutions.

There are a number of aspects to consent:

- **Consent to access;** whereby the clinician who is currently looking at the record is permitted to access that data record
- **Consent to share;** whereby the patient has allowed their own clinician to share the data with other clinicians
- **Record sealing;** allowing the patient to hide elements of their record from any access.

The complexities of consent and record confidentiality can be compounded by a lack of understanding of what can happen if data is hidden from clinicians or what data may still be visible or partially visible. For example, if a patient wishes to keep details of an HIV-test result hidden from a clinician, then should the record also conceal any anti-retroviral medications?

The existing mobile health solution providers have each taken their own technical approaches to consent management, but they all largely follow a Role-Based Access Control (RBAC) methodology to their records and data. In summary, this means users are assigned roles that they can perform within the solution and access to data and records is assigned to each role.

However, it is generally not clear as to the extent to which medical measurements on devices are covered by consent models either in terms of regulatory requirements or just the local decision made by mobile health service providers. It would add significant overhead to the measuring devices if they were required to implement a full role-based access control scheme for every measurement and function they performed. Battery life is often a significant limiting factor within these devices and adding further access control functionality would have a significant impact.

The Continua Health Alliance guidelines accept that consent and access controls may not be imposed at the individual device level, which means that this functionality must be handled at an application layer. But existing mobile health solutions take a variety of approaches. Some require access controls at the mobile device, others accept data from a known device and provide controls in the back-end application. In many regions, regulatory requirements impose significant demands on the technical designs of confidentiality systems and the lack of agreed regulatory standards across these different regimes is an issue.

Patient confidentiality

In a number of jurisdictions around the world, regulations have been enacted in law to protect the confidentiality of patient data. Examples of these include the HIPAA and HITECH regulations within the US, the Data Protection Directive in the EU, with its transposition into the Data Protection Act in the UK and similar regulations in other member states. Each of these regulations has its own specific requirements, which are outside the scope of this paper. However a number of technical architectural concepts should be followed in order to adhere to these regulations.

- Ensure an appropriate consent model is in place, from a business perspective, to inform the technology requirements of a solution
- Follow security policies that support the regulations and embed these policies within the technological design of a mobile health solution
- Follow best practice approaches to data security including encryption, strong password management, and role based access control to data.

5.2.2 Security management

The level of security around mobile health solutions is largely driven by regulatory requirements and local expectations of personal security and personal privacy. These security requirements incorporate a number of technical considerations:

Data encryption

Data needs to be encrypted both in transmission and at rest. Mobile networks already encrypt traffic, but strong encryption has not been widely established for data at rest on the current generation of mobile devices. There is a general move towards better mobile device encryption, but full coverage may still be a number of years away.

Strong encryption at a mobile device level implies a higher level of processing and increased power usage. Standards and profiles developers must take care to avoid demanding levels of encryption that are impractical on the mobile devices in the marketplace. Setting a high level of encryption will discourage adoption of these security standards due to the desire by manufacturers to keep power consumption on mobile devices low.

Authentication

Authentication is strongly tied into identity management, which is covered in the next section.

A range of authentication mechanisms are already in use in the mobile health field. The existing generation of handsets and SIM cards provide well-established PIN authentication based on a number of numeric digits or alphanumeric characters. Full electronic healthcare systems may require strong, two-factor authentication, whereby authentication is only possible by combining something the user knows with something the user physically possesses.[4] It may also be necessary to perform authentication both on the local devices and the remote servers in order to confirm there has been no local device tampering.

Figure 8. Authentication mapping between the systems within an end-to-end solution, "single sign on"

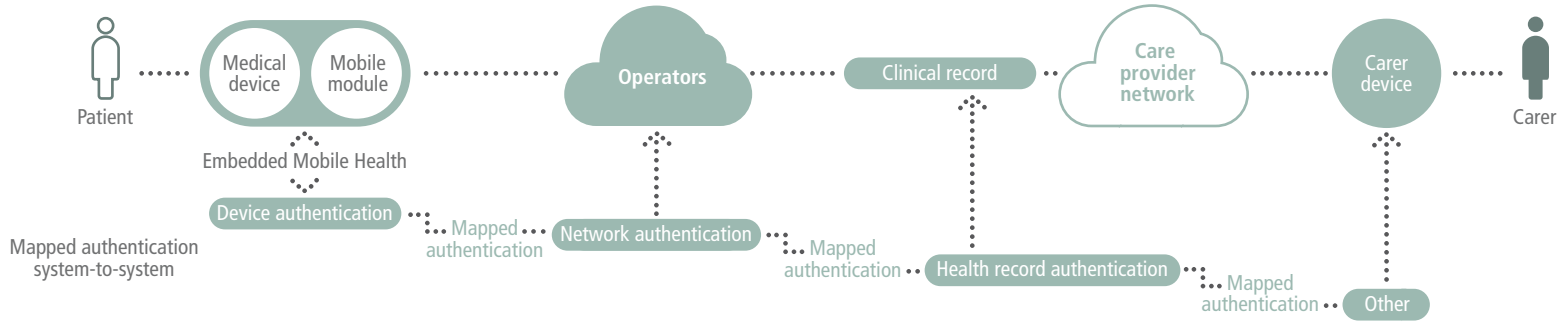
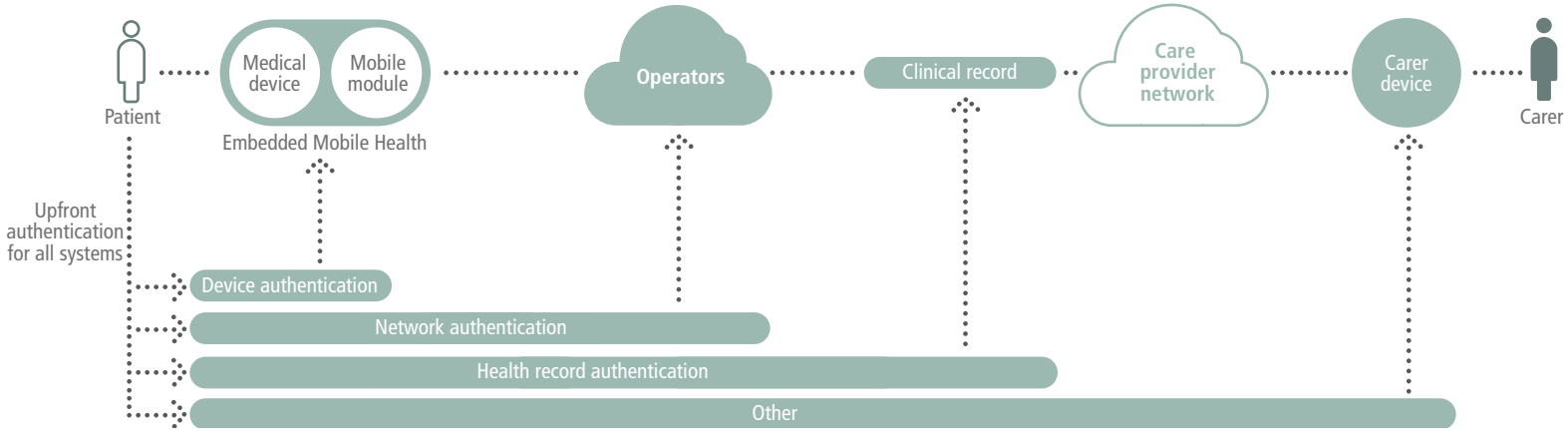


Figure 9. Authentication up front for all discrete systems requires multiple authentication points



4. A clear example of two factor authentication in electronic health systems is the English National Health Service requirement to use chip-and-PIN Smart Cards to authenticate on any health system.

Current mobile health solutions accept the local authentication and encryption standards used within their own closed end-to-end solutions. However, as solutions become more open, coordinating the various authentication requirements will become increasingly challenging. Each layer of an open mobile health solution may have its own demands for authentication, which will need to be either mapped between each layer or entered by the end-user at the start. Some solutions use a Single Sign On (SSO) mechanism at the backend service to simplify the authentication process for the end-user.

Both encryption and authentication can be handled at a very low level directly within the devices, the network services or the mobile device SIM. Newer SIM designs and specifications already include robust encryption mechanisms such as Public Key Infrastructure (PKI), which can be deployed quickly and effectively to encrypt and secure data and communication channels.

Future adoption of mobile health solutions relies upon high quality information security. These mechanisms already exist and should be used.

5.2.3 Identity management

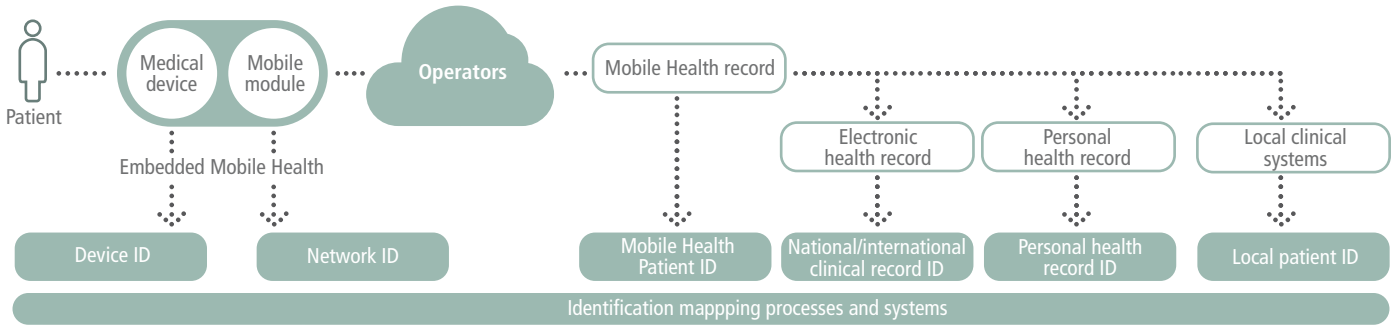
Identity management is a significant consideration for information sharing in healthcare, where data may be held and used to determine care over very long time frames. Identity management is not only related to the question of confidentiality, but is integral to providing the right care to a patient by avoiding misdiagnosis. Unique identifiers are needed to ensure that data is being associated with the right patient, and in practice this means that many identifiers may be encountered in end-to-end systems.

In mobile health services reviewed for this study, most services involving the upload of data from a device use unique device IDs as a proxy for patient identification, only mapping data to a particular patient through functionality in a back-end system. Similar arrangements are made for devices that take measurements from more than one person. In some cases, the mobile device can associate a time-bounded 'session' with a particular patient. Architecturally, this approach has the benefit of removing the requirement of additional and complex functionality on the medical devices, which typically do not have the user interfaces, processing power or endurance to support more complex algorithms. Current closed solutions are also able to disregard, or provide limited support for, alignment with healthcare provider patient identifiers, as there is very little, if any sharing, of patient data with other electronic health systems.

These closed systems use device identifiers, network identifiers (through the SIM card) and local usernames as proxies for the patient identifier. However, using these proxies prevents a patient from being uniquely identifiable within the full ecosystem. In the future, patients are likely to expect to be able to share their medical information with whichever clinician they desire, using whichever system they operate with. In addition, several patients will start to use shared devices and shared network connections (in the form of SIM cards).

However, in order to open up the mobile health ecosystem, it will be necessary to raise awareness of the patient identifiers throughout the ecosystem in order to enable patients to share local medical readings, diagnoses, or other clinical aspects with any electronic health system they wish. The current solutions will certainly involve a level of identification mapping across each of the subsystems.

Figure 10. Identification mapping across systems



Source: GSMA

Moving beyond the clinical aspects of the patient identifier, there is a financial consideration in that billing and network identifiers for each transaction will need to be mapped back through to patients performing actions. Without this level of mapping, there isn't a direct link between the costs being raised through network usage and the clinical outcomes of the patient.

5.3 Data and records management

5.3.1 Records management

There are different views on what level of health record is needed at each level of a mobile health solution. For example, the Continua Alliance and HITSP both recognise a need to support interactions between health records, such as a remote monitoring management system that takes data from mobile medical devices, and a separate health record. In some instances these two elements can be combined into one integrated system.

There is an additional complexity in the difference between Personal Health Records (PHR), owned and maintained by the patient, and full Electronic Health Records (EHR), maintained by the healthcare organisation. In some cases the mobile record is actually a form of PHR, in others it is a clinically-owned and operated record. Ultimately, the goal of any health system is to exchange health information between any of these records, but incompatible data format and interface issues remain significant barriers.

In the current range of mobile health solutions, device identifiers and user identifiers are typically used to link data from the mobile devices to a patient record – the patient identifier and the full patient history is not explicitly stored or handled at the mobile device level. The technical implementations of the current live solutions are equivalent to non-health monitoring solutions. Patient identifiers and patient records only begin to appear further along the value chain, within the clinical or hospital record systems where there is a need to coordinate medical measurements or clinical activity taken remotely with a historical patient record for a deeper clinical analysis.

5.3.2 Data management

Within a health record and within any related systems, clinical data should adhere to clinical coding standards to ensure that two systems, carrying the same health information, do not interpret the underlying clinical information differently. A number of standards do exist for clinical coding, such as SNOMED CT and LOINC. In theory, any of these standards can be used as long as it can be mapped on to other standards. In practice, this is a complex area where direct mappings are often not possible and there are clinical safety concerns where there is any transformation of data. However, most of these complexities are outside the scope of mobile health solutions.

5.4 Communications

Although there is uncertainty surrounding the standards that could be used to enable interoperable healthcare messaging, there is less ambiguity around the lower level transport communication standards. All of the live systems studied by the GSMA use standard approaches, but greater support for new emerging standards in transports, such as Bluetooth, would increase the uptake of mobile health.

Messaging

The Open Systems Interconnection model (OSI model) offers a framework to assess the availability of technical standards at each level of the communications stack. The OSI model provides a simple way of segmenting the standards that exist and allows the system and service providers to make clear comparisons of their communications standards.

Most of the healthcare-specific standards are, by necessity, higher within the model, occupying the host layers. The physical and transport layers are already covered in some detail by the existing cellular infrastructure and new standards are not necessary to allow greater interoperability.

Figure 11. An outline of how the OSI model relates to mobile health

OSI Model			
	Data unit	**Layer**	**Example**
Host layers	Data	7. Application	HL7, EDIFACT, DICOM, IEEE 11073, ebXML
		6. Presentation	
		5. Session	
	Segments	4. Transport	UDP, TCP
Media layers	Packet	3. Network	IP
	Frame	2. Data link	UMTS, others
	Bit	1. Physical	IEEE 802

Low level media layers

This study has found that the primary mechanism for handling the lower level media layers of the OSI model is to make use of the Internet Protocol standard running across the existing cellular infrastructure. There appears to be very little inclination or need to develop new standards to support the networking and transport layers of communication within the mobile health scenarios.

However, in the connected device use case, in which a healthcare sensor connects to a mobile device via Bluetooth, there are problems in the mobiles device's ability to manage the data it receives. Although this can be addressed within the healthcare application on the mobile device, this will require a different version of the application for each variant of operating system. To compound this problem there have been cases where different device manufactures have implemented the management of the Bluetooth stack in different ways on the same operating system. In this instance, there would need to be a compatible application for every type of handset.

This complexity has been managed in other types of devices using Bluetooth profiles (e.g. headsets), these profiles enable peripheral devices to connect to a mobile handsets in a 'plug and play' manner. A profile for healthcare devices has recently been released by the Bluetooth Special Interest Group (SIG), called the 'Health Device Profile (HDP)', but the uptake of this new profile, within the Bluetooth stack of new mobile devices, has been limited. Making these types of healthcare devices truly 'plug and play' will require the widespread adoption of the Bluetooth HDP within future device releases.

Mobile Health is also being considered in the development of Bluetooth Low Energy which will add another connectivity option for lower power devices. The Bluetooth SIG recently announced the finalisation of two new developer specifications for connected vital sign monitoring devices looking to make use of the short range wireless technology. The specifications, called health thermometer profile and heart rate profile, are the first mobile health profiles to be part of the upcoming Bluetooth 4.0 release.

High level host layers

The majority of the high level host layers are covered off by the standards referenced in section 3.1. In the instances where non-clinical data is being transmitted, the traditional standards used in the mobile ecosystem (e.g. SMS, web or application based services) will generally be used.

5.4.1 Networks

Mobile health services are operating across a number of different network standards worldwide, ranging from low bandwidth, but high coverage, 2G networks through to high bandwidth, but low coverage, 3G networks.

Voice versus data

A number of "health hotlines" have been launched throughout the world that rely solely on voice communications. This type of solution does not explicitly require mobile connectivity and the overall call centre solution would be the same regardless of the telecommunication device used.

A mobile network provider's capabilities in operating call centres and large numbers of customers effectively can add value to a voice-based service.

Conversely, mobile data services require specialised standards and formats tailored to the low power and low bandwidth restrictions of a mobile device.

Low bandwidth, high coverage

2G networks are not designed for transmission of large volumes of data. Low bandwidth infrastructure, such as a GPRS network, will only support low-level transmission of text, low-resolution images or direct data communications.

Here are some examples of how these networks are being used in healthcare:

- SMS-based medical enquiry services (Saudi Arabian medical content provider)
- Appointment reminders (across western Europe)
- SMS Maternity Management (Turkcell).

Low bandwidth networks are relatively ubiquitous, in both developing and developed countries. For the provision of critical care and care in developing countries, these low bandwidth networks are typically the lowest common denominator.

Adoption of mobile health services for low bandwidth networks is already moving at considerable pace. Very little effort would be required to encourage and continue the adoption of these services.

High bandwidth, low coverage

High bandwidth 3G cellular networks are well established in areas of high population density or areas of high affluence. These networks are fast enough to be used to access web sites and web services containing large amounts of text and high-quality static images or low-quality dynamic images. However, the availability of 3G networks in the developing world and areas of low population density is still relatively low, but on the increase.

Many of the more advanced mobile health solutions rely heavily on high bandwidth connections to transmit large amounts of data and high-quality images. Future adoption of these higher quality and higher bandwidth services will depend on expanding the coverage of 3G networks worldwide.

6. Speeding up progress

In summary, there are a range of well-established mobile health architecture solutions, but there are also significant gaps in architectural standardisation. A growing number of standards are available to choose from, which vary in terms of their completeness and applicability to mobile healthcare.

Progress in achieving an open and interoperable ecosystem of mobile health solutions will be fastest because:

6.1 Areas where partial standards already exist

As described earlier in this document, there are a number of well-defined standards and conformance profiles, including the Continua Health Alliance designs and the IHE profiles. The component standards for clinical messaging, clinical coding and communications, such as HL7, IEEE 11073, and various wireless Internet standards, are also clear and well established.

Within the scope of these standards, requirements for development are clear. Documentation and examples provide a good starting point. However, it is clear that the scope of these standards is limited. Going outside of the scope of the standards exposes considerable technical complexity and will require a significant amount of custom and proprietary development to create an end-to-end system. Sometimes, part of that complexity is addressed by an adjacent standard, resulting in the overlaps identified in Section 3.

Adoption of the existing standards does not preclude upgrading or migrating to more complete standards in the future. Therefore, it would seem appropriate to encourage new entrants to the mobile health ecosystem to adopt the existing well-documented standards to expedite the wider deployment of mobile health solutions.

6.1.1 Opportunities to encourage existing standards

The standards encapsulated within the Continua Alliance specification are of a high technical quality, covering HL7, Bluetooth Health Device Profiles, IEEE 11073 medical device data standards, and ZigBee communications. In addition, the IHE profiles cover much of the wider electronic health functionality. Encryption mechanisms and standards, such as PKI, are well established and defined, and the wider GSM cellular network standards are clear and widely used.

However there are two common issues encountered by developers in adopting these standards:

- **Missing or limited functionality** Due to the standards' relative immaturity, not all use cases have been fully established. Given the speed with which the mobile health ecosystem is progressing, developers have needed to continue alone rather than wait for standards to catch up with their work
- **Low uptake** The success of any standard depends on wide adoption. Many mainstream developers do not wish to be the first to adopt these standards and take the risk that they may not be suitable.

In addition, different standards and certification organisations provide different guarantees. In simple terms there are three levels of guarantee:

- **Share** Some standards bodies, such as HL7, develop and share standards, but do not test or certify the implementations; solutions are entirely self-certified
- **Test** Some organisations, such as the IHE, run plugfest events, which provide some assurance that the solution has proved that it complies with the IHE profiles. However, this is still a self-certification process to confirm you have passed the plugfest event
- **Certify** Continua provide a robust certification process and the highest level of guarantee that a product conforms with the standards in the profile. However, Continua currently only provides full certification processes for a limited set of devices and functionality.

In all of these levels there is a trade-off between the effort and resources required to test and certify a solution against the level of guarantee required to satisfy consumers and regulators.

The Continua profiles for machine-to-machine interactions between medical devices and a mobile handset represent the most significant opportunity for the GSMA to drive the mobile health agenda. The profiles are mature and also fall within an area of the end-to-end architecture where the mobile operators can exert the greatest influence. Their adoption would require the mobile industry to offer handsets with compatible personal area network radio technologies, including support for Bluetooth HDP.

6.2 Areas of low architectural complexity

The mobile industry has applied a number of processes of low architectural complexity in other areas. The technologies behind these processes are well understood and can be applied to mobile health with minimal configuration. For example:

- **Customer call centres and service management** have been widely deployed by the mobile industry and have some clear solutions. There are no significant technical barriers to improving and deploying standardised service management approaches or providing open service management architectures for network operators, device manufacturers and application providers
- **Security and encryption** already plays an important role in keeping mobile transactions secure
- **Network quality** is important to other mobile services and quality of service mechanisms can be applied to provide high availability networks and connections for critical care services.

6.3 Areas where new technologies have solved old problems

New technologies are constantly in development – the technical challenges faced within mobile health solutions are not necessarily unique to healthcare. Some of the new technologies identified outside of the healthcare ecosystem may be applicable to problems within mobile health.

Taking security management as an example, there has been a number of recent advances that could solve some of the issues related to authentication and encryption:

- **On-SIM applications** The capabilities of the SIM card have grown considerably over the past decade. Value Added Service (VAS) applications can be embedded directly on the SIM and can be controlled by the network service provider without having to dictate the requirements of the mobile device. By using solutions on the SIM, authentication of a patient, clinician or device could be handled in a low power embedded mobile device. There may also be opportunities to link a SIM to a patient, allowing choice and flexibility in the mobile devices they use. Investigation into how the SIM card could support mobile health to securely storage patient data (similar to Mobile Banking), encrypt data to enable secure SMS transmission, along with the use if SIM menu's and the SIM toolkit (STK) to provide services. The SIM card has been designed with the capability to be configurable over the air (OTA), therefore enabling a simple process for remote management
- **Near Field Communication (NFC)** NFC allows the simple exchange of data through touch, it is a short range wireless technology typically requiring a distance of 4 cm or less, to share data, pair devices, and make transactions. The technology could be used to support a number of different mobile health solutions from patient check-ins and staff location management, through to the management of patient medication
- **Wireless "Smartcard" authentication** Introducing two-factor authentication, combining something you know with something you physically have, strengthens the security of a health solution. As discussed previously, many healthcare providers require two factor authentication to access medical records or to authenticate the upload of patient data. Wireless Smartcard readers, which employ existing standards such as Bluetooth for connectivity to other devices, will support the adoption of two-factor authentication without having to significantly alter the hardware of the existing mobile devices.

6.4 Areas within control of the mobile industry

Many of the architectural components of mobile health solutions are within direct control of the network operators. Upgrading or altering these controllable elements can encourage rapid expansion in the number of mobile health solutions available, the adoption of these solutions by consumers and the potential for new value opportunities.

Some high level examples of these areas include:

- **Provide technical facilities for innovative financial models** Network operators who wish to access greater financial rewards from mobile health must provide more complex and integrated mobile health solutions. These network operators will need to provide greater access to their billing and customer relationship reports in order to identify end-to-end health transactions across multiple healthcare organisations and become more than just a data pipe
- **Application portability** Network operators can work on developing applications that can be transported across devices. Developing solution components, which sit independently from the handsets and mobile devices and will be portable to other networks, gives rise to new opportunities
- **Network capabilities** Network operators are in direct control of their network capabilities, including bandwidth and services. Increasing or improving bandwidth and coverage, and developing services that are directly within the cellular network (such as improved location-based services), would make mobile health solutions more attractive to consumers. New opportunities, such as video-based mobile health solutions, will arise with increased bandwidth in developed economies, while increased coverage will allow for better remote health services while increased coverage will allow for better remote health services in developing countries.

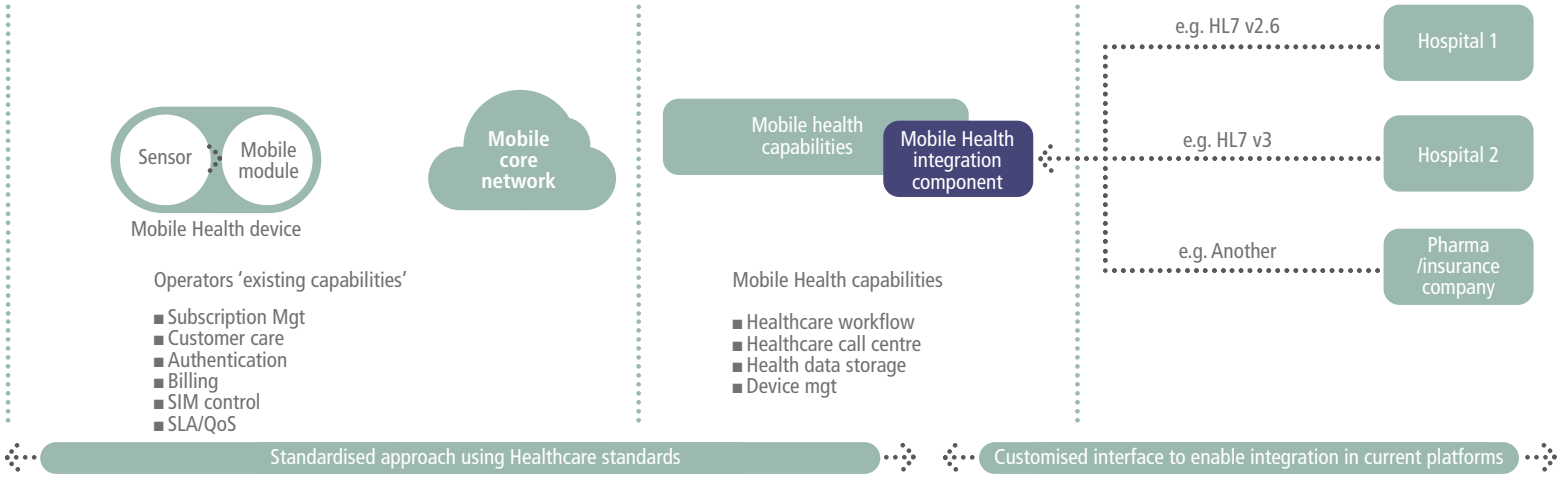
6.5 Driving a standardised approach

The GSMA's research has confirmed the need for standardisation and an environment of 'plug and play' for connected healthcare devices. Full standardisation of healthcare ICT systems should be a long term goal, but is very unlikely in the short to medium term due to the current fragmented approach to healthcare solutions. The mass market roll out of mobile health will require a mobile operator to integrate with a large number of healthcare ecosystem players, all of whom will be using different platforms and systems.

A possible approach to enable this integration could be the use of a strong centralised integration engine, or mobile health gateway, that sits between the mobile network and the healthcare systems. This gateway would act as a bridge between the mobile component of a service and the enterprise systems used by healthcare provider organisations. This integration component could take on various forms, but its fundamental role would be to fill the technology gap between healthcare systems and mobile networks and devices.

The creation of this bridging point would enable the mobile healthcare provider to simplify solutions and benefit from the economies of scale associated with a standardised service. This approach would mean that the only configuration required in the solution would be for the medical record interface to integrate into the wider healthcare ICT systems. This capability does not have to be owned fully by a mobile operator, but it is a potential way to enable the mass deployment of mobile health solutions supporting a variety of healthcare providers.

Figure 12. Standardisation using an integration engine



Mobile health solution providers could use this common component for a number of reasons beyond supporting system integration, including:

- **Differences in user interfaces between classic eHealth and mobile health** The user interface issues typically arise where large and complex arrays of patient information need to be displayed through small mobile screens. Most healthcare applications are not designed for use in a mobile environment, and user interface research has highlighted issues with displays for some key aspects, such as medication lists and reviewing x-ray studies
- **Mobile application performance and synchronous connections** Application performance issues also represent a barrier to mobile health. Most electronic record systems are fundamentally designed to work synchronously. This reduces the risk that clinicians could be working from out-of-date information. The mobile solution for these systems generally involves using high-bandwidth networks, yet the greatest value from mobile working is often in remote, rural areas where network coverage is poor. Many mobile gateway functions provide a means to interface asynchronous work flows with the core clinical systems
- **Control of differing levels of security and privacy** Mobile ecosystems typically provide a different level of security and privacy to classic eHealth systems. Integration engines can cater for this difference and apply the appropriate access controls and security mechanisms to ensure an end-to-end secure healthcare solution.

7. A route map to deliver mobile health

Network operators and device manufacturers have a number of opportunities to develop greater value from existing networks and devices. The GSMA, in collaboration with its members, should focus on a number of key architectural areas – defining, designing and encouraging standardisation in a long term timescale.

7.1 A high level reference architecture

The GSMA believes that the mobile ecosystem should define a reference architecture that will support the mobile health market and integrate into its current systems. This architecture should focus on three key areas:

- Define the existing capabilities that the mobile industry can bring to mobile health solutions
- Highlight the benefits of working directly with a mobile operator rather than an 'over the top provider' and how a mobile operator is differentiated from a traditional healthcare ICT provider
- Develop an architecture that would enable mobile operators to support the mass market deployment of mobile health products, service and devices.

This architecture should also provide details around:

- Guidance on how to integrate a mobile health solution into mobile operators' current network architectures
- Describe the different components of a mobile health solution along with the critical information around the laws and regulation that each of the components will be subject to
- Develop the outline requirements for a mobile health gateway and its capabilities
- Assess the current capabilities that can be enhanced to support new value add services for healthcare solutions e.g. use of the UICC (Universal Integrated Circuit Card).

The diagram (Figure 14) on the next page shows how the logical architectural components described throughout this document overlay with the use cases and stakeholders within the mobile health ecosystem.

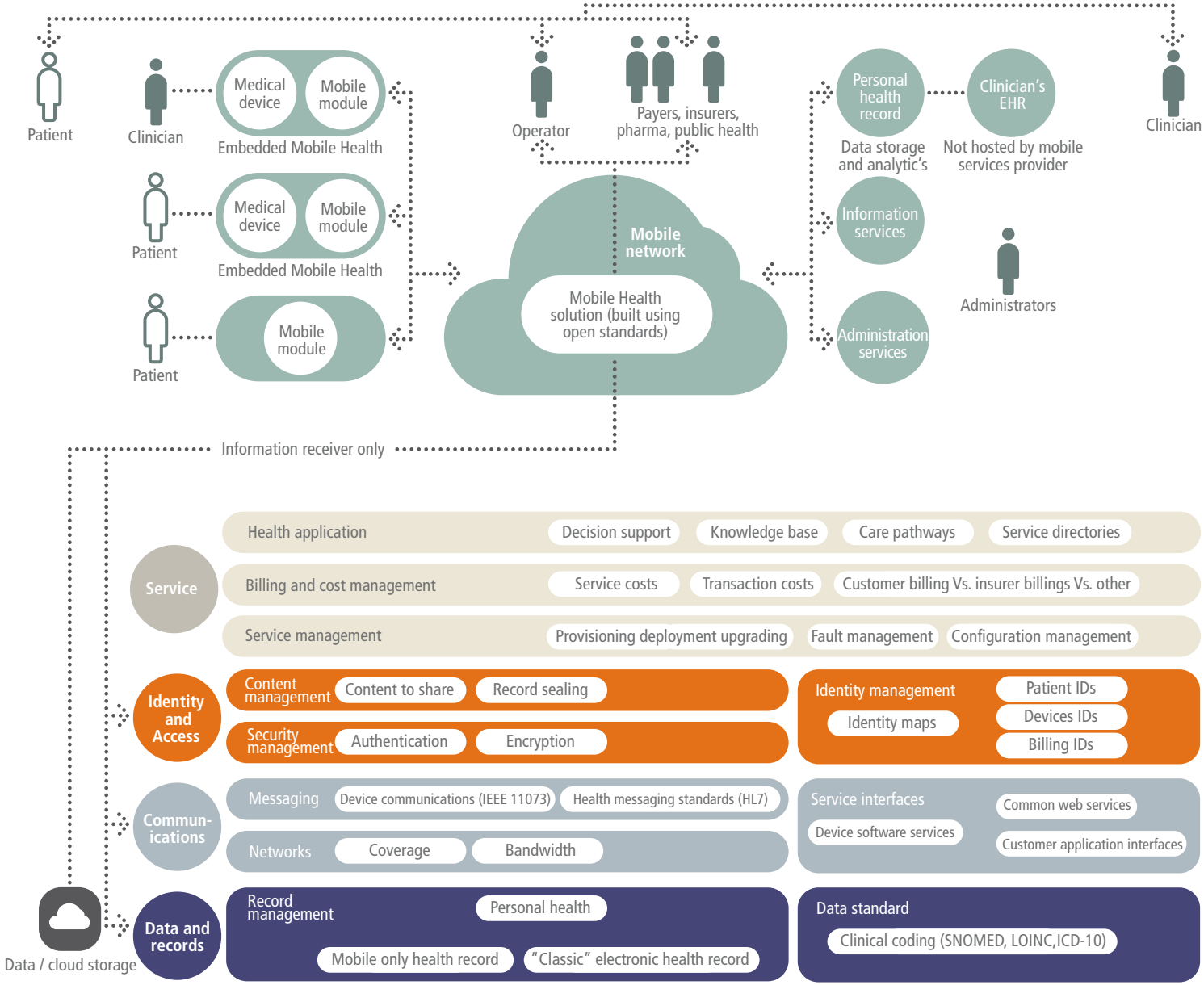
The goals of opening mobile health solutions and providing the standards to enable all stakeholders to develop components that fit their skills, are met neatly through the mobile health gateway at the heart of this diagram:

- Network providers are well placed to provide the mobile health information exchange gateway, the customer relationship management that goes alongside the solution and the data storage needed to enable integration with the wider health provision
- Application developers can continue to build software on mobile handsets that communicate with these mobile health gateways
- Handset and mobile medical device manufacturers can build solutions that operate within their own standards, such as the Continua specification, and communicate with the gateway through with their local aggregation features.

Additional stakeholders can make use of these open systems by connecting into the end-to-end solution using common standards. These include:

- Insurers and other payers who will be able to better determine service costs
- Pharmaceutical firms interested in improving their supply chains
- Public health monitoring agencies interested in healthcare trends and disease monitoring.

Figure 13. A high level reference architecture for mobile health



Source: GSMA

7.2 Applying the reference architecture

Each of the stakeholders and use cases will be required to provide different components of this reference architecture to deliver an end-to-end solution. The following tables demonstrate those architectural elements that each stakeholder must develop to complete the solution, as well as those architectural elements required by each of the primary use cases.

Table 4. Elements of the architecture required (R) and optional (O) for each high level use case

Use cases		Health information/ content management (e.g. WebMD mobile)	Health management/ scheduling management (e.g. Maternity management)	Interactive healthcare/provision (e.g. AT&T MedApps, Telecom Italia MyDoctor@ Home)
Service	Health applications	O	R	R
	Billing and cost management	O	R	R
	Service management	O	R	R
Identity and access	Consent management		R	R
	Identity management		R	R
	Security management		R	R
Communications	Messaging	R	R	R
	Networks	R	R	R
	Service interfaces	R	R	R
Data and records	Records management		O	R
	Data standards		O	R

Table 5. Elements of the architecture required (R) and optional (O) for stakeholders

Stakeholders		Device manufacturers	Application developers	Mobile network operators	Payers	Healthcare providers/ eHealth developers
Service	Health applications		R			R
	Billing and cost management			R	R	O
	Service management			R		O
Identity and access	Consent management		R	O		R
	Identity management	R	R	R	O	R
	Security management	R	R	R		R
Communications	Messaging	R	R	R		R
	Networks	R		R		
	Service interfaces			O		R
Data and Records	Records management			O	O	R
	Data standards		R	O		R

7.3 Route map for achieving a step change in mobile health adoption

As highlighted in the previous section, there are five key areas that should be the focus for the GSMA to encourage adoption of mobile health solutions. See table 6 below.

Table 6. Mobile Health architecture route map

Area of focus	Now	Short term	Long term
Areas where partial standards already exist	Complete assessment of the Continua guidelines to identify if this is the approach that the Mobile Industry will support and back.	Engage with standards developers to fill gaps, in particular IEEE 11073 and HL7 standards groups to raise awareness of the needs of the mobile industry.	Encourage a move to a single certification process that encapsulates Device, Healthcare and Telecoms approval.
	Document the encryption and security standards used within mobile industry as a USP of partnering with the mobile industry.	Engage with the IHE working groups to raise awareness of the needs of the mobile industry and Continua Mobility task force.	
	Document how patient data that is stored on a device, in transit or at rest in storage could be protected.	Investigate the capabilities used in other vertical markets such as the financial sector and if these standards can be applied to mobile health.	
Areas of low architectural complexity	Identify existing mobile solutions that could be reconfigured to support element of Mobile Health.	What are the implication on Mobile Health products and service that LTE/4G will introduce.	
Areas where new technologies have solved old problems	Document the capabilities of on-SIM value added services that could be used in Mobile Health solutions to encourage adoption. Document how NFC capabilities can be used in Mobile Health solutions to encourage adoption and simplify connectivity.	What are the new technical requirements that tablets will introduce vs mobile handsets. Continua Tap and Go interface is being defined as transport agnostic, GSMA should push the use of NFC.	Look to the gaming industry, finance industry, automotive industry for new procedures and technologies to support adoption.
Areas within control of the mobile industry	Identify that the introduction of the Bluetooth Health Device Profile (HDP) and LE would encourage the roll out of Mobile Health devices and services.	If suitable, promote the inclusion of the HDP and LE into all new mobile devices.	Identify if there is a requirement from the mobile industry to manage Quality of Service (QoS) on the RAN to support Healthcare device and submit into 3gPP for inclusion into future releases of GSM standards.
Driving a standardisation approach	Develop a reference architecture for the integration of Mobile Health solutions into a Mobile Network Operator.	Define the outline requirements of a Mobile Health gateway component and its required capabilities.	

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Glossary

Organisations

IEEE – Institute of Electrical and Electronics Engineers.

IHE – Integrating the Healthcare Enterprise.

ISO – International Standards Organisation.

Common terms

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

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

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

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

Standards

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.

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

ICD-10 – International Statistical Classification of Diseases and Related Health Problems Version 10; a coding standard for defining medical procedures and diseases.

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

SNOMED – Systemised Nomenclature for Medicine; a coding standard for defining clinical concepts.

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

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