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Working Group on Digital Health

The Promise of Digital Health: Addressing Non-communicable Diseases to Accelerate Universal Health Coverage in LMICs

September 2018

BROADBAND COMMISSION
FOR SUSTAINABLE DEVELOPMENT



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FOR SUSTAINABLE DEVELOPMENT

The Promise of Digital Health: Addressing Non-communicable Diseases to Accelerate Universal Health Coverage in LMICs

September 2018

Co-Chaired by:

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FOREWORDS

Dr. ANN AERTS

Head, Novartis Foundation
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(c) Nana Kofi Acquah

Digital technology is revolutionizing healthcare delivery. Worldwide, digital tools are leading to better and faster healthcare – healthcare that is more empowering and accessible for patients, more efficient for providers and more cost-effective for health systems.

In fact, digital health is probably the most powerful enabler that low- and middle-income communities can use to address the growing burden of non-communicable diseases (NCDs) and achieve universal health coverage. Ensuring all people can access the health services they need without suffering financial hardship is essential to achieving resilient communities – communities that are prepared for evolving health threats and enjoy greater economic prosperity thanks to healthier and more productive workforces.

Yet, despite their potential, the myriad of digital health solutions often lack a clear strategy and purpose. Consequently, they struggle to progress beyond the pilot phase, to become financially viable and integrate into national health policies and systems.

Sound national digital health strategies are essential to harness the full power of information and communication technology (ICT) for health. That is why, in September 2015, the Broadband Commission for Sustainable Development launched our Working Group on Digital Health, which the Novartis Foundation is privileged to co-chair.

Our first report, published in 2017, called for government leadership, clear governance mechanisms and strong cooperation between the health, ICT and finance sectors to achieve effective digital health. We are excited to build on that first publication with new, practical recommendations for how governments, policymakers and other stakeholders can build and scale digital solutions for addressing NCDs, so that universal health coverage can be accelerated in low- and middle-income communities.

The recommendations take the form of six building blocks: digital health strategy, leadership and governance; regulations and policies; digital infrastructure; interoperability frameworks; partnerships; and financing models.

The Novartis Foundation has implemented digital health solutions in most of its programs for the past decade, including some that are achieving scale. Time and again, we see the need for establishing these six building blocks, so I am confident that the recommendations in this report will help leaders meet today's unprecedented global health challenges. In the end, our common goal is for all people to have access to the care they need.

Finally, I would like to extend a warm "thank you" to all of the members of the Working Group on Digital Health for their engagement, commitment and collaboration on this report. As always, it has been a great pleasure and honor to work together to advance the potential of digital health to accelerate the achievement of UN Sustainable Development Goal 3: Ensuring healthy lives and promoting well-being for all at all ages.

PETER CLEVELAND

Vice President, Law and Public Policy Group, Intel Corporation
Co-chair, Broadband Commission Working Group on Digital Health

Using digital health as a transformation accelerator to improve healthcare delivery and health outcomes

In 2018, Intel Corporation partnered with the Novartis Foundation and other members of the Broadband Commission to provide practical recommendations for governments, policymakers and other stakeholders to create sustainable digital health solutions.

Over the last several years, there has been increasing recognition that digital health holds great promise to accelerate the path towards the UN Sustainable Development Goal 3 – Good Health and Well-Being. At the 71st World Health Assembly held in Geneva in 2018, the WHO passed a resolution on digital health. That resolution makes clear that digital health encompasses many different technologies, going beyond "mobile health."

Building on a previous report developed and published by the Broadband Commission Working Group on Digital Health, entitled "Digital Health: A Call for Government Leadership and Cooperation between ICT and Health," this report highlights the promise of digital health in addressing non-communicable diseases (NCDs) and supporting the achievement of the UN Sustainable Development Goal 3 in low-to-middle-income Countries (LMICs). Digital health supports all stakeholders in combating the NCD burden by empowering patients to take care of their own health, enabling health workers to better deliver care, and helping governments and policymakers manage the health system through data-driven insights.

Our research findings and the numerous case studies described throughout the report reveal that the most notable gaps or areas for prioritization include the need for evaluation frameworks and more extensive research efforts for measuring the positive benefits of digital health on health outcomes and costs; continued investment to build the foundational infrastructure needed to support the digital health ecosystem; and identification of ways to scale beyond pilots that have shown success. To address these gaps, we believe the private sector can play an important role and are eager to embrace the opportunity to work alongside other stakeholders in LMICs, contributing expertise especially in areas such as foundational infrastructure and scaling strategies for digital health.

The innovation that is happening in these countries is truly exciting and, in many cases, showcases how results can be achieved with limited resources. We hope that the important insights from this report inform governments and healthcare leaders worldwide as they use digital health to tackle healthcare's most pressing challenges.

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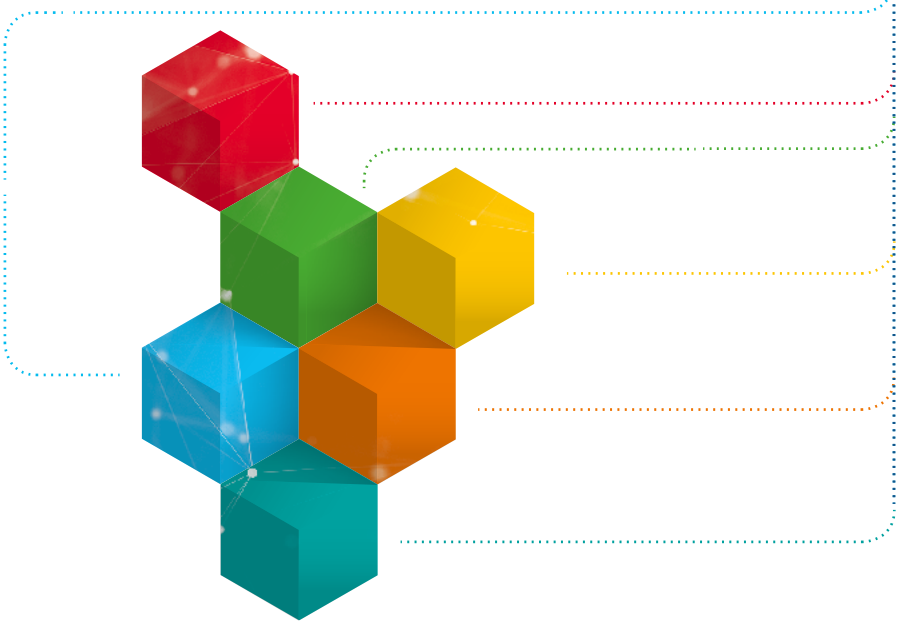
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EXECUTIVE SUMMARY

The Promise of Digital Health: Addressing Non-communicable Diseases to Accelerate Universal Health Coverage in LMICs

Digital health solutions promise to change the way healthcare is provided, driving progress toward universal health coverage and transforming outcomes for patients with NCDs

Worldwide, non-communicable diseases (NCDs) are responsible for more deaths than any other disease

Non-communicable diseases account for approximately 70% of deaths worldwide, of which three-quarters occur in low- and middle-income countries (LMICs).[1] Funding for tackling NCDs is low compared to other diseases and preventive measures in particular would have a significant impact.[2]

To combat NCDs, we need to transform the way healthcare is provided and expand access to all. Without properly addressing NCDs, universal health coverage (UHC), a target of Sustainable Development Goal (SDG) 3, cannot be achieved

Health systems must move toward universal health coverage and shift...

- from facility-based care to community-based care with a focus on increasing health system capacity and efficiency
- from episodic, curative care to long-term, continuous care to institute a people-centered focus with improved access
- from reactive care to proactive, preventive care featuring forward-looking health management with improved transparency

Digital health can help make these shifts possible

Digital health encompasses the use of information and communications technologies (ICT) in all their forms for health. This includes electronic health records showing patients' health histories, mobile apps designed to raise awareness about diseases and internet-connected devices such as those that allow doctors to monitor patients' blood glucose levels remotely.

What these technologies have in common is that they can fundamentally change the cost-quality equation of healthcare and empower patients, health providers, governments, and other stakeholders with the information and tools they need to manage their own health, deliver better care and strengthen the underlying health system, thereby radically expanding access and improving outcomes.

Investing in digital health to strengthen entire health systems can accelerate efforts to combat NCDs, and by the same token, investing in digital health specifically to combat NCDs can have wider health system benefits. Ultimately, digital health is a catalyst in transforming how healthcare is delivered and experienced, as it allows LMICs to move from disease silos in healthcare to an integrated, resilient health system.

Digital technology is driving innovation in healthcare, especially in LMICs

Unmet health needs driven by a lack of health infrastructure and trained health workers, widespread mobile penetration and relatively open regulatory environments make LMICs fertile ground for innovation. And with fewer entrenched, legacy systems to overcome, countries have an opportunity to "leapfrog" and adopt newer solutions

faster. Digital health should be considered an essential part of the healthcare system, just as medical equipment or hospital beds are.

The results so far are encouraging

A few studies have evaluated the impacts of digital health, ranging from patient-level results like reduced blood glucose levels to system-level results such as improved access to services and cost savings. In Canada, for example, the cumulative benefits of investing in digital health were estimated at around CAD$16 billion over the course of nine years.[3] The results so far are encouraging and could be used to drive further investment and scaling of digital health solutions.

To maximize the impact of digital health on NCDs in order to accelerate the achievement of UHC, solutions have to be financially sustainable

Many digital health solutions are launched as pilots and are often not designed for scale and sustainability. This can lead to a fragmented, uncoordinated landscape of standalone initiatives. The simplest solutions – namely those designed with the needs of the end user in mind, that use existing technologies and are integrated in the existing health system, and which are widely available in the context – have the highest chances of being scalable and sustainable. This is demonstrated, for example, by the national scaling of telemedicine services in Ghana.

This report provides examples, insights and recommendations for greater sustainability in digital health.

Building Blocks for Sustainable Digital Health

There is much policymakers can do to create favorable environments for sustainable digital health, and they don't have to do it alone

Six building blocks can help countries realize the promise of digital health and transform access to appropriate, effective NCD care



Six building blocks for sustainable digital health

Policymakers have a wealth of experience and knowledge to capitalize on

Many countries have already embarked on their digital health journeys. The following sections capture the key lessons for each building block specifically for NCDs, along with some examples and tools.

Digital Health Strategy, Leadership and Governance

As outlined in the 2017 report of the Broadband Commission Working Group on Digital Health,[4] strategy, leadership, and intersectoral collaboration between ICT and health are key to realizing the full potential of digital health so that it responds to national health priorities and drives progress toward universal health coverage

For policymakers, a vital first step is to set a digital health strategy that lays out a compelling vision and provides clear direction to all stakeholders in the health system

A digital health strategy also provides a supportive, predictable operating environment for solution providers. Some 120 countries already have digital health strategies in place, from Brazil to Turkey to India. Countries that don't have one or want to improve it can develop a vision and consider how their capabilities need to evolve in order to achieve it with digital health. Assessment frameworks and guidelines have been developed to support different aspects of a digital health strategy by organizations such as the International Telecommunications Union (ITU), the World Health Organization (WHO), and Intel.

Strong leadership, intersectoral collaboration and clear governance are then essential for effective implementation of a national digital health strategy

Through its in-depth country case studies, the 2017 report of the Broadband Commission Working Group on Digital Health demonstrated that countries that had been successful in realizing the potential of digital health fulfilled three pre-requisites:

- Sustained senior government leadership and committed financing
- Effective governance mechanisms
- National ICT framework that facilitates alignment between health and ICT sectors

Last but not least, a well-defined monitoring process to track implementation, impact and cost-effectiveness of a national digital health system clearly helps transform digitized health systems into "learning" systems that always improve according to the needs of the people it serves.

Regulations and Policies

Regulation is needed to protect patient safety and privacy, while allowing innovation to continue to unfold. This fosters trust in digital health solutions and facilitates their adoption

Specifically, three categories of regulation can be established:

First, data management regulation protects the privacy and security of patients' health data

Data security and privacy are particularly hot topics right now, as digital health solutions begin to allow large amounts of patient data to be collected and shared. Data-protection measures can build trust in the usage of personal health data among stakeholders.

The core regulatory challenge is to achieve high standards of data protection and quality without stifling innovation. For example, the use of cloud services has immense potential to fulfill all required data-protection measures and meet LMICs' needs for flexibility, scalability and cost-effectiveness.

Second, device regulation ensures that only safe, cost-effective, high-quality devices are approved for use

A general principle is that devices need to be regulated in proportion to the risk they pose to the patient. Established approval processes in high

income countries (HICs) can be re-used or adapted by LMICs to bridge existing regulatory gaps and provide innovators with the guidance they need to understand how regulators will classify their products.

Third, regulation of the delivery of care ensures that medical practices complemented by digital technology are safe and high-quality

Regulators can prioritize applications such as:

- Those improving prevention or early detection of NCDs
- Those supporting task shifting of care practices to less-skilled health workers
- Telehealth or telemedicine, allowing providers to centralize expertise and perform consultations and monitor NCD patients remotely
- Prescription of medicines, given that patients with chronic conditions regularly need refills

Digital health regulations and policies differ greatly among countries and are often not comprehensive. Lessons can be learned from HICs. At the same time, great examples from LMICs could be used in HICs, such as the use of e-prescriptions in India and telehealth in China.



Communication Infrastructure and Common Platforms

Communication infrastructure and common platforms connect people and solutions, and enable the sharing and use of information to manage NCDs more effectively and efficiently

Digital communication infrastructure provides the connectivity that makes the application of digital technology to healthcare possible. Policymakers should prioritize making that connectivity available and affordable to all

The cost of mobile broadband as well as internet connectivity continue to pose barriers to accessing information and digital health solutions. Access to the right quality or speed required to use digital health solutions is especially lacking in several LMICs. The cost of mobile broadband has been dropping significantly, however, it is still prohibitively high in some LMICs. Governments and mobile network operators still have a variety of ways to accelerate access, including:

- Public access points
- Stimulating competition and incentives for operators to enter less attractive markets, such as remote areas
- Promoting infrastructure sharing
- Managing radio frequencies efficiently

Governments can also assess the role that taxes on handsets and airtime play in limiting access to digital health solutions and consider making changes. Proactive measures like these can help ensure that digital health does not become a barrier to healthcare access, exacerbating existing inequalities based on income and other factors.

In addition, policymakers can also work with stakeholders to create cost-efficient digital health platforms as common assets with core functionalities that can be shared

Such platforms, or "infostructures," can include a health information exchange architecture, unique citizen (or patient) IDs, patient electronic health records or registries, Application Programming Interfaces (APIs), or health management information systems to integrate data across regions and diseases. Many of these components should be government-wide, to maximize return on investment and links across e-government programs, such as health and social services. Certainly, any investment in digital health to improve the management of NCDs will also help address other diseases and vice versa. While common digital health platforms can be challenging to design

and operate, they can ensure higher cost-efficiency (build once, use multiple times) with better integration and interoperability. Common digital health platforms in the Western Cape region in South Africa, Estonia and, as currently developed, in Gabon offer good models to learn from, and a variety of guidelines and tools provided by ITU, WHO and other stakeholders exist to help countries get started with their "infostructure".



Interoperability Framework

Interoperability allows different digital health solutions and data sources such as government programs, hospitals, community health workers and patients themselves to connect with each other. It is essential to manage NCDs in a coordinated way across all levels of care and all stages of the patient journey

Interoperability allows different ICT systems, software applications and devices to communicate and exchange data

Currently, many national healthcare systems face a lack of interoperability between their data sources and patient management systems. This is due to the use of proprietary elements or commercial software instead of open standards. Inconsistent use of existing standards can also be at fault. Remedying this is considered so crucial to the promise of digital health that it is now receiving UN-level attention.

Policymakers should consider interoperability as a cornerstone of their digital health strategy

Countries without legacy systems can be at an advantage when it comes to fostering interoperability. Diverse expertise is needed to make decisions, because interoperability entails both technical and organizational aspects. Establishing a board of national and international experts from the public and private sectors, like Chile and Mexico did, can be extremely beneficial. A fundamental role for the government is to create awareness around the importance of interoperability and the value of open standards. A variety of open standards are ready to adopt, as well as "profiles" that bring multiple standards together.

Countries that establish unique citizen IDs have the tremendous advantage that patient information can be linked and followed up over time. Examples of countries with unique ID systems are India, Thailand and Rwanda. Regional communities of practice such as the Asian eHealth Information Network (AeHIN) and organizations such as the Health Data Collaborative can also be leveraged to navigate the field of interoperability.



Partnerships

Partnering can increase the scale and impact of digital health solutions by combining expertise, ideas, assets and other resources of different stakeholders

The digital health stakeholder landscape is diverse. In general, it includes:

- Governments responsible for health-system planning and management, public health IT infrastructure and financing
- Financers, including donors and insurers, who bring financing for digital health solutions and in some cases the power to convene several partners
- Health providers, who bring medical expertise and delivery capacity
- Suppliers, such as:
  - Mobile network operators (MNOs) that bring digital communication infrastructure, go-to-market expertise and customer relationships
  - Technology companies that deliver ICT systems and digital health solutions, go-to-market expertise and sometimes regional or global reach
  - NGOs and civil society, which assure

trusted access to target populations, transmitting information about their needs and capacity-building abilities

Government and MNOs can be especially important partners for scale

Governments are key for integrating digital health solutions into national health reimbursement systems, shaping health policies, connecting with other stakeholders and defining regulations. This is especially crucial for solutions addressing NCDs, which require lifelong treatment and often lead to catastrophic health expenditures and impoverishment of entire families. For instance, the Carlos Slim Foundation's CASALUD model for diabetes care has become part of the National Strategy for the Prevention and Control of Overweight, Obesity, and Diabetes in Mexico.

And partnering with MNOs has enabled digital solutions to reach larger target populations. For example, 19 million patients have now used AxisMed's remote monitoring solution in Brazil, offered in partnership with Telefónica.

Partnering has to create value for all involved

Different organizations bring different assets and aspirations to the table, and meeting those aspirations is crucial to a sustainable partnership. Over time, there has been a mindset shift when it comes to partnering with the private sector. In early phases, private sector partners have donated digital health products or services. Now, they seek "win-win" or "shared value" models that generate benefits for the business as well as for patients, healthcare providers and other stakeholders. For example, AccuHealth entered into a public private partnership (PPP) with the Chilean government to provide patients with home monitoring devices enhanced with analytics services that get reimbursed in return.

Policymakers can create opportunities to bring stakeholders together

Governments can help bridge sector boundaries through, for example, health innovation events focused on specific needs, support to help small companies bid for contracts, roundtables, working groups, and other forums that allow stakeholders to meet and build working relationships.

Financing Models

Taking promising digital health solutions from proof-of-concept to scale requires committed and sustained financing

A variety of financing options exist:

Historically, 85% of digital health funding in developing countries has been spent on early-stage research and development or pilot programs. Now, financing models for all stages of the project lifecycle are beginning to emerge, including innovative models that generate revenues on an ongoing basis.

Common health platforms require long-term commitment

Government should take the lead in coordinating funding for digital health platforms. Donors and development banks are stepping up efforts to increase funding for core health IT systems when there is commitment from the government. Governments can also look for ongoing revenue streams to recoup initial investments, as Senegal with their Agence de la Couverture Maladie Universelle (ACMU) agency platform did. For example, this can be achieved through pay-as-you-use models that make common digital health platforms more accessible for governments, healthcare providers and other healthcare stakeholders.

Diverse financing options can be used to fund solutions that plug into the common digital health platform

A range of financing options can be used as part of a business model, with the objective of protecting patients from financial hardship. The ultimate goal is for digital health solutions to be covered by public or private health insurances. Other models can be used in combination with reimbursement schemes or as a financing bridge until a health insurance is established.

- **Donor grants** to jump-start digital health solutions until they have proven to work and can cover their own costs or be absorbed into the public health system, such as MomConnect in South Africa
- **Out-of-pocket payment** is the least preferred option but can cover specific needs with a quick adoption rate and become more affordable for low-income groups through cross-subsidization or a "freemium" approach, like that of Grameenphone in Bangladesh or the subscription-based model from MedicallHome in Mexico offering 24/7 telehealth support for a low fixed fee
- **Direct government financing**, where resources are available or provided through loans; in addition to common health platforms this is typically used for time-limited public health campaigns, such as the joint WHO-ITU Be He@lthy Be Mobile initiative
- **Public or private insurance reimbursement** is the ultimate goal. This includes micro-insurance for digital health services that can bring substantial health benefits, such as those provided by babyl in Rwanda
- **Pay-as-you-use or licensing**, which generates a constant revenue stream for providers while matching users' needs, as illustrated by the Leap mLearning platform from Amref

Obviously, if development and operating costs are low, less funding is needed.

Smart design, local integration and maintenance, as well as bulk purchasing can be used to bring down the costs of digital health.

Conclusion

Policymakers, donors, private companies and other digital health stakeholders can use the practical lessons, examples and tools described in this report to foster sustainable digital health solutions that address the specific needs of patients with NCDs and help countries accelerate the achievement of universal health coverage

Digital health solutions promise to change the way healthcare is provided, to both acute and chronic patients

They have the potential to fundamentally change the cost-quality equation and empower patients, health providers, health managers and policymakers with the information and tools they need to manage their own health, deliver better care and strengthen the health system. Digital health can expand access to quality healthcare and improve prevention and patient outcomes, including for patients with chronic conditions such as NCDs. Investing in digital health to accelerate efforts to combat NCDs will yield benefits for the entire health system and make it more efficient and resilient.

Realizing the promise of digital health involves establishing the following six building blocks:

- A national digital health strategy backed by strong political leadership and multi-stakeholder governance
- Regulations and policies that protect patient safety and privacy, while allowing innovation to continue apace
- Connectivity among people and systems by supporting digital

communication infrastructure and building common platforms

- Data shared and leveraged to manage care better by establishing interoperability frameworks
- Partnerships among the diverse health system stakeholders with roles to play
- Adequate financing models for a common health platform and digital health solutions to make it all possible and protect people from financial hardship

And policymakers do not have to deliver alone. They can learn from and with others on the same journey

Many countries have begun their digital health journeys and a wide variety of organizations are actively engaged, seeing digital health as an opportunity to address the growing NCD burden to accelerate the achievement of UHC. Generally, investments into digital technology that aim to strengthen health systems will benefit patients with NCDs and digital solutions for NCDs will similarly help make systems more resilient.

No matter how far they are in their journeys, policymakers have the opportunity to learn from the experience of other countries and can bring together stakeholders with the resources, expertise and assets needed to fulfill the potential. Countries embarking on the journey toward realizing the potential of digital health can start taking small steps, focusing on "must-have" elements to lay the foundations for future development.



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ABOUT THIS REPORT

This report highlights the promise of digital health in addressing NCDs and supporting the achievement of universal health coverage (UHC) in LMICs.

Report's objective and target audience

The objective of the report is to describe market insights, examples and lessons learned from LMICs and HICs, and to provide practical recommendations for governments, policymakers and other stakeholders within the digital health ecosystem with regard to the creation of sustainable digital health solutions.

Governments and policymakers are the primary target audience for this report, though it also targets international organizations, donors, private-sector entities, non-governmental organizations (NGOs) and civil society groups working to support global health and digital development.

Explanation of icons:

Further reading

Examples

Background information

This publication builds on a February 2017 report from the Broadband Commission Working Group on Digital Health entitled "Digital Health: A Call for Government Leadership and Cooperation between ICT and Health," which called for governments to improve leadership, governance mechanisms and stakeholder alignment in order to support national digital strategies.[5] The Working Group is co-chaired by the Novartis Foundation and Intel, and is composed of leading digital health experts from governments, international NGOs, academic institutions and the private sector.

The Working Group commissioned Accenture to collect and analyze primary and secondary research material, and to compile the resulting insights and recommendations in a report. In the process, interviews were conducted with more than 80 digital health stakeholders including members of the Working Group on Digital Health and external experts, and more than 200 secondary reports were collected and analyzed. Primary research data was collected through phone interviews and in workshops.*

The report begins with an introduction of the current NCD and UHC landscape and follows with observations and recommendations detailing how governments and policymakers can build sustainable digital health solutions to achieve UHC and reduce the NCD burden faced in so many LMICs. Each section describing the building blocks for sustainable digital health solutions ends with conclusions and next steps.

* While the report draws on Accenture research, the views and recommendations expressed are based on the interviews and secondary research carried out for the purpose of the report, and should not be considered to represent the views of Accenture.



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1 The Promise of Digital Health



Digital health solutions promise to change the way healthcare is provided, driving progress toward universal health coverage and transforming outcomes for patients with NCDs. They are fundamentally altering the cost-quality equation and empowering stakeholders with the information and tools they need to manage their own health, to deliver better care, and to transform access and outcomes system-wide across diseases.

Innovation is accelerating, especially in low- and middle-income countries where unmet health needs, widespread mobile penetration and relatively open regulatory environments offer fertile ground.

The results so far are encouraging, and policymakers are asking what they can do to help realize the potential and make digital health solutions sustainable.

Non-communicable diseases: the leading cause of death and disability globally

Non-communicable diseases (NCDs), such as cardiovascular disease, cancer, diabetes and respiratory disease caused 41 million deaths in 2016, accounting for 71% of deaths globally.[6] Unlike communicable diseases (CDs), NCDs are chronic and sometimes lifelong conditions. Approximately 15 million people between the ages of 30 and 69 years die annually from NCDs, during their prime working years. Over 85% of these deaths occur in LMICs[7], which often have health systems that are better suited to delivering acute care for urgent medical conditions.[8] According to the World Bank, LMICs are economies whose per capita gross national income (GNI) was below US$12,235 in 2016. This includes the 47 least-developed countries (LDCs), which have a GNI below US$1,025.

Up to 80% of cases of heart disease, stroke and type 2 diabetes, and 40% of cancers, could be prevented

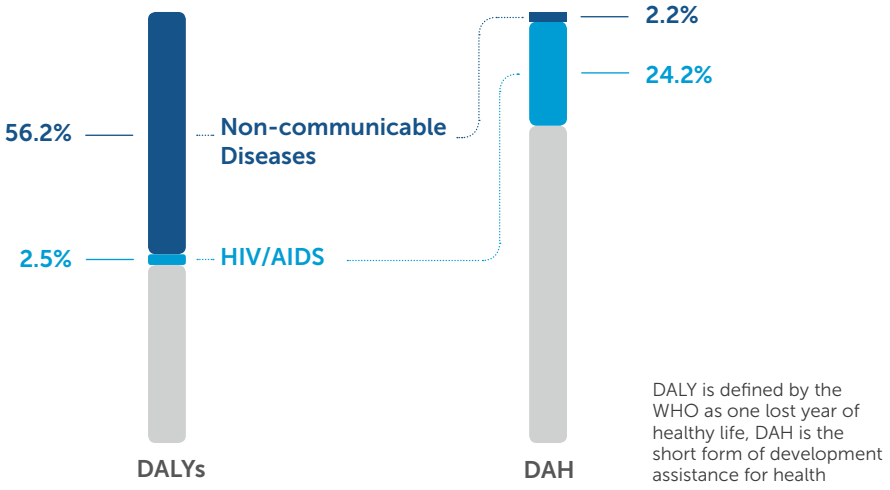
There is international consensus that the NCD burden needs to be addressed, as evidenced by the objectives included in the Sustainable Development Goals (SDGs). Specifically, SDG 3, on the issue of "health & well-being," aims to reduce premature mortality within NCDs by one-third by 2030.[9]

Tackling the NCD funding gap

However, funding for tackling NCDs (especially donor funding) lags behind that earmarked for communicable diseases such as HIV/AIDS or tuberculosis. Even though NCDs cause 56.2% of disability-adjusted life-years (DALYs; defined by the World Health Organization as "one lost year of 'healthy' life") in LMICs, only 2.2% of development assistance for health (DAH) in 2017 was allocated to NCDs. By contrast, HIV/AIDS is responsible for 2.5% of DALYs in LMICs but received 24.2% of the year's health-related development assistance. [10, 11] DALYs are one way of measuring the overall disease burden, while DAH represents funding provided by donors and international agencies to improve health in LMICs (see Figure 1).

Additional funding addressing NCDs would have a significant impact. The WHO estimates that up to 80% of

Figure 1 **Global NCD burden and funding (DALYs 2016, DAH 2017)** [12,13]



cases of heart disease, stroke and type 2 diabetes, and 40% of cancers, could be prevented through measures that reduce harmful use of alcohol, tobacco, unhealthy diets and physical inactivity.[14]

With the aim of promoting prevention, the World Health Assembly endorsed the WHO Global Action Plan for the Prevention and Control of NCDs 2013 – 2020. The Global Action Plan provides a roadmap and menu of policy options intended to help achieve nine NCD targets by 2025. Drawing on international experiences, a range of practical activities for addressing NCDs is recommended, including disease screening, health-worker training and lifestyle interventions.[15] In addition, the Chronic Care Model[16] identifies NCD prevention and early diagnosis, recognition of the social determinants of health, and enhanced community participation as being crucial in curbing the progression of NCDs, and hence for avoiding the debilitating conditions that arise in the later stages of such diseases, which are particularly costly to treat.

Unfortunately, budgets for preventive interventions remain low, even in HICs. For example, HIC members within the Organization for Economic Co-operation and Development (OECD) spend an average of just 3% of their healthcare budgets on prevention and public health literacy.[17]

NCD-prevention activities and healthy-living policies should seek synergies across diseases, thus enabling funders and policymakers to increase their impact by bundling resources. For example, risk factors such as smoking or obesity often lead to more than one disease in the same individual. In some cases, NCD strategies can also be aligned with those addressing communicable diseases, as dependencies between the two types may exist. For example, diabetes triples the risk of developing tuberculosis.[18] There are also HIV-associated cancers.[19] When addressing NCDs, leveraging solutions that have already worked for the long-term management of diseases like HIV/AIDS or tuberculosis can thus be of great benefit to NCD programs. "There is no typical 'NCD patient.' A doctor can come across a pregnant woman who is HIV positive and has diabetes and hypertension with kidney disease. We need to combine multiple medical disciplines to address NCDs," said Dr. Nao Malombo Sipula, Founder, and CEO of the WatIf Health Portal, an AI-driven chronic disease management system.[20] Avoiding siloed investments will help benefit collective digital health needs across diseases and across the health system.

NCDs and universal health coverage

As defined by the WHO, universal health coverage (UHC) is achieved when people and communities receive the health services they need without being exposed to financial hardship. The assessment of UHC focuses on three aspects:[21, 22]

- Equity in access to health services (e.g., everyone can receive care) and has access to essential medicines
- The quality of health services (e.g., good enough to improve health outcomes)
- The cost of health services (e.g., should not lead to financial hardship)

While UHC has become more common since 2000 and is one of the targets of Sustainable Development Goal (SDG) 3, more than half of the world's population continues to lack access to essential health services. This is largely due to a lack of affordable, high-quality healthcare. Each year, almost 100 million people are forced into poverty due to out-of-pocket healthcare expenses.[23] Advanced UHC structures tend to exist in countries where governments are responsible for the organization of healthcare, while financing is accomplished through an insurance

system, as in Australia, South Korea and many Western European countries.[24]

LMICs with limited budgets for achieving UHC can begin addressing the needs of patients with NCDs by strengthening their primary healthcare (PHC) systems. Strong PHC systems have been found to be the most effective way to address NCDs and achieve UHC.[25] PHC systems are also best positioned to take the required holistic people-centered approach to health. To truly address NCDs, forward-looking management of the underlying NCD risk factors is essential. This includes prevention and screening for risk factors, promotion of healthy lifestyles starting as early as possible in life (i.e., childhood), early disease diagnosis to avoid organ damage, and ongoing support to ensure patients adhere to treatment.[26]

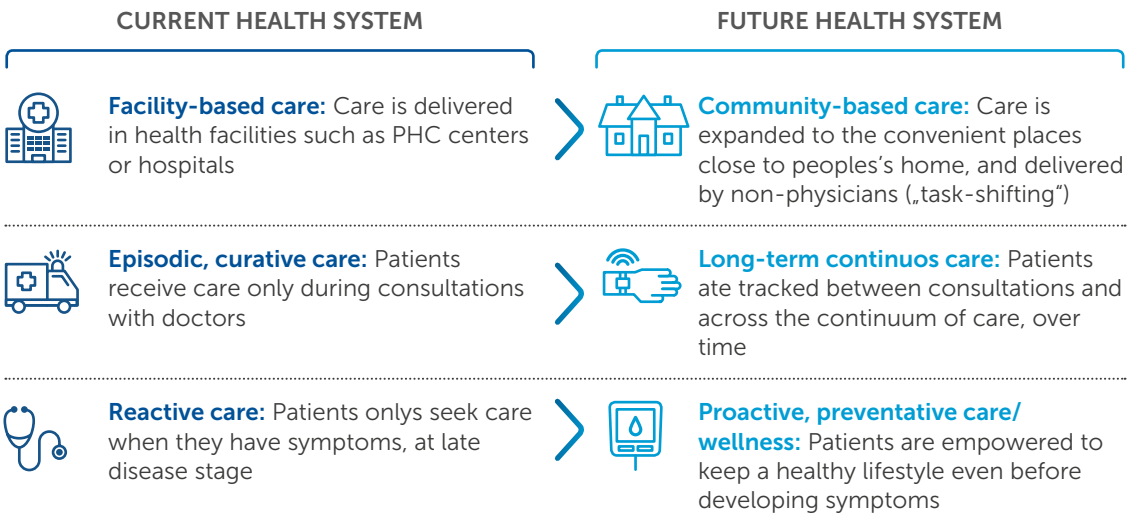
Improving care in underserved settings

There are many ways to address these challenges in underserved settings (Figure 2).

The first is to **increase health-system capacity and efficiency** by shifting responsibility for comparatively simple health interventions (e.g., hypertension, obesity and diabetes screening) to health workers with less training and fewer qualifications than fully trained doctors, and who may also be closer to their communities. This process is referred to as "task shifting," and is intended to ensure tasks are performed by adequately trained providers close to patients' residences.[27] For this to work, clear roles and responsibilities must be defined, and the appropriate (re)training of healthcare workers must be provided. In addition, relevant information should be provided to health workers if they are to remain informed and make efficient decisions.

The second approach is to **empower individual members of the population** to take care of their health and well-being on a continuing basis. This requires both improved access to healthcare and a shift toward people-centered care, focusing on people's comprehensive needs rather than on individual diseases.[28] Increased patient awareness of NCD causes and prevention strategies, along with personalized recommendations for behavioral change and opportunities for patients to monitor their own health metrics, can contribute to successful prevention and long-term management of NCDs. New people-centered

Figure 2 **Transforming the health system to address NCDs and UHC goals**



interventions have to be designed jointly with the individuals affected in order to meet their needs and ensure a high adoption rate.

The third option is to **invest in the population-wide prevention** of NCDs by addressing underlying risk factors and improving early detection. Limited national budgets for NCD prevention could be allocated by prioritizing measures with the greatest impact, for example with reference to the University of Washington's Disease Control Priorities[29] or the WHO's "best buys." Best buys are cost-effective, high-impact prevention initiatives, such as mandated cervical cancer screenings, or mass-media campaigns on the risks of smoking and tobacco.[30]

For this to happen, patients, health providers, governments and other stakeholders need to be enabled with the right information at the right time, through the right tools. The next sections of the report describe how digital health systems can support this kind of healthcare-system transformation.

What is digital health?

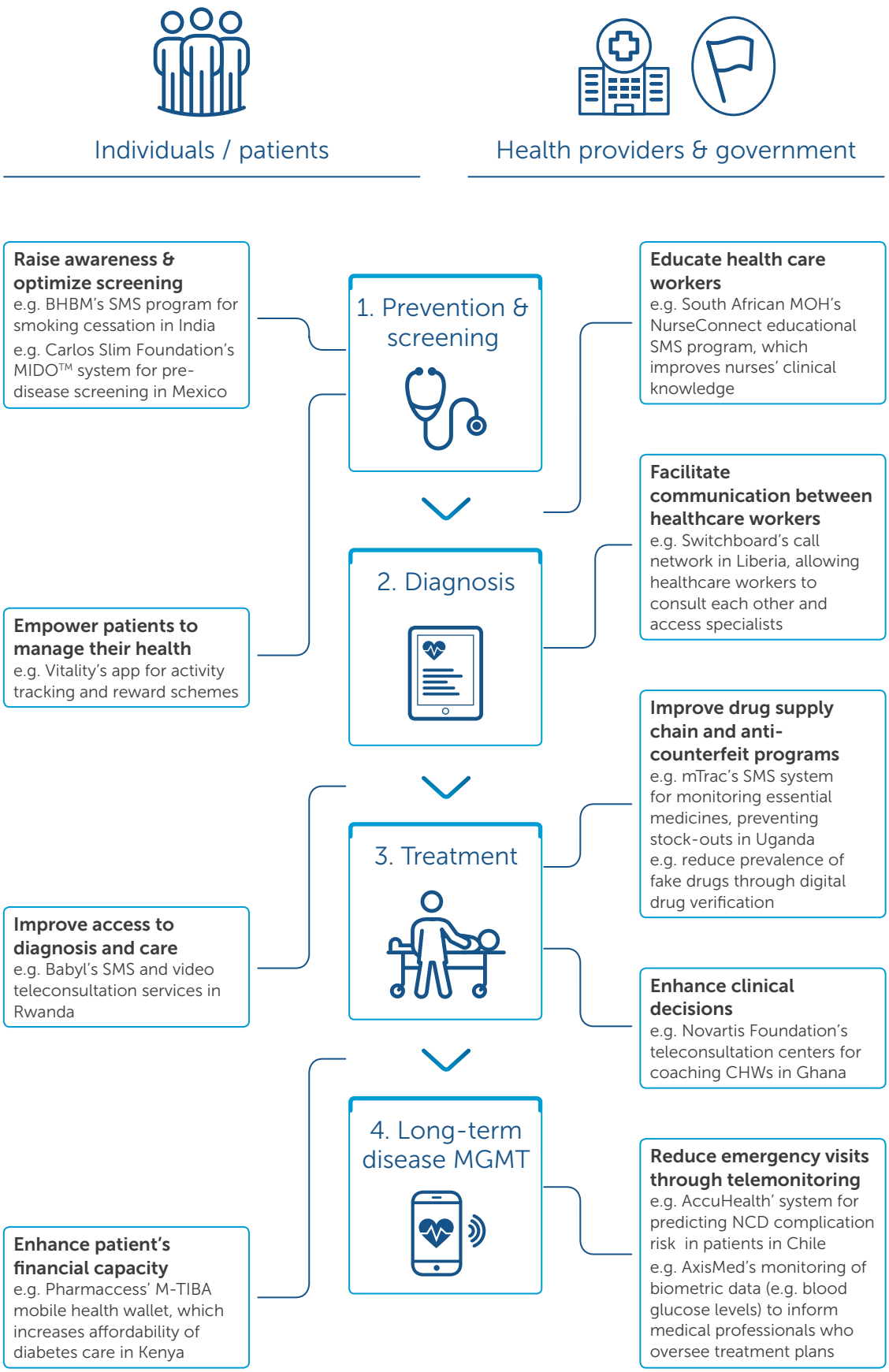
Digital health is a broad term that generally describes the use of ICT for healthcare purposes. This includes eHealth and mHealth products and services,[32] including telehealth. Alternative definitions identify additional technologies or technical fields as potentially relevant digital health characteristics, such as innovations in diagnostics (e.g., genomics), internet-of-things (IoT), and artificial intelligence.[33] In recent years, the international community has recognized the potential of these technologies to support the achievement of the Sustainable Development Goals. In May 2018, the 71st World Health Assembly adopted a landmark resolution on digital health proposed by India and 14 other WHO Member States.[34]

> "Today we have an extra tool [to support UHC] that we did not have… years ago, digital technologies. Mobile technologies and telemedicine can make a huge difference in helping to reach people… with medical services… train health workers and improve health data."
>
> Tedros Adhanom Ghebreyesus, Director General of WHO at the launch of the Commonwealth Centre for Digital Health in April 2018.[31]

Digital health as the catalyst to transforming healthcare experience and delivery

Digital health systems can be used by health-sector stakeholders along the care continuum, from prevention to long-term disease management, and play a key role as a catalyst for change in supporting healthcare delivery. Generally speaking, such strategies increase the potential to achieve universal health coverage.[35] Governments and policymakers can use population-based data to activate tailored prevention programs and make informed decisions about the health system. Health workers can deliver health more efficiently, thanks to the exchange of relevant information, digital tools for improved care delivery and tailored training programs. Finally, people in general and patients specifically can be empowered to stay healthy, manage their diseases and access care more frequently or easily. Figure 3 shows a selection of digital health solutions that are helping to transform how healthcare is delivered and experienced.

Figure 3 **Examples of digital health solutions for patients, health providers and national health systems / governments**



Fulfilling the digital health promise

If the digital health sector is to fulfill its promise as a catalyst in transforming healthcare, making it easier to reach universal coverage for NCDs in LMICs, it should act as an enabler for:[36]

1. **Efficient and high-quality care delivery, including:**

   - Innovative service-delivery models bringing healthcare from facilities into communities and remote places; matching of health workers' skills with tasks and delegating where appropriate
   - Robust clinical decision-making with the support of intelligent information systems
   - Efficient communication and use of information across healthcare providers
   - Provision of tailored and face-to-face training and technology to extend health workers' skills, enabling them to handle a broader range of clinical situations

2. **People-centered and continuous care, including:**

   - Providing accessible healthcare solutions through physical, remote and virtual touchpoints
   - Support along the care continuum for people living with NCDs, moving from episodic treatment to long-term health management
   - Empowerment of patients by providing them with information and soliciting their active engagement in treatment plans that include self-monitoring

3. **Proactive and preventive care, including:**

   - Support for people living with NCDs and associated co-morbidities across the population, by promoting healthy lifestyles and preventive measures, and focusing on risk factors and patients in pre-disease stages
   - Provision of timely and secure access to the kind of longitudinal, population-based and forward-looking data that can help prevent NCDs and improve delivery of care
   - Precision profiling with algorithms embedded in information systems that can be used within communities and at primary-care clinics

As digital health solutions improve NCD management and help countries progress toward universal health coverage, they should be considered to be an essential aspect of the healthcare system, just like medical equipment and hospital beds are. Ultimately, health systems enabled by digital health solutions will gain resilience and be able to deal more effectively with evolving health threats, whether they come from infectious diseases or NCDs.

Digital health solutions should be valued as an essential aspect of the healthcare system, just like medical equipment and hospital beds are

It must be noted that digital health tools can lead to changes at the level of the overall health system. For example, investing in early detection and screening for NCDs will lead to the identification of many more patients requiring treatment. This might put some pressure on primary care centers and hospitals. However, giving these individuals prompt treatment will avoid or delay future complications linked to uncontrolled symptoms, and as a result reduce future demand for

Figure 4 **Emerging digital health technology trends** [37, 38]

TECHNOLOGY TRENDS	DESCRIPTIONS	IMPLICATIONS FOR UHC AND NCDS	APPLICATIONS
 **5G and connected devices**	5G is the next generation of wireless services. It will serve as the foundation for IoT, and improve user experience through greater efficiency and speed, and lower latency – the amount of time between a request and the execution of a computing command.	• Data from devices and sensors can be aggregated, enabling imaging, diagnoses, and data analytics through computing at the edge • Access to quality care can be improved through the rapid sharing of information and data among providers and patients • Patients can be empowered to engage in self-care in the comfort of their home	• Widespread use of videos, imaging, virtual reality—whether for emergency services, routine care, or provider training • Chronic disease management through continuous monitoring that uses sensors on/in the body and in the environment • Online web platforms, which can perform better than traditional offline diagnostic devices, e.g. pocket ECGs
 **Artificial intelligence (AI)**	Advanced analytics identifies patterns within healthcare data to create more efficient and sustainable models of care. AI as an underlying technology (including machine/deep learning, and cognitive systems) uses human-like reasoning to find hidden patterns in data, interacts with natural language and supports automation of interactions	• The challenge of attaining clean and complete data sets can be addressed • Healthcare data can be leveraged to provide targeted preventive care for a community, reducing both disease burden and costs • HCP decision-making can be augmented with clinical decision support tools powered by AI capabilities	• Monitoring devices that apply advanced analytics and AI to derive insights on diseases and identify patients who are at sudden risk of decline, whether in the hospital or home, so that providers can proactively intervene • Image scanning and classification automation to improve speed and accuracy of diagnosis and treatment
 **Blockchain**	Blockchain, or distributed ledger technology (DLT), enables multiple parties to share access to administratively decentralized databases. It facilitates the trusted exchange of data over a network and does not require an intermediary.	• Secure, auditable data sharing can be enabled • AI and machine learning technologies can be accelerated • Interoperability pressures can be alleviated • Healthcare data can be monetized	• Supply chain management, e.g. World Bank's Blockchain lab experimenting with tracking drug stocks • Counterfeit drug prevention • Medical record sharing (e.g. between providers; for clinical trials management) • Claims adjudication • Smart contracts
 **Diagnostics & 'omics'**	Accelerated advances in ‚omics' fields (e.g., genomics) facilitate low-cost state-of-the-art diagnostics tests within the community or even the household. In combination with AI, they support rapid decision-making, and enable personalized follow-up	• Access to diagnostic methods in areas with low healthcare access can be enhanced • New diagnostic methods can be carried out even by low-skilled workers, enabling rapid scaling • Care quality can be improved, by providing health professionals with accurate data about patients	• Point of care diagnostics with supplies that do not require cold chain • Systematic risk assessment of NCDs and its predecessors such as prediabetes • Systematic risk management of NCDs using low cost laboratory tests

more expensive secondary care and emergency treatments. In addition, digital health tools have the potential to expand access to care for some patients.

Governments must therefore anticipate such changes as they integrate these new tools into their healthcare systems.

Emerging digital health technology trends

The digital health universe encompasses a variety of technologies and is fueled by innovation. The maturity level of these technologies varies greatly. Some technologies or technology-driven business strategies, such as mHealth, have already been widely adopted over the past few years. Other technologies, such as "virtual assistants" as applied to healthcare, still need to evolve. However, even mature technologies can still undergo further innovation, producing new digital health solutions. In the case of mHealth tools, the already broad range of lifestyle and wellness apps is currently being complemented by new digital therapeutics that have a measurable impact on a disease's progression and can often be used on mobile phones. Digital therapeutics are technologies that can complement or even replace traditional clinical treatments.

Investment totals often serve as one indicator of a sector's dynamism. According to the Startup Health Insights report (2017), startup investments in the digital health sector rose from US$2.9 billion in 2013 to US$11.5 billion in 2017, thus nearly quadrupling in that time.[39]

Recently developed digital technologies that have currently been adopted by only a few countries may become mainstream in five to 10 years, thus ultimately forming the basis for entirely new digital health solutions (Figure 4 presents a selection of such technologies).

Weeding out counterfeit drugs through digital tools

Counterfeit drugs and substandard products (licensed but of inferior quality) account for about 10% of the medications used globally. However, that share is considerably higher in certain parts of Africa. According to the WHO, such products result in over 200,000 deaths per year on the African continent, mainly from childhood pneumonia and malaria.[40] This number could be much higher when all diseases are considered.

In 2013, WHO launched the Global Surveillance and Monitoring System with the aim of encouraging countries to report incidents of substandard and falsified medical products in a structured and systematic format. The goal was to help develop a more accurate and validated assessment of the problem. By November 2017, WHO had issued 20 global medical-product alerts and numerous regional warnings, and had provided technical support in over 100 cases.[41]

Along with WHO efforts and stronger law enforcement, digital technologies are vital in helping to combat fake medicines.

Several companies have developed solutions addressing the issue. One of the best examples is from Ghana; here, the company mPedigree uses a simple sticker on the packaging, which, when scratched with a fingernail or coin, reveals a numeric code that can be verified by SMS. This provides a direct confirmation of the drug's authenticity. Operating in 12 African countries, the company says 75 million people have benefited directly or indirectly from this strategy.[42]

Several other companies use similar methods. However, this approach focuses on the final step of the supply chain and relies on a centralized source of information, which itself could be vulnerable to hacking.

The future of anti-counterfeiting technology could require a transparent public registry made possible by using blockchain technology. This would allow medications to be tracked through the entire supply chain, from manufacture to final delivery, without any possibility for modification of records by unauthorized individuals.[43]

Measuring the impact of digital health solutions

The number of digital health solutions is constantly growing. In 2017, there were 325,000 mobile health apps available worldwide, representing a 25% year-on-year increase.[44] Users may very likely be overwhelmed by the sheer number of apps. Which digital health solutions actually work? Which ones lead to positive patient outcomes? The WHO is currently applying its classification of digital health interventions framework to synthesize evidence in the literature, seeking to identify which specific digital interventions have demonstrated a positive impact for healthcare systems. The resulting WHO guidelines will be released in 2018.[45]

In Canada, the cumulative benefits of investing in digital health between 2007 and 2015 were estimated at around CAD$16 billion

Due to the broad range of functionalities, measuring the impact of digital health solutions is not an easy task. However, WHO is focused on determining which functionalities have proven their value. Solutions that are directly patient-facing (e.g., disease management apps) can be assessed on the basis of clinical outcomes such as lower blood glucose levels or even "hard" impact measures such as fewer emergency visits.

By contrast, assessments of solutions operating at the level of the healthcare provider or health system itself (e.g., health management information systems, training or supply-chain management solutions) may need to examine secondary, "proxy" impact measures such as planning and process efficiencies or improvements in access to healthcare services. A nationwide study seeking to assess the impact of digital health systems was recently conducted in Canada; here, the cumulative benefits of investing in digital health in Canada between 2007 and 2015 were estimated at around CAD$16 billion.[46]

A number of digital health programs that have shown demonstrable benefits with regard to NCD prevention and management, while also being deployed at a relatively large scale, are shown in Table 1.

Demonstrating the impact of a digital health solution is important for convincing health systems, providers and patients to adopt it. Solutions such as remote teleconsultations can disrupt the traditional interactions between physicians and patients, and stakeholders may be reluctant to use them unless the right incentives and a positive effect on health outcomes can be proven. In addition, impact figures can play a key role in convincing governments and payers to finance or, respectively, reimburse digital health innovations.

There are still some limitations in demonstrating the impact of digital health solutions. The distinction between mobile apps that enhance general wellness and true medical devices that bring clinical benefits to patients has only recently come into focus.[47] Moreover, there is a general lack of methodological rigor in digital health solution evaluations.[48, 49, 50]

More examples are needed that demonstrate both significant impact and a sound approach to evaluation. Seeking to address this challenge, the WHO recently developed a framework for countries, health managers and providers to properly measure and evaluate the efficacy and usefulness of digital health solutions.[51]

Table 1 **Digital programs demonstrating impact in NCD prevention and management**

PROGRAMS	SOLUTION	IMPACT
WellDoc – BlueStar Diabetes Management App[52, 53] **(United States)**	**Diabetes management** – Mobile prescription therapy system for diabetes that provides users with access to real-time individualized coaching, educational tools, medication regimen support and health records that can be shared with providers to inform clinical decision-making.	➔ 1.2% or greater decline of HbA1c levels in users compared to patients undergoing usual care ➔ 58% reduction in emergency room visits ➔ Average saving of US$254 to US$271 per user per month.
Discovery – Vitality Health App[54, 55] **(South Africa and other countries)**	**Reduce risk factors** – App-based activity tracking and rewards program used by insurance companies to incentivize members to lead healthier lifestyles. Users can earn rewards ranging from reduced premiums to gift cards and discounted flights by meeting activity goals and making healthy food choices.	➔ Admission rates to the hospital were 7.4% lower for cardiovascular diseases, 13.2% lower for cancers, and 20.7% lower for endocrine and metabolic diseases ➔ Deployed by five of world's leading insurers ➔ 6 million individual users
Be He@lthy, Be Mobile (BHBM) – India mTobacco Cessation[56, 57] **(India)**	**Smoking cessation** – As the world's largest mobile-based smoking cessation program, India's mTobaccoCessation is helping people quit tobacco use through interactive support delivered by mobile phones.	➔ 7.2% six-months quit rate ➔ 2.1M+ users enrolled as of Aug 2017
Novartis Foundation – Ghana Telemedicine[58] **(Ghana)**	**Telemedicine** – The Ghana Telemedicine program connects community health workers with specialists via a 24-hour teleconsultation center.	➔ Reached 6 million patients ➔ 31% unnecessary referrals avoided through teleconsultation ($31 USD saved per avoided referral), as more than half of all teleconsultations could be resolved directly by phone
Carlos Slim Foundation – CASALUD[59, 60, 61] **(Mexico)**	**NCD prevention and disease management program** – Proactive prevention of NCD risk factors using MIDOTM and disease management through SIC (an NCD information system). In addition, mobile technologies are used to provide online training to health professionals and community workers, monitor the supply of medicines and lab tests and empower patients.	➔ Implementation as a national policy, with outreach to +12,000 primary care clinics. ➔ 1M+ individuals screened with MIDO ➔ 1.8M+ patients with daily updates in the NCDs Integrated Dashboard ➔ Increased A1c testing in diabetic patients throughout participating clinics in Mexico from 10% in 2014 to 54.8% in 2018
AccuHealth[62] **(Chile)**	**NCD risk prediction** – Wearable sensors linked to a smart monitoring device that connects to the AccuHealth virtual hospital remote monitoring center. Data mining and predictive modeling anticipate any health deterioration that would require an ER visit or hospitalization.	➔ Monitored over 15,000 patients ➔ 42% decrease in emergency room visits.
AxisMed[63] **(Brazil)**	**Remote monitoring solution** – Tracking and transmission of biometric data with personal device (e.g., blood glucose levels and blood pressure) from chronic patients to medical professionals who oversee their treatment plans.	➔ Over 80% of patients monitored have adhered to their treatment plan ➔ Reduced hospital emergency ward visits by two-thirds.

Sustainable digital health solutions

If digital health solutions are to achieve positive impact with regard to reducing the incidence of NCDs and helping LMICs attain universal health coverage, they must be sustainable. Sustainability should be regarded as having several key aspects:

- **Integration capability:** Digital health solutions should be implemented in a way that integrates easily with:
  - Existing clinical processes and workflows
  - The health system's general structure and challenges, as well as associated needs (e.g., tiered healthcare providers, reimbursement system)
  - The current or planned technology infrastructure, thus ensuring interoperability
  - Other national technology systems, such as a citizen ID program or health information/monitoring system

- **Scalability:** If they are to play a role in achieving UHC, digital health solutions should be able to reach all targeted users, whether on a national or regional level. Digital solutions that are simple to use, leverage a country's existing digital infrastructure and make use of existing user relationships of any kind are most easily scaled.

- **Financially viability:** As budgets are often constrained, new financing models that share benefits and risks between ecosystem partners should be tested. In parallel, cost-containment measures should be applied. Users should be protected against financial hardship through the use of an insurance structure.



(c) Andre Malerba / Novartis Foundation



Building Blocks for Sustainable Digital Health



2

There is much policymakers can do to create favorable environments for sustainable digital health, and they can learn from and with others on the same journey. Six building blocks can help countries realize the promise of digital health and transform access to appropriate, effective NCD care.



Governments, policymakers, product developers and other stakeholders around the world are seeking scalable and financially viable digital health solutions that can be integrated into national health systems. We have identified six primary areas – here called "building blocks" – in which focused activity on the part of governments and policymakers can facilitate this process:

- They can articulate a vision and set direction through national digital health **strategies** backed by strong political **leadership** and multi-stakeholder **governance**
- They can put **regulations and policies** in place that protect patient safety and privacy, while allowing innovation to continue apace
- They can increase connectivity among people and systems by supporting **digital communication infrastructure and rationalizing investments by building common digital health platforms**
- They can ensure data can be shared and leveraged to manage care better by establishing **interoperability** frameworks
- They can foster **partnerships** among the diverse health system stakeholders for shared and complimentary expertise, investments and risks
- And they can explore different **financing models** in the context of new business models to make it all possible

These six building blocks were inspired from the seven components of WHO's eHealth Strategy Toolkit, as illustrated in Figure 5 below, with each playing a specific role in meeting the needs of the various stakeholders in the digital health ecosystem, from patients to health providers to governments and thereby realizing the promise of digital health.

Figure 5 **Six building blocks for sustainable digital health solutions**



The need for customer centricity and human-centered design is acknowledged throughout this report as a prerequisite for high adoption rates and the success of digital health solutions. However, as human-centered design is not specific to digital health, it is not discussed in further detail in this report. Thus, we do not include a building block that corresponds directly to the WHO Toolkit's "Services and Applications" component. Further information on human-centered design can be found at www.designkit.org (free design toolkit by IDEO).

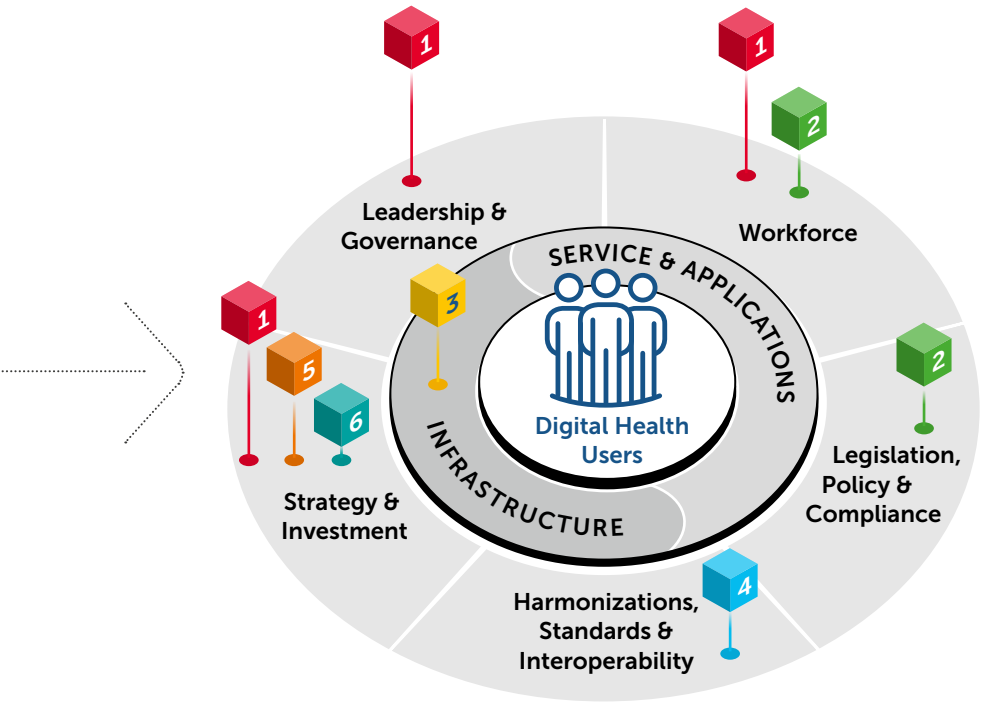
The six building blocks for sustainable digital health are described in greater detail in the following sections. After an examination of each area, the report offers practical recommendations for using digital health systems to strengthen NCD management in low-income settings, and to help attain UHC.

How to read the following sections

The following sections describe how governments and policymakers can create a favorable environment conducive to embedding sustainable digital health solutions. Many countries have already launched their journey toward digital health, generating many lessons to be learned from their experience.

The targeted audience of this report can expect to find:

- Observations about overall trends in health systems globally
- Examples and good practices from both HICs and LMICs that help others understand more fully what works at regional, national or cross-country levels
- Tools and guides from international organizations
- Actionable recommendations on how to get started and further improve existing initiatives



Source: Components from WHO, National eHealth Strategy Toolkit, 2012
Visualization adjusted from Digital REACH Initiative Roadmap, 2017 (inspired by PATH and Vital Wave)

2.1

BUILDING BLOCK 1

Digital Health Strategy, Leadership & Governance

Strategy, leadership and intersectoral collaboration are key to realizing the full potential of digital health so that it responds to national health priorities and drives progress toward universal health coverage.

For policymakers, a vital first step is to set a digital health strategy that lays out a compelling vision and provides clear direction to health system stakeholders.

Strong leadership, intersectoral collaboration between ICT and health and clear governance are then essential for effective implementation of a national digital health strategy.



(c) GSMA

→ KEY TAKEAWAYS

As outlined in the 2017 report of the Broadband Commission Working Group on Digital Health, strategy, leadership, and intersectoral collaboration between ICT and health are key to realizing the full potential of digital health so that it responds to national health priorities and drives progress toward universal health coverage

For policymakers, a vital first step is to set a digital health strategy that lays out a compelling vision and provides clear direction to all stakeholders in the health system

- A digital health strategy also provides a supportive, predictable operating environment for solution providers. Some 120 countries already have digital health strategies in place, from Brazil to Turkey to India.
- Countries that don't have one or want to improve it can develop a vision and consider how their capabilities need to evolve in order to achieve it with digital health.
- Assessment frameworks and guidelines have been developed to support different aspects of a digital health strategy by organizations such as the International Telecommunications Union (ITU), the World Health Organization (WHO), and Intel.

Strong leadership, intersectoral collaboration and clear governance are then essential for effective implementation of a national digital health strategy

- Through its in-depth country case studies, the 2017 report of the Broadband Commission Working Group on Digital Health demonstrated that countries that had been successful in realizing the potential of digital health fulfilled three pre-requisites:
  - Sustained senior government leadership and committed financing
  - Effective governance mechanisms
  - National ICT framework that facilitates alignment between health and ICT sectors
- Last but not least, a well-defined monitoring process to track implementation, impact and cost-effectiveness of a national digital health system clearly helps transform digitized health systems into "learning" systems that always improve according to the needs of the people it serves.

2.1

Why is this relevant to digital health sustainability?

Developing a national digital health strategy is a key element in creating a digital health ecosystem able to address a country's top-priority health needs. This strategy should include a policy framework and harmonized set of goals, and should clearly define necessary future investments in health-related digital technology. This will allow local resource allocations to be planned in advance. The ITU-WHO National eHealth Strategy toolkit[64] has been used by many countries as a reference guide for eHealth strategy development.

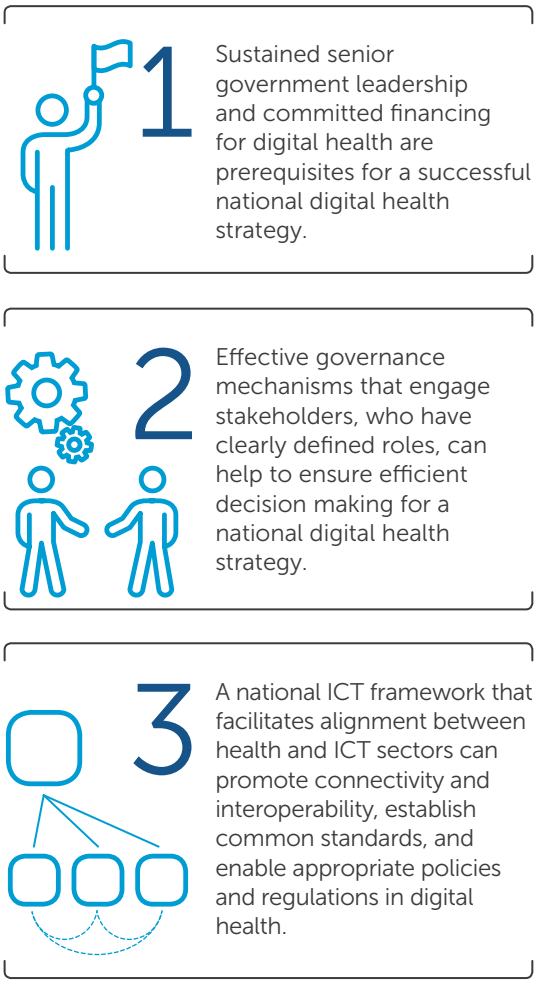
A digital health strategy helps with coordinating and integrating digital health solutions

Before a national digital health strategy has been implemented, it may prove difficult to coordinate digital health solutions at the national level. This can result in deployment of a myriad of digital solutions that are not interoperable and only address siloed health problems. Such a lack of harmonization can have negative effects on health system performance, both in normal operations and in emergency situations. One well-known example of such a situation was the Ebola outbreak in West Africa in 2014; here, the absence of interoperable data systems within the countries affected created an unclear and asynchronous information picture, significantly hampering outbreak management.[65, 66]

Siloed health data – that is, the presence of multiple data stores referencing similar issues that, for one reason or another, cannot be compared or integrated with one another – makes it difficult for countries to define and implement coordinated responses to NCD-related problems. Various approaches have been taken to overcome this problem; for example, as one means of reducing the fragmentation of health initiatives on a national level, Uganda implemented an eHealth moratorium to prevent the proliferation of uncoordinated digital health pilots.[67]

The February 2017 report published by the Broadband Commission Working Group on Digital Health identifies three key success factors that influence a country's ability to realize the full potential of digital health: 1) visionary leadership that commits sustained financing to digital health; 2) effective intersectoral collaboration between the health, ICT and finance sectors; and 3) the presence of a national ICT framework that promotes interoperability, sets common standards, and complements digital health policies and regulations (Figure 6).[68]

Figure 6 **Key elements for implementing a national digital health strategy**



Health authorities need to be proactive in driving the implementation of digital health strategies that address the growing NCD burden and respond to top-priority national health problems. These strategies should be viewed as an integral part of the country's healthcare information and delivery systems. This section outlines key lessons learned and examples of successful leadership and governance initiatives in the area of digital health in low-income settings.

Digital health strategies

The scope and focus of national health strategies will differ depending on the government's ambitions. For example, is the goal to achieve universal healthcare? Tackle the NCD burden? Or simply to integrate digital technology more effectively into the country's health system? A national health strategy should be specific enough that it addresses the population's highest-priority health needs, and should additionally identify existing gaps in the health system. The strategy then needs to be translated into an action plan, with clear, measurable targets (e.g., "digitization of all patient records in two years").

As of mid-2018, 120 countries have developed strategies in the digital health, telehealth or eHealth fields.[69] In some cases, these strategies have been successfully implemented at the national level as primary healthcare initiatives addressing NCDs (see "Examples of national NCD and digital health strategies and projects" on page 38).



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2.1

Examples of national NCD and digital health strategies and projects

(1) PHC and UHC strategy:

Brazil's Family Health initiative

Brazil's renewed 1988 constitution identified healthcare as a right. The Estratégia de Saúde da Família, or Family Health Strategy (FHS), was established in 1994 to support this policy transformation by improving the country's integrated primary healthcare system. Community health workers (CHWs) are at the core of the FHS program and currently serve 67% of Brazil's population. Multidisciplinary teams of CHWs, nurses and physicians register families, monitor patients' adherence to diabetes- and hypertension-drug regimens, and run health education sessions.[70] CHWs are equipped with mobile phones and tablet computers to enable remote diagnoses and real-time communication with primary healthcare clinics. A national program intended to expand access to related technological tools is being developed.[71] The FHS program has shown positive results, with a 13% reduction of chronic disease hospitalization rates over an eight-year study period.[72] While the PHC strategy itself played a key role in this outcome, continued commitment from policymakers was also crucial in order to prevent cuts in associated federal allocations, thereby securing the resources needed to carry out the country's long-term health strategy.[73]

(2) NCD Strategy:

Mexico's CASALUD model and Salud Movil

In 2013, Mexico's president launched a National Strategy for the Prevention and Control of Overweight, Obesity and Diabetes, with the goal of reversing the rise in NCD incidence, and particularly of type 2 diabetes.[74, 75]

The Carlos Slim Foundation's CASALUD model was incorporated into the national strategy in October 2013. Under the leadership of the Ministry of Health (MoH), three digital health programs were launched:

A) MIDO, for the detection of NCDs. This operates in 27 states, and more than 1 million adults have been screened

B) An NCD information system (SIC). This operates in 12,000+ primary care clinics as Mexico's official NCD information system, holding data on more than 1.8 million patients.[76] Using information from SIC, Mexico's MoH coordinated a centralized procurement of A1c blood-glucose tests, ultimately providing 54.8% of the country's diabetic patients with such tests, up from 10% in 2014.

C) Online training of health professionals and health workers with continuing medical education credits and academic endorsement. To date, 17,000+ health professionals have been trained.

Another initiative driven by the national strategy is Salud Movil, operated by the Fundación Mexicana para la Salud A.C. (FunSalud) and led by the Ministry of

Health's General Directorate of Health Promotion. This initiative facilitates the exchange of personalized SMS text messages between patients and health professionals, with the aim of helping patients better manage their diseases. The program includes preventive messages intended to motivate changes in diet, physical activity and smoking habits. The proof of concept included 30 health centers in seven states; by March 2018 (starting in 2016), the results indicated improvements of between 67% and 86% in the prevention of lower-limb ulcers in diabetes patients, as well as an improvement of 46% to 96% with regard to increased awareness of complications associated with type 2 diabetes.[77, 78] The MoH is now using these impact figures to develop the National Program of Digital Health, which addresses NCD risk factors such as hypertension.[79]

(3) Strategy for NCD care and UHC achievement:

India's Ayushman Bharat Program ("Modicare")

The national health policy adopted by India in 2017 seeks to address the rise in NCDs and reduce poverty-inducing healthcare spending. The new policy aims to achieve universal healthcare, including preventive care and emphasizes the importance of SDGs.[80] In order to meet the policy's goals, the government launched the Ayushman Bharat program, or "Modicare," in 2018. This includes two core initiatives: 1) increasing the presence of community health and wellness centers, thus enhancing access to and the affordability of primary healthcare, and 2) establishing the world's largest government-funded insurance program in order to increase coverage for the country's most vulnerable residents, which comprise as much as 40% of the national population.[81, 82] Other components of the initiative emphasize expanding access to healthcare through technology, as well as integration into the Aadhar biometrics program, which establishes unique digital identities for every citizen, in order to unambiguously identify people seeking care.[83]

(4) Health IT strategy:

Turkey's Healthcare Transformation Program[84]

In 2003, MoH launched the ambitious "Healthcare Transformation Program (HTP)," an initiative to restructure delivery of healthcare and to increase access of citizens to these services.

The implementation of the program is in progress. Actions were initially taken at the primary care level and can now can be found at all hospitals in Turkey:

- Keeping patient records in a structured manner and using EHR software that has the capability to transfer data to MoH.
- Mandating hospitals to use a hospital information system in order to increase their management efficiency and quality of medical services delivered.
- Merging different reimbursement systems used by different social security systems.

The MoH also established a Healthcare Informatics Department to design the National Health Information System (NHIS). NHIS receives and stores electronic health records of all patients, which is now accessible to citizens on a mobile portal. Health record collection starts at the prenatal stage and continues into all stages of that person's life. The longitudinal patient records are especially significant in the context of lifelong NCDs.

2.1

Leadership and governance in digital health

National-level leadership is vital for ensuring the sustainability of a digital health solution, as it can drive plans forward throughout the solution's lifecycle. Buy-in from policymakers should be sought so that they can communicate the value of the selected technological solutions. Good governance techniques will in turn allow the government to coordinate the various digital solutions being implemented. For example, managers should track deliveries and compare them against planned milestones, and should collect sufficient data to demonstrate impact and cost-effectiveness.

Commitment from top political figures

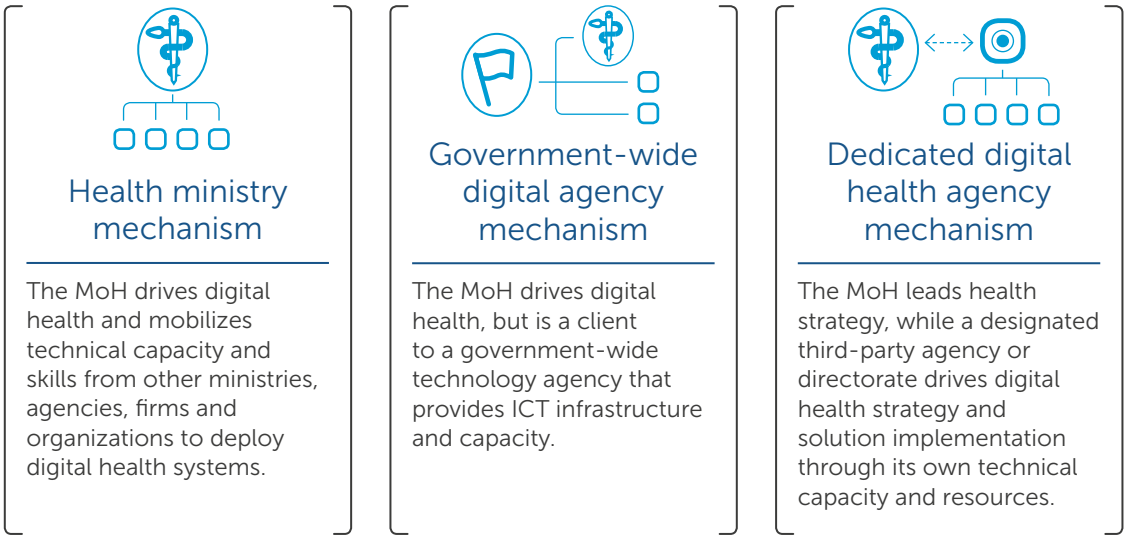
Political leaders should commit to establishing a digital health vision, developing a digital health strategy and ensuring execution of that strategy. For example, Rwandan President Paul Kagame's leadership was crucial in initiating ICT reforms that led to the development of a national ICT infrastructure and the establishment of data standards. President Kagame also oversaw the creation of the "Vision 2020" document, a roadmap for the country's social and economic transformation that envisions the achievement of universal healthcare using a community-based health insurance mechanism.[85]

Leadership by other high-level stakeholders is also important, even beyond the health ministry's IT or data-initiative head. When a minister or permanent secretary takes charge, the digital health agenda can advance faster.[86] For example, in Tanzania, the Ministry of Health and permanent secretary are strong advocates for sustainable, system-wide digital transformation. This resulted in a revision of health policies and health workforce training curriculum to incorporate digital health and data use.[87]

Governance

Governance refers to the way that intragovernmental and intersectoral collaboration is organized by entities that advise, coordinate, support, regulate, monitor and implement a digital health strategy.[88]

Figure 7 **Three governance models for digital health**



The February 2017 report released by the Broadband Commission Working Group on Digital Health presents three possible governance mechanisms for the digital health field (Figure 7). Each governance mechanism offers advantages and drawbacks, and should be adapted to the local environment. The case studies from the 2017 report also showed that many countries shift between governance mechanisms as needed. Examples of countries using each structure are given in the 2017 report.[89]

Overall, research into this area underscores the importance of intersectoral collaboration in defining and executing the digital health strategy. Within the government, this should involve both the health and ICT authorities (typically the Ministry of Communication and an eGovernment agency), but also any other ministries that may be relevant (e.g., Education, Finance, Social Welfare). The eGovernment agency's involvement is particularly important to ensure that digital health solutions are connected to the country's other public services.

Governance mechanisms and working groups are also key to facilitating coordination with donors and development banks, and across digital health solutions providers such as private-sector companies and NGOs. Finally, health insurers and other financers should be included in the governance structure in order to ensure that the national strategy will receive sustained and committed financing.

Research underscores the importance of intersectoral collaboration in defining and executing the digital health strategy

Tanzania's eHealth Steering Committee and Governance Unit

As part of their eHealth strategy, Tanzania established the eHealth Steering Committee that is co-chaired by Permanent Secretaries from Ministry of Health and Ministry of Local Government. The steering committee convenes bi-annually and brings leaders from Ministry of Health and its institutions, eGovernment Agency, Ministry of Communications and Technology, local government, private hospitals, donor agencies and other implementing partners together. This committee oversees the implementation of digital health and makes policy decisions. The steering committee has a team called Program Management which advises the steering committee on technical matters, such as designing procurement requirements for software.

In addition, a high-level Governance Unit, composed of executive sponsors from the Ministry and the donor community, meets quarterly to review the progress made in Tanzania's Digital Health Investment Road Map.[90] Investment recommendations were developed by the Ministry of Health, Community Development, Gender, Elderly, and Children, and the President's Office of Regional and Local Government.[91]

Malawi's Health Equity Network

In Malawi, the government also involves civil society when making decisions on health budgeting and policies. Some 50 civil society organizations have joined the Malawi Health Equity Network, an independent organization which lobbies and advocates for equitable access to healthcare.[92]

2.1

Using digital global goods to coordinate donor activities

As LMICs start to advance their health and IT agendas, it is crucial that donors align their investments with national digital health strategies to reduce fragmentation, duplication and lack of interoperability. Entities within the digital health ecosystem have started to realize the importance of coordinating donor activities; in response, a donor-driven digital health coordination initiative called the Digital Investment Principles was recently launched. These principles identify priorities for donors associated with aligning activities with countries' national digital health plans, and call for the utilization of digital global goods – a term that in this context refers to reusable, adaptable technology solutions that have been proven to work.[93]

Digital Square, a partnership between leading digital health experts from more than 30 organizations and countries, takes an innovative approach to co-investing in digital health solutions in emerging countries. Digital Square pools funding from various donors and directs the coordinated investments into global goods that are assessed by a peer review committee and a governing board. Assessment criteria consider whether these global goods 1) can be deployed at a significant scale, 2) can be used across multiple countries, 3) can receive funding from multiple sources, 4) are interoperable with existing standards and systems, 5) are (usually) free and open-source, and 6) already benefit from a strong community of support.[94]

An example of a global good supported by Digital Square is the Digital Health Atlas for Inventories and Routine Registration of Digital Health Investments, a global technology registry that takes the form of a web-based platform. Coordinated by WHO, it provides tools that governments, implementers, agencies and donors can use to inventory and curate global and national-level digital health tools and implementations. Furthermore, it enables users to provide detailed project descriptions identifying goals, functionalities and shared common infrastructure assets, a feature critical for mapping, monitoring and fostering coordinated digital health investments, and for facilitating the planning necessary to meet government health goals.[95]

Monitoring and evaluation

A monitoring and evaluation (M&E) framework is needed to track digital health programs in a consistent and end-to-end manner, thus providing visibility into the implementation of the digital health strategy. Impact and effectiveness data is also required to facilitate policy decisions and validate requests for further investment and resource allocation.[96] According to WHO, only 7% of digital health initiatives in LMICs have been evaluated.[97] WHO's "Monitoring & Evaluating Digital Health Interventions" guidelines, published in 2016, can be used as a reference in this project.[98] Two examples of nationwide M&E initiatives are described below.

Canada and Mexico – Examples of successful M&E initiatives

Canada

Canada Health Infoway, an independent non-profit organization, was created to help Canada accelerate the development of digital health solutions aimed at improving health-service delivery. An analysis of the project indicated that the cumulative benefits of investing in digital health in Canada between 2007 and 2015 totaled CAD$16 billion.[99]

This review sought to measure the impact of various digital health tools for different stakeholders. For example, the benefits of electronic medical records (EMR) were measured by collecting the number of Canadian physicians who reported using an EMR to document patient information. The benefits of telehealth solutions were assessed on the basis of the expenses avoided by consumers using the services, such as travel avoided through the substitution of virtual consultation for an in-person visit to an urban center. Capturing the quantitative benefits of investing in digital health was crucial for demonstrating accountability to funders, and for promoting widespread adoption by clinicians and other healthcare professionals. Future pan-Canadian assessments of digital health benefits will also examine implementation of an interoperable EHR system that has been used in the country for several years.[100]

Mexico

As part of its National Strategy for the Prevention and Control of Overweight, Obesity, and Diabetes, the Mexican Ministry of Health partnered with the Carlos Slim Foundation (FCS) to implement the CASALUD model in PHCs across the country.[101] CASALUD uses performance metrics such as process measures and clinical outcomes to report on its impact. These metrics are displayed on an open online integrated dashboard.[102] The dashboard, which updates data daily in real-time for over 12,000 primary care clinics and 1.8 million patients, collates and displays data at various levels, ranging from individual health facilities to regional, state and national levels.[103] This allows the government to monitor local policy implementations and progress toward national strategy health goals. Examples of metrics monitored include the percentage of total population screened, treatment consistencies, and drug or lab tests stock-out rates.39 Clinical outcomes monitor clinical factors like A1c levels, blood pressure in hypertension patients, and numbers of patients diagnosed with diseases.[104]

National ICT and digital health frameworks

ICT and digital health assessment

An ICT framework is associated with a national broadband plan or a larger national ICT strategy, which are often driven by a ministry of communication and eGovt agency. By contrast, digital health frameworks are linked to digital health strategies that are usually the mandate of a health ministry. In order to ensure maximum impact, a digital health strategy should be developed in alignment and coordination with a national ICT and broadband strategy.

For LMICs lacking an implemented national digital health strategy or for those planning to implement a technology solution within their health system, defining a vision for the country and assessing existing technological capabilities are a good starting point. Once a vision is defined and extant capacities have been identified, a government can (1) develop a holistic, technology-driven, integrated digital health system, and (2) articulate how capabilities in the digital health strategy will need to evolve.

2.1

ICT and digital health assessment

Intel developed the following framework for assessing an existing digital infrastructure that has been applied to two recent situational analyses conducted in Mongolia and Senegal as part of plans to implement an integrated digital health solution addressing cardiovascular and other non-communicable diseases in both countries.

Health information technology systems and hardware:

- What are the existing systems and what is the level of integration (i.e., interoperability) among these systems in a country or region?
- What are the computing capabilities of these existing systems? As imaging and other data-driven applications are introduced, will the systems have the resources to support them?
- If healthcare organizations have their own core health IT systems, what security and maintenance procedures are in place?
- What database management systems are in place and what is the data storage capacity? Is cloud hosting possible?
- Can the current systems address monitoring and an evaluation of metrics that provide insight and feedback around the objectives of the digital health strategy?

Internet connectivity and telecom network infrastructure:

- Does a country have high penetration of 2G, 3G or 4G and is it considered reliable?
- Does a country have national 5G, IoT, Artificial Intelligent strategies for smart digital health services?
- What are the bandwidth capabilities of these existing networks? Is the bandwidth at network level able to cope with the growing demand (also NOT from health services, e.g., video-chats, streaming on smartphones)?
- At the organizational level (e.g., primary care clinics) does the organization have at least asymmetric digital subscriber line connectivity?

Delivery system considerations:

- Does a country use digital medical records, patient registries or national digital IDs to help with digital record keeping?
- Is the drug supply chain adequate and automated?
- Are algorithms for screening and treating patients automated and in place for addressing NCDs?
- To what extent are devices such as cell phones, smart phones, and computers used (i.e., penetration among certain populations or regions), and could they be leveraged as part of a digital health strategy (e.g., used for reminders, tracking, monitoring)?

Policy-level considerations:

- What are the current MoH practices around budgets and reimbursement for primary care services and for digital health?
- Is there a government agency responsible for implementing IT and informatics to support the digital health strategy?
- What personal data policies and laws exist that are specific to data processing and use of data?
- Is there adequate and continuous training for healthcare professionals related to health IT and digital health?

The **ITU-WHO National eHealth Strategy toolkit**[105] can also provide guidance on how to gather information on a country's eHealth environment. **The Asia eHealth Information Network (AeHIN)** has also developed a framework for identifying and addressing gaps in governance, architecture, program management, standards and interoperability that is helpful in assessing digital health implementation. This network approach for supporting national and regional digital health programs will be used to identify priorities in digital health implementation processes across the AeHIN member countries in Asia.[106]

Defining the digital health strategy

Once capacities, needs and priorities have been identified, governments can use technology and health assessment results to define their digital health strategy and action plan, beginning with planning for small initial steps (quick wins) and then designing a long-term roadmap.

The development of a digital health strategy can be done in three phases. In the first phase, a country can attempt to take advantage of what already exists. The core technology includes connectivity, hosting capabilities as well as existing applications and devices that can be integrated into a digital health system. This includes, for example, PCs that allow personnel to connect and interact and mobile devices that physicians or individuals already use. The second phase can involve targeting the development of a health IT platform including, for example, information systems and EHRs. Decision-making in the third phase can be driven by optimization needs. At this point, additional infrastructure can be built only if it makes sense from a cost standpoint.

Digital skills training

Having a workforce trained in digital skills is essential to defining and realizing a digital health strategy. ICT and digital health technology competencies are needed among both users of digital health services and those who work in digital health to have (1) basic operational skills (e.g., connecting a mobile phone to the internet, making a "missed call" to sign up to a public health program, using an interactive voice response system to pay a health insurance premium), (2) generic functional skills (e.g., how to enter patient screening data into the system at the health center or how to share health data with other health providers), and (3) more specialized, adaptive skills (e.g., how to program the software of a medical device, run analytics for health data or how to implement a health information exchange solution).[107]

The ITU and WHO Regional Office for Africa have recognized the importance of providing digital skills training in transforming public health. As part of their efforts to prepare a new generation of African digital health leaders, the ITU and WHO just planned two regional training workshops for both Francophone and Anglophone Africa. The trainings come with continuous capacity development and mentoring programs to upskill these future leaders at ministries of health or ICT.[108]

2.1

Practical recommendations

In conclusion, strong government leadership is needed to establish a digital health vision and then effectively coordinate strategy development and deployment. The implementation of digital health initiatives should be overseen by a robust governance body involving cross-sector stakeholders. The following eight recommendations are practicable for most LMICs:

1. **Define a digital health strategy that supports the transformation of NCD management:** Assess the health needs of a country and consider how digital health solutions can address them. Use established frameworks for maturity assessment, such as the questionnaire from this report or additional toolkits such as the Health Information Systems Interoperability Maturity Toolkit.[109] Define a vision and roadmap that feature clear, measurable milestones. For countries just beginning their digital health journey, taking small steps to address initial gaps while planning for long-term goals are important.

   The strategy should account for:

   - Long-term planning, as many NCDs require chronic management
   - Patient centricity, to address co-morbidities (e.g., obesity, diabetes, heart diseases) and the ability to follow a patient across different disease areas
   - Patient education and empowerment that involves how to manage the disease themselves, providing the tools for self-monitoring, changing behavior that exacerbates morbidity, and demonstrates how adhering to treatment results in better outcomes
   - Countries can consider investing in digital global goods (e.g., open source solutions such as DHIS2, OpenMRS, OpenLMIS) as the basis for their technology solutions in order to avoid wasting resources on re-inventing already-present solutions and leverage economies of scale for development.

2. **Enact strong high-level government leadership:** Without high-level government endorsement and committed multi-year financing, the road to implementation may prove arduous. The appointment of a visible, high-level digital health champion (ideally the president or prime minister) who can align efforts across different sectors will help stress the importance of a digital health strategy. In addition, appointing other high-level government officials (e.g., a permanent secretary) can help advance a digital health agenda even further.

3. **Align with stakeholders both within and outside the government:** Deploying a national digital health strategy is a complex and costly undertaking, so joint work from various ministries or government bodies is essential. The digital health champions should be empowered to connect with other stakeholders within the government, especially with the Ministry of Health, Ministry of Communication and e-government agency as well as those external to the government such as donors, the private sector and NGOs from health, ICT and adjacent sectors (e.g., banking, food), including them in government-based working groups.

4. **Set up a governance structure:** Establish an intersectoral governance system with an action-oriented taskforce that advocates, advises, builds the capacity and monitors digital health initiatives. Refer to three possible governance structures from the previous Broadband Commission Working Group report. Align the governance structure with the objectives of the digital health strategy.

5. **Stimulate innovation:** Consider setting up an investment fund for digital health and attract other sources of funding that can complement MoH resources. Define the role of government and other stakeholders in enabling innovation and provide best practice examples.

6. **Establish a robust monitoring and evaluation framework that draws on existing frameworks such as the WHO's Guidance on Monitoring & Evaluating Digital Health Interventions.[110] Also worth bearing in mind when establishing such a framework:**

   - Keep key performance indicators simple, fit-for-purpose, easy to access and measure, and consistent with available capabilities and infrastructure
   - Harmonize key performance indicator (KPI) frameworks across digital health initiatives to allow comparison
   - Ensure KPIs consider the impact from both the private sector (e.g., revenues and cost efficiencies) and the public sector (e.g., social impact)
   - Listen to patients with NCDs to ensure that KPIs are also linked to patient outcomes
   - Consider partnering with academics for developing the monitoring and evaluation framework
   - Ensure timely and appropriate decision-making based on monitoring and evaluation

7. **Invest in training and knowledge sharing:** Collaborate with universities and other learning organizations to define digital health skills required, identify gaps in the current educational offer, promote the creation or upgrade of training opportunities for different user segments such as prospective college students, workforce and managers. Training opportunities can include digital health degrees, digital modules in medical schools, executive education or reaching a consensus on certification procedures. It is also important to ensure that government officials and managers working on digital health strategy are well-trained.

   For knowledge sharing, create forums to share digital solution success stories and drive greater understanding of the value of digital health solutions or embed within existing health forums to increase awareness of digital health's potential and promote knowledge-sharing (e.g., SDG platforms). Collaborate with large regional organizations such as WHO to collect best practices.



BUILDING BLOCK 2

Regulations and Policies

Regulation is needed to protect patient safety and privacy – while allowing innovation to continue to unfold. This fosters trust in digital health solutions and facilitates their adoption.

Policymakers can focus on three categories of regulation that are critical to realizing the promise of digital health for universal health coverage and effective NCD care: data management regulation, device regulation and delivery of care regulation.

Countries that are just beginning their regulatory journeys can learn from and "leapfrog" the experiences of both HICs and LMICs.



(c) PATH/Will Boase

→ KEY TAKEAWAYS

Regulation is needed to protect patient safety and privacy, while allowing innovation to continue to unfold. This fosters trust in digital health solutions and facilitates their adoption

Specifically, three categories of regulation can be established:

First, data management regulation protects the privacy and security of patients' health data

- → Data security and privacy are particularly hot topics right now, as digital health solutions begin to allow large amounts of patient data to be collected and shared.
- → Data-protection measures can build trust in the usage of personal health data among stakeholders.
- → The core regulatory challenge is to achieve high standards of data protection and quality without stifling innovation.
- → For example, the use of cloud services has immense potential to fulfill all required data-protection measures and meet low- and middle-income countries' (LMICs) needs for flexibility, scalability and cost-effectiveness.

Second, device regulation ensures that only safe, cost-effective, high-quality devices are approved for use

- → A general principle is that devices need to be regulated in proportion to the risk they pose to the patient.
- → Established approval processes in high income countries (HICs) can be re-used or adapted by LMICs to bridge existing regulatory gaps and provide innovators with the guidance they need to understand how regulators will classify their products.

Third, regulation of the delivery of care ensures that medical practices complemented by digital technology are safe and high-quality

- → Regulators can prioritize applications such as:
  - Those improving prevention or early detection of NCDs
  - Those supporting task shifting of care practices to less-skilled health workers
  - Telehealth or telemedicine, allowing providers to centralize expertise and perform consultations and monitor NCD patients remotely
  - Prescription of medicines, given that patients with chronic conditions regularly need refills
- → Digital health regulations and policies differ greatly among countries and are often not comprehensive.
- → Lessons can be learned from HICs. At the same time, great examples from LMICs could be used in HICs.

2.2

Why is this relevant to digital health sustainability?

The rapid innovation in digital health requires appropriate policies and regulations to be in place to ensure that patients are treated ethically in terms of safety and efficacy, data governance and security, and the reuse of patient data to enable health-system improvement. In addition, given that conventional facility-based healthcare in LMICs will be insufficient to address NCDs, new ways of delivering healthcare for patients with such diseases are urgently needed. Digital health programs will certainly help facilitate this goal. Policies should therefore support governmental ambitions to address NCDs using digital health tools in order to accelerate UHC achievement.

Defining appropriate regulations for digital health has been challenging both in HICs and LMICs, because digital health is a relatively new field. Traditionally, the collection of NCD data occurred in highly regulated clinical settings, and clinical data were typically stored in regulated public health registries at hospitals or in physicians' archives. The introduction of digital health systems changes this picture, as patient data can be accessed online and can be stored in multiple locations. In addition, NCD data can nowadays be collected using ordinary smartphones and tablets, rather than requiring the traditional approved medical devices found only in clinical settings.[111] This complexity is further amplified by the diversity of digital health solutions, which range from "wellness" apps to health-worker training platforms and clinical decision-support systems. This means that different regulations come into play in different circumstances. In LMICs, there is often limited regulatory oversight of digital health solutions, resulting in highly variable quality, ethical and safety standards.[112]

This new set of circumstances can be addressed using three types of regulations (see Figure 8), all of which need to be in place to manage the lifecycle of digital health solutions from creation to delivery and scaling[113] (please note that reimbursement is addressed in Building Block 6):

Figure 8 **Three types of regulations for digital health**

1

Data-management including data-protection and quality regulations, standards and governance mechanisms

- collectively ensure the safe and ethical collection, use and sharing of digital health data.

2

Medical-device regulations

- approval and use of safe, cost-effective and high-quality – but also highly diverse – digital health solutions.

3

Regulations governing the delivery of medical care

- enables medical practices to be supported and enhanced by digital health solutions.

Data management: from protection to quality

Data collection and analysis is at the core of most digital health solutions, especially with regard to helping patients manage chronic illnesses. Digital health technologies offer innovative ways of continuously monitoring specific vital signs and biomarkers, and of gaining insight into disease progression and potential options for improved treatment. Ethical use of this data can help healthcare professionals and caregivers to manage individual patients proactively, perform early intervention to avoid disease exacerbation and coordinate care between stakeholders.[114] Furthermore, the analysis of large datasets drawn from groups of patients over time can be used to improve overall healthcare delivery, resource utilization and ultimately patient outcomes.

However, as with all personally identifiable information, digital health data can potentially be misused for unethical purposes such as blackmail, used unethically by insurance providers, or used in well-meaning but unapproved ways by clinicians and researchers. Therefore, data governance and usage regulations must ensure a high level of data protection from hacking, but also include provisions regarding the ethical use of data and informed patient consent.[115] The potential vulnerability of data in the healthcare sector is reflected by the number of data breaches at health organizations resulting from targeted hacking. In the United States, according to the U.S. Office for Civil Rights, there were 342 such reported data breaches in 2017, resulting in the theft of 3 million patient records.[116] Data security is traditionally ensured through technical means like firewalls, data encryption and user authentication. However, new vulnerabilities are discovered routinely, so proper IT system management is essential. Within the digital health field, the use of phishing emails by hackers to obtain login information for health data systems has been acknowledged as a relevant privacy and security threat. The U.S. Health Insurance Portability and Accountability Act (HIPAA) identifies a number of administrative, physical and technical safeguards that organizations should put in place to ensure data security. In addition, the Food and Drug Administration (FDA) has highlighted the use of digital medical devices as a potential security risk, because they often connect to the internet without using the highest security standards, thus leaving them open to hackers.[117]

Data security and privacy regulations enhance trust in digital health

As the potential misuse of data can undermine the benefits provided by digital health systems, all stakeholders need to be reassured that data security and privacy measures are mandated and enforced through appropriate policies and regulations. This will ultimately enhance the trust accorded to regulators and digital solution providers, and facilitate adoption of digital health systems by healthcare professionals and patients.[118]

Data-protection regulations

While data-protection laws around the world in recent decades have been inspired by the same set of principles (OECD guidelines, 1980), implementation and enforcement approaches have been different.[119] Data protection mainly consists of two dimensions: data security, to protect data from unauthorized access, and data privacy, to protect data from being used without prior consent. According to a classification system produced by international law firm DLA Piper (last modified in 2018), the strength of data-protection laws varies heavily around the world. Australia, Canada, many countries in the European Union, the United States and South Korea all have strong data-protection laws in place, while most LMICs either have

moderate to weak laws, or their degree of protection could not be assessed.[120] In many cases, different aspects of existing legislation are redundant or contradict each other. In parallel, new areas such as cloud services frequently arise, requiring new regulations because processing entities may not be aware where the data is in fact located, for example.[121]

In the European Union, the new General Data Protection Regulation (GDPR) came fully into force in May 2018.[122, 123] The GDPR does not specifically focus on health data, but rather regulates the processing of personal data of EU residents by public and private organizations overall, covering both data-security and data-privacy issues. For sensitive data such as healthcare data, additional safeguards need to be applied, such as consent. A person's consent is needed to use data for a specific reason. The GDPR requests that data-protection impact assessments be performed for products or services for which data processing entails a privacy risk for individuals. Non-compliance can result in considerable fines. Among the primary reasons for the adoption of the GDPR was a desire to modernize and harmonize the previous framework (Directive 95/46) in order to eliminate the fragmentation of older data-protection rules, and update these rules more generally.[124, 125] Since the GDPR also applies to any organization that processes personal data related to EU data subjects even if it operates from outside of Europe, dependencies need to be assessed on an individual-case basis (e.g., data processing of EU residents in LMICs).

Since May 2018, a person's consent is needed to use data for a specific reason in the European Union

In the United States, the HIPAA also covers the issues of data security and data privacy, while focusing specifically on health data, or more specifically on health plans, health clearinghouses and health providers.[126] There is considerable overlap between HIPAA and the GDPR, though some differences do exist; for example, the GDPR allows individuals with some exceptions to request access to or demand deletion of their personal data ("the right to be forgotten"), which can be challenging for healthcare organizations with multiple data systems. The GDPR's requirement of ongoing risk assessment is not echoed in HIPAA.[127] In the United States, being "HIPAA-compliant" has become both an essential requirement and a promotable benefit for innovative healthcare companies. However, proving compliance requires an external audit; this can be performed by entities such as the not-for-profit Health Information Trust Alliance (HITRUST), which has created a Common Security Framework (CSF) and offers a certification for companies to ensure they are following the data-protection standards.[128, 129]

In summary, LMICs can look to the GDPR or HIPAA in combination with the HITRUST CSF as inspiration for the regulation and protection of personal health data. The GDPR's rigor may exceed the ambition of countries with low regulatory maturity, but it illustrates topics that should be considered when seeking to build trust in the use of personal health data for all stakeholders.

How to make use of data and comply with data-privacy requirements

The use of personal health data by authorized entities must be controlled and regulated. People using healthcare data should be properly trained, and appropriate data-privacy controls such as user authentication and authorization when logging into data systems are essential. Informed consent must be gained for the use of patient data for intended purposes, and wherever possible, data should be de-identified (anonymized) or aggregated.

In most countries, the use of large sets of health data is still unusual, and in some cases, large programs have even

Health data in the cloud and cross-border usage

Data storage and additional services in the cloud – as provided by major IT suppliers globally – have become the norm for many companies. This produces new data-protection questions, such as where the data is located, and how security safeguards can be applied according to international standards.[130]

Why are cloud services attractive? "Cloud computing is a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications and services) that can be rapidly provisioned and released with minimal management effort or service-provider interaction."[131]

A shift into the cloud offers many benefits, such as a reduction of upfront investment in infrastructure, a reduction in the required specialist knowledge for maintenance, and the flexibility to scale a digital solution's IT infrastructure up or down as needed. This is combined with advanced data-protection measures, as many cloud service providers are certified by organizations such as the HITRUST Alliance. This helps ensure trust in their offerings, and indicates their capability to manage sensitive health data.

In some countries, governments are moving toward cloud services for patient data. For example, in the United Kingdom, the NHS and social care providers can use cloud services for data as long as they are hosted within the UK, the European Economic Area or other countries with adequate security measures.[132]

Cross-border usage: In addition to cloud services, which may involve data being sent to other countries solely for storage and processing purposes, the cross-border use of data more generally needs to be regulated. Both the European research community and patient organizations have raised concerns that there is a lack of coordination between countries, especially in scientific tasks (e.g., cancer research), where consolidated data pools could help to generate insights. This may lead to different data-protection standards, putting investments and the secure cross-border data flow at risk. As it has sought to address this challenge, the EU Commission has made considerable progress with regard to promoting data exchange across member states. For example, the implementation of Directive 2011/24/EU supports cross-border health system interoperability and access to health data among member states. The directive identifies specific areas where cross-border digital health activities can add significant value within health systems, such as the sharing of patient summaries and the use of e-prescriptions.[133]

Cross-border initiatives remain at an early developmental stage in LMICs. Under the category of "Legislation, Policy and Compliance," the Regional East African Community Health (REACH) digital roadmap, commencing in 2017, identifies the regional responsibility to form and harmonize data policies and standards, and develop cross-border agreements. These should support real-time disease monitoring across countries, cross-border health records management, and access to broader insurance coverage.[134] The latter two issues are relevant for people suffering from NCDs as well as conventional diseases.

For LMICs, cloud services offer a flexible, secure option for hosting digital health data, providing data-analysis solutions and allowing countries to scale services as needed without major upfront investments in IT hardware. However, in order to take advantage of cloud services and cross-border data exchange, regulations must be adjusted appropriately.

failed. The NHS "care.data" program, which pooled patient records for use by healthcare professionals and pharmaceutical companies, failed due to privacy concerns following the insufficient communication of potential benefits and risks.[135, 136] However, some successful examples of countries leveraging health data do exist; for instance, in Denmark, the population fully supports the use of data by healthcare professionals to improve healthcare provisioning (see "Common Health Platforms" on page 74).

A longitudinal linked database was established in the mid-1980s in the Canadian province of British Columbia, and now contains more than 30 years of data on all health services (physician, pharmaceuticals, hospitalization) used by province residents, as well as vital

statistics (births, deaths, marriages) and other types of data (e.g., disease registries, workers' compensation). Patient IDs are encrypted to ensure uniqueness (thus maintaining the database's longitudinal integrity) but cannot be easily linked back to the original patient. This data is available to researchers (including students) upon request, facilitating legitimate research requiring longitudinal and/or cross-sectional data.[137]

Another relevant approach has been implemented in Estonia, where blockchain technology is used as an additional data-privacy measure in a system that tracks all medical-record transactions. The system uses a standard database system with integrated blockchain technology that collectively provides a full audit trail for patient records.[138] Data-record authenticity can be proven, and a record's history cannot be changed. This facilitates data integrity and data privacy, because no one can manipulate the data without leaving a trace.[139]

Africa offers several notable examples of LMICs with successful health-data privacy regulations and policies. On a country level, South Africa has conducted pioneering work in the area of data-protection regulations. The country enacted the Protection of Personal Information (POPI) Act in 2013; this law establishes data-privacy requirements that give individuals more control over how their personal information is collected, distributed and used, and which hold entities accountable if they misuse data or use it in a non-transparent manner.[140] The act established an independent body, the Information Regulator, to enforce and guide compliance by public and private bodies. The regulations implementing the act were released to the public for review and feedback in 2017.[141] While

Enhancing data protection using blockchain

Blockchain is a distributed-ledger technology that enables multiple parties to share access to administratively decentralized databases. It facilitates the trusted exchange of data over a network, does not require intermediaries and can be used to enhance data integrity.

With blockchain, participants cannot pose as someone else or deny that a transaction occurred; nor can a record transaction be modified after the fact. This makes blockchain especially conducive to transactions where trust or security concerns may arise when sharing data across organizational boundaries.

In the healthcare sector, blockchain applications could include medical-record sharing, claims adjudication and counterfeit-drug prevention. Estonia has already successfully used blockchain for the secure exchange of patient health records. The Estonian E-Health Foundation is using blockchain as an additional security measure specifically by archiving activity logs related to patients' health records.

Because blockchain-related incentives, technical acumen, and legal and regulatory frameworks are still being developed, the deployment of blockchain technologies in the healthcare sector remains at an early stage. Nevertheless, there is a growing sense that they hold a transformative potential for healthcare IT and digital health systems. In LMICs too, blockchain technology can help to facilitate health-data privacy, especially under UHC conditions where large amounts of health data from different sources need to be connected.

the Regulator faces common hurdles such as the need for sufficient funding as the legislation is finalized, it is already playing a role in various data-protection networks and legal decisions.[142] The effective date of POPI has yet to be proclaimed by the president, and this is unlikely to be before the end of 2018.[143]

On a regional level, a key initiative was the adoption of the African Union Convention on Cyber-security and Personal Data Protection in June 2014. This established legal frameworks for data security, electronic transactions and personal-data protection on the regional and national levels. It addresses the need for harmonizing cyber-security legislation across the African Union's 54 member states.[144, 145] In addition, members of the Economic Community of West African States (ECOWAS) have developed the ECOWAS Supplementary Act A/SA.1/01/10 on data protection, which stands out as a binding regional data-protection agreement. This act specifies the content of data-privacy laws, and requires the 15 member states to create a data-protection authority.[146, 147]

Data-governance standards and quality

Modern data-protection regulations like GDPR must include an appropriate level of data governance. Data records for each individual need to be accurate, up-to-date and structured in such a way that they can be accessed, modified and deleted upon request.

Data quality plays an important role in enabling high quality and continuing healthcare, with accurate and up-to-date data being crucial. Population health management and planning also requires high-quality data.[148] Data is generally considered to be high quality if it is "fit for [its] intended uses in operations, decision-making and planning."[149] This implies that data has to be collected and managed based on agreed data-quality standards, thus preventing inaccurate or incomplete data from being stored (including in the conversion from paper-based files to electronic data). While ensuring data quality is certainly in part a technical challenge, it also depends on appropriately training the people involved, and having the right processes in place for data collection. HCPs and CHWs need to understand that complete and accurate data entry is critical.[150]

Poor data quality may lead to wrong healthcare decisions for individuals, and may even have a negative impact on population health management. This latter risk has been illustrated in South Africa, where routine health data from the primary healthcare system is collected and stored in the District Health Information System (DHIS). Recent studies of this system have reported that the quality of the data, including the data used to track prevention of mother-to-child transmission of HIV (PMTCT), is suboptimal and is thus hindering efforts to strengthen service delivery.[151] In this case, the shortcomings in data quality were not due to the deliberate input of wrong information, but rather to missing information or inaccurate descriptions. As a result, the University of the KwaZulu-Natal region, the Department of Health, and the Institute for Healthcare Improvement launched a large-scale effort in 2008 to improve the quality of PMTCT services in three provincial health districts. This program included an intervention that helped make the public health data recorded by the DHIS for planning and progress-reporting purposes considerably more complete and accurate.[152]

Data quality plays an important role in enabling high quality and continuing healthcare, with accurate and up-to-date data being crucial

Policies and procedures for improving data quality should be established, as implemented by the Irish health-

information and data-quality authority. In addition, ongoing monitoring processes and/or regular data-quality audits should be used to ensure compliance with policies and procedures.[153] In India, for example, the Ministry of Health and Family Welfare drafted the Digital Information Security Healthcare Act, which establishes a National Digital Health Authority tasked with promoting data standards, privacy and security.[154]

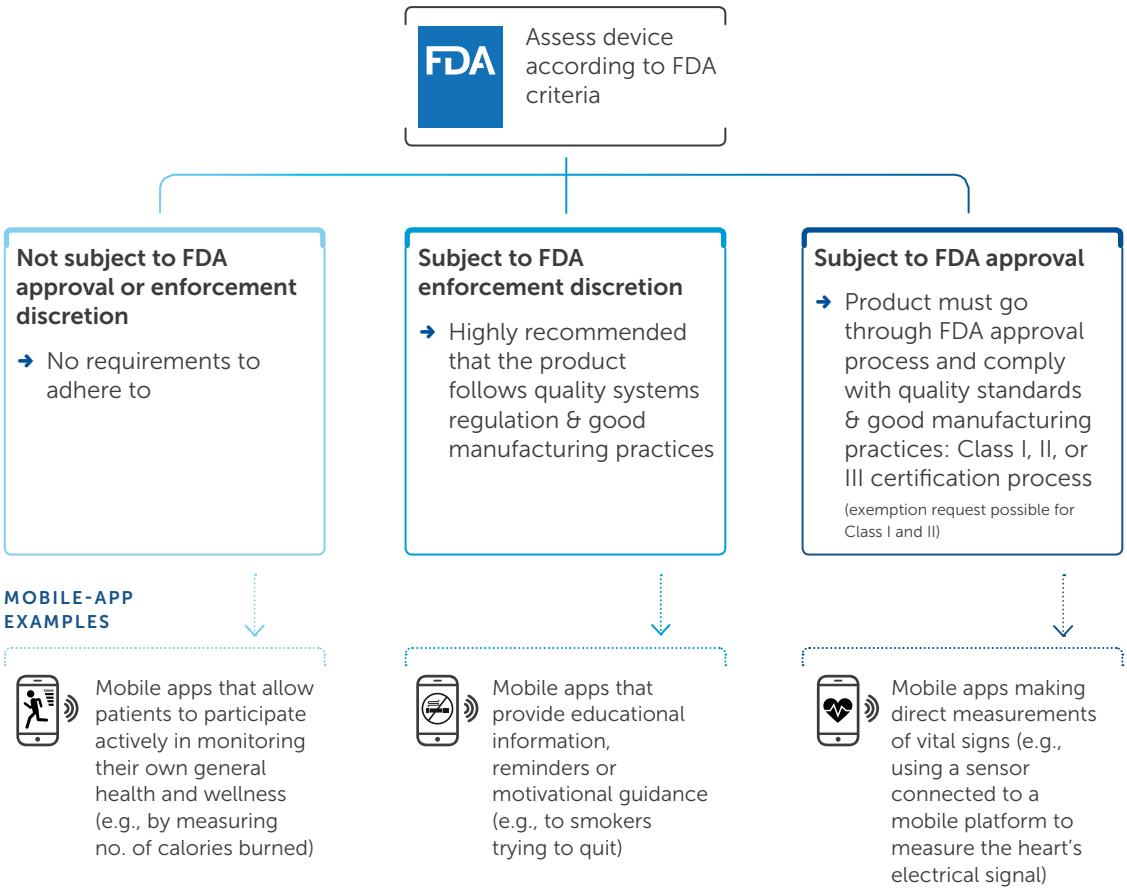
Medical-device regulations

In the context of NCDs, "medical device" means any instrument, implant, software or reagent (for in vitro use) that is intended by the manufacturer to be used for human beings for the purposes of diagnosis, prevention, monitoring, the treatment or alleviation of disease, or the investigation, replacement, modification or support of the anatomy or of a physiological process.[155]

Medical devices range from basic items such as tongue depressors or rubber gloves to complex mechanisms such as artificial hearts or kidney dialysis machines. Similarly, digital health solutions can also range from simple apps allowing patients to track blood pressure over time to complex apps connected to devices that measure blood glucose levels, which include complex calculations and provide insulin-dosing recommendations.

Software and digital medical devices are regulated in most countries based on the level of risk they entail for the patient, with the level of regulatory oversight naturally increasing with the risk. This regulatory classification has implications

Figure 9 **Food and Drug Administration (FDA) approval process for medical devices**



for development costs and speed to market for digital health solutions. This sub-section focuses on the approval process for digital health solutions in HICs and LMICs, and highlights how existing regulations can be adapted to the fast-changing digital health landscape.

Regulations in HICs

Many HICs have comprehensive digital health regulations (that include medical devices) that are still evolving. In the United States, the FDA has established an approval process for medical devices that requires them to comply with quality standards and good manufacturing practices. Medical device providers undergo a risk-based device assessment that, depending on its outcome, may make their devices subject to FDA approval; moreover, all providers are recommended to follow FDA regulations. For device manufacturers, FDA approval provides the advantage that their devices can then be prescribed by doctors, and qualify for reimbursement by insurance providers. Devices subject to FDA approval are assigned to one of three regulatory classes – Class I, Class II or Class III – based on the level of oversight necessary to provide reasonable assurance that they will be safe and effective (Figure 9).[156]

When it comes to core health IT systems, such as health management information- and data-exchange systems, the potential safety risks are very generally low, and as such the FDA does not oversee them. Instead, the FDA focuses on medical-device functionality, regardless of whether the device is an app or a system such as a real-time bedside-monitor alarm.[157]

In the EU, digital health technologies such as apps and devices with sensors may fall within the scope of medical-device regulations (e.g., Regulation (EU) 2017/745 and Regulation (EU) 2017/746) that define what a medical device is and specify manufacturers' technical and

FDA's digital health regulations

In the case of mobile health apps, the FDA focuses on functionality rather than the technical platform on which they are built. When mobile apps are used for the diagnosis, treatment or prevention of disease, or the app affects the function of the body, they are considered to be medical devices, in which case they are regulated by the FDA.[158] An example of a mobile medical app might be an app connected to a blood-glucose strip reader, and thus functions as a glucose meter.

Last year, the FDA took several steps to adapt medical-device regulations to the demands of the digital health sector. For example, it created the Software Pre-Certification Pilot Program, which allows manufacturers that have demonstrated a culture of quality assurance and organizational excellence to launch digital health solutions faster.[159] In October 2017, the organization issued new software-as-a-device guidance, eliminating the need to seek FDA approval for every product upgrade during an iterative software-development process.[160] Finally, the FDA released draft recommendations on clinical and patient decision-support software, clarifying which types of software require FDA oversight.[161]

Other countries could learn from the FDA's efforts in simplifying the approval processes by considering the pre-certification of digital health vendors, issuing guidance on the classification of digital health products, and adapting regulations to the rapid pace of software innovation. This in turn would allow safe digital health innovations to be launched more quickly, and thus become available to the population.

procedural obligations.[162] As in the United States, the designation of "medical device" in Europe depends on the purpose of the product.[163] As a first step toward gaining approval for commercial release, the digital health product must be awarded the Conformité Européenne (CE) mark. Unlike in the United States, this approval is not given by a governmental authority; rather, for Class I devices, manufacturers can perform a self-assessment, while for higher-risk Class IIa or b and III devices, assessment must be performed by a "notified" (i.e., accredited) body appointed by the competent authorities of an EU member state.[164] Obtaining this CE mark is likely to become more difficult after the new EU Medical Device Regulation takes effect in May 2020, as this measure will impose a new, stricter classification system for medical-device software.[165] A piece of software is classified as a medical device in Europe when it is intended by the manufacturer to be used in the diagnosis, prevention, monitoring, treatment or alleviation of disease, as specified in the Medical Devices Directive.[166]

Technological innovation in the field of digital health solutions has outpaced the growth of regulatory frameworks, which remain underdeveloped in many countries

To ensure that regulations on technology are "fit for purpose," the EU Commission has established expert working groups that include private companies as members. The Commission can thus seek the feedback and advice of stakeholders directly affected by the regulations.[167]

Other countries can learn multiple lessons from the EU Commission's approach to approving digital health solutions. First, the EU's classification of digital health solutions on the basis of medical impact and potential risk to patients could be re-used and adapted. Second, European regulations are standards that are applied by regulatory bodies within individual countries. LMICs could consider a similar approach by relying on domestic regulatory oversight, which would take local culture and languages into account, while also creating or enhancing regulations at the regional level. Third, manufacturers can award themselves the CE mark in Europe in the case of low-risk products. LMICs could similarly reduce local regulatory-system burdens by empowering digital health providers to conduct their own assessments. Finally, other countries could also consider partnering with the private sector for the definition and implementation of regulations.

It must be noted that the FDA's approval of digital health solutions in the United States, or similar decisions by notified bodies in Europe, is independent of reimbursement for such products or services, a question that is determined by payer organizations such as insurance companies. Although approval usually occurs before reimbursement, solution-providing companies in HICs often consider the strategies for both simultaneously, and adapt their R&D and commercialization plans accordingly to maximize chances of business success.[168] In addition, the documentation required to demonstrate effectiveness during the approval process can also be used to build the case for reimbursement. Please refer to Building Block 6 for details on financing sustainability.

Regulations in LMICs

LMICs are only at the beginning of their journey with regard to defining medical-product regulatory systems for ensuring high quality standards and the safe use of drugs, vaccines and medical devices. As yet, such countries often lack the governance capabilities and structures necessary to approve new health solutions, as well as the capacity to conduct post-approval market monitoring, which involves collecting information on product safety and quality, and taking enforcement actions when regulations are breached.[169] The National

Quality labeling – Helping users navigate through the health-app maze

The number of health apps is growing rapidly, reaching 325,000 worldwide in 2018,[173] making it difficult for users to assess the quality. In the United Kingdom, the NHS laid the foundation for regulating the safety and effectiveness of health apps by launching the NHS Apps Library, in beta form, in April 2017. This library currently contains 46 apps that help patients select digital health tools for a variety of conditions such as diabetes and chronic obstructive pulmonary disease (COPD). All apps undergo a robust assessment process (the so-called Digital Assessment Questions), thus ensuring that only trusted, high-quality apps are available through the site. The assessment considers clinical and technical standards including clinical effectiveness, regulatory approval, privacy, confidentiality and interoperability.[174] The vision is that patients will easily be able to access apps that are labeled "Being tested in the NHS" or "NHS Approved." As part of the NHS' commitment to building a solid evidence base, independent third parties such as Our Mobile Health are also included in the process of assessing apps.[175] In addition, the NHS helps app developers comply with regulations by providing guidelines on its Developer.nhs.uk website.[176]

(c) Shutterstock



How can a user ensure that a health app can be trusted? The NHS in the UK launched a health app library that helps patients select digital health tools for a range of NCDs.

In Europe, MedAppCare is the first company to have developed a rigorous and independent methodology for assessing mobile health apps. It is supported by the French Public Investment Bank, the Ile-de-France region and the Fondation de France. It evaluates the quality of apps based on technical and medical criteria such as data security and privacy, content quality, usability and user satisfaction. The company then produces a ranking of apps, helping users to select the apps best tailored to their purposes, and provides guidance to app developers on how to improve their products. Healthcare professionals highly value this kind of independent quality assessment, with 61% of pharmacists and 55% of doctors saying they would be more inclined to recommend a connected health solution if it had an independent quality label.[177]

Academy of Medicine (formerly the Institute of Medicine) in the United States has identified three "minimal" elements needed for any sustainable regulatory system for medical products: (1) a rule-making process for stakeholders to comment on proposed regulations; (2) a protocol for various regulatory agencies to share information and oversight; and (3) an approach to identify when regulatory actions are needed.[170]

Technological innovation in the field of digital health solutions has outpaced the growth of regulatory frameworks, which remain underdeveloped in many countries. In India, for instance, digital health providers must comply with a number of laws drafted when the technology for telemedicine was not yet available.[171] Nevertheless, the government is aware of the need to streamline the development process and introduce regulations and initiatives relevant to the digital health sector. For example, it recently introduced the Startup India campaign, which provides funding and tax incentives to boost innovation. Moreover, with the new Medical Device Rules 2017 (GSR 78E) – set to take effect from January 2018 – the Indian government has made significant steps toward streamlining the development processes for digital health solutions.[172]

Even though LMICs typically have fewer digital health regulations in place than HICs, they can learn from other countries' experiences as they develop their own regulatory frameworks or adapt existing regulations, "leapfrogging" over points



What does "leapfrogging" mean?

LMICs provide a fertile ground for digital health innovation because of their urgent health needs, rapid mobile-phone penetration and relatively narrow body of regulations compared to developed countries, which have highly entrenched health systems. This enables them to adopt radical technology innovations without having to evolve or replace established legacy systems, a kind of innovation sometimes known as "leapfrogging."

For example, the team that built Swasthya Slate, a diagnostic tool that can complete 33 medical tests, first attempted to manufacture the product in the United States. They soon realized that the FDA approval process was long and convoluted due to the hospital policies and HIPAA regulations that make it difficult to collect the relevant medical-grade data, and also due to the bureaucracy associated with testing sensor-based medical products. The team then decided to develop the product in India instead, where the government was more receptive to pilot projects testing the device based on commonly available quality sensors in a large population and confirming the required accuracy.[178, 179, 180] This story illustrates the importance of setting appropriate levels of regulations that ensure quality and safety within digital health solutions without stifling innovation.

Similarly, Zipline, an American company manufacturing medical drones, launched its blood delivery services in Rwanda, where regulations were less stringent than in the United States, and where the Rwandan government expressed a strong interest in the innovation. Since its launch in 2016, Zipline has taken over 20% of blood deliveries within rural Rwanda.[181] Following Zipline's quick, successful launch in Africa, the U.S. government expressed a willingness to partner for the delivery of blood to rural populations in the United States.[182]

of development taken by countries that started earlier. For example, LMICs could build on the risk-based classification system used by HICs for their own assessments of digital health solutions. This could in fact be an opportunity to create an innovation-friendly regulatory environment in which approval processes are simpler and better fit to their purpose.

Regulations on delivery of care

As described in Section 3, digital health solutions support the overall transformation of the health system toward a more patient- and population-centered approach. They can enhance the quality and efficiency of medical practices, empower front-line workers and patients, and bring care closer to patients. By digitizing interactions between stakeholders in the care process, digital health solutions promote health-system sustainability, since these solutions require fewer resources than traditional practices (e.g., SMS-supported reminder services to improve therapy adherence) and reduce usage of traditional infrastructures. However, laws and regulations facilitating the utilization of digital health solutions are required; including, for example, laws regarding the legal status of electronic signatures and the legal status of electronic files.

This sub-section explores regulations relating to the delivery of care to NCD patients. Thus, it addresses the issues of prevention, screening, task shifting, teleconsultations and e-prescriptions.

Prevention and screening

There is increasing awareness of the need for prevention and early screening of NCDs. In the United States, for example, the Association of State and Territorial Health Officials actively promotes the development of prevention policies for NCDs.[183]

Digital health solutions can support these policies by enhancing current prevention

and screening practices. For example, the Be He@lthy, Be Mobile (BHBM) team has implemented mobile-health (mHealth) initiatives that involve sending informational SMS text messages that supplement existing national policies.

Mexico offers another illustration of the successful use of digital health solutions to support NCD patient screening. The country's traditional NCD prevention policy was based on screening patients using a paper-based risk-factor questionnaire. This was mainly used with patients already seeking healthcare services at medical facilities. To increase the number of screened people, the Carlos Slim Foundation launched Medición Integrada para la Detección Oportuna (MIDO), or Integrated Measurement for Early Detection, which is an NCD screening and proactive prevention service. MIDO's algorithms apply a systematic risk-assessment approach to patient screening, identifying people as healthy, at risk (or pre-disease) or sick based on their health status (e.g., weight, blood pressure, blood glucose). The emphasis is on the detection of patients in pre-disease stages such as pre-obesity, pre-diabetes and pre-hypertension. In addition, MIDO enables community-based care with a MIDO Module for use in primary care clinics, and a MIDO Backpack for use at the community level, where state governments perform household visits to do proactive NCD screenings. This successful approach has allowed more than 1 million people to be screened with MIDO including the collection of medical data, which represents a significant increase relative to the former screening policy.[184, 185]

Task shifting

There is a crippling shortage of health workers in many countries, a situation that can undermine efforts to achieve UHC. For example, in Malawi, the lack of health workers is so extreme that there is only around one physician caring for every 100,000 people.[186]

Task shifting, or the delegation of clinical practices to health workers with lesser medical qualifications, can be a pragmatic way of addressing workforce shortages. Both HICs and LMICs have moved in this direction. For example, in Singapore, nurses and pharmacists were recently given the authority to prescribe medicines.[187] In Malawi, government officials have changed guidelines to enable nurses to prescribe certain drugs such as those used in antiretroviral therapies, while in Ethiopia, new care units called "Health Extension Workers" have been added to the civil-service system to strengthen community-level care.[188, 189] In addition, a study from the United States showed that health promotion by barbers resulted in larger blood-pressure reductions when coupled with medication management by trained pharmacists in barber shops.[190]

Task shifting, or the delegation of clinical practices to health workers with lesser medical qualifications, can be a pragmatic way of addressing workforce shortages

Digital health solutions can support task shifting of this kind. For example, the WatIf Health Portal app from South Africa trains staff without a medical background to collect NCD clinical data such as blood pressure, and also supports nurses by providing information on treatment protocols and care pathways. WatIf was chosen by MTN Business as the "app of the year" in 2017 in the category of Best Health Solution.[191] However, the regulations and polices currently in place in LMICs tend to be focused on clinical practices rather than digital health solutions as enablers for task shifting, even though this latter category provides support for training and clinical decisions. Policymakers should thus develop pragmatic regulations that facilitate task shifting with the help of digital health solutions, while ensuring these solutions' quality.

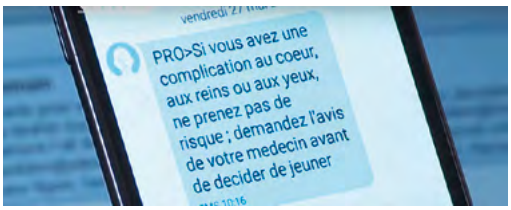
2.2

Be He@lthy Be Mobile – Using mobile technology to improve NCD prevention

The Be He@lthy, Be Mobile (BHBM) initiative was founded in 2013 as a joint partnership between the WHO and the International Telecommunication Union (ITU). BHBM harnesses the power and reach of mobile phones to help national health systems address NCD risk factors. It focuses on providing people with information enabling them to make healthier lifestyle choices in order to help prevent and manage NCDs. The information is delivered via SMS directly to end users, and the initiative also provides training on diabetes to health workers.[192]

The initiative currently works with governments from 10 countries, supporting programs that address a number of NCDs and related risk factors. Goals include tobacco cessation, diabetes prevention and cervical-cancer awareness. Programs are run by the government and integrated into existing NCD-control services, thus ensuring they work to strengthen the system as a whole. The largest programs are in India, Philippines, Senegal, Zambia, Tunisia and Egypt. Over 2.1 million people are registered in India's mTobaccoCessation service, and over 250,000 people have registered for the country's mDiabetes program. Zambia has sent at least 500,000 people messages on the issue of cervical cancer. More than 50,000 people are enrolled in Tunisia's mTobaccoCessation service, while Senegal and Egypt have seen hundreds of thousands of people sign up to receive SMS messages on managing diabetes during annual campaigns run during Ramadan.

The initiative's programs show that digital health can significantly expand populations' access to critical information related to NCD prevention. By using existing technology, such programs can reach significantly greater numbers of people than does traditional outreach. This technology also facilitates other benefits such as real-time information regarding the program outreach. The mTobaccoCessation program in India, for example, used an online dashboard showing the number of registrations in real time, categorized by demographic attributes such as gender and geographical location. This allowed the program managers to provide up-to-date information to policymakers on the progress of the program.[193, 194]







The Be He@althy Be Mobile (BHBM) initiative provides people with information on healthy lifestyle choices via SMS. Goals include tobacco cessation, diabetes prevention and cervical-cancer awareness.

Photos: (c) WHO

Rising user rates have demonstrated the popularity of mHealth with users. In Senegal, for example, annual registrations in a mDiabetes program run with the government of Senegal increased exponentially from 10,000 in 2014 to 117,000 in 2017. An impact assessment has also indicated that the program is achieving results; sending diabetes-education messages via SMS was associated with a significant improvement in glycemic control in people with type 2 diabetes.[195]

Communities for Healthy Hearts (CH2) – An example of task-shifting to the community level for hypertension screening to address the burden of cardiovascular disease

Vietnam's National Strategy on Prevention and Control of NCDs calls for delivering hypertension screening and care at the community level for adults over the age of 40. "Communities for Healthy Hearts," supported by the Novartis Foundation and PATH, provides hypertension screening services in convenient locations such as barbershops, nail salons, coffee shops and markets in Ho Chi Minh City, in a partnership between the city health authorities, PATH and the Hanoi School of Public Health. This new healthcare delivery model builds on lessons from successful community-based HIV and tuberculosis services, as well as on a similar hypertension program in Ghana, called Community-Based Hypertension Improvement Project (ComHIP).

Patient data within the Communities for Healthy Hearts program is tracked using an online database (eHTN.Tracker) that allows local health workers and community volunteers to access and follow up on a person's medical record. The eHTN.Tracker system is connected to an optional SMS reminder service that allows people to receive SMS messages regarding treatment, healthy behaviors and appointment reminders.[196]

Preliminary results of the program show significant improvements in the number of screenings performed, the number of people referred for diagnoses, the number actually receiving follow-up diagnoses and the number of hypertension patients receiving treatment (Figure 10). Care coordination is improved, as approximately 82% of those diagnosed with hypertension through Communities for Healthy Hearts are today under treatment, compared with the reported 13.6% of hypertension patients who were managed at care facilities before the start of this initiative.[197]

Similarly, Ghana's ComHIP program, which is supported by FHI 360, the London School of Hygiene and Tropical Medicine and the Novartis Foundation, has also proven that screening, diagnosis and treatment for hypertension can productively take place outside of health facilities and within the community, particularly by involving non-traditional healthcare providers.[198]

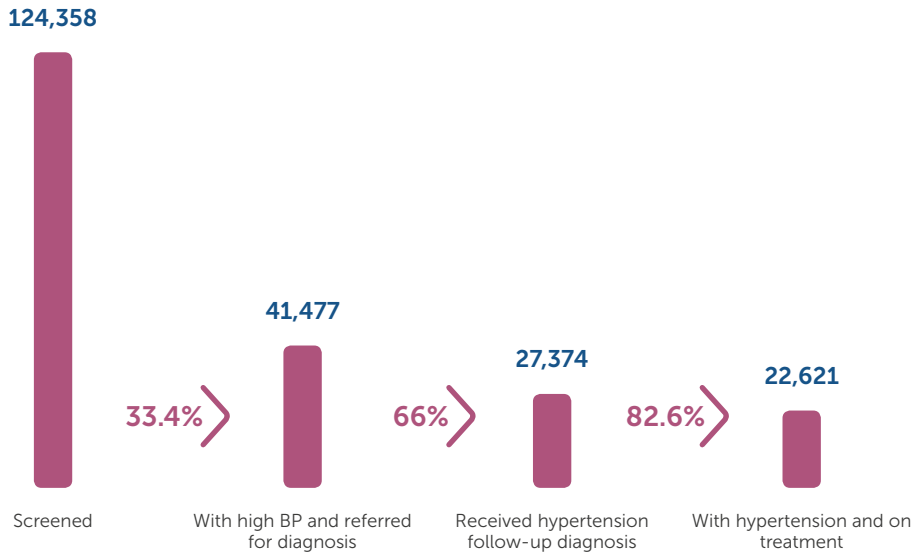


Figure 10 **Results of Communities for Healthy Hearts (March 2018)**

2.2

Remote care – Teleconsultations and e-prescription policies

Teleconsultations and e-prescriptions support care delivery in geographic areas with few doctors, and are hence powerful tools for moving toward UHC. LMICs are only just starting to craft regulations designed to facilitate such solutions, thus promoting healthcare delivery that is more efficient and cost-effective than traditional methods.

Regulatory movement enabling remote consultation has also been observed in India, which has begun drafting telemedicine law governing the practice of doctors diagnosing patients remotely. Some time is still needed to finalize this process.[199] The Indian government is also contemplating allowing doctors to practice across state lines using telemedicine technologies, but divergent views between the national and regional governments have clouded the regulatory outlook for this goal.[200]

India has also made some progress in the area of e-prescription regulation. E-prescriptions are authorized as long as they follow existing regulations (specifically, the Information Technology Act 2000 (IT Act) and the Drugs and Cosmetics Act 1940) and are authenticated by means of a digital signature.[201] The Indian government has also tried to facilitate the adoption of e-prescriptions by recommending the creation of a national portal to manage online transactions with registered drug retailers and wholesalers. The regional government in West Bengal went even further, implementing a unique registration system for e-prescriptions. This has allowed hospitals in this region to issue more than 3 million prescriptions electronically.[202]

However, e-prescriptions are often not regulated in emerging markets. By default, regulators retain the requirements associated with traditional paper prescriptions, which necessitate a formal stamp and a doctor's signature. In many countries e-prescription systems are not established yet, and SMS or other digital documents as proof of prescription are very often not acknowledged.[203] This in turn raises questions as to the practicality of teleconsultations in general, as doctors operating under these regulatory conditions would be unable to follow up their consultations with prescriptions.

Telemedicine in China – How 200 million people benefit from doctors at their fingertips

Telemedicine is gaining momentum in China as a way of dealing with rising healthcare costs and overstretched healthcare facilities. The government issued guidelines in 2014 intended to promote the adoption of telemedicine, including direct-to-patient diagnosis and remote patient monitoring. For example, local health officials have been instructed to provide funding to telemedicine services. Standards have been established allowing only designated medical institutions to provide telemedicine services, and a telemedicine cooperation agreement between healthcare providers has been created, allowing these providers to consult each other remotely.[204]

The boom in telemedicine in China can be illustrated by the success of Ping An Good Doctor, an online medical platform launched by Ping An Health Insurance Company in 2015 for online consultations and appointment booking. In December 2017, nearly 200 million registered users on the platform were being served by about 9,000 online physicians, including 1,000 physicians paid by Ping An and supported by artificial intelligence technology. It is now the largest telemedicine platform in the world.[205, 206]

In some cases, it is not a lack of regulation, but the presence of restrictive regulations that make it difficult for digital health solutions to find their way into clinical practices. One such example is South Africa, which implemented regulations restricting teleconsultations. An incident involving the Hello Doctor telemedicine venture in 2011 illustrates the regulatory hurdles created in this way.

Teleconsultations in Brazil have also raised some ethical questions regarding the doctor-patient relationship. That country's Federal Medical Council requires a doctor to be sitting next to the patient during any virtual consultation with a second doctor. The ethical responsibility would lie with the doctor that is physically present at the patient's side.[207] Such a setup does not capture the full value of teleconsultation, as patients cannot speak to their doctor remotely, from the comfort of their own home, and thus may not benefit from long-term, ongoing NCD care.

As governments seek to achieve UHC, they must also pay attention to developing an appropriate framework for the reimbursement of teleconsultations and telehealth services more generally.

If these issues are not addressed, there is a risk that clinicians will continue to emphasize face-to-face, reimbursable services, thus failing to realize the potential of telehealth. Further details on reimbursement models can be found in Building Block 6.

As governments seek to achieve UHC, they must also pay attention to developing an appropriate framework for the reimbursement of telehealth services

Hello Doctor in South Africa – Saying hello to virtual medical consultations

Hello Doctor provided teleconsultation services and e-prescriptions via partner pharmacies in South Africa. It was forced to put its business on hold after the Health Professions Council of South Africa (HPCSA) claimed it was violating patient rights, and warned the public against using the service.

The HPCSA argued that teleconsultations via phone breached physician-patient relationship protocols and patient confidentiality, and violated the principle of informed consent. HPCSA's ruling, which remains valid today, was that patients could only be diagnosed using teleconsultations, or receive an e-prescription, when they had had previous face-to-face consultations with the general practitioner (GP) involved, thus allowing the doctor some familiarity with the patients' medical histories. The HPCSA thought this would address the fear that a patient might invent a medical condition just to get a drug prescription. However, many people challenged this regulation, arguing that it assumes a private-sector relationship between a patient and doctor who see each other regularly. This could never work for the 84% of the population that uses the public health services, and thus represents a roadblock to UHC.[208, 209]

2.2

Practical recommendations

Digital health solutions stand at the intersection of various regulatory domains. To ensure their safe and ethical use, national regulatory frameworks must catch up with the pace of innovation. LMICs are only at the beginning of their regulatory journey, with increasing awareness of the need to adapt regulations to digital health systems. As they update their old legal frameworks, they can draw on successful existing examples from HICs and even some other LMICs.

Create appropriate data-protection and data-quality policies and regulations, thus enabling digital health systems to support UHC:

1. Work to reach agreement between relevant stakeholders (healthcare providers, regulatory bodies, ministry/department of health, etc.) regarding the scope of relevant health data and corresponding data sources. The consideration of country-specific UHC use cases can help these entities agree on and prioritize relevant data points.
   - Decide on required data-quality standards and targets. Agree on the responsibilities and tasks that will have to be carried out along the data life cycle (from capture to deletion).
   - Request that healthcare providers comply with data-quality standards based on existing or to be developed policies.

2. Establish the data-privacy and data-security policies and regulations necessary to protect the health data referenced under point 1 above.
   - Establish or enhance the body that will be responsible for regulating data-security and data-privacy issues.
   - As appropriate, draw inspiration from established regulations or acts such as the GDPR or HIPAA.
   - Create external certification programs, as exemplified by the HITRUST model, to support implementation and ongoing compliance.

3. Allow flexible data exchange and data management to make digital health data available to any designated user.
   - Consider cloud-based data hosting. This reduces upfront investment and the need for specialized data-management personnel, while also enabling flexible infrastructure scaling and access from anywhere.
   - Update regulations to facilitate cross-border data exchanges (e.g., allowing cross-border health records management and access to broader insurance coverage).
   - Support health information exchange (HIE) efforts to create a common foundation of data at the level of individuals.

4. Track compliance with policies and regulations. This enables adjustment as needed, and fosters trust both in regulators and digital health solution providers; this in turn facilitates the adoption of digital health solutions by healthcare professionals and patients alike.

Approval and safety:

5. Create or enhance the body responsible for regulating digital health solutions, and establish a streamlined and evidence-driven process for the approval of digital health solutions.

6. Draw on lessons from existing regulatory frameworks in the United States, the European Union and other countries to enable the global dissemination and harmonization of successful regulatory practices.

7. Provide guidelines to help providers and suppliers of digital health solutions to navigate the regulatory environment and master the approval process.



(c) PATH/Gabe Bienczycki

8. Align the medical-device approval process with reimbursement strategies to maximize access to digital health solutions and hence move toward UHC.

9. Support user-level assessment of digital health solutions. Consider collaborating with independent assessment bodies to review the quality and effectiveness of health "wellness" apps that may not be covered by existing regulations.

Delivery of new healthcare services:

10. Evaluate opportunities to improve healthcare delivery with a focus on NCDs, supported by digital health solutions. This can play a significant role in achieving UHC. Assess existing healthcare delivery regulations within the country, and adapt them as needed to enable the delivery of new healthcare services. Do not reinvent the wheel; rather, collaborate with existing digital health providers, and align policies with products.

11. Analyze the data collected from digitally enabled prevention and screening programs, and use the conclusions to adapt national policies and goals, enhance project management and facilitate decision-making.

12. Facilitate task shifting where appropriate. Assess the risk-benefit ratio associated with such shifts, for example by analyzing a given medical intervention's degree of invasiveness for patients. Ensure safe and efficient task-shifting practices by establishing digital health policies and guidelines, particularly as they relate to clinical decision-support and training platforms.

13. Define policies for teleconsultations and e-prescriptions, thus allowing smooth integration with current clinical practices. Address the ethical concerns of professional medical bodies and patients by communicating the benefits and limitations of teleconsultations. Establish monitoring mechanisms to ensure that remote care fulfills the required quality standards.

14. Consider aligning regulations with other countries so as to enable remote care across borders – especially in support of least-developed countries.



BUILDING BLOCK 3

Communication Infrastructure and Common Platforms

Communication infrastructure and common platforms connect people and solutions, and enable the sharing and use of information to manage NCDs more effectively and efficiently.

Policymakers can help make mobile and internet communications available and affordable to all and consult with stakeholders to design digital health platforms as a common asset with core functionalities that benefit the fight against not only NCDs, but other diseases as well.

KEY TAKEAWAYS

Communication infrastructure and common platforms connect people and solutions, and enable the sharing and use of information to manage NCDs more effectively and efficiently

Digital communication infrastructure provides the connectivity that makes the application of digital technology to healthcare possible. Policymakers should prioritize making connectivity available and affordable to all

- The cost of mobile broadband as well as internet connectivity continue to pose barriers to accessing information and digital health solutions.
- Access to the right quality or speed required to use digital health solutions is especially lacking in several LMICs.
- The cost of mobile broadband has been dropping significantly, however, is still prohibitively high in some LMICs. Governments and mobile network operators still have a variety of ways to accelerate access, including:
  - Public access points
  - Stimulating competition and incentives for operators to enter less attractive markets, such as remote areas
  - Promoting infrastructure sharing
  - Managing radio frequencies efficiently
- Governments can also assess the role that taxes on handsets and airtime play in limiting access to digital health solutions and consider making changes.
- Proactive measures like these can help ensure that digital health does not become a barrier to healthcare access, exacerbating existing inequalities based on income and other factors.

In addition, policymakers can also work with stakeholders to create cost-efficient digital health platforms as common assets with core functionalities that can be shared

- Such platforms, or "infostructures," can include a health information exchange architecture, unique citizen (or patient) IDs, patient electronic health records or registries, Application Programming Interfaces (APIs), or health management information systems to integrate data across regions and diseases.
- Many of these components should be government-wide, to maximize return on investment and links across e-government programs, such as health and social services.
- Certainly, any investment in digital health to improve the management of NCDs will also help address other diseases and vice versa.
- While common digital health platforms can be challenging to design and operate, they can ensure higher cost-efficiency (build once, use multiple times) with better integration and interoperability.



(c) Nana Kofi Acquah / Novartis Foundation

2.3

Why is this relevant to digital health sustainability?

In any environment, network infrastructure, whether wired or wireless, must be in place to allow users to connect to each other and data to be exchanged. Thus, such infrastructure is a prerequisite for the success of digital health systems, devices and applications. The characteristics of this connectivity, including its scope of geographic coverage, quality, speed and price, will play a key role in determining whether a given digital health program will be adopted by patients, healthcare consumers and healthcare workers (both facility-based and in the field).

A common health platform would result in fewer duplicate systems and an overall better allocation of resources

However, in order to build and operate sustainable digital health solutions, this communication infrastructure also needs to be complemented by adequate information technology infrastructure. The infrastructure needed to create a common health platform, for example, consists of several components, including a health information exchange, a patient-centered electronic health record system, unique patient identifiers and a health information management system. A common health platform can help consolidate data from patients and healthcare providers, reduce fragmentation between different products and services, improve data quality, and even link to other eGovernment platforms (e.g., by making use of a unique citizen ID). A common health platform would result in fewer duplicate systems and an overall better allocation of resources.

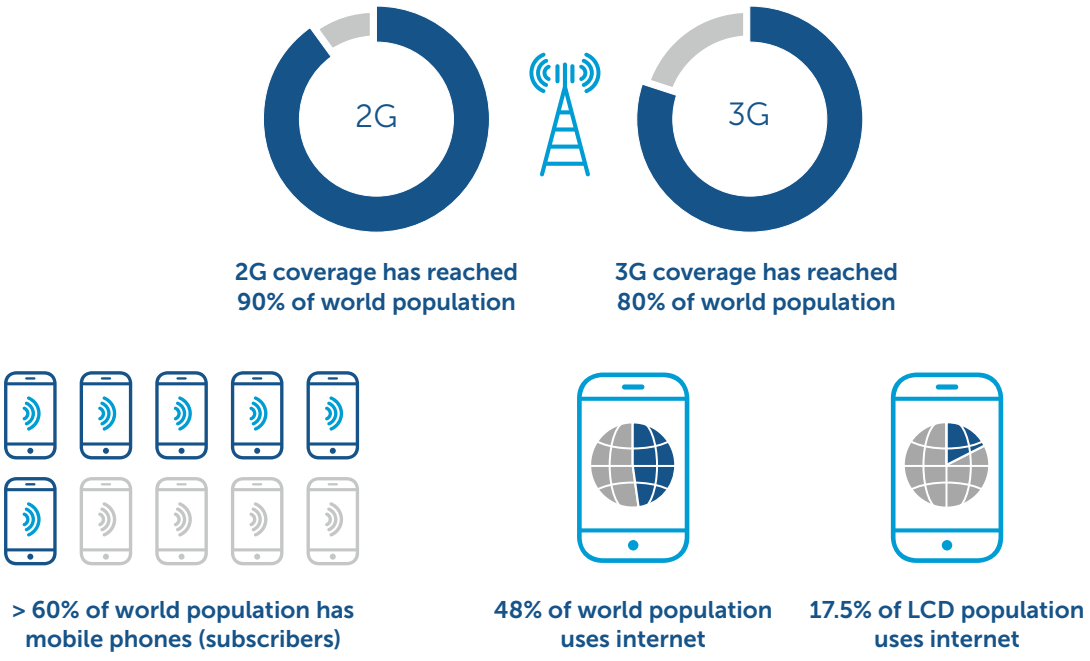
Access to communication infrastructure: coverage, affordability and use

While much of the world's population today has access to mobile internet connections, there are still large coverage gaps in LMICs, and especially in LDCs.[210, 211] In total, half of the world's population still lacks internet access; the bulk of this group lives in LMICs, with the lack resulting from gaps in mobile-network or fixed-line coverage, or from high connectivity costs. In LDCs alone, the internet-connected share of the population is considerably lower still (see Figure 11).[212]

Over the past few years, global connectivity prices have experienced significant price declines. Mobile broadband prices as a percent of GNI halved between 2013 and 2016.[213] Unfortunately, prices are still prohibitively high within some low-income countries. A calculation by the Alliance for Affordable Internet (A4AI) based on ITU data showed that in 2015, 1 GB of data costs about 18% of the average African's monthly income,[214] whereas in Europe and the United States, this value is below 1% of income (as calculated by GNI per capita).[215] In 2018, the Broadband Commission for Sustainable Development lowered its global 2025 affordability target for fixed or mobile-broadband services from less than 5% of monthly per capita GNI to less than 2% of monthly per capita GNI. If this is reached, it would enable many more people to afford broadband services (fixed and mobile).[216]

The cost of mobile devices presents another affordability hurdle for users, which is compounded by additional costs such as government handset taxes and airtime taxes.[217] If these costs are not reduced, many people in LMICs will remain unable to access digital communication technologies. In some

Figure 11 **Communication infrastructure coverage**



Sources: GSMA and ITU, Statistics from 2016 and 2017 (see references in text)

cases, as in Costa Rica and Columbia, governments have used universal-service funds (USFs are funded by telecommunication service providers/operators, often through regulatory fees[218]) to support demand-creation programs, thus increasing the penetration of broadband services and devices (such as PCs and mobile phones) among underserved population segments.[219]

Low (digital) literacy rates and the relative scarcity of digital content translated into local languages[220] are additional factors hindering internet access in developing countries. These issues also need to be addressed, but are outside the scope of this report.

There are many ways to further increase coverage and affordability, with the appropriate mix depending on a country's ICT maturity. Comparatively large facilities require high-speed wired connections or mobile broadband connections using 3G or 4G networks. For areas without 3G or 4G network coverage, microwave or satellite connections can be alternative options.

Four promising approaches are highlighted below, with a focus on rural areas. Each holds the potential of increasing individual access to healthcare, while also improving the support and information available to healthcare workers.

1. Add public internet access points

When private internet access is not possible for low-income populations, accessing the internet in a public setting (for a fee, or even for free) may be the only option.[221] Post offices, shops, community centers, health facilities and other such locations can serve as access points where people can use the internet on computers available to the public or access the internet on their own phones or devices through a wireless network (e.g., a WLAN hotspot). Public access could also be partially supported by universal-service funds. The goal of USFs is to ensure that telecommunications services are accessible at affordable prices, and to help governments achieve their universal-service targets.[222]



Digital technology and inequalities in access to healthcare

Using digital health solutions to enhance access to healthcare can potentially lead to an ethical dilemma in LMICs. Digital health solutions bring benefits only to those who can access digital technologies. Those who lack internet or mobile access, and thus cannot use the digital health solution, may be left with no other alternative, thus exacerbating inequalities. In LMICs, citizens may not be connected to the internet for three main reasons:

- Access may be too expensive in relation to household income (economic factors)
- Their home area may not be furnished with wired internet access, or be covered by internet-capable mobile networks (technical factors)
- They may personally lack digital literacy, a factor often correlated with cultural and sociodemographic factors such as age; 67% of young people between 15 and 24 years access the internet in developing countries, as compared to only 41% of the populations overall[223] (cultural factors)

However, the promise of digital health systems can still be fulfilled for those who cannot access the services directly. The following options will keep the digital door open for those users who might otherwise be at a disadvantage:

- Support by family and friends: Services can be accessed by a family member on behalf of an elderly or (digitally) illiterate person
- Support by healthcare system: Services are accessed by community health workers with internet access or at primary healthcare facilities that help poor, illiterate users, or which function as connected points in areas without adequate coverage

Alternatively, access-point networks may be constructed though private initiatives. In Bangladesh, for example, Grameenphone established communication information centers at more than 450 locations to provide internet access and additional services to rural populations.[224]

2. Support competition and innovation

The global price declines for mobile broadband services over the past few years[225] can be attributed to healthy competition between communication operators supported by policies and regulatory guidelines. Only a few countries still feature a single operator.[226] However, bringing robust coverage to rural areas, where operating margins are likely to be lower, may require additional financial support through means such as a reduction of mobile-operator taxes[227] or subsidies for infrastructure development. As one example, the first entity to invest in a rural area could be provided with financing.[228] Colombia offers a successful example in which a universal service fund has been used to subsidize ICT development; here, the fund is structured so as to be financially autonomous, and projects are awarded in a highly transparent manner using a public tender process.[229]

Competition and innovation can also be boosted in two other ways:

Support small entrepreneurs: Local entrepreneurs can be provided with new opportunities through the issue of local communication-operator licenses that allow recipients to establish new communication services. This policy was successfully tested in rural India, where communities, working in conjunction with a local communications-services provider, were authorized to apply for a low-cost franchise agreement. This would typically be with a mobile-network operator, and would include the provisioning of the required infrastructure.[230] Governments can facilitate such business opportunities for small or medium-sized enterprises by providing adequate financing support. According to a World Bank study, the provision of financing options for rural entrepreneurs could

become a viable policy initiative and relevant factor in improving market efficiency.[231]

Provide free access with restricted content: Internet.org, a partnership of several companies led by Facebook, offers free access to selected websites and content. This approach does not improve coverage but affordability and can open parts of the internet to underserved areas, while also potentially providing access to health-related websites if an agreement with the service operators can be made.

3. Promote infrastructure sharing

Building and running network infrastructure is very costly for mobile and fixed operators. Moreover, infrastructure takes time to be deployed. One approach to reducing these hurdles is to promote the sharing of network infrastructure between operators. This can take the following forms.

- Mobile virtual network operators: Rather than owning infrastructure, these operators rent it from existing network providers, and generally providing inexpensive communication packages.

- Government-driven wholesale models, with a central provider and multiple retailers. While these models should efficiently avoid the apparent cost of network duplication and cover rural areas,[232] examples indicate that wholesale models are difficult to establish. A recent GSM Association (GSMA) study on wholesale models examines five countries with wholesale plans; however, just one of these countries (Rwanda) established a model with reduced scope,[233] while another (Mexico) just started at the beginning of 2018 after several years of delay.

- Voluntary infrastructure-sharing agreements between operators. Under this model, operators would jointly invest in building ICT infrastructure such as cell sites (e.g., mobile towers and antennas).[234] A 2015 APC & Deloitte study[235] estimated that infrastructure-sharing between two partners can lead to a cost reduction of 45%.

4. Support innovative management of mobile communication frequencies

The range of radio frequencies suitable for mobile data and voice communications is limited, and therefore expensive to own by MNOs. This cost is typically passed on to customers.[236] Furthermore, single providers are not necessarily able to use the allocated frequencies to full capacity.[237]

Two considerations are important with regard to using radio frequencies more efficiently. First, releasing frequency spectrum allocated to other purposes for commercial broadband use would help diminish frequency scarcity in densely served environments. In rural areas, giving mobile network operators cost-effective access to low-frequency spectrum can be advantageous, because geographic coverage can then be increased with fewer antennas, which means lower infrastructure costs.[238] Second, spectrum users should be allowed to transfer their spectrum rights, and should have a high degree of flexibility in the choice of the consumer services they provide with their spectrum.[239] Available spectrum could be shared between mobile operators under agreed location and time-sharing conditions, based on a license-fee.[240] Modern spectrum management needs to be controlled and automated. For more on this issue, refer to the ITU-R Handbook on Computer-Aided Techniques for Spectrum Management (CAT), Edition of 2015.

Building and running network infrastructure is very costly and time-consuming for operators. One approach to reducing these hurdles is to promote the sharing of network

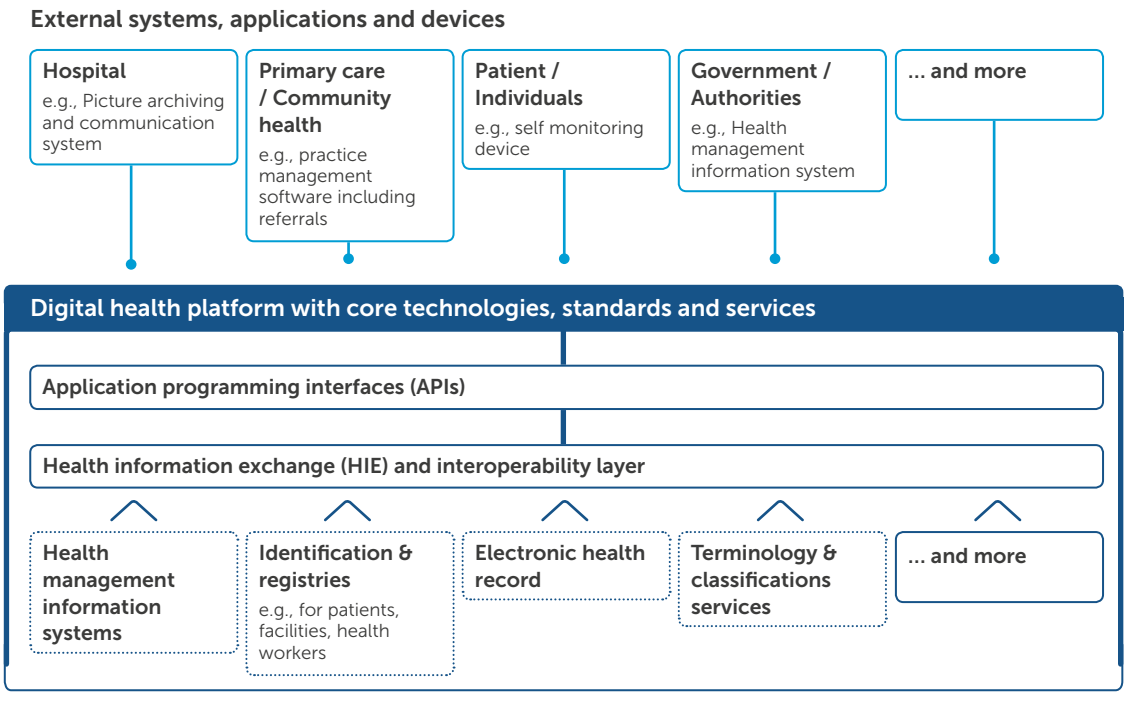
ICT service costs can also be managed through user-behavior or technology choices. Costs associated with digital health solutions (e.g., an SMS-based coaching service focusing on disease management) can vary based on underlying technologies such as the choice of contact or feedback channels. For example, WhatsApp messages might be a cheaper, viable alternative to communication via SMS. In South Africa, SMS messages accounted for 75% of the total cost of the MomConnect program before it switched to WhatsApp.[241]

In underserved regions, solutions should also be designed with online and offline modes. This enables users in unconnected areas to make use of a solution in offline mode when no connection is available, and then to upload data to a server once connectivity is restored. For example, CASALUD's NCD disease-management model in Mexico offers online and offline versions of several applications including the Chronic Disease Information System, which provides an online and offline database in which physicians can store patient data relating to NCD care.[242]

Common health platforms

Naturally, digital health solutions need more than just an underlying communication infrastructure. Another fundamental necessity is an integrated information infrastructure such as a common health platform. There is no standard definition of a common health platform, but this would typically consist of a set of components such as: 1) a health information exchange architecture to manage data flows and consolidate various data sources (e.g., from patients or healthcare providers) that is supported by an interoperability layer that coordinates data interactions between external systems and the HIE; 2) application programming interfaces (APIs) that specify and facilitate the exchange of data between applications; 3) a health management information system (HMIS) that tracks aggregated population data across regions and diseases; 4) identification functionality including unique patient IDs (potentially with biometric identification) and registries for facilities and health workers;

Figure 12 **Components of a common health platform**



5) an electronic health record system that gives healthcare providers a holistic view of a patient's health status; and 6) terminology and classification services to describe data standards. External systems, applications and devices can then be plugged into the platform as long as these conform to the platform standards and APIs (see Figure 12).

For tasks also performed by other systems, a digital health platform could use functionality provided by a common government-wide platform (e.g., when using unique citizen IDs for login and authentication purposes). However, as noted by World Bank Lead Health Policy Specialist Dominic Haazen, "We don't want to be constrained by the lowest common denominator of a platform. We should use a common government-wide platform to the extent possible and then add what is needed to ensure maximum utility for the health sector." In general, common health platforms help to minimize fragmentation and duplication of investment within a sector, as functionality is built once and can be re-used multiple times.

Within LMICs healthcare systems, especially in primary care settings, data collection is often still paper-based. A 2017 assessment of Senegal's "Better Hearts, Better Cities" program indicated that patient health information is collected and stored on paper from the community health level up to the district health-center level. Data collection on paper can lead to data-quality problems such as informational gaps and inconsistent data points collected for different patients, in part due to the use of different data-collection templates. In addition, extra effort is needed to translate paper-based data into a digital format, delays data analysis and readouts.[243]

Even after digital health systems have been implemented, data silos can emerge. In the past, digital health projects have often been designed and implemented as independent systems aimed at solving a single problem or addressing a specific disease (e.g., HIV or malaria). These systems may be adequate for their narrow purposes, but are not based on an underlying architecture that enables data sharing or provides a full view of a patient's health data. A study from South Africa showed that in that country, different entities built parallel infrastructures with different electronic medical-record systems, either for specific research interests or to fulfill reporting needs by donors.[244] Access to the data is thus hampered by the coexistence of many individual systems, which results in "islands of isolated information" that cannot realize digital health's potential for improving patient outcomes.[245]

> "We should use a common government-wide platform to the extent possible and then add what is needed to ensure maximum utility for the health sector."
>
> World Bank Lead Health Policy Specialist Dominic Haazen,

The 2016 WHO Atlas of eHealth Country Profiles brings these two challenges (paper-based medical documents and siloed data) into context by showing that only a few countries have electronic health record (EHR) systems in place at a national level. Only 10% of countries (13 out of 125 examined) use EHRs in most (i.e., more than 75%) of their primary-care facilities. This number has likely risen over time, but still highlights the relative immaturity of national agendas for interoperable health systems, especially in LMICs. Despite widespread awareness of how health information exchanges and common health platforms can be essential in overcoming challenges such as data silos, their adoption has been slow. However, Denmark provides one example of a successfully integrated platform (see "Examples of common health platforms in HICs" on page 78).

Estonia's e-Solutions project offers another inspiring example of common health platform implementation. In contrast with Denmark's national health services platform, e-Solutions

offers services across sectors, such as eGovernment (e.g., internet-based voting), education (e.g., online classes), business and finance (e.g., online tax payments), and healthcare (see "Examples of common health platforms in HICs" on page 78).

A number of common health platforms have also been developed in LMICs. For example, one region in South Africa is supported by openHIE, an organization that offers approaches and open-source reference technologies, some of which are offered as a cloud-based solution. Another example of a common health platform is currently being developed in Gabon (see "Examples of common health platforms in LMICs" on page 79).

From technology to infostructure

It is important to note that the core technology itself is often not the main challenge when implementing a common health platform. Rather, the difficulties are linked to choosing specific functionalities and defining the appropriate interfaces between the various organizational and technology components.

To facilitate the construction of integrated digital health systems, the ITU in collaboration with WHO and other stakeholders has developed a Digital Health Platform Implementation Handbook. This serves as a guide for implementing digital health platforms (DHP), which act as underlying information infrastructures, or "infostructures" for digital health systems.



The Digital Health Platform Implementation Handbook

The "infostructure" described in the Digital Health Platform Handbook is an integrated set of common and reusable components intended to support digital health applications and systems. It consists of software elements and shared information resources that collectively facilitate integration, data definitions and messaging standards, thus enabling interoperability within public healthcare systems. The DHP infostructure provides a horizontal base to connect vertical silos of information and functionality housed in individual digital health applications and systems.

Accelerated development

A well-designed DHP will improve health systems by ensuring that existing digital health applications work together effectively, and by accelerating the development of new applications and tools. This is possible because standards are defined, interfaces are in place and components can be re-used. This kind of digital health tool promises to significantly improve the availability and quality of information available to support decision-making by health authorities, healthcare delivery organizations, and by individual clinicians and patients. This ultimately improves healthcare delivery and patient outcomes.

Efficiency gain

The DHP approach of leveraging common, reusable components – that is, elements that are implemented once, but are re-used across multiple healthcare organizations – reduces redundancy. This efficient design allows digital health resources to be shifted to innovative work on new DHP components, and also to the less glamorous but essential tasks of system updates, technical fixes and maintenance.

Future proof

The reusability and interoperability of the DHP components allows external applications and systems to plug into the platform, as long as these conform to the DHP's standards and APIs. Moreover, DHP-based digital health systems can more easily accommodate changes in technology, new medical devices and artificial-intelligence advancements.

For more information, refer to the ITU publication entitled: "Digital Health Platform Implementation Handbook: Building an Information Infrastructure 'Infostructure' for Health" (planned publication autumn 2018)

Guides and Resources on digital health investment

A number of other guides and resources also provide information on developing and coordinating reusable digital health investments.

1) The planned ITU/Digital Impact Alliance (DIAL) "ICTs for a Sustainable World" campaign, which is aimed at developing digital solutions helping to achieve the Sustainable Development Goals and provides a mapping of common functionalities across sectors. This will help create a roadmap for developing common health platforms that involve multiple sectors (planned publication autumn 2018).

2) WHO's planned "Guidelines on Digital Health Interventions for Health Systems Strengthening" are designed to help facilitate informed digital investments that address quality and coverage needs and strengthen health systems, while also providing donors and governments with confidence that the right decisions are being made. The goal is to support the institutionalization of evidence-driven decisions and long-term government investment (planned publication December 2018).[246]

3) WHO's "Classification of Digital Health Interventions v1.0 – A shared language to describe the uses of digital technology for health" categorizes the different ways in which digital and mobile technologies are used to support health system needs. It provides a common language for assessing and articulating digital health functionalities. This classification is also part of the guides cited above.[247]

4) The Digital Health Atlas (DHA) offers governments, technologists, implementers and donors a set of tools and guidelines to improve the use, planning and coordination of digital health information systems. Understanding the inventory of existing digital health solutions and systems has been a critical step in countries such as Sierra Leone and Lesotho, which have used the Digital Health Atlas to create government review and monitoring procedures for digital health investments. The Atlas features recognized, mature and open-standards-based digital health software products that are supported by vendor communities and have been proven to add value within digital health ecosystems. This helps ensure investments are based on best practices in line with the Digital Investment Principles and Principles for Digital Development (see page 109 for further information on donor and investment coordination). The DHA is available at: www.digitalhealthatlas.org.

2.3

Examples of common health platforms in HICs

Denmark's national health services platform

Denmark (population 5.7 million) has established a national health services platform that connects all GPs and hospitals in all five of its regions, and allows patients to check their records using their Danish ID number. All Danish GPs and hospitals use electronic medical records, which facilitate the exchange of data across sectors and systems. A total of 97% of laboratory test results are delivered online, and 100% of prescriptions are transmitted to pharmacies electronically.

According to Healthcare Denmark, a coalition of public and private actors that provides information on Denmark's healthcare system, the GP is the gatekeeper in the Danish system. GPs handle preventive healthcare and treatment, and coordinate services across healthcare professionals. After consultation, patients can be referred to a hospital or a specialist, or to prevention-oriented services such as weight-loss or smoking-cessation programs. A total of 90% of all patient cases are handled by GPs without referrals.

Denmark provides two additional services related to digital health and primary healthcare:

1. Sundhed.dk is the national health portal. Danish healthcare professionals, as well as all citizens, can access their secure medical records through this platform. This service adds transparency – and therefore trust – to the health system, and empowers people to take care of their health.
2. The platform also offers a telemedicine solution for patients with chronic diseases. A successful COPD pilot, which includes measuring vital signs at home, is being rolled out nationwide through 2019.

The national service platform is based on a health data exchange as part of its core health IT system, and an eHealth portal for various users who are identified using a unique ID. These are three key pillars of Denmark's common health platform.

The country's health legislation gives the minister of health the power to set specific requirements regarding the use of ICT for healthcare purposes, including requirements for the use of common infrastructure.

Estonia's e-Solutions platform for healthcare

The e-Solutions platform supports two primary healthcare-related functions:

1. ehealth records and portal

Every person in Estonia (population 1.3 million) who has visited a doctor today has an online medical history. The national health information system integrates data from Estonia's various healthcare providers, creating a single record for each patient. Since 2015, over 95% of data generated by hospitals and doctors has been digitized. The platform gives doctors access to patients' electronic records (e.g., test results, X-ray images) and offers patients a view of their own and their children's records. By logging into the portal using their unique ID, patients can review their previous consultations and prescriptions, receive general health advice, and get an overview of case summaries, immunization data, dental-care documents, health-examination results, health certificates and access to medical bills reimbursed by the Estonian Health Insurance Fund. Doctors also queried the portal half a million times in the course of a single year.

2. e-Prescription

The centralized e-prescription system facilitates the paperless issue and handling of medical prescriptions – indeed, 99% of all drugs are today issued to patients using an e-prescription. The system connects every hospital and pharmacy in Estonia, cutting down on paperwork and doctor visits, and ultimately saving time and effort. Doctors prescribe drugs electronically, and patients can pick up their medicines at a pharmacy using their ID card.

In many respects, the e-Solutions platform is comparable to Denmark's platform. There is a central information-exchange layer called X-Road that is used across all sectors. The electronic health record system pools data from various sources via X-Road. Access to the health records is granted via an electronic ID. The health information is kept completely secure, while still being accessible to authorized individuals. The system uses blockchain technology to ensure data integrity and data privacy. The transparency generated in this way provides a level of trust that has allowed the system to be rapidly adopted, which has in turn empowered its users.

Examples of common health platforms in LMICs

Advancing platforms in South Africa

Both the MomConnect program at the national level in South Africa (population 55.9 million) and the Western Cape's Provincial Health Data Center make use of openHIE components. Both projects are helping South Africa progress toward its UHC ambition.

MomConnect has evolved from several similar but independent mobile health pilot projects on the issue of pregnancy. Today it is a consolidated, nationwide initiative focusing on maternal health. It has been integrated into at least one common platform, and has added new patient-engagement functionality to South Africa's national health IT system. From a technology perspective, MomConnect is a part of an openHIE architecture that includes a master patient index (openEMPI) that is is interoperable with the national-level medical record system, a master health-facility index and a health-management information system., This schema could allow MomConnect to be extended to additional applications, population groups and use cases – for example, to NCD-related services. This approach is a big step forward toward UHC.

The Provincial Health Data Center (PHDC) in the Western Cape province is a common health platform based on an information exchange architecture that connects multiple nodes such as laboratory, supply-chain and pharmacy data systems, but also includes patient-facing systems (e.g., MomConnect). PHDC has successfully established a patient registration system featuring unique IDs used both for hospital and ambulatory services. This reached nearly full coverage in the Western Cape region as of 2013, enabling users to view a full patient history. As an additional function, alerts can be triggered and sent to doctors for processing when clinical indicators appear for specific patients. The next version of TIER.Net, the national HIV- and tuberculosis-monitoring system, will be fully integrated with the PHDC, providing primary care facilities with data-capture tools and EMR functionality.

Although PHDC and MomConnect have some connections, they serve different purposes and use different data-management concepts (e.g., for their respective master patient indexes). At the same time, they make use of common functionalities such as such as the Open Health Information Mediator (OpenHIM), which improves interoperability by fostering safe information flows between different health systems. In addition, PHDC is the first clinical system in South Africa to integrate MomConnect data into its own database. This set of examples shows that South Africa does not yet have a nationwide common health platform, but does have strong regional capabilities, which can form the basis for a future extension to the entire nation.

South Africa's current set of services and functions could be generalized to larger countries, which could also use provincial or regional initiatives to catalyze common national-level health platforms.

An e-government initiative with digital health capabilities in Gabon

The government of Gabon (population 2.0 million) asked the World Bank to develop the eGabon project, funded by a US$56 million loan. It is the flagship initiative of a broader eGovernment plan, which is in turn driven by a national economic diversification strategy to establish Gabon as an ICT hub.

The goals for eGabon include the following:

(1) Develop a platform that improves the country's national health information system

(2) Foster a digital innovation ecosystem that helps expand the ICT sector and diversify the country's economy

The objectives of the proposed national health information system as follows:

- Create an integrated digital health system, covering all levels of care in the public and private sectors, including telehealth
- Ensure interoperability with existing systems, including a patient ID system
- Develop a national electronic medical record system and clinical decision-support capability
- Ensure the ability to extract high-quality data directly from clinical systems for efficient reporting
- Facilitate interfaces with the national health-insurance system to speed claims processing

By establishing interoperable systems across public- and private-sector healthcare entities, eGabon is an element of the country's current five-year strategic health framework. The platform can subsequently be used as a framework that the government can expand to sectors outside of health.

2.3

Practical recommendations

The creation of high-quality communications infrastructure and the development of common health platforms remains challenging in LMICs. However, both goals can be regarded as pre-requisites for attaining universal health coverage, and for enabling effective NCD screening, diagnosis and ongoing monitoring.

Communications infrastructure, specifically the characteristics of coverage and affordability, continues to improve. However, prices remain prohibitively high in some LMICs. Costs can be mitigated and coverage expanded through strategies including the provision of free public internet, innovative service models, infrastructure sharing and efficient frequency management. These may require funding by public and private stakeholders. In addition, some LMIC population segments might still be excluded from digital health solutions; to avoid social inequalities, non-technological solutions must also be used (e.g., by drawing on family members and internet-connected community health workers to help non-connected individuals obtain digital services).

Common platforms are cost-efficient and offer a set of common functionalities

The development of common health platforms is challenging, as it requires planning with multiple stakeholders, shared investments and new governance structures. These challenges may be offset by new digital solutions' higher cost-efficiency (build once, use multiple times), a common set of available functionalities, and better integration and interoperability. Examples from HICs such as Denmark and Estonia and LMICs such as South Africa and Gabon can serve as role models for other nations seeking to develop common health platforms. In addition, toolkits and guidelines published by international organizations can provide additional guidance. Generally, LMICs should draw on other countries' experiences to leapfrog ahead, skipping technological stages that some HICs are only now beginning to outgrow. Practical next steps for both areas (communications infrastructure and common health platforms) are presented below.

Access: coverage and affordability

1. Create awareness of connectivity issues, and make coverage and affordability within mobile/fixed broadband and mobile cellular networks a strategic digital health topic:

Promote the importance of improving mobile and broadband coverage and affordability. Identify the benefits this will bring for digital health and NCD services, for all population segments within the country. Support the creation of long-term mobile/fixed broadband plans based on current and future coverage targets (rural and urban regions), affordability targets (cost thresholds), and digital health needs (use cases based on UHC goals and NCD-management objectives).

- Collaboration: Health ministries/departments should work closely with communications ministries/agencies, private-sector network operators and eGovernment agencies to create aligned strategies, joint plans and co-investments.

- Network development: Consider different development models to enhance coverage and affordability depending on regional needs (e.g., increase public access to internet, support competition and innovation, develop policies for infrastructure and resource sharing, support flexible spectrum management). Use

universal-service funds to help spur network rollouts in underserved areas, or to promote innovative digital health topics such as public internet access. Place a high priority on establishing good connectivity in care settings in which digital health can have a significant impact (e.g., from larger health facilities all the way down to community health workers).

Common health platforms

1. Make platform development a strategic topic across sectors:

Include common health platform concepts in the national digital health strategy, and ensure these concepts are aligned with related strategies elsewhere in government and in other sectors. Promote the advantages of an integrated information infrastructure or a common heath platform across sectors. Seek to align around a common set of functionalities, thus reducing duplicate efforts.

2. Define functionalities and use cases for a common health platform:

Make use of published guidelines to define high-priority functionalities and describe probable use cases (see WHO's Classification of Digital Health Interventions and Guidelines on Digital Health Interventions for Health Systems Strengthening). Use cases will necessarily depend on a given country's health needs and plans, and will depend on the current level of digital health maturity and any previously defined strategies. Tasks that may help facilitate the achievement of universal healthcare may include:

- Gathering and exchanging health data through a health information exchange that connects many devices, applications and health systems, thus providing all appropriate healthcare stakeholders with an integrated data view. Consider a progressive approach to including information from paper-based sources as well as more advanced digitized sources.
- Creating electronic health record systems and health portal functionalities, thus enabling healthcare professionals and patients to retain information in centralized client records, and giving them the ability to access relevant health records.
- Developing telemedicine capabilities to support remote consultations and self-monitoring, as well as establishing e-prescription functionalities to allow for remote prescriptions.

3. Establish an information- and application-architecture blueprint and roadmap:

Based on relevant use cases, establish an information and application-architecture blueprint (infostructure) for a common health platform. The ITU's Digital Health Platform Handbook will be useful in guiding this task, as will reference to existing architectures such as openHIE (the community of practice focusing on health information exchange). Ensure that this platform is driven by relevant data-exchange standards.

Create a roadmap prioritizing the development of functionalities that will ultimately support a common health platform. These can grow incrementally and be shared between partners while also making a conscious trade-off with smaller solutions that offer appealing quick-wins but do not fit into the defined architecture. Consider using cloud-based and open-source technologies to ensure technical scalability and cost efficiency.



2.4

BUILDING BLOCK 4

Interoperability Framework

Interoperability allows for the integration and leveraging of different digital health solutions and data sources among government programs, hospitals, community health workers and patients themselves. It is essential to manage NCDs in a coordinated way across all levels of care and all stages of the patient journey. Interoperability allows different ICT systems, software applications and devices to communicate and exchange data.

Policymakers should consider interoperability a cornerstone of their digital health strategies and think about building on open standards in consultation with an expert group.

Countries without legacy systems can be at an advantage when it comes to fostering interoperability.

→ KEY TAKEAWAYS

Interoperability allows different digital health solutions and data sources among government programs, hospitals, community health workers and patients themselves to connect with each other. It is essential to manage NCDs in a coordinated way across all levels of care and all stages of the patient journey

Interoperability allows different ICT systems, software applications and devices to communicate and exchange data

- Currently, many national healthcare systems face a lack of interoperability between their data sources and patient management systems.
- This is due to the use of proprietary elements or commercial software instead of open standards. Inconsistent use of existing standards can also be at fault.
- Remedying this is considered so crucial to the promise of digital health that it is now receiving UN-level attention.



(c) Nana Kofi Acquah / Novartis Foundation

Policymakers should consider interoperability as a cornerstone of their digital health strategy

- Countries without legacy systems can be at an advantage when it comes to fostering interoperability.
- Diverse expertise is needed to make decisions, because interoperability entails both technical and organizational aspects.
- Establishing a board of national and international experts from the public and private sectors can be extremely beneficial.
- A fundamental role for the government is to create awareness around the importance of interoperability and the value of open standards.
- A variety of open standards are ready to adopt, as well as "profiles" that bring multiple standards together.
- Countries that establish unique citizen IDs have the tremendous advantage that patient information can be linked and followed up over time.
- Regional communities of practice and organizations can also be leveraged to navigate the field of interoperability.

2.4

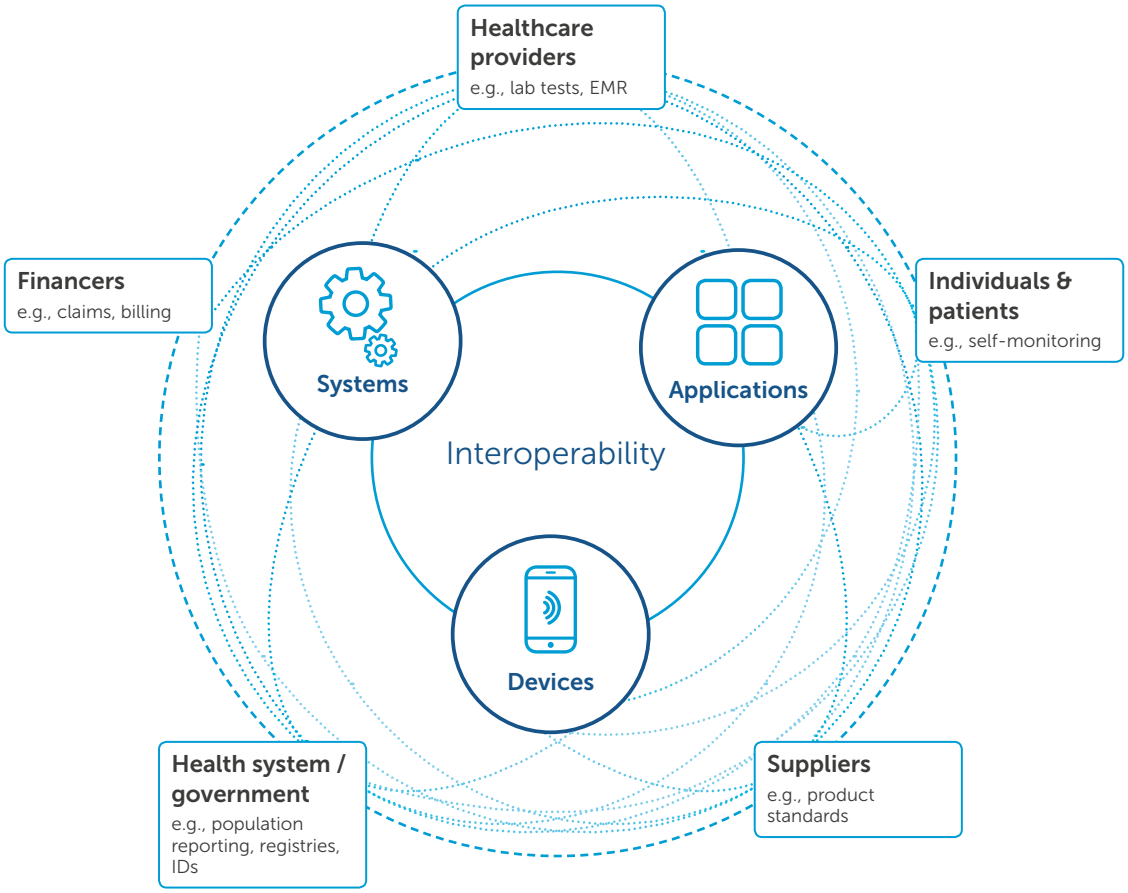
Why is this relevant to digital health sustainability?

If a national health system is to realize the benefits of digital health technologies, its various components must be interoperable. Only with seamlessly connected health data systems, devices and applications can data be integrated from and exchanged between various sources and stakeholders such as health providers, payers and patients (Figure 13).

Interoperability between system components facilitates NCD care and progress toward UHC more broadly, as it allows patients' data to be accessed:

- Across diseases (important for co-morbidities)
- Over time (important for identifying disease progression and monitoring/ chronic disease management)
- Across healthcare settings (e.g., facility-based in a hospital, through apps used by a community health worker)
- By healthcare professionals and by patients themselves (as systems incorporate new data coming from patient self-monitoring processes)

Figure 13 **Interoperability ecosystem for digital health**



Multifaceted interoperability

The board of the Healthcare Information and Management Systems Society (HIMSS), a global, non-profit organization focused on technology in the health sector, defines interoperability as "the ability of different information-technology systems and software applications to communicate and exchange data and use the information that has been exchanged." Health information systems that are interoperable can work together within and across organizational boundaries to advance the effective delivery of healthcare for individuals and communities.[248]

Interoperability – or its lack – is a critical concern for all healthcare stakeholders. The following use case illustrates how interoperability is required in a primary healthcare setting:

A GP talks with a patient about a small diabetic ulcer, and consults his EHR to understand the patient's medical history. The EHR combines information from various sources, including a recent lab result and long-term blood glucose levels. This holistic overview of the patient's medical record supports the GP in making treatment decisions that ensure continuity of care. Based on the available information, the GP prescribes the appropriate medication and schedules a follow-up with a community health worker in the village where the patient lives.

This scenario highlights how interoperability is needed so that various data sources (e.g., lab results from information systems or from other medical records, self-monitored data) can be easily consolidated and continuously updated to provide insights on patients' health status.

Four dimensions need to be considered for interoperability to be achieved:[249, 250]

- Technical interoperability – Information can be exchanged between two technologies, regardless of the content-interpretation process (e.g., exchange of data between tracking devices and mobile phones)
- Syntactic interoperability – Data is exchanged using a defined syntax or form (e.g., exchange between applications with a defined document format)
- Semantic interoperability – Data is exchanged using shared reference information (e.g., a data point such as a lab value is automatically recognized and positioned in the right field within an electronic record)
- Process interoperability – Parties involved have agreed on process workflow (e.g., a follow-up or referral triggers a predictable action. This is also relevant for aligning treatment pathways)

> Interoperability is the the ability of different information-technology systems and software applications to communicate and exchange data and use the information that has been exchanged

The last dimension of process interoperability is primarily an organizational topic, for which alignment between stakeholders is needed. For the other interoperability dimensions, the required technical and data standards already exist, and are established as such. Why do so many countries nevertheless show such limited interoperability in their health systems? According to GSMA, the limiting factors are the use of proprietary elements or commercial software packages that do not support existing open standards, or in some cases the slow adoption and inconsistent use of those existing standards.[251]

LMICs can potentially leapfrog mature markets because they are often less encumbered by legacy infrastructure and systems, and can thus apply existing standards.



Selected interoperability standards and bodies

IEEE 11073: This family of standards produced by the Institute of Electrical and Electronics Engineers (IEEE) defines a common framework for information exchange between medical devices, including personal health devices used outside of a clinical context.

HL7: The Health Level Seven International (HL7) organization defines global standards for information exchange between healthcare applications. The HL7 Clinical Document Architecture uses XML (a mark-up language) to define the structure of documents to be exchanged. HL7 FHIR (Fast Healthcare Interoperability Resources) is a draft standard that defines data objects and an application programming interface (API) for the exchange of data.

IHE: Integrating the Healthcare Enterprise (IHE) is an initiative by healthcare professionals and vendors to improve information exchange across health systems and different use cases. IHE promotes the adoption of existing standards like HL7; to do so, it defines IHE integration profiles specifying exactly how standards are to be orchestrated to allow interoperable data exchange within specific areas (e.g., access to health documents using mobile devices).

PCH Alliance: The Personal Connected Health (PCH) Alliance, a HIMSS-aligned organization, maintains the Continua Design Guidelines for personal connected health devices and systems based on open standards (such as IHE profiles and HL7). The guidelines are written to facilitate secure and interoperable data exchange. The ITU's Telecommunication Standardization Sector (ITU-T), the UN-affiliated standards-setting body, has given Continua's guidelines the status of an international standard for personal health systems.[252]

For additional information on this topic, see GSMA's "Digital Healthcare Interoperability" report.[253]

South Africa's interoperability framework

South Africa has addressed an earlier lack of interoperability with a country-specific framework called the "National Health Normative Standards Framework for Interoperability in eHealth in South Africa" (HNSF), the second version of which was published in 2014. The need for this framework arose when it became clear that the country's fragmented, vertical health-system architectures could not achieve the desired benefits in connecting stakeholders ("network effects"), particularly after they failed to meet the goals set by the country's National eHealth Strategy 2012 – 2016. The HNSF is a step toward a complete health enterprise architecture specification for South Africa (including interoperability), and will eventually define how national eHealth solutions interoperate to promote people-centered, continuous care. Use cases focusing on non-communicable diseases (e.g., diabetes), communicable diseases (e.g., HIV/TB), maternal and child health, and emergency management (e.g., injuries) helped define the requirements, data types, exchange protocols, standards, implementation guidelines and governance model. In addition, a set of recommendations was derived from the analysis of these use cases. One recommendation was that eHealth investment should focus on supporting people-centric healthcare across diseases, in order to move away from facility-based silos. The HNSF can be regarded as a role model for others seeking to build interoperability frameworks in Africa.

From a technology standpoint, South Africa uses openHIM (Health Information Mediator), a technical layer designed to ease interoperability between disparate information systems, as its main interoperability layer. This is part of the openHIE architecture. The work on openHIM is supported by the Africa Health Information Exchange reference implementation, which was funded to advance specific components in support of the HIV/TB response. The resulting

applications can be applied across diseases. In addition, AIHE also supports the implementation of the unique patient identifier to connect different sources on the patient level. [254]

Unique patient ID – The key to enabling person-centric healthcare

The existence of a unique patient or citizen ID is a key enabling condition for integrated healthcare systems. If data points from different digital health systems are to be connected, for example to establish an integrated patient data set or update an electronic health record, a unique patient ID is necessary. A few countries have implemented unique IDs, often in the context of eGovernment initiatives. HIC examples include Singapore, with its SingPass program and Estonia with its eID cards. A few LMICs have also taken innovative approaches to patient identification, as shown by two examples drawn from a recent report by the World Bank.[255]

Unique IDs are necessary for interoperable digital health systems to

Thailand's BORA identification system

Established in 1984, Thailand's BORA identification system includes a digitized national population register based on household and civil registration information. It covers over 99% of the resident population. It registers Thai citizens and eligible migrants, stateless persons and refugees, each of whom receive a 13-digit personal identification number (PID) at the time of birth or at their first household registration. The PID and national ID smart card have become a ubiquitous part of daily life in Thailand as the primary means of authenticating individuals' identities. Because PIDs are also used as proof of identification for a wide range of purposes, for instance to prove residency within a constituency for the purposes of voting and to confirm an address for official correspondence, there are significant incentives for individuals and the government to keep this data up-to-date. The fact that all government agencies use PIDs facilitates interoperability between systems.

Thailand's identification system has been leveraged to increase access to healthcare and enhance the efficiency of health systems in several ways. The most significant contribution is the instrumental role that the national population register and PID – a lifetime unique identifier – played in enabling the government to implement its Universal Coverage Scheme (UCS) successfully in 2001, guaranteeing subsidized healthcare to all citizens. The UCS reportedly reduced the uninsured share of the population from 29% to 5% in less than two years.[256]

India's Aadhaar system

India's Aadhaar system, which is based on a 12-digit unique ID number issued to each resident of the country, was launched in 2010. As of the end of 2017, over 1.19 billion Aadhaar numbers had been issued, covering nearly 90% of the population. The Aadhaar database contains biographic and biometric data for each individual, including name, gender, date of birth, address, a digital photo, 10 digital fingerprints and two iris scans. These biometrics are used to ensure uniqueness at the time of enrollment and for later cloud-based authentication purposes. Rather than relying on a card, individuals authenticate themselves using their Aadhaar number in combination with demographic data, a fingerprint, and iris or a one-time password, which are checked against the central database.

For healthcare purposes, Aadhaar technologies are integrated into care facilities' online patient appointment-scheduling tools, and are used to track the performance of health workers and improve the identification of insurance beneficiaries. One focus of India's new national health strategy is to increase the use of technology to improve health services.

Source: World Bank. 2018. The Role of Digital Identification for Healthcare: The Emerging Use Cases, Washington, DC.

be able to create a people-centered view combining data from various sources over time. The goal of longitudinal data collection is not only to facilitate informed decisions in the present, but also to support forward-looking methods able to identify at-risk population segments (e.g., through predictive analytics). A unique ID is used to integrate historic data with a patient profile for each individual. From a technology standpoint, the OpenHIE architecture offers another component, called openEMPI, that supports the management of a patient master file.

If information beyond patient-level health data is available, these additional sources can also be integrated into an analysis, thus sparking data-driven insights and informing decisions on a population-health-management level. Ethiopia provides a good example of a decision-support application that combines various data sources.

Overseeing interoperability

Given the multifaceted nature of interoperability, the sector needs a specific board of experts tasked with promoting the interoperability of health systems, coordinating the different areas and making the necessary decisions on which standards to adopt. This expert board could fall under the joint governance structure operated by the ministries of health and ICT, if such a structure is in place. This option is commonly recommended in interoperability strategies or guidelines, and should be addressed in the national digital health strategy. The expert board should act as the central informational hub and decision point for all national issues touching on interoperability, ensure that relevant NCD and UHC use cases are correctly reflected in the interoperability standards (e.g., mobile access to health documents), and promote the adoption of interoperability requirements for the procurement of technology or devices.

A number countries have actively supported interoperability for digital health systems:

1) In Mexico, the Ministry of Health implemented the Sistema Nacional de Información Básica en Materia de Salud (SINBA) or Nominal Basic Health Information System, which aims to develop a framework for the convergence of healthcare information systems. This includes guidelines for the information that each digital health program should contain, definitions of variables and web services enabling entities using EHR systems to connect to SINBA.[258]

2) In Chile, a center for health information systems was established with a mandate that goes beyond interoperability standards (see page 89).

Integrating health data to make data-driven decisions[257]

Health data on Ethiopia's 100 million citizens is fragmented and scattered across more than ten disconnected systems. The Federal Ministry of Health (FMOH), supported by Zenysis, successfully integrated data from these systems and additional sources into a single platform – the Ethiopian Data Analytics Platform – within 12 months.

The platform allows decision-makers to quickly analyze more than 600 million data points, and thus gain the insights needed to improve resource allocation, service delivery and health outcomes. The FMOH has used the platform to optimize the country's nationwide immunization program (generating several millions of dollars in savings as estimated by the government) and allocate more than US$100 million to maternal and child health programs based on data-driven insights.

National Center for Health Information Systems in Chile[259]

Until 2008, the implementation of EHRs in Chile was mainly driven by individual efforts at private hospitals and academic medical centers that could afford such projects. During this time, a public procurement framework called the Information Systems Healthcare Network (SIDRA) was put in place, with the goal of allowing health departments to buy pre-assessed health information technology solutions. Although interoperability was one of the concerns, there was no push to address this issue through the adoption of standards. Furthermore, the SIDRA strategy did not include private health providers, a fact that created additional information silos. This means that today, data exchange between the 29 public health departments is not possible and private-provider data cannot be integrated into a common system.

To address this issue, the Chilean Public Development Agency (CORFO) funded the creation of the National Center for Health Information Systems (CENS) in 2016. The center focuses on interoperability, software certification and the promotion of formal health informatics training programs. However, CENS goes beyond the pure data-exchange standards, creating the organizational context necessary to support interoperability. It encourages interactions between all healthcare stakeholders, both public and private, to advance the establishment of national standards and define certification procedures both for software and healthcare workers.

CENS works with internationally standards-setting organizations to identify best practices for the deployment of recognized standards in the Chilean market. Moreover, it adapts these standards to fit local needs when required. To accomplish this, CENS has initiated cooperation agreements with international entities such as IHE Europe and Salud.uy.

A coordination body such as CENS facilitates interactions between public and private health stakeholders, and hence allows care practices to be aligned. This makes access to care more flexible, and ultimately helps achieve universal healthcare.

3) In South Africa, an eHealth Standards Board (ESB) was requested to oversee the implementation of the National Health Normative Standard Framework (HNSF). The ESB worked closely with healthcare providers and other relevant stakeholders to develop, adopt and maintain eHealth standards-based profiles and base standards.[260]

The consequences of a lack of guidance around interoperability were made glaringly obvious during the European United4Health (U4H) project. U4H was co-funded by the European Commission to deploy and assess the impact of innovative telehealth services for the remote monitoring of patients with chronic conditions such as diabetes. It ran between 2013 and 2015, and involved 19 deployment sites across 10 European countries. Analysis of the project found that most sites took a short-term view when choosing their technical solutions, and focused on immediate project goals rather than deploying a service that would be scalable and sustainable. This was partly due to the fact that vendor-engagement and e-procurement stategies were not aligned. For example, some sites did not implement a new procurement process because they had pre-existing framework agreements for the provision of technology. One key lesson learned was that procurement that ignores common data-exchange standards complicates future scaling efforts, and makes it difficult to integrate projects with existing databases and applications.[261] In the case of the U4H project, these problems led to reduced functionality and a need to expend additional time and effort when seeking to scale or integrate with other systems.

Ignoring common data-exchange standards complicates future scaling efforts

2.4

Promoting interoperability

A number of initiatives exist around the world that have worked efficiently to navigate the complexity of interoperability. The three instances presented below begin with a high-level UN agenda addressing the issue, followed by a toolkit that can be used to assess whether a country's health systems are interoperable, and final a look at the value of using interoperability profiles instead of basic standards.

1. **WHA resolution calls for national action:** The topic of interoperability continues to receive substantial attention from the United Nations. Interoperability was placed on the agenda of the World Health Assembly (WHA) in 2013,[262] and the body also approved a new resolution on digital health in May 2018 that included interoperability as one of the core topics. The latest resolution calls on member states to support the implementation of the resolution and sets a list of priorities. In the area of interoperability, it urges member states to work toward and support interoperability for digital health technologies in part by promoting the use of international and open standards as an affordable, effective and easily adaptable solution.[263]

A number of initiatives exist around the world that have worked efficiently to navigate the complexity of interoperability

2. **Health Data Collaborative (HDC):** The HDC is an initiative undertaken by multiple global health partners such as NGOs, governments and universities working with countries toward two goals: (1) improving the quality of national health data, and (2) tracking progress toward the health-related SDGs.

   The HDC's Digital Health and Interoperability Working Group (DHIWG) has the objective of "optimiz[ing] the use of health information in LMICs to support achievement of the SDGs through the implementation of foundational digital health infrastructures." This includes the creation of digital health "public goods," with alignment between investments recommended.[264]

   The DHIWG has produced a Health Information Systems Interoperability Maturity Toolkit that consists of an interoperability maturity model, a maturity assessment tool and a guide. The toolkit's assessment results can be used to help countries create a plan to improve interoperability between the components of their digital health systems.[265]

3. **The advantage of frameworks:** The IHE profiles and PCHAlliance guidelines cited at the beginning of this section (see "Selected interoperability standards and bodies" on page 86) facilitate an approach that relies on overarching frameworks rather than individual standards. These frameworks orchestrate the underlying standards with a focus on implementation. Making use of such frameworks allows countries to focus their energy on actual use cases rather than on how different standards come together. Denmark was the first country in the world to adopt the Continua guidelines as a national standard for telehealth devices. These standards are now the foundation of a framework for implementing telehealth nationwide.[266]

Practical recommendations

Interoperability is a cornerstone of any modern health system. It allows for the reliable exchange of data between devices, applications and systems, and facilitates a seamless user experience for stakeholders at all levels. Furthermore,



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interoperability standards enable an open healthcare ecosystem where new digital solutions can be developed and easily integrated in the future. To enhance interoperability within a country, existing standards should be implemented and used consistently across national health solutions. Next steps for policymakers include the following:

1. **Make interoperability a strategic priority:** Interoperability should be identified in the national digital health strategy as a prerequisite for the success of digital health initiatives. Stakeholders should examine and select relevant use cases within the national context, including primary and specialized care as well as non-facility-based activities such as prevention, telemedicine and self-care.

2. **Set up a standards and interoperability board:** Establish an expert board tasked with overseeing standards-selection and interoperability issues. This board should help define the country's approach toward interoperability, taking relevant use cases into account. Collaboration between national and international public and private actors, as has taken place in Chile, is necessary in order to reflect the spectrum of needs and required expertise. Once created, the board can act as a centralized information hub and decision point, and should define a national technical architecture. Procurement teams need to make sure that interoperability requirements are listed in public tenders as selection criteria.

3. **Create awareness of the importance of interoperability:** Policymakers should work to ensure that relevant stakeholders (e.g., ministries, care providers, health IT providers, digital health technology procurement agencies) are aware of the value of interoperability, and are conscious of the problems that occur in its absence. This can take place through training workshops, for example in collaboration with the expert board or with universities.

4. **Make use of existing interoperability profiles and base standards:** Most standards that a government might need already exist, but bringing them together in the right way is complex. Policymakers should investigate the frameworks produced by the IHE initiative (called interoperability profiles) that align and orchestrate the necessary base standards (like HL7), and facilitate implementation. Interoperability issues related to personal connected health devices, a topic relevant both to enabling self-care and achieving UHC, are addressed by Personal Connected Health Alliance's (PCHA) global standards and implementation framework. Countries such as Denmark have successfully used the PCHA guidelines to boost people-centered care.



BUILDING BLOCK 5

Partnerships

Partnering can increase the scale and impact of digital health solutions by combining expertise, ideas, assets and other resources of different stakeholders.

Government and mobile network operators can be especially important partners for scale, helping digital health solutions reach larger target populations and even integrate into national health systems.

Partnering has to create value for all stakeholders involved.

Policymakers can create opportunities to bring stakeholders together and build working relationships.



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→ KEY TAKEAWAYS

Partnering can increase the scale and impact of digital health solutions by combining expertise, ideas, assets and other resources of different stakeholders

The digital health stakeholder landscape is diverse. In general, it includes:

- Governments responsible for health-system planning and management, public health IT infrastructure and financing
- Financers, including donors and insurers, who bring financing for digital health solutions and in some cases the power to convene several partners
- Health providers, who bring medical expertise and delivery capacity
- Suppliers, such as mobile network operators (MNOs), technology companies, and NGOs and civil society

Government and MNOs can be especially important partners for scale

- Governments are key for integrating digital health solutions into national health reimbursement systems, shaping health policies, connecting with other stakeholders and defining regulations.
- This is especially crucial for solutions addressing NCDs, which require lifelong treatment and often lead to catastrophic health expenditures and impoverishment of entire families.
- Partnering with MNOs has enabled digital solutions to reach larger target populations.

Partnering has to create value for all involved

- Different organizations bring different assets and aspirations to the table, and meeting those aspirations is crucial to a sustainable partnership.
- Over time, there has been a mindset shift when it comes to partnering with the private sector.
- In early phases, private sector partners have donated digital health products or services.
- Now, they seek "win-win" or "shared value" models that generate benefits for the business as well as for patients, healthcare providers and other stakeholders.

Policymakers can create opportunities to bring stakeholders together

- Governments can help bridge sector boundaries through, for example, health innovation events focused on specific needs, support to help small companies bid for contracts, roundtables, working groups, and other forums that allow stakeholders to meet and build working relationships.

2.5

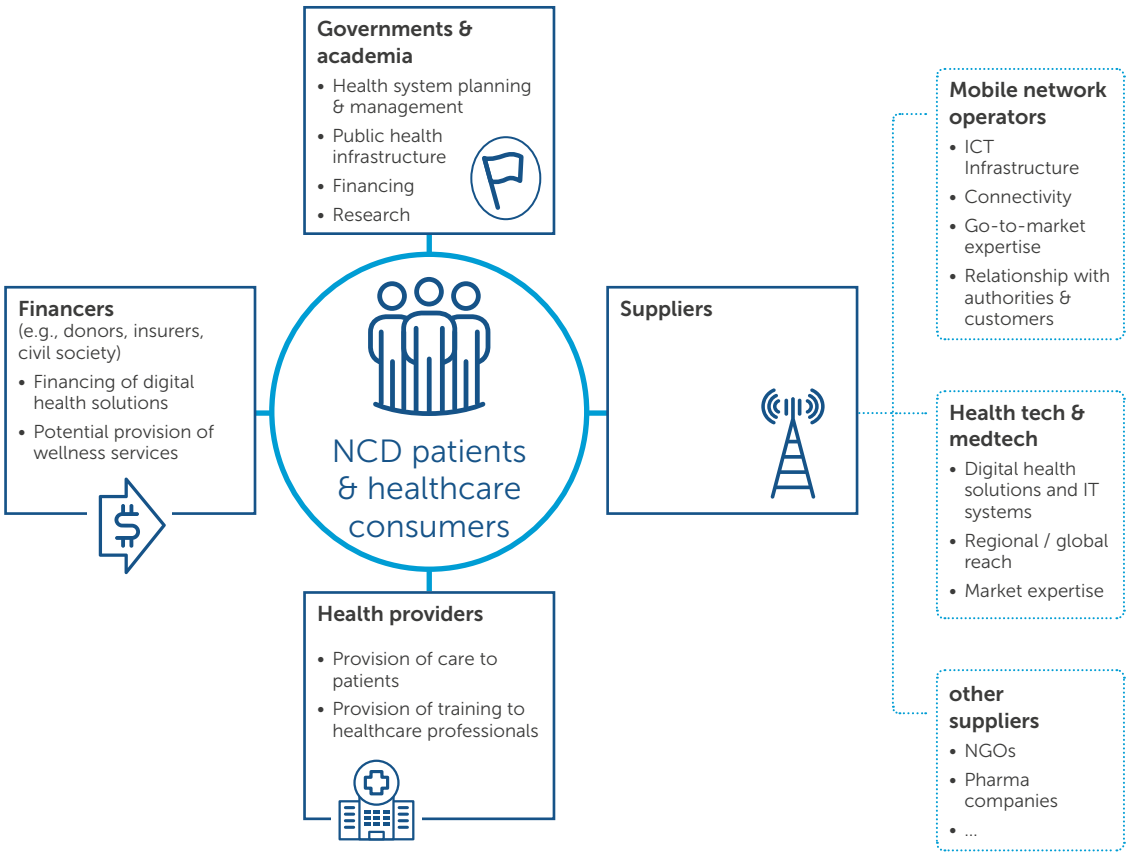
Why is this relevant to digital health sustainability?

Multi-stakeholder partnerships for delivering and scaling digital health solutions are gaining in popularity in both HICs and LMICs. These partnerships engage organizations across sectors, and may include government entities, mobile network operators (MNOs), health providers, technology companies, insurance companies and more.[267] "Partnerships" in the context of this report means any collaboration of stakeholders whose mission is to deliver a digital health solution (e.g., sale of a diagnostic device) or help shape a country's digital health ecosystem (e.g., with the task of defining interoperability standards).

Partners can gain distinct benefits from working together; for instance, health services can be improved by sharing complementary knowledge and assets, and by exchanging ideas on policies and strategies. These partnerships also create value at the system level by coordinating the creation and delivery of digital health solutions.

Stakeholders bring different assets to digital health partnerships (Figure 14). Governments aim to improve overall health within their populations by strengthening the healthcare system. Private companies may include MNOs, health technology providers, health insurance companies and pharmaceutical companies. These entities aim to improve their products or services, make a profit, and gain or retain customers by delivering value-added solutions. NGOs aim to make a social impact. A partnership is sustainable only when all these aspirations can be addressed, allowing the various stakeholders to find value in partnering.

Figure 14 **Key assets in multi-stakeholder partnerships for digital health**



Joining forces to educate community health workers in Kenya

Leap, an mLearning platform for training community health workers in Kenya, is the outcome of a successful partnership between NGO Amref Health Africa, the government of Kenya, the M-Pesa Foundation, Accenture Development Partnerships, and Safaricom Limited and Vodafone (Mezzanine), both private companies.

Leap's mobile-learning solution delivers interactive training through SMS text messages and voice recordings across rural and urban settings. Leap training programs are customizable, thus allowing health workers to access information on diseases relevant to their communities, such as hypertension and diabetes.[269]

The various partners each contributed different capabilities needed to build and deliver a scalable platform:

- Amref was responsible for Leap's vision and strategic direction, and provided day-to-day project leadership and community engagement.
- The Kenyan Ministry of Health provided strategic direction and regulatory oversight.
- Mezzanine led the custom development of the technology platform, and provided multi-channel mobile health solutions.
- Safaricom provided the extensive telecom infrastructure and data centers required to deploy Leap across Kenya.
- Accenture Development Partnerships co-funded the project and provided its consulting expertise on issues of program strategy, delivery, technical design, mobility and learning methods.
- The M-Pesa Foundation co-funded the project.[270]

Each entity had a unique role and set of offerings, whether financial, cultural, technical or managerial. The sum, as reflected in the end product, was greater than if any entity had tried to deploy the solution on its own. As a result of this successful teamwork, 70,000 community health workers across Kenya have access to the Leap platform, including more than 35,000 who have actually been trained using the system, with a 92% completion rate and 88% reduction in attrition rate (which leads to less costs associated with replacing health workers)[271].

Over time, there has been a mindset shift regarding the provision of digital health systems in LMICs. Traditionally, private-sector partners have donated services or products as part of their corporate social responsibility portfolios. As this type of support has often proved to be short-term and unsustainable, there has increasingly been a shift toward partnership models in which private-sector companies contribute their assets and profit-seeking know-how, while sharing the responsibilities and risks associated with delivering digital health solutions with the public sector.[268] The development of the Leap platform in Kenya provides an illustration of how different stakeholders can lend their expertise to make a powerful social impact.

The rest of this section describes additional examples of multi-stakeholder partnerships. It will focus by turn on different stakeholders that play key roles in ensuring the sustainability and scalability of digital health solutions. Sub-sections are structured around three key outcomes that can be achieved by partnering with stakeholders:

- Ensuring that a project is integrated with the national health system
- Increasing access to ICT and a targeted customer base
- Making use of technology assets

2.5

Key outcomes achieved through partnerships

Ensuring integration within the national health system

As described under Building Block 1, strong government leadership and advocacy is critical to ensuring the sustainability of digital health solutions. According to Safaricom Product Manager for eHealth Judy Njogu, "You cannot achieve scale in digital health unless you are working with the government."[272]

Even before a national strategy for digital health has been defined, it is important to foster partnerships between digital health providers and the government. This helps avoid possible situations of conflict between proposed new products or services and new policies or regulations (e.g., with regard to data privacy and security requirements for electronic health records).[273]

"You cannot achieve scale in digital health unless you are working with the government."

Safaricom Product Manager for eHealth Judy Njogu

In a number of instances, collaboration with top levels of the governments in LMICs has been critical to the success of local digital health programs, as illustrated by the examples of CASALUD in Mexico and babyl in Rwanda (see "Examples of digital health partnerships with governments" on page 98). However, it should be noted that engagement with local government agencies can be equally important for the purposes of gaining necessary support, as shown by MedicMobile in Nepal. Finally, MomConnect in South Africa highlights the importance of the government in facilitating scaling (see "Examples of digital health partnerships with governments" on page 98).

Increasing access to ICT and customer base with MNOs

Mobile network operators play a substantial role in facilitating digital health solutions in LMICs. MNOs' core business is to provide mobile-phone users with telecommunication services, including wireless voice and data communication. However, the largest MNOs, including Vodafone, Telefónica, America Movil and Telenor, have also started to provide digital health solutions in LMICs on a business-to-government, business-to-business and business-to-consumer basis. Their wireless infrastructure, combined with their regional or national scale, makes them attractive partners for other entities seeking to create sustainable digital health solutions. In return, MNOs are interested in digital health solutions because they provide a differentiated, consistent source of revenue (see "Examples of digital health partnerships with MNOs" on page 100). MNOs are expected to play an even bigger role once the advanced capabilities of 5G networks become a reality.

Beyond their core offering of providing network connectivity, MNOs can also enhance the scalability and sustainability of digital health initiatives by 1) providing partners access to a large customer base, 2) leveraging their strong relationships with local authorities in locations where other technology players may lack a presence, and 3) sharing their experience with customer relationship management to improve services such as mobile user registration and health-related payments. In return, MNOs can generate new revenue streams through these additional offerings beyond their normal connectivity services (see "Examples of digital health partnerships with MNOs" on page 100).[274]

Making use of technology assets

Companies providing devices, platforms, software and equipment for digital health solutions also play important roles in these multi-stakeholder partnerships. Beyond providing the digital health devices, they are also key in building the back-end infrastructure of health systems.

On a regional level, Microsoft and Accenture' s partnership with governments in the ID2020 project, which aims to address challenges in population identification, provides an example of the benefits of involving technology providers in health initiatives.

On a national level, NGO Jembi Health Systems played a key role in providing the interoperability technology layer needed for MomConnect and NurseConnect to reach more than 2 million pregnant women and new mothers and 24,000 nurses in South Africa.[275] Jembi has worked closely with the South African Department of Health to use the data from MomConnect and NurseConnect to establish a registry of MomConnect users. When building the health information exchange technology, Jembi followed the information-exchange requirements described in the South African National Department of Health's Normative Standards for Interoperability Framework.[276, 277, 278]

For such regional and national-level partnerships to be successful, technology providers should position their project so that it resonates with the government's goals. This was a key lesson for the implementers of mTrac, a mobile-based disease-monitoring and medicine-tracking system that collects real-time data on medicine stocks in Uganda. Here, the team explained that their solution was not a standalone pilot overlapping with other national initiatives, but rather a way to enhance the health management information system through the creation of a transaction and communication layer. The mTrac solution could therefore be repurposed for drug-supply tracking campaigns, and for the purposes of expanding health records to the communities.[279] To obtain stakeholders' buy-in, communication of the expected benefits of a digital health solution should be tailored to the goals of the partners. mTrac is now acting as the MoH's national communication channel, with more than 15,000 registered and trained community health workers recorded in its database. A total of 70% of all health providers in Uganda are already using mTrac.[280]

ID2020 – Partnering for digital identity

It has been estimated that 1.1 billion people worldwide currently lack an official government-provided identity card or number. This undermines the efficiency of public services, such as primary healthcare. For example, Malawi's national health system provides free health services to all Malawians, but because few people can prove their citizenship, an estimated 20% to 60% of patients from neighboring countries also access local services in Malawi, stretching health providers beyond capacity. Launched in 2016, ID2020 brings together 150 private-sector companies, 11 UN agencies, as well as governments (e.g., the United States, the United Kingdom, Norway, Malawi and Tanzania) and non-profits. Microsoft and Accenture are building an open-source technology layer that enables the ID2020 vision to improve the population's access to critical social and financial services such as voting, healthcare, education, mobile communication and banking.[281] ID2020 is an example of a public-private partnership, a type of contract between a public agency and a private entity (for-profit or not-for-profit) for the provision of services, facilities or equipment.[282] A PPP leverages private-sector capabilities and best practices to support government initiatives.

2.5

Examples of digital health partnerships with governments

Carlos Slim Foundation: Shaping the national NCD policy with the Mexican government

Partnering with the Mexican government was crucial for scaling the CASALUD model and integrating it into the country's health system.[283] Since 2013, CASALUD has expanded its operations nationally in partnership with the Federal Ministry of Health and all 32 state governments.[284] The government has played several roles in this partnership, such as:[285]

- Incorporating CASALUD in the National Strategy for the Prevention and Control of Overweight, Obesity and Diabetes, which was launched in October 2013; CASALUD was designated as a reference model in 27 states
- Leading the deployment of relevant CASALUD components, for example by integrating SIC (an NCD information system) and ICAD (the Index of Quality of Care of Diabetes) into national health policies
- Validating the CASALUD model by providing technology oversight through the Health Information Systems department, clinical oversight through the National Center of Prevention and Control of Diseases, overall strategic oversight through the Ministry of Health
- Deploying health-promotion and prevention-education programs through MIDO, CASALUD's systematic-risk-assessment tool
- Using CASALUD's integrated dashboard in the Mexican Observatory of NCDs for the purposes of epidemiological monitoring
- Providing funding for medical supplies, health workers' salaries and internet connections

Thanks to this partnership, the Carlos Slim Foundation succeeded in expanding its Integrated Quality of Care System and Quality Index of Diabetes Care in Mexico to cover 32 states, and its Networks of Excellence in Diabetes to 27 states.

babyl: Partnering with the Rwandan government for reimbursement and definition of quality standards

The role of the government in digital health partnerships can also be illustrated by babyl's collaboration with Rwanda's Ministry of Health and Social Security Board. These partnerships allowed babyl (a mobile healthcare-services app) to deploy its platform to government health centers, so that patients who have had phone consultations with babyl can subsequently access their prescriptions and laboratory tests from the health centers. This collaboration was crucial in ensuring that the state insurance entity would provide reimbursement for the teleconsultation service (95% of the service costs; for more details, see "Public insurance-led financing" on page 111).

In addition, babyl worked directly with the government to define national regulations on quality and safety standards in digital health. As part of this standards definition process, the government facilitated a series of workshops with key stakeholders such as local clinicians from health facilities, while babyl shared its previous experiences working with the UK's Care Quality Commission to define standards in that country.[286]



A nurse explains a mobile app to a patient that helps assess his risk for being overweight, obesity and diabetes. The NCD screening service is one of three digital health programs aiming to reverse the rise in NCDs, and has been scaled to 27 Mexican states.



The Carlos Slim Foundation partnered with the Mexican government to scale its NCD disease-management model and integrate it into the country's health system.

Photos: (c) Carlos Slim Foundation

MedicMobile: Partnering with local governments for long-term ownership

Non-profit software company MedicMobile demonstrated the crucial role played by government engagement when rolling out its open-source decision-support, supervision and analytics software tool for health workers in Nepal. Part of the cost of this program stemmed from the need to pay for SMS text messages. Because Nepal went through a state-restructuring process toward the end of 2017, in which programming and budgeting authority was devolved to local municipalities, MedicMobile had to work with local government units known as village development committees to secure funding to cover these costs.[287] In general, "Getting local buy-in separately from existing national agreements is critical to the long-term ownership and success of digital health programs, since the implementation happens at the local level," says MedicMobile Asia Regional Director Shreya Bhatt. In parallel, MedicMobile also entered into a strategic partnership with the national Ministry of Health, signing a memorandum of understanding in 2017. This national engagement was helpful during the local partnership discussions, as the ministry's overarching support helped win the trust of local officials.[288]

MomConnect: Scaling in partnership with the South African government

MomConnect is a health-education messaging service and feedback mechanism (help desk) for pregnant women, mothers and health workers in South Africa. MomConnect's rapid implementation (within one year of launch, almost half a million pregnant women were enrolled) was made possible due to a strong consortium of partners spearheaded by high-level government leadership.

The minister of health supported the solution from the onset, carrying out road shows in all South African provinces to demonstrate the platform's impact, directly participating in monitoring the utilization of help-desk features, assessing registration trends at the provincial level, and publicly celebrating milestone achievements. Provincial health managers then handled the task of integrating MomConnect with existing local programs for mothers and children. The engagement of leaders at all levels of the health system was essential to the success of this digital health initiative, and should be viewed as a goal in other projects as well.[289] However, it should be noted that once political commitment is secured at the highest level, good-governance strategies become essential in executing and evaluating the initiative.



(c) Johnson&Johnson

MomConnect, a messaging service for pregnant women in South Africa, was able to scale rapidly due to strong high-level government support.

2.5

Examples of digital health partnerships with MNOs

Africa - Switchboard

In Ghana, Liberia and Tanzania, MNOs Vodafone and MTN partnered with the non-profit organization Switchboard to set up a free calling network for health workers. This valuable nationwide network enabled isolated doctors from rural areas to seek clinical advice from colleagues and refer patients to further care free of charge. This network also provided a way for doctors to report data on patient health, drug supply levels and lab results directly to the Ministry of Health. The government could in return send critical health messages to large groups of doctors in the event of a disease outbreak, for example. In Ghana and Liberia, Switchboard has scaled nationally, reaching 100% of the countries' doctors,[290] with 4 million calls made since 2008. This model has benefited the MNOs as well, as they have been able to generate revenue from the paid calls that doctors make to family and friends.[291]

Latin America – AxisMed

Telefónica acquired a controlling stake in 2013 in AxisMed, a chronic-care-management provider, to begin providing a remote monitoring solution for patients with chronic conditions in Brazil. Under the service, patient data such as blood glucose levels is transmitted to health workers who manage patients' NCD treatment.[292] AxisMed benefits from Telefónica's 90-million-person customer base in Brazil (through Telefónica's Vivo subsidiary), which enables it to reach out directly to patients using mobile apps, SMS and videos.[293] Telefónica in turn can provide a value-added service directly to customers, leading to new mobile-subscriber acquisition and better customer retention. Since launch, this digital health solution has reached 19 million patients across Brazil.[294]

Asia – Tonic

Telenor, the Norwegian multinational telecommunications company, partnered with Grameenphone, Bangladesh's largest MNO with a customer base of 60 million mobile subscribers, to launch Tonic. This initiative provides digital health solutions including wellness information via SMS and the internet, teleconsultations, discounts on hospital services via a SMS containing the partner code, and insurance coverage for healthcare claims paid directly to the member's mobile banking wallet. The offerings are provided as free or opt-in services to Grameenphone customers.[295] In addition to providing connectivity and access to customers, Grameenphone also lends its established expertise in microfinance to the initiative, enabling health insurance to become a natural extension to Grameenphone's business.[296] As of February 2018, 5 million people are using Tonic services.[297]

Africa – EcoHealth

In Zimbabwe, Econet, Zimbabwe's largest telecommunications company, partnered with Cumii, a technology provider focusing on primary-care-level health management, to support diabetes care management. Together they offer SMS healthcare tips, teleconsultation and telemedicine solutions, enabled through SIM cards provided by Econet. Customers can pay directly for these services through Econet's mobile payment solution.[298] The SMS HealthTips service averages around 1 million subscribers each month, with about 200,000 receiving weight-management tips and 100,000 receiving diabetes-management tips.[299]

Creating an enabling environment for partnerships

There are many ways to promote innovative digital health partnerships in. On a local level, governments can mobilize players to collaborate to meet public health goals.

On a national level, the government and policymakers should encourage the involvement of local community members, whether this be digital-device manufacturers, health workers or health authorities. For example, the Communities for Healthy Hearts program in Ho Chi Minh City showed that building trust within the community facilitated local buy-in for the initiative's hypertension screening and care services. Local engagement was achieved by training volunteers who were already well-known in their neighborhood, and by partnering with local health authorities that referred patients to the health checkpoints.[300] Another example of local engagement is offered by Zipline, the drone-based blood-delivery service in Rwanda, which relied on recruiting and training local engineers and flight operators. This was a key element in convincing users that the drones were meant for public-health purposes rather than military or intrusive surveillance work.[301]

On a cross-border, regional level, best practices in the digital health field can be disseminated by organizations such as the WHO and the African Union, allowing stakeholders to benefit without necessarily entering into partnerships. In some cases, independent organizations also establish formal collaborations. For example, PATH launched the Better Immunization Data Learning Network, an innovative partnership model that brings national governments together to 1) identify shared digital health problems and solutions, 2) design common information-system products, practices and data policies, 3) experiment with these designs in a few countries, and

On a national level, the government and policymakers should encourage the involvement of local community members, whether this be digital-device manufacturers, health workers or health authorities

Boosting local innovation in digital health – examples from the UK and Norway

DigitalHealth.London (DH.L) acts as a "front door," assisting high-potential digital health companies, often at minimal cost, to navigate the complex London healthcare system. This increases their ability to forge partnerships and establish pilot-project opportunities with healthcare providers and other organizations. Companies are selected based on their potential to solve the real problems faced by the health system. The hub provides a marketplace for exchange between buyers (the healthcare providers and commissioners that are scouting for digital health solutions) and sellers (digital health companies). Contracts are often brokered through DH.L, which is seen as a trusted and impartial broker. To date, DH.L has engaged directly with about 460 healthcare professionals, and has closely supported an estimated 1,083 digital health companies over the last 2+ years.[302]

The municipality of Oslo in Norway wanted to improve primary healthcare services for elderly people. The local government collaborated with Norway Health Tech, a network of industry and research institutions, to produce health solutions tailored to people with special needs. The partnership provided incubator funding to support startups and created consortiums that would include small companies that would normally have little access to large-scale public-private partnerships.[303]

finally 4) use the lessons learned to inform national and global decision-making. This approach enables demand-driven, pragmatic solutions to be created by digital health specialists across countries.[304]

Cross-border collaborations between startups and governments can also take the form of digital health innovation events such as hackathon competitions, where local healthcare groups fund winning teams in developing their ideas into fully functioning prototypes. In the United States, Stanford has organized the Health++ Hackathon, which is a two-day event that brings together 300 engineers, designers, business experts and healthcare professionals.[305] In 2017, this hackathon identified the NutriLink app as a top innovator with the promise of successfully addressing nutrition challenges in India.[306] The successful app developer is set to collaborate with the government and policymakers, with plans to scale up to reach larger audiences and provide aid in making decisions.[307]

Practical recommendations

Governments can take a leading role in setting up and managing multi-stakeholder partnerships, or can alternately facilitate collaborations by creating a favorable environment for other stakeholders. The following guidelines are applicable to both scenarios.

1. **Identify the health needs and the right partners to address them:** Assess health gaps relating to NCD-management programs and universal healthcare ambitions that can be addressed using digital health tools. Identify the key capabilities and assets needed to deliver each identified solution and identify the right partners, for example through hackathons, regional digital health initiatives or by partnering with international organizations. Adapt procurement processes so that established businesses and startups alike can participate. Consider partners drawn from the broader health ecosystem, too, such as gyms but also food companies, to focus on nutrition.

2. **Create an environment where partners can meet:** Organize round tables and integrate stakeholders (e.g., via industry associations) into working groups to encourage the creation of mutually beneficial partnerships. Bring together health and

Promoting innovation in East Africa – the Digital REACH Initiative

The Digital REACH Initiative is a collaboration between the East African Community (EAC), individual EAC partner states (e.g., Burundi, Kenya and Rwanda), development partners and the private sector. It aims to improve health outcomes in East Africa through the strategic application of ICT and the harmonization of digital health strategies, policies and standards. For example, one of the proposed projects is to build a so-called East Africa Open Science Cloud for Health, which could be used for tracking NCD prevalence across partner states. The overall launch of the Digital REACH Initiative is planned for the end of 2018.[308, 309]

IT stakeholders so that digital health solutions are designed to address a specific health need. If a national digital health strategy is in place, with defined working groups overseeing digital health, use those to create opportunities for partnerships and collaborations.

3. **Make sure the structure of the partnership is clear:** Define partnership roles, responsibilities, incentives, business cases, rewards and risks from the beginning, so that each partner is clear on what it brings to the table as the collaboration works to achieve health goals. Be aware that the type and pace of operations in companies may be different from that in the non-profit and public sectors. Thus, it is essential that expectations are aligned and communication lines are clearly established.

4. **Support partners in realizing the benefits of collaborations:** Connect foreign companies with local players and community members. This will help the companies obtain local market insights, while building local-community trust. Build a business case and plan for scale from the start by developing a sustainable business model (see "Cost containment" on page 118).

5. **Monitor and evaluate the performance of the partnership:** Define a strong monitoring and evaluation strategy upfront for measuring the health impact of multi-stakeholder interventions (see "Monitoring and evaluation" on page 42). When appropriate, involve a neutral party such as an NGO to act as a coordinator or broker between the government and the private sector.

(c) Nana Kofi Acquah / Novartis Foundation





BUILDING BLOCK 6

2.6 Financing Models

Sustained financing is needed to take promising digital health solutions from proof-of-concept to scale. Policymakers and other digital health stakeholders have a variety of financing options for common digital health platforms, which require significant, long-term commitment, and for specific digital health solutions, which have more diverse financing needs if they are to protect people from financial hardship. A range of financing models can be used. The ultimate goal is for digital health solutions to be covered by payers such as insurance companies. Other models can be used as financing bridges until reimbursement schemes are established.

Obviously, if development and operating costs of digital health solutions are low, less funding is needed. Smart design, local integration and maintenance, as well as bulk purchasing can be used to bring down the costs of digital health.

→ KEY TAKEAWAYS

Taking promising digital health solutions from proof-of-concept to scale requires committed and sustained financing

A variety of financing options exist:

- → Historically, 85% of digital health funding in developing countries has been spent on early-stage research and development or pilot programs.
- → Now, financing models for all stages of the project lifecycle are beginning to emerge, including innovative models that generate revenues on an ongoing basis.

Common digital health platforms require long-term commitment

- → Governments should take the lead in coordinating funding for digital health platforms.
- → Donors and development banks are stepping up efforts to increase funding for core health IT systems when there is commitment from the government.
- → Governments can also look for ongoing revenue streams to recoup initial investments.
- → For example, this can be achieved through pay-as-you-use models that make common digital health platforms more accessible for governments, healthcare providers and other healthcare stakeholders.

Diverse financing options can be used to fund solutions that plug into the common digital health platform

- → A range of financing options can be used as part of a business model, with the objective of protecting patients from financial hardship.
- → The ultimate goal is for digital health solutions to be covered by public or private health insurances.
- → Other models can be used in combination with reimbursement schemes or as a financing bridge until a health insurance is established:
  - Donor grants to jump-start digital health solutions until they have proven to work and can cover their own costs or be absorbed into the public health system
  - Out-of-pocket payment is the least preferred option but can cover specific needs with a quick adoption rate and become more affordable for low-income groups through cross-subsidization or a "freemium" approach
  - Direct government financing, where resources are available or provided through loans; in addition to common health platforms this is typically used for time-limited public health campaigns
  - Public or private insurance reimbursement is the ultimate goal. This includes micro-insurance for digital health services that can bring substantial health benefits
  - Pay-as-you-use or licensing, which generates a constant revenue stream for providers while matching users' needs.

Obviously, if development and operating costs are low, less funding is needed

- → Smart design, local integration and maintenance, as well as bulk purchasing can be used to bring down the costs of digital health.

2.6

Why is this relevant to the sustainability of digital health?

Historically, 85% of funding for digital health in Africa has been spent on early-stage R&D and pilot programs.[310] Many digital health solutions relied on donor grants with a limited timeframe that does not allow for scale-up success, particularly in cases where a sustainable business model has not been defined from the start.[311] Another potential issue is that donor funding generally targets individual projects and can therefore create siloed programs that overlap with ongoing initiatives in the country. Although pilot funding is important for proving the cost-effectiveness of a digital health solution, achieving financial viability for scaling digital health solutions in LMICs is a key challenge. Indeed, many digital health pilots in LMICs lack long-term viability planning and run out of funds before they are fully implemented.

"We need to look for funding outside of, or in addition to, public investments."

Fiona Adshead
NCD Alliance.

More stable, sustainable sources of funding can come from governments, but public funding for digital health is usually low in LMICs. "We need to look for funding outside of, or in addition to, public investments," says Fiona Adshead from the NCD Alliance. In addition, private investments are also limited, due to the high-risk nature of such initiatives and the lengthy duration of idea-to-market for commercial solutions. As a result, digital health implementers are exploring various multi-stakeholder partnerships in order to leverage partner capabilities, co-invest and share risks (see Building Block 5).

This section documents various financing mechanisms for core health IT systems (e.g., EHRs) and digital health solutions (e.g., mobile apps) from HICs and LMICs, in the context of emerging business models that could inspire governments as they seek sustainable digital health solutions. Generally, investing into digital health should benefit NCDs programs, while NCD investments will also need to help establish digital building blocks for collective benefit.

Financing for health IT systems

Initial financing to develop a health IT system infrastructure

A core health IT infrastructure needs to be in place in order to accelerate the development and scale of digital health solutions in LMICs (see "Common health platforms" on page 74). This infrastructure may include an HIE platform for collecting data from different data sources, electronic health records that bundle patients' health data in one place, a health management information system with analytics for obtaining population-level information, or a unique patient ID system that tracks an individual patient's data across multiple providers and services. A national IT framework of this nature allows various digital health solutions to be linked up with a horizontally and vertically integrated health system. The system must be built on interoperability standards that allow for the collection, exchange and analysis of longitudinal data from patients with NCDs. Investing in such an infrastructure in the early stages of a country's digital health journey would facilitate the development of future digital health solutions.

The funding of such core health IT systems should be clearly linked to the digital health strategy of a country (see "ICT and digital health assessment" on page 44). However, governments in LMICs with limited resources often do not prioritize financing for such infrastructures. "Donor funding is more

often directed at specific digital health programs rather than helping a country build its digital backbone," said Andrew Bushell, the Global Program Head for Diabetes and Metabolism at Novartis. However, donors and commercial and/or development banks have been stepping up efforts to increase funding for the core health IT system in cases where the government shows leadership in implementing their national strategy in digital health.[312]

In recent years, several LMIC countries have recognized the benefits of making long-term investments in health IT and infrastructure and have prioritized funding appropriately. In some cases, governments have even found a way to generate ongoing revenue from assets to recoup part of their initial investment. This can be seen, for example, in Senegal, where the national health agency "Agence de la Couverture Maladie Universelle" (ACMU) is planning to implement an integrated healthcare system in 2019 that is expected to generate ongoing revenues.

Health platforms might also be financed by a "pay-as-you-use" scheme that provides solutions, often including hardware and software, to users who pay only when they need to use it (i.e., for a service rather than a product). This means that the party purchasing the pay-as-you-use service does not need to pay for IT development costs. In addition, this model encourages technology providers to keep their solution (including hardware) up-to-date and their users trained as they continue to receive draw fees.

This recurrent income allows the service provider to recoup its investment in infrastructure costs. This also reduces users' upfront costs in cases where the provider can manage the financing risk. A similar model is the "platform-as-a-service" model whereby applications are developed and deployed in the

ACMU Senegal's platform for the digital transformation of community-based health insurance

ACMU's Integrated Information System for the Management of Universal Health Coverage (Système d'Information de Gestion Intégré de la Couverture Maladie Universelle) aims to digitalize health insurance by integrating data from health plans and claims as well as biometric identification systems. Sources of data come from all health service points, such as health posts, public health institutions, pharmacies, private clinics and health insurance funds. This platform enables ACMU to improve health insurance services and health claim management, thus moving the government of Senegal toward its long-term goal of having one central health insurer for its population.[313]

The ACMU developed an innovative approach to generating ongoing revenue from all participating stakeholders:

- Financing via user fees: Each user (e.g., pharmacies, clinics) pays a fee to access the platform. For example, each pharmacy and private clinic pays CFA franc 25,000 per month (approximately US$45).
- Transaction fees: Fees are issued for each electronic contribution payment made on the platform that comprise an estimated 5% of annual income.
- Crowdfunding: Civil society, the diaspora population, businesses and NGOs can directly finance ACMU projects in a transparent and traceable manner.

Estimates suggest this approach could result in an estimated CFA franc 6,885 million (approximately US$12.5 million) of revenue annually. The initial system investment costs could therefore be recovered over time and create a self-sustaining funding pool for the platform's future maintenance and operations.[314]

cloud and customers purchase the resources they need on a pay-as-you-use basis, accessing them through a secure internet connection.[315] Because the provider can provide support and upgrades remotely, application costs are more effective. The provider can also easily update the software because it is hosted on the cloud and not locally.

An example of these models is a health information system called ZiDi that is provided by Micro Clinic Technologies and deployed by Huawei in Kenya. ZiDi provides digital management solutions for county hospitals, health centers and dispensaries in Kenya. It tracks health services and the consumption of vaccines, and forecasts patient demand in over 50 health facilities with more than 5,000 regular users so far. ZiDi allows both public and private sector actors to deploy a "platform-as-a-service" model with three service plans (Table 2).[316, 317]

Financing models for digital health solutions

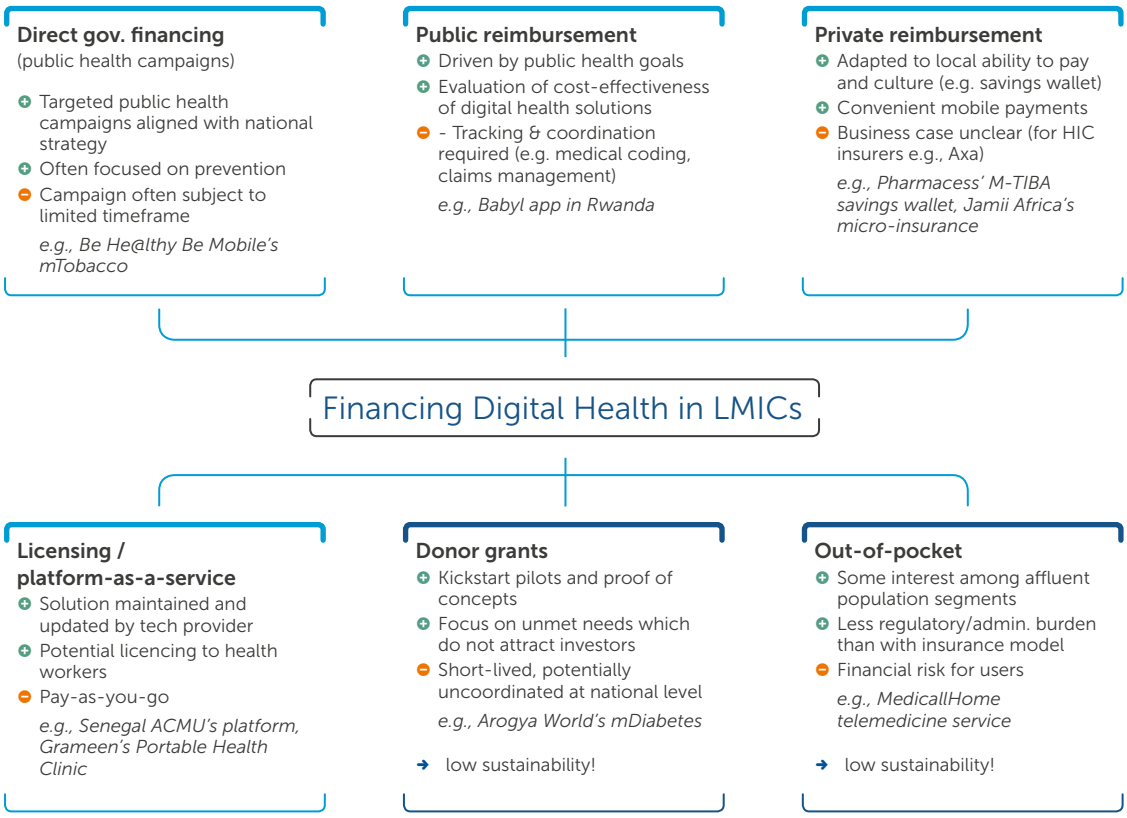
This section describes ways to finance digital health solutions that plug into the infrastructure of a core health IT system previously described (see "Common health platforms" on page 74). These solutions are therefore tailored more to individual customers such as patients or health practitioners rather than the health system as a whole. For example, this section focuses on digital health solutions such as the financing of SMS services designed to send educational material to patients with diabetes that can be plugged into a common digital health platform instead of focusing on the digital health platform (Figure 15).

Table 2 **Examples of service plans for platform-as-a-service model**

SERVICE PLAN	FINANCING STRUCTURE	TYPICAL CUSTOMERS
Full platform as a service offering	Clinics are provided with the hardware and software as a service and pay 50-70 cents per patient within a three-year contract. The service includes installation, training for five users, customer support, data storage, access to reports and e-patient records via the web.	Clinics in high-demand, low-income catchment areas.
Software as a service offering	This is similar to a full-service offering, except here subscribers purchase their own equipment and pay 20-25 cents per patient within a two-year contract. A surcharge is applied for software testing and installation on the devices.	Large networks of clinics or hospitals that are able to procure and manage the equipment
Software product licensed offering	Customers pay a one-time licensing fee and then pay for each additional user license and a percentage of total cost for annual renewals with version upgrades.	Low-volume or specialty clinics with limited users, seeking an offline solution / NGOs with fixed budgets.

Source: Huawei's ZiDi platform

Figure 15 **Financing models for digital health solutions in LMICs**



Direct government financing

There are multiple examples of direct government financing for customer-facing digital health solutions that are part of public-health campaigns fostering proactive NCD management and prevention.

The WHO-ITU Be He@lthy, Be Mobile (BHBM) initiative, for example, focuses on supporting governments seeking to ensure mobile-based NCD prevention and management services are both large-scale and sustainable.[318] The initiative encourages governments to cover at least 30%-50% of costs for the initial setup and maintenance of a mobile health service, and then works to transition the model toward greater government funding and ownership over time.[319]

Some governments have found innovative ways to finance these public health campaigns enabled through digital channels. Costa Rica, for example, in its effort to finance several tobacco cessation services by means other than so-called sin taxes, now includes an SMS-based program run by the BHBM initiative.[320]

Direct government financing of digital health solutions (e.g., remote patient monitoring devices) can prove challenging because many governments lack the financial resources necessary to implement digital health solutions and are often not aware of the extent of their benefits. Additional funders must therefore be identified to initiate and sustain digital health initiatives.

Donor funding

Donor grants represent a classic financing model for digital health solutions. This funding approach has

historically allowed innovative solutions to be developed and piloted among populations in need. However, such grants usually do not provide sufficient funding to allow for national scale-up efforts or coordination with other ongoing digital initiatives.[321]

For example, Arogya World successfully reached 1 million Indians through their mDiabetes program that relies on a combination of donations from civil society organizations and private sector philanthropic donations from companies such as MSD India and Johnson & Johnson. However, scaling its services to the national level will require Arogya World to acquire support from the Indian government and integrate into the national strategy. The government does not currently support Arogya World because of its study design, which collects patient-reported results from real-world settings instead of conducting randomized controlled trials.[322]

For countries that depend heavily on donor funding, it is important that the government take the lead in overseeing donor activities. For example, the Rwandan government invited key donors to sit on working groups that manage digital health implementation. This collaborative approach also ensures that donor-funded digital health projects are transparent and coordinated.[323]

Donor funding is not the conventional means of financing solutions in a sustainable manner. However, the CASALUD model from the Carlos Slim Foundation in Mexico has shown that a donor-funded initiative can successfully reach national scale and be sustainable. Donor-funded solutions therefore need a long-term commitment from donors that is coupled with close collaboration with the government. Upon establishing proof-of-business and cost-effectiveness, donor-funded models can transition to a government-funded model. MomConnect in South Africa is another example of a digital health program that was successfully jumpstarted by donors.

MomConnect: Transitioning from donor funds to other financing sources

When launched in August 2014, the MomConnect initiative was implemented by the South African National Department of Health (NDOH) with financial support by donors (e.g., USAID, PEPFAR, Johnson & Johnson, UNICEF and Elma Philanthropies) and discounted mobile inventory rates that were provided by all four of the MNOs in South Africa (Vodacom, MTN, Cell C and Telkom).

From the start, however, donors clearly communicated to the government that their support would not exceed a few years, and it was agreed that the NDOH would assume responsibility for funding and ongoing operation costs once stability and scale are reached. From August 2014 to October 2017, with the use of donor funds alone, MomConnect managed to reach over 1,638,000 registered users on the platform. Since October 2017, the government has covered program costs for the monthly SMS and unstructured supplementary services and now works with NGOs like Praekelt.org and Jembi Health Systems and donors such as Grand Challenges Canada, to enhance program sustainability and scalability. This includes setting up an independent governance body and running surveys on the platform in order to generate income and decrease reliance on donor funding.

Programs that integrate transition planning from the start can successfully move from a 100% donor-funded model to a more sustainable model.[324]

Social impact bonds – An investment alternative for digital health

Social impact bonds offer an alternative to the traditional means of acquiring investment funds such as bank loans or donor grants. With an emphasis on achieving specific program outcomes, social impact bonds draw on elements of a public private partnership. The main parties involved include the (mostly private) investor that provides upfront capital, the service provider that delivers the social service, and the outcome funder who pays back the investment and an agreed return on the investment to the investor. The outcome funder can be a government or a third party like a donor or foundation.[325]

According to the Brookings Institution (2017) almost 40% of impact bonds in developing countries (11 out of 28) were related to health. One example in Africa is the investment in a physical rehabilitation program supported with digital health tools.[326]

Advantages of social impact bonds include:

- Attracting new funding sources (including from the private sector)
- Facilitating alignment of incentives between funders and implementers toward achieving development outcomes
- Fostering evidence-based development[327]

Public insurance-led financing

An alternative to donor grants is public insurance-led financing, which involves public health insurers paying for digital health solutions that are believed to bring significant health benefits to the population. Some HICs have begun taking advantage of this option, marking a critical first step toward UHC by lowering the financial barrier to connected devices or digitally enabled health solutions for vulnerable populations. It is still not common to see outcome-based funding models where health insurers and digital health solution providers partner to reduce healthcare costs and share cost reductions that are achieved.

1) United States

In the United States, coverage for telehealth and digital health solutions have expanded incrementally in recent years. Private insurers have traditionally covered telehealth services more liberally than Medicare, the public insurance program in the United States for the elderly and people with disabilities. However, Medicare is also beginning to expand coverage for a wide range of telehealth services. If the Evidence-Based Telehealth Expansion Act that was introduced into Congress in 2017[328] passes, telehealth services that offer equivalent quality of care at reduced or equal cost of in-person visits would be reimbursed by Medicare. There is bipartisan support for incentivizing provider use of telemedicine and reimbursement, as members of both parties believe these tools have the potential to improve disease management and reduce costs.[329]

Some HICs have begun marking a critical first step toward UHC by lowering the financial barrier to connected devices or digitally enabled health solutions for vulnerable populations

2) EU

In Europe, there have also been positive steps taken in terms of government coverage of digital health solutions, as several countries are making notable efforts toward public reimbursement.

In France, decree n° 2010-1229 was passed in October 2010 to enable the reimbursement of telemonitoring for patients who suffering from three chronic diseases simultaneously. Under this decree, both healthcare providers and heath technology providers are each reimbursed €300 every six months for

providing telemonitoring services. This national rollout is currently ongoing and involves the software provider Cegedim and medical devices company Visiomed Group. The national health insurance system CNAM is currently defining the reimbursement tariff. Because some questions remain regarding impact, French national authorities have moved forward cautiously with digital health reimbursement.[330]

Belgium is also exploring the reimbursement of digital health solutions and dedicated US$3.5 million in 2017 to pilot the reimbursement of 24 health apps and remote monitoring devices across six months. The objective of here is to use the lessons learned to broaden the use of reimbursement approaches for digital health in 2018.[331]

In general, the reimbursement of digital health solutions is only just emerging and is not yet sufficient to support a full scale-up of digital health in European health systems

In Germany, a few digital services have made their way into standards of care through selective contracting with public insurers, such as Tinnitracks for tinnitus relief or Caterna for amblyopia treatment.[332] In addition, the country is experimenting with populated-based integrated care models that are enabled by digital health. In these models, health providers partner directly with health insurers to provide high-quality, cost-effective care. For example, Gesundes Kinzigtal, a joint-venture between a network of physicians and a healthcare management company, contracted with two sickness funds that insure about half of the 69,000 inhabitants of the Kinzigtal region. This approach targets patients suffering from multiple chronic diseases and makes use of digital health technology such as electronic health record systems that are shared among participating health providers, digital tools for comparing prescribing behaviors among physicians and remote patient monitoring devices.[333, 334]

Switzerland is one of the most mature markets for teleconsultations in Europe, as telehealth is included in the offerings of all larger health insurance companies as a way of triaging patients on the phone. It offers the possibility of e-prescriptions, referral to a face-to-face appointment with a general practitioner or specialist, and even the exchange of digital pictures. This model has shown to lower premiums by about 15%-20% for individual contributors.[335]

In general, the reimbursement of digital health solutions is only just emerging and is not yet sufficient to support a full scale-up of digital health in European health systems. The reimbursement landscape in HICs is currently very heterogeneous, making it difficult for global digital health providers to access the market.[336] Additional difficulties include the increasing pressures on public payers for funding new technologies, the slow implementation of assessment criteria for reimbursement, the lack of evidence of digital health's clinical impact on patients, as well as the perception among small-to-medium enterprises of cumbersome reimbursement procedures.[337] In addition, reimbursement policies for digital health are dependent on regulations that allow health services to be delivered remotely in the first place (see "Regulations on delivery of care" on page 60).

3) Latin America

In Latin America, an interest in financing digital health was seen in Chile, where Fonasa, the National Health Insurance Agency of Chile, launched a telehealth program for diabetes and hypertension care. The program was developed as a PPP with AccuHealth, which provided patients with home monitoring devices and virtual communication tools for patients to connect with physicians. It used its data processing algorithms to detect signs of potential complications. If patients required a medical consultation or hospitalization, they were referred to a public health facility. Fonasa financed

the care program on a per-capita basis based on a pre-defined package of care services that are tailored to patients' diseases.[338]

4) LMICs approach

In LMICs, reimbursement by public payers is even more challenging than in HICs, due to the lack of financial resources and insufficient awareness of how digital health can help achieve UHC. However, a few government-funded pilots have been observed which are not (yet) supported by a supporting reimbursement policy.

Private insurance-led financing

Private companies have also started offering financial coverage for digital health solutions. Some of these private insurance-led models are specifically tailored to the needs of low-income patients, thus featuring low prices and delivery through mobile channels, which leverages the high penetration of mobile payment services in LMICs.

1) Micro-insurances

The micro-health insurances that have been developed in some LMICs as a means of pooling risks and reducing out-of-pocket health expenditure offer one successful example. Research has shown that micro-insurances have a positive impact on protecting low-income populations by reducing the risk of catastrophic health spending and increasing access to healthcare.[339]

The micro-health insurances that have been developed in some LMICs as a means of pooling risks and reducing out-of-pocket health expenditure offer one successful example

Micro-insurance policies are well adapted to low-resource settings with high mobile phone penetration. For example, the Tanzanian startup Jamii Africa built a mobile platform carrying out all the administrative tasks of a classic insurer. It also partnered with Jubilee Insurance and Vodacom to cut administration costs by an estimated 95%. Jamii Africa offers users inexpensive health insurance services via USSD, starting at only US$1 per month.[340]

In addition, there are micro-insurance companies offering insurance bundled with digital health solutions, thus enhancing patients' access to both finance and healthcare professionals. An example of this model is the insurance technology company BIMA, which provides mobile-delivered mhealth services such as teleconsultations and coaching tools that are packaged with

Reimbursement of babyl in Rwanda

In Rwanda, babyl launched its USSD platform (app) in 2016. The platform allows patients to book appointments, get triaged, consult with a doctor and get prescriptions or laboratory tests using codes over patients' phones. Patients are then able to redeem their prescriptions in 145 partner pharmacies, 300 health centers (400 by end of July 2018) and laboratories throughout the country. babyl is also testing in-house an AI-powered triage app that creates a patient's "digital twin" with data that is synced with their medical tests and simulates patient's organs in healthy and diseased conditions.

Because babyl has partnered with the Rwanda Social Security Board, which insures about 85% of the population, much of the cost is covered by insurance, leaving some 15% being covered by patients' co-payments. This successful model has allowed babyl to acquire 500,000 subscribers with more than 180,000 consultations in the first eight months of being launched. It is the unique example of a reimbursed digital health solution in Rwanda.[341, 342]

its insurance service. Micro payments are collected from the mobile phone balance of customers. BIMA now operates services for over 25 million customers, most of them from LMICs such as Bangladesh, Pakistan and Tanzania.[343]

2) Standard private health insurers

HICs focus

Private insurers in healthcare are more advanced in the United States than in Europe in terms of using digital health solutions, which includes remote monitoring of patients in order to reduce risks and costs. A good example is Kaiser Permanente in the United States, a large health insurer and provider caring for over 12.2 million patients. It has invested over US$400 million in technology platforms, providing over 50% of its care to patients through virtual visits, its mobile app or through the online portal.[344] In addition, WellDoc Inc., which provides personalized patient coaching, medication reminders and cloud-based analytics for NCD management, sells directly to primary care physicians and endocrinologists and is secured by reimbursement from private health insurers.[345]

Also, some European insurance companies started adding their own digital health component to existing insurance schemes, with the aim of supporting the aging population and fragile persons at home, thereby reducing risks of generating a chronic disease and re-admissions to the hospital.

For example, the AXA Group sells well-being and prevention services, sometimes directly to corporate clients, and

M-TIBA – A mobile health wallet financed by transaction fees

M-TIBA, a "mobile health wallet," launched in 2015 by Safaricom, Pharmaccess and CarePay in Kenya is leapfrogging healthcare in LMICs.

This mobile solution allows people to save, borrow and transfer money ring-fenced for healthcare at very low transaction costs. In Africa, many people prefer to save money rather than pay into insurance schemes, and M-TIBA's success comes from its ability to pool different payment streams in one mobile wallet which combines, for example, saving with insurance entitlements. Mobile e-wallet entitlements for care can be submitted through one's own savings, family remittances, insurance and donor funding. The first mobile insurance schemes are being developed in partnership with a county government in Kenya.

Entitlements can be exchanged for healthcare services provided in a network of contracted clinics. With every transaction, medical data is collected in real time, generating a wealth of data insights into costs of care, quality and patient behavior.

PharmAccess, a group of non-profit organizations dedicated to improving access to quality healthcare in Africa, recently kicked off a pilot with Sanofi to assess how its mobile health wallet could improve access, quality and affordability of diabetes and hypertension care. The program involves providing patients with mobile vouchers for services such as medical tests and consultations. The level of subsidy is adapted to patients' income levels. With every transaction made by the patient, real time medical and financial data is collected, thus allowing healthcare providers to track patients' adherence to the treatment and payers to better target patients while providing the opportunity to monitor quality of care across the population.

Financing for this mobile platform is based on transaction fees. Healthcare providers pay 0.5% on every transaction (e.g., patient payment, claim management). Patients therefore do not pay any fees, which fosters broad usage among low-income patients. In addition, PharmAccess is exploring opportunities to monetize the aggregate data collected across patients and feedback the returns, for example, in the form of discounted insurance premiums.[346]

teleconsultations and remote monitoring services for insured customers. This allows AXA Group to differentiate itself from competitors in a market where customer volatility is a key issue. This also illustrates a general shift in the mindset of private health insurers from being a payer of healthcare services to becoming a partner in maintaining the well-being of customers. However, a key challenge is the difficulty in demonstrating the long-term impact and value of business models associated with digital well-being and prevention for AXA as a payer.[347]

LMICs focus

Private health insurers have tried to extend their role as as a partner in wellness to LMICs, but their business model must be more clearly defined. To date, they have offered primarily an add-on digital health solution to customers who are able to afford private health insurance. For example, AXA Egypt is selling the MyDoctor app for teleconsultations and remote monitoring for chronic diseases only for its insured customers that are included in the health insurance premium. The app is not sold as a standalone. The private health insurance market is predominantly B2B in Egypt, as only few very affluent people directly purchase private medical care.[348]

Another notable business model involving a private health insurance in LMICs is the Vitality scheme in South Africa.

The Mexican government is also seeking to boost the reimbursement of digital health by private health insurers. Currently, the government is funding pilots under the National Strategy for the Prevention and Control of Obesity and Diabetes, launched in October 2013. For example, FunSalud's Movil Salud, described under "Digital health strategies" on page 37, is currently paid by the MoH (40%) and the Interamerican Development Bank (60%). To ensure the sustainability of the program, FunSalud will reach out to the National Association of Health Insurance Companies to seek reimbursement by private health insurance companies.[349]

Out-of-pocket financing

Out-of-pocket payment for receiving care – the main risk for financial hardship – is still a common model in low-resource settings. People have proven

Vitality – What will 10,000 steps a day buy you?

Discovery Health, South Africa's largest private health insurer, launched Vitality in 1997, a pioneering insurance scheme centered around "insuring shared value." The program actively supports and rewards people for improving their health, and shares the resulting insurance savings with them through better price points and further incentives to drive ongoing positive behavior change.[350] If people hit their fitness goals tracked on the Vitality app, or complete a range of health checks, they receive points that can be spent at partner companies such as Starbucks, Apple, Virgin Active, British Airways and Ster-Kinekor.[351] Some of these rewards in turn enhance health, thus creating a positive feedback loop.

In South Africa, the monthly membership fee is approximately US$20 for Vitality members that is matched by a similar contribution from the insurer. In addition, members pay a contribution toward subsidized preventive care services (e.g., dietician visit, nurse-administered health screening tests) and other services from partner organizations including wellness providers, retailers and fitness device manufacturers. Vitality is available in 15 international markets covering 7 million members. The model is sold to other insurance companies.[352, 353, 354]

The Vitality scheme has demonstrated a significant impact in a 1-year study on admission rates to the hospital, including a reduction in 7.4% of those admitted for cardiovascular disease, a reduction of 3.2% in cancer admissions, and a reduction of 20.7% in endocrine and metabolic diseases admissions.[355, 356]

generally willing to pay for value-added services, such as teleconsultations for reducing the waiting time to see a doctor, particularly in cases where traditional public health facilities are not accessible.

Subscription fees for telemedicine in Mexico

An innovative example is MedicallHome, a telemedicine service offered in Mexico. The service costs around US$5 per month per household, including unlimited 24/7 access to doctors via phone and discounts for clinics, hospitals and labs.[357] This setup combines an innovative subscription model (fixed premium per household for telemedicine service) with standard out-of-pocket fees at discounted rates for all additional healthcare services. The subscription model is attractive for two reasons: First, the model provides a product with ongoing revenue for the provider and it does not suffer from the regulatory burden of an accredited health insurer. Second, coverage focuses on what the customer has subscribed to – there is no broad portfolio of services to be paid for that include services that will never be consumed. The service in Mexico already reaches more than 1 million households.[358]

Another model based on out-pocket payments is the "freemium" approach where customers benefit from "free" digital health solutions as part of another service, such as mobile connectivity, and pay a premium for additional digital health solutions. In general, these freemium models for digital health allow basic digital health solutions to reach a maximum number of users, thus supporting UHC, while customers wishing to have extra services can pay out-of-pocket. This is the case for subscribers of Grameenphone's Tonic wellness service, also described in the previous section. The free version is available to all Grameenphone users and offers basic health insurance and teleconsultations. In the advanced and premium versions of Tonic, users can pay an extra monthly fee in order to make higher health insurance claims, receive health tips on an app and access an appointment booking system with registered doctors.[359]

Another way to achieve equity and financial viability is to segment the population by people's ability to pay for healthcare and then adapt the price of health services accordingly. In this model, wealthier customers pay higher prices that effectively subsidize lower-income groups. This approach was adopted by the Ugandan government for enhancing the access to top priority health products such as mosquito nets and contraceptives.[360] Similarly, the government in Rwanda uses differential pricing for making health insurance premiums affordable to people with low incomes.[361]

Licensing

An innovative way to generate a constant stream of revenue for digital health providers is to license out their products or platform. This licensing model can be observed for digital health solutions focused on training health workers on how to deliver health services more efficiently and meaningfully. For example, Amref's Leap solution, a mobile learning platform, provides health training to community health workers in Kenya. It recoups the cost of the initial infrastructure investment by providing access to the platform through user fees to ensure scalability and sustainability.[362]

In parallel, Amref is also experimenting with reimbursement models in which the Kenyan government pays for driving adoption of the national health insurance scheme. CHWs are incentivized to sign up community members to the National Hospital Insurance Fund (NHIF) through a digital platform called mJali. NHIF pays Amref a commission of 5% for every enrollee, and Amref then passes 60% of this commission on to the CHW, the rest of which is then used to maintain and scale the mJali platform, which is ultimately tied to the health insurance system.[363]

Portable Health Clinic In Bangladesh – Fee-based services by female health workers

In Bangladesh, 65% of the population lives in rural areas, where there are insufficient healthcare facilities and qualified doctors. Long traveling distances mean that health providers in cities are out of reach for rural residents. Grameen Communications and Kyushu University set up the "Portable Health Clinic" initiative in 2007 to develop digital health technologies based on the social needs of the "unreached population" in Bangladesh.

This initiative has grown into a nationwide network of village healthcare micro-entrepreneurs, a social business case that provides NCD preventive healthcare services for urban and rural residents. This innovative business model (Figure 16) encompasses the creation of women micro-entrepreneurs who provide fee-based services to villagers thanks to medical tools licensed by Grameen. Since 2010, 42,026 health check-ups have been conducted by the Portable Health Clinic.[364, 365, 366]

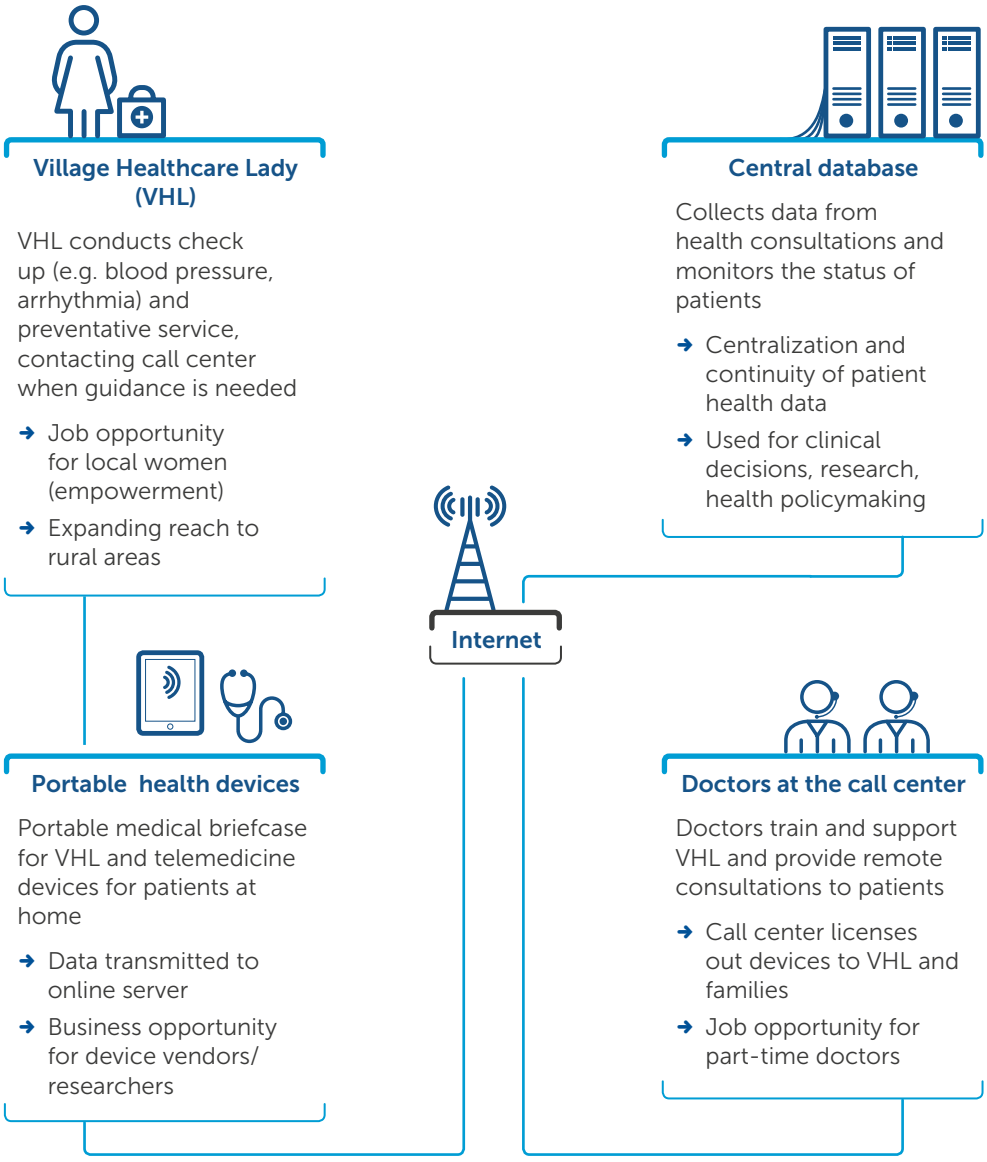


Figure 16 **Grameen's Portable Health Clinic Model**[367]

A variant of the licensing model involves the direct use of digital health solutions by health workers in the care delivery process. For example, the innovative "Portable Health Clinic" allows local community workers in Bangladesh to conduct health check-ups.

A similar model is employed by Living Goods in Uganda, which deploys a network of women CHWs who provide diagnosis and treatments to families. CHWs are incentivized to perform well, as they earn a percentage of what they sell. They are also empowered through the SmartHealth app, which allows them to register household members, record health information and manage their own schedule.[368] The app is currently financed by donations received by Living Goods and is provided for free to CHWs.[369]

Cost containment

In the journey toward a sustainable business model, cost management measures need to be found in addition to revenue-generating measures.

The financing of a digital health solution needs to account for the total cost of ownership including cost of infrastructure (e.g., hardware including customer devices), broadband plans, software and operations costs such as appropriately skilled staff required for support and maintenance but also training needed for end users.[370] Open-source and cloud solutions support a flexible setup without large upfront investment. Cost management takes into account both the initial, one-off investment, as well as the ongoing operational and maintenance costs of digital health solutions.

A **simply designed, "no-frills" device or service** requires less financing, offers better value for money, and is therefore more sustainable. There are many cases in which a simple object addresses a key social burden that does not involve high financing. An example is the smart bracelet designed by Grameen Intel for detecting indoor levels of carbon monoxide that result from cooking and heating methods widely used in India and Bangladesh. Such household air pollution causes chronic diseases such as lung cancer and COPD and contributes to 4.3 million deaths every year, according to the WHO.[371] The smart bangle is tailored to users (mostly women and children) at a cost of US$10, is attractively designed, water resistant and has a 10-month battery life. It also addresses other chronic diseases by sending wellness messages.[372]

In addition, **engaging local integrators** can be key to bringing costs down. This was the experience of the team building Swasthya Slate, a diagnostics device for monitoring measures such as blood pressure, blood sugar and heart rate. By changing the manufacturing from the United States to India, the founder was able to bring down costs from tens of thousands of U.S. dollars per unit to US$800 per unit with additional sensors.[373] Leveraging the know-how of the local workforce is therefore key to creating a digital health solution that the local population can afford.

In LMICs, early screening and diagnosis is a challenge due to the lack of diagnostic equipment. Recent **innovations in diagnostic hardware and software development** have helped reduce the costs of diagnostic equipment for facilities (e.g., see Swasthya Slate example above) or field workers by using smart devices or additional attachments to such devices. These developments have helped facilitate cost-effective, highly mobile diagnosis solutions such as MobileODT – a device that supports cervical cancer screening and treatments through a simple adaptor that is docked on to a smartphone camera.[374] The evolving market of cost-effective diagnostic tools has to be continuously screened in a structured manner so that new tools can be suggested at the right time and be procured by LMICs.

In many countries, according to Hani Eskandar from ITU, there is no authority or agency that **organizes or aggregates demand** for digital health projects, health supplies or devices. However, an aggregated purchase order for telemedicine or tracking devices could help bring volumes significantly up and prices considerably down. Additionally, an alignment on shared functionalities for health IT investments can reduce costs for individual stakeholders appreciably, as investments can be split between several parties (see "Common health platforms" on page 74). In addition, national digital health strategies can expand the quantity of digital health solution orders, which promotes greater cohesion among orders and coordinated purchasing, and this, in turn, can bring costs down.

Practical recommendations

In conclusion, financing digital health IT systems and solutions remains challenging in LMICs due to the limited financial resources and lack of awareness of the benefits of digital health. Reimbursement of digital health solutions is one important way forward in achieving SDG 3, and although this remains a challenge for most HICs, some have taken the necessary steps in this direction. Examples in LMICs have shown that financing models that are not based on public reimbursement can also be sustainable. Governments should therefore also seek partners such as micro-insurers in establishing innovative business models and thereby share the burden of project risks. Scaling the pilot after cost-effectiveness has been demonstrated is essential to success. In parallel, cost-containment measures should be considered.

When it comes to the investment of the core health IT system (e.g., HIE, EHR, HMIS), governments should incorporate this into their national strategy and look for ongoing sources of revenue to recoup their initial investment. If governments show leadership in implementing their national digital health strategy, commercial and/or development banks and donors will support financing.

Assess current financing mechanisms and seek innovative business models

Health IT systems:

1. Governments should include financing for health IT systems in their national strategy. Public funds and government investments (via debt or loans from commercial and/or development banks) should be allocated for core health IT systems (e.g., to create HIE, EHRs and registries including patients and care providers). According to the recently published Digital Health Principles,[375] donors and banks show a willingness to finance core health IT systems if governments show leadership and commitment for the implementation of a strategy. In addition, innovative financing mechanisms such as the platform-as-a-service model, for example, should be pursued as they involve transaction-based fees for recouping capital investment.

Reimbursement of digital health solutions is one important way forward in achieving SDG 3

2. Governments should aim to harmonize systems across regions instead of every country creating their own bespoke version of a health IT system. Defining, building and deploying digital global goods that can be used in multiple countries for the same core tasks should be targeted.

Digital health solutions:

3. Promote the coverage of digital health solutions through national insurance reimbursement. Evaluate HCP's and patients' needs to address NCDs and promote digital health solutions that address these needs. Define medical codes for the reimbursement of digital

health interventions. In addition, provide reimbursement guidelines to digital health providers.

4. In parallel to setting up the national reimbursement of digital health, encourage business models driven by other stakeholders such as private insurers. Organize roundtables to bring potential business partners together, supporting them by articulating how the digital health solution benefits the stakeholders and end-customers. Create a business-friendly environment for finance companies to allow processing of mobile payments or the development of savings or micro-insurance models to cover PHC services. Partner with the private sector and create incentives for private sector investments.

5. For national prevention programs such as WHO Best Buys, coordinate donor-driven initiatives to reduce fragmentation and redundancies while planning the shift toward government co-ownership and co-funding of the initiatives.

Activate cost-containment measures:

6. Adopt a user-centric approach for designing low-cost, simple digital health solutions that serve the purpose of patients with NCDs or respective care professionals.

7. Support aggregation of demand, for example, by investing in common platforms and leveraging a national digital health strategy for telemedicine or tracking devices as a means of increasing volume and reducing costs.

8. Make use of local integration and maintenance workforces in order to reduce dependencies from abroad.



(c) Nana Kofi Acquah / Novartis Foundation



3 Conclusions



Policymakers, donors, private companies and other digital health stakeholders can use the practical lessons, examples and tools described in this report to foster sustainable digital health solutions that address the specific needs of patients with NCDs and help countries achieve universal health coverage more rapidly. Digital health solutions promise to change the way healthcare is provided, to both acute and chronic patients.

Digital health should be viewed as an essential part of the healthcare system, just as medical equipment or hospital beds are. Realizing the promise involves putting into place the six building blocks presented here.

And policymakers do not have to deliver alone. Many countries have begun their digital health journeys and a wide variety of organizations, across sectors, are actively engaged.

Digital health shows great promise in supporting the transformation of health systems in LMICs in order to better address NCDs and achieve UHC. Digital health solutions support the efficient delivery of care in new ways that empower all healthcare stakeholders and are more preventive, thereby helping health systems save costs. The example of Canada, where investing in digital health solutions such as EMR and telehealth saved CAD$16 billion over nine years, stands out in this regard. [376] Digital health solutions also render NCD care more accessible for patients living in remote areas far removed from health clinics. Continuous, connected data also allows health providers and government officials to make better and more informed decisions with impact on the health system as a whole.

Governments and policymakers alike have a major role to play

If this promise is to deliver its intended benefits, we need sustainable digital health solutions. Governments and policymakers alike have a major role to play in this regard. Launching digital innovations may seem daunting, but many countries have already taken on the challenge, providing experience that others can learn from. Indeed, government and policymaking practitioners can draw on the examples and good practices featured in this report in developing guides and tools suited to their local environment.

A critical starting point for governments is to show leadership by striving for shared goals among the players in a digital health ecosystem and making this a reality. However, prioritizing digital health in a national strategy does not mean that government must deliver everything itself. It should seek to create a national and regional ecosystem that features partners with complementary capabilities and assets from various sectors.

Other "must-haves" that governments should consider for the safe, ethical and efficient delivery of digital health solutions include accessibility to communication infrastructure, data-protection policies, safety regulations for digital health solutions and basic system interoperability in order to make data available for a health management information system and healthcare delivery. Rather than implementing siloed, "quick fix" technologies, the focus should be on common assets such as "digital global goods" that involve reusable, adaptable technology solutions that have demonstrated their impact.

In addition, one of the biggest nuts to crack remains financial sustainability. Governments should aim to protect citizens against financial hardship linked with out-of-pocket payments for healthcare. This can be done through financing support and by promoting innovative financing models for digital health solutions. Putting in place a national reimbursement system for digital health technologies would ensure financial accessibility in the long run. This report affirms the idea that digital health investments targeting systemic robustness should benefit NCD programs. At the same time, NCD investments must also contribute to establishing digital building blocks for collective benefit.

Once these "pre-requisites" for digital health are in place, governments can work on long-term goals such as creating a robust health IT system infrastructure with electronic health records and flexible interfaces into which new solutions such as telemonitoring can be integrated. These initiatives will contribute to coordinating and embedding individual digital health solutions on a national scale, which helps health systems become resilient to health challenges and achieve UHC. Ultimately, such measures would reduce the NCD burden, improve patient outcomes and bring down costs for the health system overall.

This report has highlighted successful examples of digital health solutions and recommendations for making them sustainable in LMICs. The goal has been to provide governments in these countries examples and recommendations for jumpstarting sustainable digital health within their respective healthcare system. Moreover, because digital transformation is by nature a cross-domain issue, LMICs should also view these first steps in digital health as an opportunity to strengthen their health system across diseases and beyond health in general. For example, educating populations on healthy lifestyles can improve their capacity for economic, political and social participation – and thereby contribute more to society. **Using digital health technologies to enhance healthcare delivery should therefore be considered to be as essential to health systems as medical equipment or hospital beds are.**

(c) Matthew Dakin / Novartis Foundation



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ACRONYMS AND ABBREVIATIONS

ACMU ..... Agence de la Couverture Maladie Universelle
AeHIN ..... Asian eHealth Information Network
BHBM ..... Be He@lthy, Be Mobile
CAT ..... computer-aided techniques
CD ..... Communicable disease
CE ..... Conformité Européenne
CENS ..... National Center for Health Information Systems
CHW ..... community health workers
ComHIP ..... Community-Based Hypertension Improvement Project
COPD ..... chronic obstructive pulmonary disease
CORFO ..... Chilean Public Development Agency
CSF ..... Common Security Framework by HITRUST
DAH ..... development assistance for health
DHA ..... Digital Health Atlas
DHIS ..... District Health Information System
DHIWG ..... Digital Health and Interoperability Working Group
DHP ..... digital health platforms
EAC ..... East African Community
ECOWAS ..... Economic Community of West African States
EHR ..... electronic health record
EMR ..... electronic medical record
ESB ..... eHealth Standards Board
FCS ..... Carlos Slim Foundation
FDA ..... Food and Drug Administration
FHS ..... Family Health Strategy
FMOH ..... Federal Ministry of Health
GDPR ..... General Data Protection Regulation
GNI ..... gross national income
GP ..... general practitioner
GSMA ..... GSM Association
HCP ..... healthcare professionals
HDC ..... Health Data Collaborative
HIC ..... high income countries
HIE ..... health information exchange
HIPAA ..... Health Insurance Portability and Accountability Act
HMIS ..... health management information system
HNSF ..... Health Normative Standard Framework
HPCSA ..... Health Professions Council of South Africa
ICAD ..... Index of Quality Care of Diabetes
ICT ..... information and communications technologies
IEEE ..... Institute of Electrical and Electronics Engineers
IHE ..... Integrating the Healthcare Enterprise
IoT ..... Internet-of-things
IT ..... information technology
ITU ..... International Telecommunications Union
KPI ..... key performance indicator
LMIC ..... low- and middle-income countries
M&E ..... monitoring and evaluation
MIDO ..... Medición Integrada para la Detección Oportuna
MNO ..... mobile network operators
MoH ..... Ministry of Health
NCD ..... non-communicable disease
NDOH ..... National Department of Health
NGO ..... non-governmental organization
NHIF ..... National Hospital Insurance Fund
NHIS ..... National Health Information System
OECD ..... Organization for Economic Co-operation and Development
OpenHIM ..... Open Health Information Mediator
PCH ..... Personal Connected Health
PCHA ..... Personal Connected Health Alliance
PHC ..... primary healthcare
PHDC ..... Provincial Health Data Center
PID ..... personal identification number
PMTCT ..... prevention of mother-to-child transmission of HIV
POPI ..... Protection of Personal Information
PPP ..... public private partnership
REACH ..... Regional East African Community Health
SDG ..... Sustainable Development Goals
SIDRA ..... Information Systems Healthcare Network
SINBA ..... Nominal Basic Health Information System
UCS ..... universal coverage scheme
UHC ..... universal health coverage
WHA ..... World Health Assembly
WHO ..... World Health Organization

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