



Policy and regulation for innovation in mobile health



Executive summary

As healthcare systems around the world tackle the challenges of rising demand and expectations, mobile communications are opening up new possibilities for improving access, for freeing time for clinicians to spend on care rather than administration, and for engaging people in their own health and wellness.



There is growing international evidence that mobile solutions can improve both the quality and the cost-effectiveness of care. However, significant policy-related and regulatory barriers must be overcome before these solutions can fulfil their promise.

Consumer-focused as it is, mobile communications technology is ideal for empowering patients to manage their wellbeing and health. To realise this potential, supportive healthcare policies are required. Effective use of mobile health enables a shift from a 'curative' healthcare model to one in which the patient is an active partner in care, consenting to the risks of treatment, making choices and increasingly taking responsibility for their own health.

Reimbursement provides one of the most effective mechanisms for driving behaviours in healthcare, particularly in the heavily regulated markets found in more developed economies. At present, most healthcare payment models incentivise work done,

rather than the outcomes achieved. Mobile health enables an ongoing relationship with a healthcare provider that offers improved outcomes.

For mobile health to come to fruition, reimbursement incentives need to reflect this shift from care provided in isolated encounters. Not only should mobile health seek reimbursement regimes that promote healthy outcomes, but it is equally important to have policies that enable a move towards consumer choice.

In terms of regulation, the main challenge lies in finding the right balance between the very different regulatory motivations, and resulting dynamics, of the communications and healthcare industries while also coping with significant regional variations. Medical approaches to regulation result in closed, integrated solutions where the provider has control of the architecture. To support innovation and serve a mass consumer market, mobile health needs the sort of globally harmonised standards and interoperable approaches that have allowed the telecommunication industry to thrive.

There is also uncertainty about what constitutes a medical device, and particularly about where the boundary should be drawn between a device and the communications infrastructure it uses: when might this include a handset and how are 'apps' to be treated? The solution can be found in adopting a modular approach to medical devices that regulates a specialised mobile health device or application differently from the mobile network to which it is attached. Clear interfaces based on common standards are a key part of this solution. This must be accompanied by a shift from pre-market assurance to in-service risk management of the end-to-end solutions.

In the longer term, governments need to work with both mobile communications and healthcare sectors to create an environment that supports innovative solutions by rewarding positive health outcomes and providing regulatory controls that are proportionate to the risks and applied evenly.

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Mobile health scenarios

mHealth has been defined by the United Nations Foundation as “Using mobile communications – such as PDAs and mobile phones – for health services and information.”

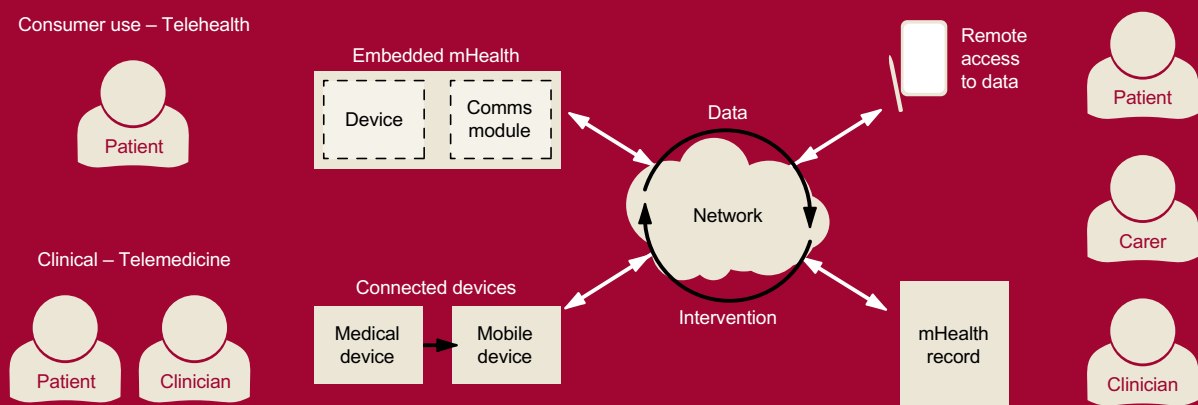
Reflecting this definition, basic mHealth services may simply be using the standard capabilities of a mobile handset to access health related information, for example via SMS messaging or internet connection, or perhaps by linking back to an electronic medical record application. In a basic service, a diabetic patient may text the results from their blood glucose monitor to a clinician, or receive SMS reminders to take medication at appropriate times.

Mobile technology also enables more advanced services. Of particular interest in this paper are connected services that incorporate medical devices. These extend the capabilities of the mobile by carrying data directly from the medical devices across the mobile network through to a data platform where users can access the information in a relevant format.

There are different ways in which this device connectivity can be established. The range of issues that arise from the different approaches is best illustrated by two examples. The first is where one or more medical devices are connected via Bluetooth or another short-range technology to a standard mobile phone, which sends the data across the network. (For instance, a diabetic person could connect their blood sugar monitor to their mobile phone and send readings over the mobile network to their doctor or to a specialist nurse.) The second example is where a mobile module is directly embedded into the medical device, enabling direct connectivity of the device to the network.

These two examples illustrate one of the central issues in this paper: where does the boundary lie between a medical device and the communications infrastructure it uses, and how is that interface to be regulated?

Figure 1: Embedded devices represent an important subset of mHealth devices



1. Introduction

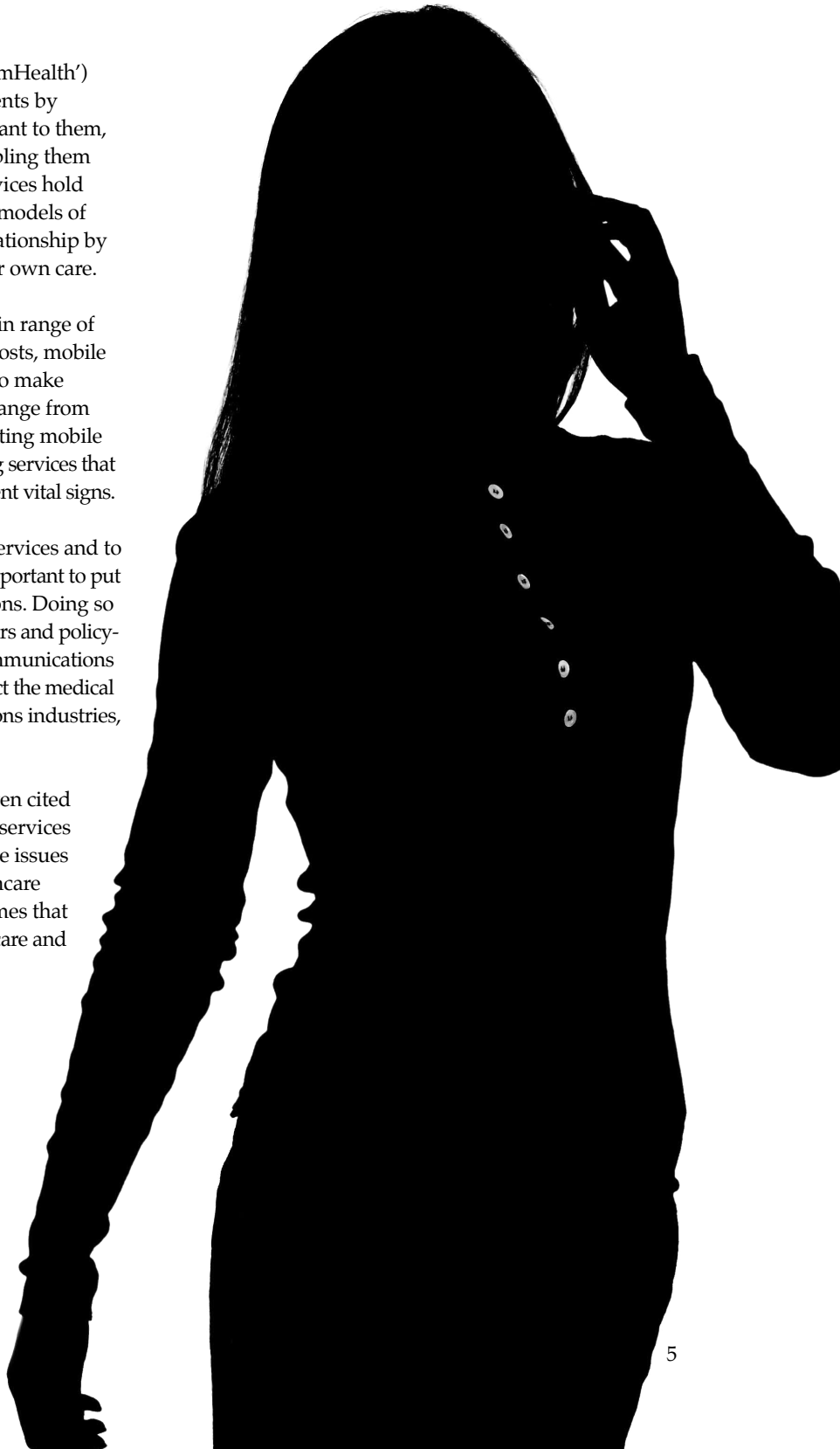
The pressures on healthcare systems worldwide have never been greater (rising expectations, ageing populations, declining workforce). There is a powerful argument for using telecommunications to help clinicians remotely diagnose and care for patients, and engage people in their own health and wellness. Growing evidence from around the world confirms that these approaches improve both the quality and the cost-effectiveness of care.

Central to the case for mobile health (or 'mHealth') services is their ability to empower patients by providing better information that is relevant to them, and improving access to care, whilst enabling them to continue in their daily lives. These services hold the potential to enable new preventative models of care and transform the doctor-patient relationship by making people active participants in their own care.

With 80% of the world's population within range of a mobile network and a dramatic fall in costs, mobile technologies are better placed than ever to make this contribution. Potential applications range from SMS medication reminders based on existing mobile capabilities to advanced remote monitoring services that use connected mobile devices to track patient vital signs.

To accelerate adoption of mobile health services and to ensure that they fulfil their promise, it is important to put in place supportive policies and regulations. Doing so will require collaboration between regulators and policy-makers in both healthcare and mobile communications industries. These are global issues that affect the medical device, health software and communications industries, and need a global response.

Healthcare policies and regulation are often cited as key barriers to bringing mobile health services to market. This paper examines how these issues are driven by factors specific to the healthcare environment and goes on to identify themes that would support the convergence of healthcare and telecoms interests in mobile health.



2. Healthcare policy: allowing mHealth to become a driver for change

Because it is consumer-focused, mobile communications technology is ideal for empowering patients, allowing them to manage their own wellbeing and health. That means it can be used to drive changes that healthcare providers are already keen to see, such as a shift towards prevention rather than cure.

However, tapping into the power of consumers represents a fundamental shift for the healthcare industry. Currently, a complex legacy of policy, regulation and funding agreements stands in the way. Clear leadership and supportive policy actions will be required if the full potential for mobile health is to be realised.

mHealth can enable new models of care

Today, most medical practice is still based on a 'curative' model in which people seek advice from an expert medical practitioner. Healthcare professionals have been in control of treatment and services, often leading to paternalistic notions of the doctor-patient relationship.

As demand rises unsustainably, there is a growing interest from governments in developing new and more sustainable healthcare delivery models; these typically seek to improve access to and quality of care while controlling costs. Changes include evolving the role of the patient, making them an active participant in their own care and giving them greater personal control and independence in management of conditions. There is also an increased focus on prevention and the promotion of good health and wellness, and a shift of the emphasis of ongoing care away from the hospital. This shift is in harmony with the current trend for people to become more interested in 'wellness', and to use informal channels such as the internet to access healthcare.



In order to be able to take this more active role in their care, people need to understand health risks, make choices and take responsibility for their own health. To do so they need access to information that is relevant to them. mHealth applications are an ideal way of giving them that information access, and empowering them to participate in their care. Patient empowerment is not just about access to information; it is also about control over personal information and being given choice over medical service.

Creating a supportive environment for mobile health

There is much that must be done by policy-makers before healthcare systems can take advantage of the potential of mobile health. Healthcare is perhaps the last industry to embrace the use of electronic information. Adoption of electronic records is patchy, and it is even more unusual to share information across care settings to provide continuity of care – yet these are vital building blocks for mHealth. There are laws that get in the way of or even prohibit the use of electronic communications for healthcare, and rules regarding privacy and security are unclear, unevenly applied or unduly burdensome.

Leadership is also required to ensure the technology reflects the desire to empower patients. There is widespread recognition that common technological standards and interoperable approaches are needed to support an open and patient-centred system in which high-quality care can still be provided as people move across organisational and national boundaries. Interoperable technologies are supportive of innovations that can adapt to individual needs and desires, and are an essential enabler for greater patient choice about what care is provided, how and by whom. While some industry standards for interoperability exist, their adoption remains low. Purchasers are still largely healthcare

providers who have yet to recognise the benefit of interoperability, and solutions that are available to consumers lack integration back into healthcare systems. Public policy can help drive the adoption of standards through the work of standards-setting bodies, and through the inclusion of these standards in public procurements.

Reimbursement as a stimulus for innovation

Reimbursement schemes provide the financial logic for healthcare delivery, and offer one of the most effective mechanisms for driving behaviours in healthcare, particularly in the heavily regulated markets found in more developed economies.

The importance of mHealth is that it can improve health outcomes, for example by allowing a better quality of life or reducing the incidence of urgent care. Some of these effects can occur years later, such as the benefit of good early control of diabetes; others are measurable only at population level, such as the benefit of addressing smoking or overweight. The difficulty is that at present most healthcare payment models incentivise work done, rather than outcomes achieved. That system works to entrench old ways of working – treat rather than manage – particularly in more competitive and fragmented systems. Furthermore, such an approach results in a narrow scope to the definition of ‘healthcare benefit’, and a narrowing of the timeframe during which health outcomes can be measured.

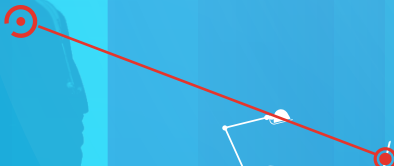
Mobile health enables an ongoing relationship with a healthcare provider that offers improved outcomes as well as reduced costs. For mobile health to come to fruition, reimbursement incentives need to reflect this shift from care provided in isolated encounters to one that rewards positive health outcomes. As an early step, reimbursements should be used to encourage new approaches that extend traditional practices, such as using email or the internet for consultations.

Global government initiatives on eHealth and mHealth

Healthcare policy reforms are a crucial enabler for the adoption of mHealth. Policies must enable a move towards consumer choice, backed by reimbursement regimes that promote healthy outcomes. Governments are already taking positive steps in this area and developing specific initiatives, for example:

- Pakistan has appointed a national coordinator for eHealth and has recently published an eHealth action plan which includes the use of telemedicine services.
- As part of a wider strategy for 'ubiquitous health', South Korea has recently introduced new legislation to remove barriers to remote consultations in healthcare.
- In the U.S., the Food and Drug Administration (FDA) and Federal Communications Commission (FCC) have recently signed a Memorandum of Understanding "to promote collaboration and ultimately to improve the efficiency of regulatory processes applicable to broadband and wireless enabled medical devices".
- The European Union has supported a programme of technology and market development for personal health systems which includes mHealth solutions, and has established large-scale pilots to demonstrate the benefits of these systems.

As well as blazing a trail, these initiatives also provide an opportunity to gather and share evidence for what works in mHealth.



3. Regulation: harmonising two cultures

Regulatory issues arise in mHealth largely as a result of the very different regulatory motivations for health and communications. The regulation of the communications industry places an emphasis on fostering competition and applying ‘just enough’ regulation. This creates a dynamic that is supportive of the innovation and experimentation seen in the industry.

In contrast, healthcare regulations have been developed to protect the public, guided by the principle ‘first do no harm’. This emphasis on precaution has historically resulted in a less dynamic industry. There are long product development lifecycles and a view that, because of the costs of the evidence required for regulatory approval, changes to devices already on the market should be the exception.

The key differences between these two approaches are highlighted in Figure 2.

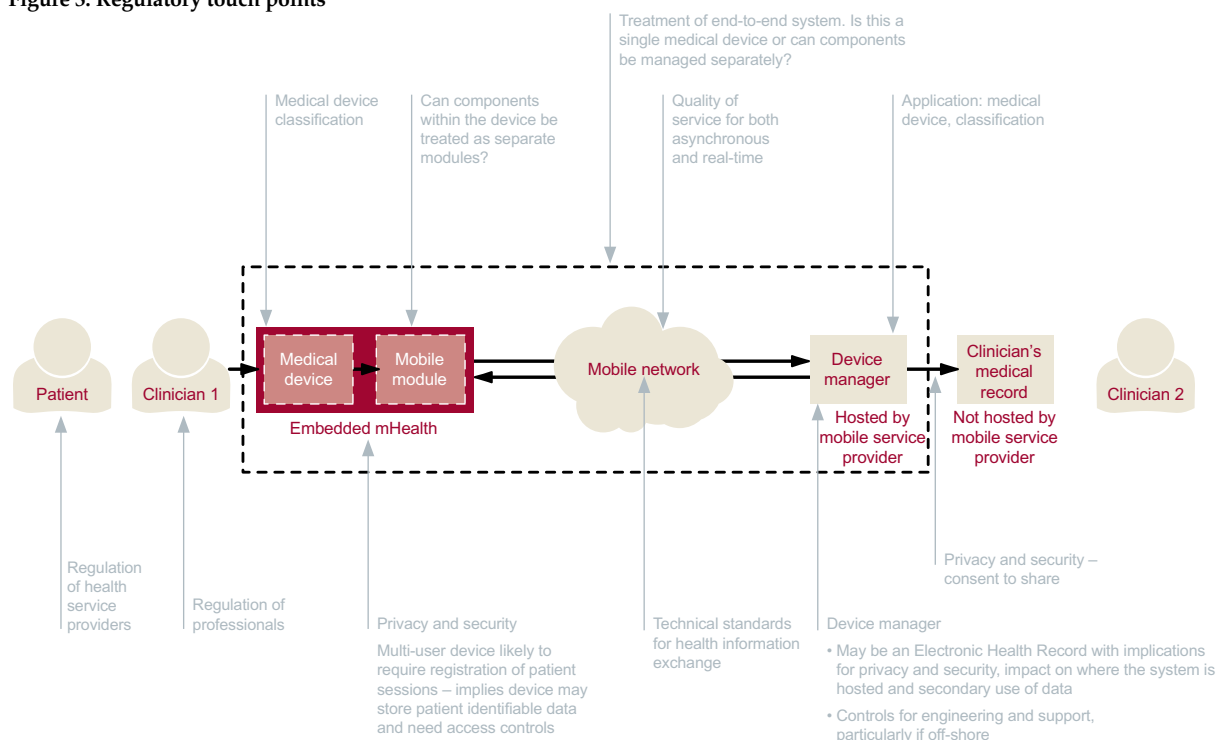
Safety for mobile health can be fully understood only by considering the behaviour of the end-to-end system, and this creates a significant number of regulatory touch points. Figure 3 illustrates potential touch points for an end-to-end mobile health solution. These touch

Figure 2: Contrasting motives in healthcare and communications regulations

Healthcare	Communications
Patient-centric	Market-centric
Safety first	Maximise consumer value
Demonstrate efficacy	Foster competition
‘At least do no harm’	‘Just enough’

points arise from regulations relating to medical devices, to privacy of medical information and to the provision of healthcare services. The extent and nature of the touch points will vary according to the design of the solution, and the need for the architecture to support interoperability for each element.

Figure 3: Regulatory touch points



Medical approaches to regulation tend to require closed, integrated solutions where the provider retains control of the end-to-end architecture. In contrast, the telecommunications industry has thrived because it has an open architecture supported by standards and approaches for interoperability.

To support innovation and serve a mass consumer market, mobile health needs to combine both approaches, using standards to enable a more open architecture, while still assuring the safety of services and the high levels of privacy protection required for medical records.

Medical device regulations

Medical device regulations have yet to address the new challenges posed by mHealth. Originally designed for physical devices, they classify devices according to the relative risk they pose to individuals. But the safety and efficacy of an mHealth device can only be fully understood by considering the end-to-end system of which the medical device is a component – and this system might be viewed as including the mobile network.

The key regulatory issues for mHealth fall into two main areas. First, there is uncertainty about what constitutes a device, and particularly about where the boundary should be drawn between a ‘device’ and the communications infrastructure it uses. Regulators are currently grappling with these boundary issues. For instance, in Europe a display screen is considered to be a medical device if it is used to view x-ray images to make a diagnosis, but not when the same image is viewed for other purposes.

Second, disproportionate regulatory controls may arise from uncertainty about the risk associated with aspects of an end-to-end mHealth system, such as the remote monitoring software that collates readings from a patient and compares them to a threshold value. To illustrate this latter idea further, let’s look at some specific applications from a regulatory point of view.

In moving to offer mobile health solutions, regional variations in regulation make it difficult for global players to achieve economies of scale. A Global Harmonisation Task Force for medical device regulation exists, but national regulators are only

beginning to address connected devices and there is significant potential for further fragmentation. Some countries are taking an extremely cautious approach requiring extensive testing, while others recognise the need for a more open approach. Faced with this uncertainty, some parts of the market provide opportunities to drive adoption, but a globally harmonised approach would help in realising the true potential of mobile health.

Individual applications and their regulatory implications

The healthcare regulatory implications of a specific mHealth solution depend on two key variables:

- The nature of the medical intervention, including the extent to which it is time-critical.
- The role of the telecoms provider in delivering the service.

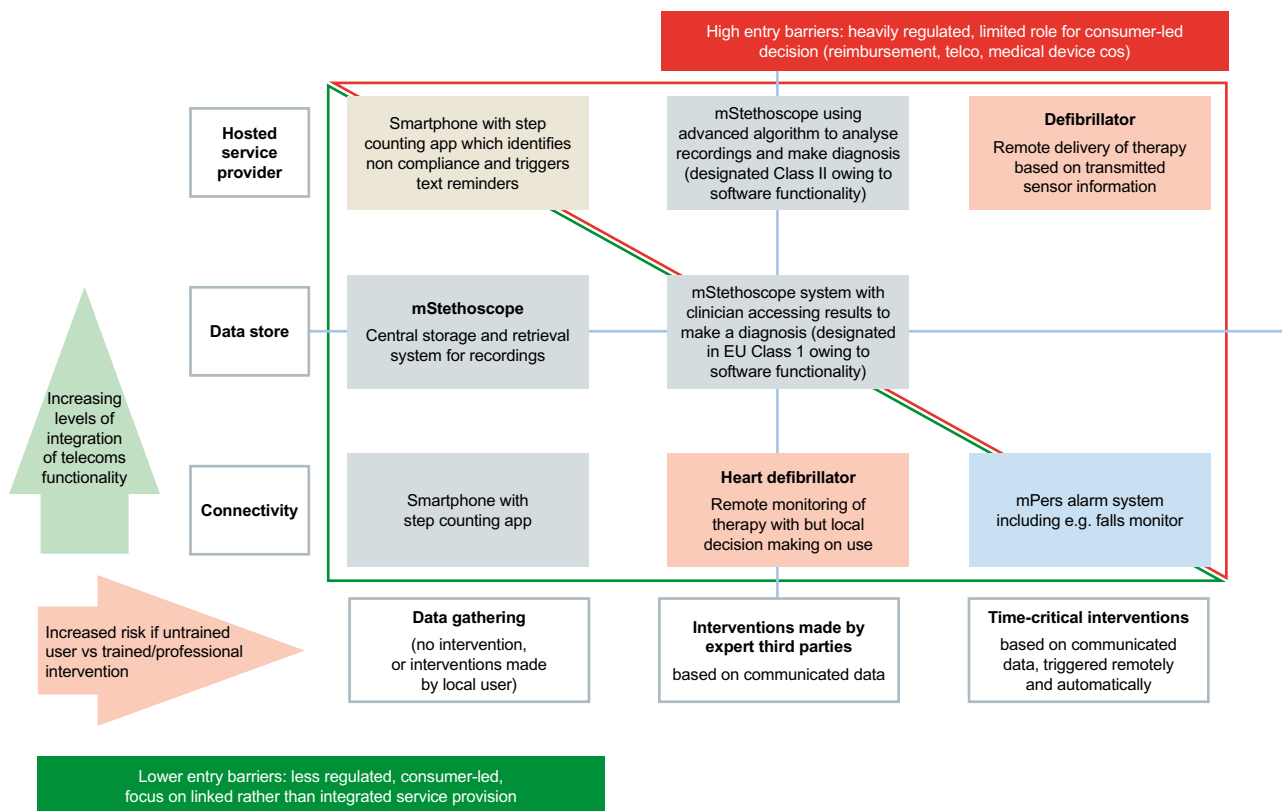
Figure 4 summarises how these two variables determine the level of risk attaching to a given mHealth application, and illustrates where some sample mHealth applications fit into the risk matrix.

To understand how Figure 4 works, consider the implications that regulations can, and should, have on a mobile network operator seeking to offer an mHealth service. The impact of such regulations depends on how the service is positioned on the two axes of the chart.

- The horizontal axis of Figure 4 represents the nature of the medical intervention implied by the device, and the extent to which the associated service is time-critical. The time-critical nature may vary from simple data gathering with no direct intervention, through to a semi- or fully-automated decision and intervention process.
- The vertical axis of Figure 4 represents the specific role that the network operator seeks to play in the delivery of such a service, which may vary from simply offering a ‘pipe’ to offering direct hosting of the service itself. In the latter case, those involved could be regulated as providers of healthcare.

These two variables together determine the regulatory imposition on network operators for a given mHealth application. This model also brings out an important theme in regulation: the need to

Figure 4: How intervention levels and the telecoms provider role jointly determine risk



retain the end-to-end nature of regulation, but at the same time introduce modularity to encourage innovation and foster competition.

A pragmatic approach to mHealth regulation

To take full advantage of mHealth’s potential, the two industries need to work together to deal with incompatibilities between regulatory approaches. It’s important not to shy away from the high-risk areas (i.e. those where there is a significant ‘culture clash’ between the two regulatory approaches) – the riskiest applications are typically the ones with the most potential value.

The complex, consumer-driven nature of mobile communications means that it is simply not feasible for the mHealth product suppliers to test and lock down every possible combination of device, application and network environment prior to

placing those products on the market. There is also a danger of ‘over-testing’: placing a validation burden on a particular component or solution that is not justified by its usefulness.

It will be necessary for healthcare regulators to accept alternative approaches, in which greater emphasis is placed on service operators’ responsibility for managing the ongoing safety of mHealth services, rather than demanding prior-to-use validation of every aspect of such a service.

Privacy and security in mHealth

Trust is an essential part of the doctor-patient relationship. In surveys, doctors are consistently ranked the most trusted professionals and preserving this trust is fundamental to the way information is used across healthcare systems. For mobile health to flourish, it will be crucial to maintain this trust and extend it to players across the mHealth ecosystem.

Privacy plays an essential part in establishing trust. mHealth privacy is about ensuring transparency, choice and control for individuals in the communication and use of health data.

Many countries have legislation in place to protect privacy, including specific rules governing health information. At the same time, the telecommunications industry has longstanding experience in protecting privacy: mobile network operators are subject to additional obligations such as security breach notification and protecting confidentiality of both information and communications.

It is unlikely that mHealth requires completely new approaches, but it will be important to remove any unnecessary regulatory barriers and ensure legal certainty. Also needed are consistent approaches to privacy and security across an emerging ecosystem of new players, business models and technologies.

Moves to empower individuals will give them more choice in health care provision and greater control of their health information. As a result there will be fresh privacy challenges. Most systems have until now relied on providers retaining complete control of the end-to-end system, but now we need to ensure the same confidence within a more open system with multiple players and services.

Boundaries are becoming blurred between the responsibilities and obligations of the different players, some of whom currently are not explicitly subject to telecommunications or e-privacy regulations. It is important that consistent approaches to privacy are applied across all sectors to ensure consumer confidence and provide clarity for industry players.

Mobility itself also poses new questions. For instance, patients may roam across borders and expect consistent delivery of health information services and common standards for the treatment of their privacy.

Also, if mobile operators in search of economies outsource to third countries that do not have formal data privacy laws, there will be not only a potential impact on user confidence, but also a further layer of compliance complexity for healthcare providers. Home country legal obligations to protect data privacy will have to be upheld in destination countries with different privacy regimes.

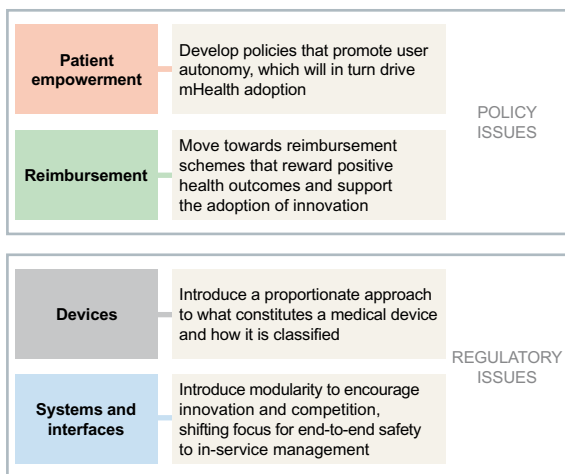
So, while there is little that is truly unique about privacy in a health context, governments will need to provide greater clarity in certain areas. They must define how regulations apply in an open ecosystem, create a level playing field across all aspects of mHealth, and address the need to maintain confidence and trust when services extend across national borders.

As regions with fewer privacy-specific regulations, or none, consider mHealth, it is likely that they will need to reinforce or introduce such regulations. In these regions there is a real opportunity to establish a coherent and consistent approach to privacy in mobile health.

4. What needs to change for mobile health to succeed?

Our observations on the policy and regulatory landscape of mHealth can be summarised in terms of four themes, shown in Figure 5. These themes describe a set of principles that need to be applied by policy-makers and regulators for mHealth to realise its full potential.

Figure 5: Four themes summarising policy and regulatory considerations for mHealth



Policy: patient empowerment

It is user autonomy that will really make mHealth work, particularly as users are increasingly eager to take responsibility for their own health and wellbeing.

Policy-makers should therefore look for ways to empower patients. This aim can be achieved through a wide range of policies, for example:

- Giving consumers and frontline practitioners more say in how the healthcare budget is spent – something that is already happening in some countries where personal budgets are being introduced for certain aspects of care.
- Introducing legislation to enable the wider use of electronic communications in healthcare, and to clarify and simplify privacy and security rules.
- Promoting the adoption of common technological standards and interoperable approaches to maximise choice and to allow the industry to be more customer-focused. Adoption of these standards can be mandated, or specified in public procurements.
- Revising regulation to avoid an unnecessarily heavy-handed approach in this area. There is already a

thriving market in smart-phone ‘apps’ for health, although regulators have yet to establish clear ground rules for how these apps are to be treated.

Policy: reimbursement

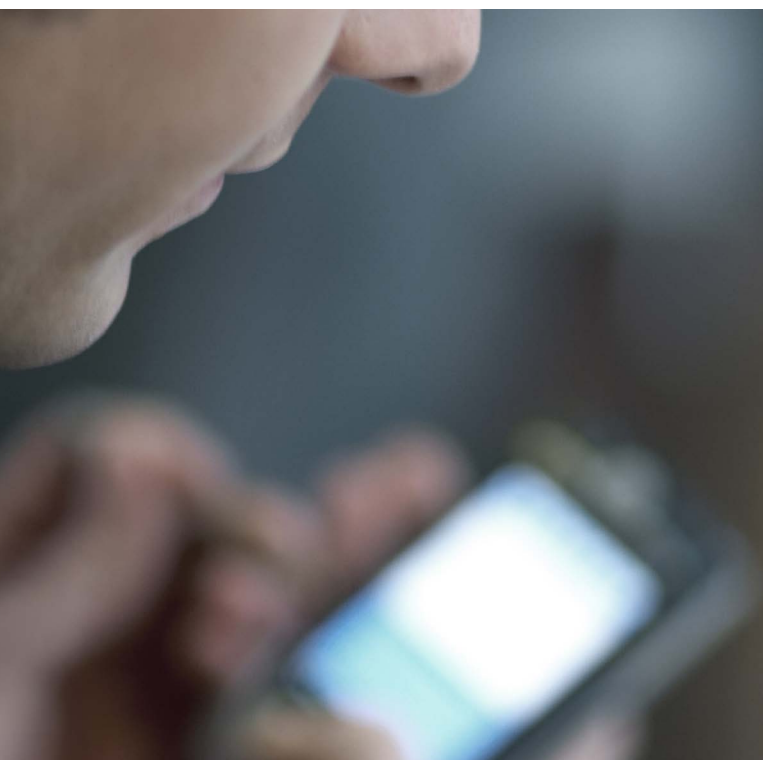
To enable successful development of mHealth devices, it is vital to reward health outcomes. The current approach to reimbursement of healthcare products or interactions, which rewards work done, is inadvertently stifling business innovation.

Already, there are general trends towards introducing tariffs that reward positive performance, and towards providing patients with greater choice and control over the way money is spent on their care. However, these trends are likely to be slow. Governments can accelerate the process by commissioning health technology assessments to provide independent evidence of the economic case for mHealth; by providing seed funding for innovative services ahead of wider payment reforms; and by enabling services for which there is an existing case, such as allowing email consultations.

Regulation: devices

While there has been significant recent progress in harmonising and simplifying medical device regulations around the world, these efforts have yet to reflect the new possibilities raised by connected medical devices. As a result, most device assurance regimes are overly burdensome for mHealth. Current regulatory concepts, such as the interpretation of the term ‘intended use’, blur the distinction between what is, and is not, a medical device.

To get mHealth products on to the market in a realistic timescale, regulators need to refine their approach to deciding whether a particular device is a medical device, and in what risk classification group it belongs. As outlined earlier, some consideration must be given to the real-time nature of the service, and the degree to which ‘harm could be done’, not just the technicalities of how the device functions. For example, the heart



rate monitor used by an enthusiastic athlete to monitor performance should be seen quite differently to the same monitor being used in the provision of critical patient care.

A clear boundary between medical devices and the communications infrastructure they use is needed to support alignment of the respective regulatory regimes. This boundary is not always straightforward to draw, particularly as the industry moves to adopt devices with embedded mobile connectivity.

Regulation: systems and interfaces

Medical device regulators need to consider alternative ways of evaluating the safety and reliability of mHealth services. Taken to extreme, current regimes would require an aviation approach to safety in which every possible configuration and failure mode is tested and locked down prior to release onto the market. Given the complexity and consumer-driven nature of mHealth services, this approach would lead to exponentially rising costs as systems and people became more connected.

Regulators in the U.S. and EU are beginning to recognise and respond to these issues. The challenge here is to allow innovation and diversity without an unacceptable sacrifice of safety, reliability or security. Achieving this balance requires two steps.

The first step is to enable a modular approach to technology based on the use of standard interfaces, such as those now being certified by the Continua Health Alliance. This approach would, for instance, allow the use of a normal mobile phone for an mHealth service, while the application that runs on it, or the device it connects to, could be a regulated medical device.

The second step retains the need for some end-to-end management of risk, but shifts the burden of regulation from pre-market assurance of the medical device towards greater in-service management of the risks through the application of operational standards. There are already moves in this direction. For instance the NHS in England has adopted the IEC 80001 standard for the management of risks in networks incorporating medical devices.

5. Achieving healthcare goals through mHealth: a strategy

Healthcare systems worldwide face difficult challenges in terms of meeting the needs and, where possible, the expectations of growing and ageing populations. They need to address inequalities in access to care and the increasing incidence of chronic illness. To do all this, it will be critical to harness the power of mHealth, and because of the difficulties outlined above, it is important to get started now.

The healthcare sector needs to work with the mobile telecommunications industry to review its policies and regulations in order to enable new models of care that:

- empower patients
- reward outcomes
- regulate technology (devices, systems and interfaces) in a way that lets it get to market quickly.

Figure 6 sets out scenarios showing how mHealth can be developed alongside wider healthcare reforms, and highlights the key policy and regulatory changes needed at each stage.

Figure 6: mHealth policy and regulatory scenarios

Theme	Now	Short term	Medium term	Long term
What could healthcare look like	Care delivered in face-to-face encounters.	Health systems respond to growing pressures by focusing on high-cost therapies.	Increasing resources focused on preventative services and promoting healthier lifestyles.	User empowerment and self-care a key aspect of healthcare systems.
How mHealth can help	A few innovators are experimenting with remote monitoring. Developing economies interested in improving information for health workers.	Rising use of connected devices for remote monitoring in chronic disease management. mHealth solutions offered direct to consumers on a self-pay basis in unregulated markets and geographies.	Connected devices for self care established at scale in some regulated markets. Growing use of connected devices to assist diagnosis and treatment in developing economies.	Use of embedded devices in the community by beneficiaries is considered a normal aspect of healthcare in all global markets.
How regulation could affect mHealth	Significant regulatory uncertainty driving closed end-to-end solutions.	Clarity from regulators on how current regulations apply to mHealth.	Recognition of interoperable mHealth devices as discrete regulated entities. Regulatory changes shift some emphasis to users and health service providers	Regulation supportive of mobile mHealth including cost-sensitive high- volume/ low-margin markets.
How reimbursement could affect mHealth	mHealth unrecognised by payers outside a few early adopters willing to fund larger scale implementations.	Moves in limited areas to fund mHealth services for high value, low-volume groups.	Moves in some leading regions to fund mHealth services for high value, low volume groups.	Policy actively driving adoption and use to achieve health outcomes



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