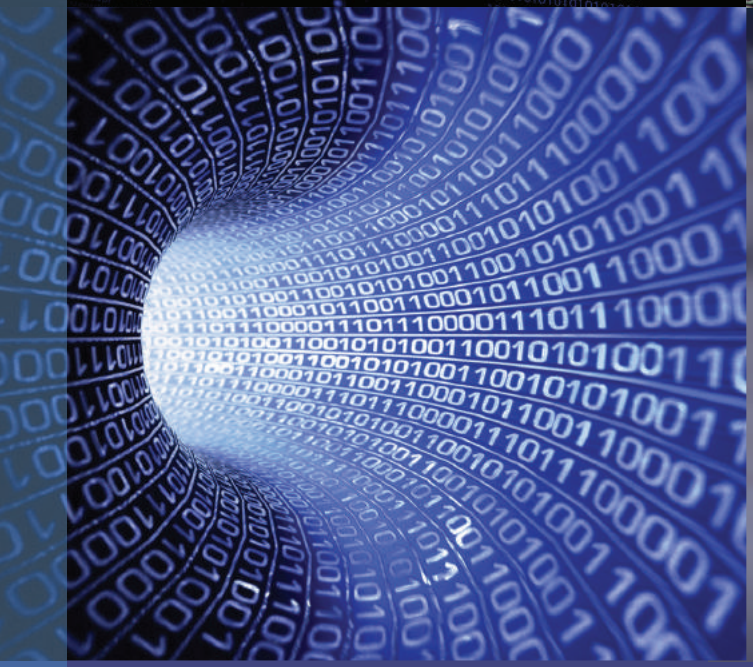

Digital Health: A Call for Government Leadership and Cooperation between ICT and Health

February 2017

BROADBAND COMMISSION
FOR SUSTAINABLE DEVELOPMENT

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Co-Chaired by:

Report developed with the support of:

Acknowledgments

This report was developed through an iterative and collaborative process drawing on expertise from the members of the Broadband Commission Working Group on Digital Health (Working Group), which was established by the Broadband Commission for Sustainable Development. The direction of the report, the coordination of experts, and the development of the content were provided by Aya Caldwell (Novartis Foundation), Florence Gaudry-Perkins (Digital Health Partnerships) and Brendan Smith (Vital Wave). In addition, critical contributions were made by Edward Kelley, Joan Dzenowagis, Misha Kay and Garrett Mehl from the World Health Organization (WHO), Hani Eskandar and Phillippa Biggs from the International Telecommunication Union (ITU), David Novillo from the Pan American Health Organization (PAHO), and Rob Childs and Jeanine Vos from the GSMA. Research, interviews, analysis and report formatting were conducted by Vital Wave. John Maurice provided editorial support. Acknowledgment is also due to those interviewed for the report (full list in Annex 2). Support of the Working Group was given by Anna Polomska of the Broadband Commission Secretariat at ITU. Responsibility for the information and views set out in this report lies entirely with the authors and the Working Group.

The Working Group met on a quarterly basis, reviewed material from the research and discussed the strategic trajectory of the report. Special acknowledgments are due to the following individuals (listed by affiliation and surname alphabetically):

Broadband Commission Members and the Commissioners' Focal Points:

- Himar Arjun Singh (Bharti Airtel)
- Carolyn Florey and Kate Wilson (Digital Impact Alliance)
- Rob Childs and Jeanine Vos (GSMA)
- Adam Lane (Huawei)
- Antonio Garcia-Zaballos (Inter-American Development Bank-IDB)
- Jennifer Esposito (Intel)
- Eunice Lim (IMDA Singapore)
- Hani Eskandar (ITU)
- Eun Ji Kim (KT)
- Paul Mitchell (Microsoft)
- Ann Aerts, Aya Caldwell, Karthikeya Parameswaran, Joris VanDam (Novartis Foundation)
- Barry French, Julia Jasinska, Alireza Khosrow, Elizabeth Rojas Levi, Valerie Noto, Rajeev Suri (Nokia)
- Hon. Jean Philbert Nsengimana, Government of Rwanda
- Amelia Neumann-Samek and Sam Pitroda (Former Advisor to the Prime Minister, Government of India)
- Chandrika Bahadur and Jeffrey Sachs (SDSN/Earth Institute at Columbia University)
- Indrajit Banerjee, Dov Lynch and Cedric Wachholz (UNESCO)

External Members:

- Alvin Marcelo (AeHIN)
- Jonathan Jackson (Dimagi)

- Richard Gakuba (Health Systems Innovations)
- Haitham El-noush (Norad)
- David Novillo Ortiz (PAHO)
- Lesley-Anne Long and Dykki Settle (PATH)
- Joan Dzenowagis, Misha Kay, Edward Kelley, Garrett Mehl (WHO)
- Zlatan Sabic (World Bank)

A special thanks to the individuals who helped to put together the country case studies (listed by country):

- Ron Parker, Infoway, Canada
- Piret Hirv, Ministry of Social Affairs, Estonia
- Khadzir Sheikh Ahmad, Ministry of Health, Malaysia
- Fazilah Shaik Allaudin, Ministry of Health, Malaysia
- Ousmane Ly, ANTIM, Mali
- Carolyn Florey, Digital Impact Alliance, Nigeria
- Olasupo Oyedepo, ICT4HEALTH Project, Nigeria
- Helge T. Blindheim, Directorate of eHealth, Norway
- Alvin Marcelo, Asia eHealth Information Network, The Philippines
- Angelito Abando, PhilHealth/Department of Health, The Philippines
- Jovita Aragona, PhilHealth, The Philippines
- Beverly Lorraine Ho, Department of Health, The Philippines
- Pio Justin Asuncion, Department of Health, The Philippines
- Jay Bernolia, PhilHealth, The Philippines
- Erick Gaju, Ministry of Health, Rwanda
- Richard Gakuba, Health Systems Innovations Ltd, Rwanda
- Hon. Jean Philbert Nsengimana, Government of Rwanda

Foreword

Houlin Zhao
Secretary-General, International Telecommunication Union (ITU)

Improved health and well-being underpin a number of the Sustainable Development Goals (SDGs) as well as the obvious, health-related goal of Universal Health Coverage (UHC), SDG3, which aims to "ensure healthy lives and promote well-being for all at all ages." Broadband represents a powerful means to accelerate progress toward the attainment of the SDGs. We need to look at innovative cross-sectoral strategies that can leverage the power of high-speed networks to improve education, healthcare and the delivery of basic social services to everyone, especially the poorest people who need healthcare most urgently. Without significant improvements in people's health and, equally, without information and communications technologies, we cannot achieve the SDGs.

ITU has promoted cooperation through its work with financial players on digital financial inclusion, its work with local planning authorities on smart cities, and with its work with key health stakeholders on eHealth issues to develop national eHealth strategies, initiate mobile health initiatives, fight epidemics (such as Ebola) and study the impact of electromagnetic fields on human health.

Cross-sectoral collaboration is not easy. Players come from different backgrounds, with different approaches and priorities, and may understand different things on the basis of the same words or phrases. Nowhere is this truer than in digital health, where the needs are great, the investments are significant and lives are at risk. This report aims to set out the underlying framework for governance conditions which can improve the introduction of digital health and ensure that it goes as smoothly as possible.

That is why I welcome this report in particular—not just as another academic study of information technology concepts, but as a practical exploration of the issues around how eHealth is being implemented and working in a number of countries. It is my hope that by taking onboard the key messages of this report, stakeholders from all backgrounds can maximize the chances of a successful introduction of digital health programs. We call on countries to develop their innovation capacities, digital health strategies and action plans so everyone can benefit from the digital revolution.

Ann Aerts
Head, Novartis Foundation

Chair, Broadband Commission Working Group on Digital Health

The digital age is upon us and it has the potential to revolutionize how healthcare is delivered. Digital tools can increase access to health, empower patients, and provide better health information and education for all. They can also facilitate the use of real-time data to ensure that surveillance systems are more action-oriented and prioritize limited resources.

Despite its promise, however, the digital health landscape today is highly fragmented. The result is a myriad of digital health projects and applications that rarely reach scale and if they were to expand could even strain the health system. An important step toward addressing the fragmentation is a national digital health strategy. These strategies are essential to facilitate standards for interoperability, regulations and policies to support digital health solutions.

To help solve these challenges and to uncover how we can truly harness the power of information and communications technology (ICT) for health, we need a better understanding of the key elements involved. That is why, in September 2015, we launched the Working Group on Digital Health at the annual meeting of the Broadband Commission for Sustainable Development.

We began by conducting a series of interviews with key stakeholders, experts and countries. At the same time, a thorough literature review and consultations with experts were undertaken. Together, the results brought us to an inescapable conclusion: with digital health solutions, we must address the priority health needs of the country; and to do so we need committed senior leadership from government with sustained financial resources to ensure a strong national digital health strategy.

A case study analysis from eight countries demonstrates that the success of any national digital health strategy is dependent on strong intragovernmental cooperation between the health, ICT and finance sectors. It is clear that, in order for digital health to scale, investments and expertise are needed from the three sides. We also found that clear governance mechanisms are needed to support this cross-sectoral work within a government.

At the Novartis Foundation, we believe optimizing digital health supports our programmatic and policy work to improve health outcomes in low-income settings. We have leveraged digital health in most of our programs for the past decade and have observed first-hand the problem of fragmentation of digital health applications. We see the need for stronger collaboration between ICT and health policy makers. We are therefore delighted to have the honor to chair the Broadband Commission Working Group on Digital Health, with Nokia as co-chair. We hope that the shared experiences outlined in this report, from different countries and experts with differing perspectives, will help to achieve what is needed for digital health to realize its full potential and transform the way the unprecedented scope of global health needs are addressed.

Rajeev Suri
President and Chief Executive of Nokia

Chair, Broadband Commission Working Group on Digital Health

When we talk about healthcare and the digital technology revolution, public policy becomes deeply personal. It has an immediate, emotional impact. That is because we have all lost loved ones who went before their time, and our anguish is intensified by the knowledge that quicker, more effective treatment might have saved them.

And it is also because we are moved by the unfair access to healthcare across the world and sense that technology and knowledge should be available to any human being, including the poorest of the poor.

We, at Nokia, believe we have the opportunity to make a difference by harnessing the power and potential of digital technology to prevent countless debilitating diseases around the world. There are many components to the digital health technology framework: cloud platforms, open integration layers, mobile networks, security and privacy. The new 5G networks, for example, will unlock the doors to so many possibilities. 5G will make it possible to share the sophisticated medical techniques currently known only in the richer regions with the remotest poorer regions in the developing world.

Already we are making strides. The technology is ready and we are experimenting and promoting small-scale developments around the world to learn how it can best be applied. As just one example, Nokia has deployed Withings, connected health devices and services to help corporations promote wellness at home and in the workplace and to reduce healthcare costs. The next step is to share the technology with every corner of the globe. To do that we need the leadership of national governments. Health and telecommunication should be united, working closely with regulators—to avoid potential roadblocks, change old practices and spread new knowledge on how to leverage technology for healthcare.

Without a strong drive and vision, nothing can happen.

Nor will it happen unless we nurture a rich culture of cooperation between technology providers, health organizations, financial institutions and governments—exactly the kinds of relationships we build through the Broadband Commission Working Group on Digital Health.

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Key Terms

Digital health and eHealth (used interchangeably in the report): Umbrella terms to encompass all concepts and activities at the intersection of health and information and communications technologies (ICTs), including mobile health (mHealth), health information technology, electronic health records (EHRs), and telehealth, and encompassing three main functions:

- the delivery of health information, for health professionals and health consumers, through the Internet and telecommunications media,
- using ICTs to improve public health services (e.g., through the education and training of health workers), and
- using health information systems (HIS) to capture, store, manage or transmit information on patient health or health facility activities.

Digital health solution: An individual product or service (or combination of multiple products or services) created to serve a specific health system objective, often encompassing a set of hardware, software, infrastructure and services required to meet this objective.

Digital health system: The interrelated set of technologies, processes and structures within a digital health ecosystem, typically encompassing numerous individual solutions and organizations.

Governance: The structures, processes, standards, and decision-making authorities that support, regulate and monitor the use of digital health technologies, operational tactics, and data sharing. Typical governance components include steering committees for strategic decision-making, technical working groups (TWGs) to provide expert advice in key domain areas, and program management units to execute and implement approved strategies and decisions.

Health information system/Health management information system (HIS/HMIS): A term encompassing all types of paper and digitized data in the health system including, for example, diagnostic images, laboratory, clinical and pharmaceutical records, system administration data, and relevant demographic and other personal data. The term electronic HIS (eHIS) is sometimes used to refer specifically to digitized data.

ICT/ICTs: Information and communication technologies or digital technologies including the hardware, software, and networking capabilities that enable mobile phones, tablets, laptops and desktop computers, as well as servers and other equipment found in data centers.

Implementing partners: Organizations, including private-sector companies and non-governmental organizations (NGOs), which are contracted or funded by governments or donors to implement development programs, including those with digital health components.

Interoperability: The ability of different information technology systems and software applications to communicate, exchange data and use the information that has been exchanged.

Key performance indicator (KPI): A metric that measures progress toward stated business and organizational goals.

Low and middle-income countries (LMICs): Defined by the World Bank as having a per capita gross national income below US$12,476 (2017 fiscal year); often referred to as developing countries or emerging markets.[1]

Monitoring and evaluation (M&E): A system and process that entails tracking performance toward stated goals and assessing impact.

mHealth: Mobile health, a subset of digital health/eHealth. mHealth services are accessed by users on mobile devices with platforms such as SMS (short messaging service) texting services, mobile data applications and tablet computer programs with specific healthcare functions.

MoH/DoH: The Ministry of Health (MoH), Department of Health (DoH), or other similar agency charged with overseeing the delivery of health services and improving healthcare for a country's population.

MoICT (or DoICT): Ministry (or Department) of Information and Communication Technologies, often charged with overseeing national strategies and standards related to the use of ICT within and outside the government.

Semantic interoperability: The ability of devices and systems to exchange data so it can be accessed, understood, interpreted and acted upon appropriately.

Sustainable Development Goals (SDGs): The successor initiative to the Millennium Development Goals which concluded in 2015, are a world charter of 17 goals and 169 aspirational targets to be attained by 2030.

Telehealth: The use of telecommunication technologies such as video and imaging to support the virtual delivery of healthcare services and the provision of health education.

Universal health coverage (UHC): Defined by the WHO as a situation in which "all people can use the promotive, preventive, curative, rehabilitative and palliative health services they need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship.[2]

WHO-ITU National eHealth Strategy Toolkit (WHO-ITU Toolkit): A comprehensive roadmap for leaders to build a national eHealth (or digital health) strategy.

1. World Bank, *Country and Lending Groups*, 2017, https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country--and-lending-groups
2. World Health Organization, *What is Universal Coverage?*, 2017, http://www.who.int/health_financing/universal_coverage_definition/en/

Executive Summary

Digital Health: A call for government leadership and cooperation between ICT and health

Digital health, sometimes called electronic health or eHealth, is the use of information and communication technologies (ICTs) for health purposes. Wisely and widely used, digital health can bolster access to healthcare, raise the quality and diminish the costs of providing it and empower patients to take more responsibility for the management of their own health. Figure 1 provides a framework of different categories of digital health solutions. Examples of digital health include:[1]

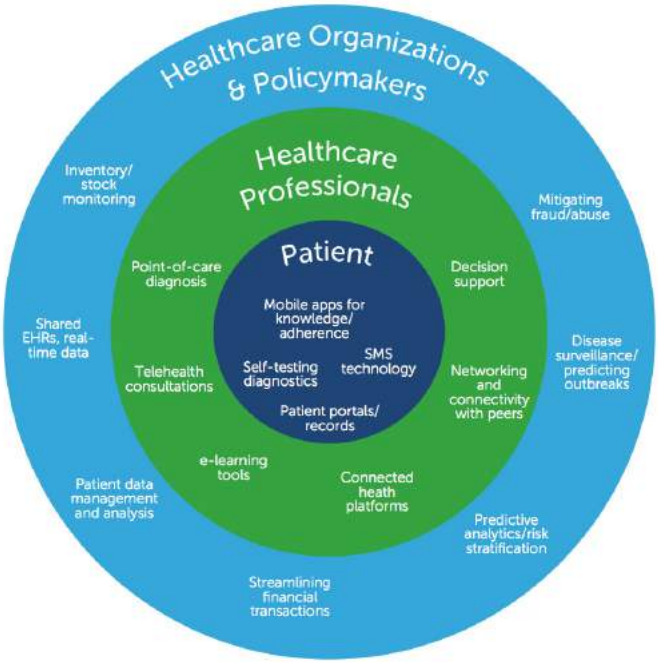
- connecting remote, rural and underserved communities with referral centers and expert care,
- training healthcare providers (e.g., by eLearning and mLearning),
- improving quality of care through digital solutions for diagnosis, clinical decision support systems, supportive supervision or monitoring patient compliance with treatment,
- optimizing resource allocation and lowering healthcare costs through more efficient care coordination (e.g., with electronic medical records),
- improving data management for surveillance, reporting, accountability and monitoring, and
- facilitating communications between health workers, specialists and patients.

About this report The Broadband Commission Working Group on Digital Health (Working Group) is co-chaired by the Novartis Foundation and Nokia and is composed of leading digital health experts from governments, international and non-governmental organizations (NGOs), academic institutions and the private sector. The Working Group commissioned Vital Wave to conduct research and to interview digital health leaders from twenty countries to explore

Report value and audience

Digital health, which is the use of information and communication technology (ICT) to provide health services, can advance the goal of Universal Health Coverage (UHC) and improve the quality and efficiency of healthcare services worldwide. Today, many countries are moving to the complex task of implementing national digital health strategies, and effective leadership and cooperation approaches are needed to coordinate the often fragmented ecosystem of digital health solutions and programs. This report provides insights into the importance of government leadership, governance, and intragovernmental cooperation in digital health for government leaders and policy makers at the intersection of the health and ICT sectors. It draws on the experience of countries in a variety of geographic and resource settings and builds on existing digital health literature by shedding light on leadership approaches and on governance mechanisms for engaging health and ICT stakeholders.

Figure 1: Digital Health Categories and Solutions



Source: 2017 Ernst & Young AG

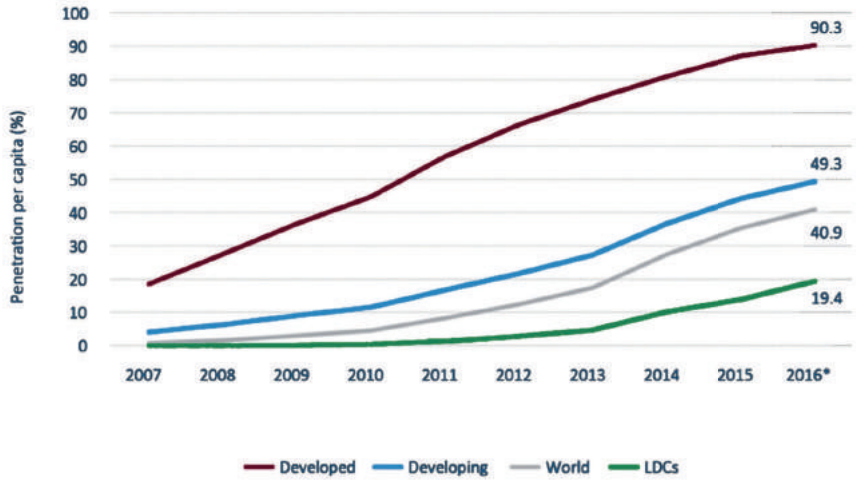
the role governments play in developing and implementing digital health. This report documents the results of the exploration with a view to providing practical guidance on leadership, governance and intragovernmental cooperation to leaders in health and ICT who wish to adopt a digital health strategy. The work conducted in consultation with the Working Group produced eight case studies of countries that have achieved success in developing and implementing digital health strategies.

The promise of digital health As WHO points out in a recent report, "It has become increasingly clear that universal health coverage (UHC) cannot be achieved without the support of eHealth."[2] As leaders confront the Sustainable Development Goals (SDGs) and the quest for UHC, digital health has an evident potential to facilitate the achievement of these goals.

Mobile connections globally now stand at 7.6 billion, and mobile broadband penetration has risen sharply in the last ten years (Figure 2). Smartphone penetration is already at 48%, and predictions are that there will be 5.6 billion smartphones by 2020, with 90% of users in low- and middle-income countries (LMICs).[3] The number of mobile health (mHealth) products and services has doubled in the past five years in LMICs,[4] and there are now over 165,000 mobile applications for health services.[5] More recent advances in technology in domains such as network speed and efficiency, cloud computing, device connectivity and data analytics are accelerating the conversations and dynamics around the promise of digital health.

Clinical evidence that ICTs have an impact on health outcomes is only starting to surface but is eagerly awaited by many members of the ICT and health communities. The impact of ICTs on expenditures, however, is starting to emerge. **Canada**, for example, measured the cost savings generated by its digital health investments and reported an aggregate saving of CAN$16 billion since 2007.[6] A myriad of studies have forecasted the cost savings that digital health might generate, such as a 2013 GSMA study which estimated that mHealth technology could result in a US$400 billion cost savings over a five-year period in high-income countries.[7]

Figure 2: Mobile Broadband Penetration Growth, 2007-2016



Source: ITU

Challenges Despite these benefits, implementing digital health is not without its challenges. They include unsustainable funding, high capital expenditures, limited workforce capacity and poor collaboration between the health and ICT sectors. Moreover, countries continue to face a proliferation of uncoordinated digital health projects resulting in fragmentation, unnecessary duplication and data silos which hamper the promise of large-scale health data analytics. This fragmentation is often compounded in donor-dependent countries by a lack of coordination among external funders, which strains the healthcare system as healthcare workers have to spend time on multiple systems that are often not able to communicate with each other.

Digital health systems and solutions are never designed in a vacuum, but are introduced within existing complex legacy systems built around static or historical paper-based records and images. Although digital health offers the prospect of long-term cost savings, it usually requires significant investments upfront, as well as regular expenditure on training, maintenance and upkeep.

With the marriage of the ICT and health worlds, digital health systems have to navigate through two very different policy and regulatory worlds. Issues surrounding information sharing and privacy must be considered.

It may be essential for medical staff to communicate within and between different clinics and hospitals to avoid potentially life-threatening situations for their patients. But this asset of digital health raises concerns about the security of the data being exchanged and the rights of patients to privacy where individual records are concerned.

The role of governments Government leaders can play a fundamental role in fostering an enabling environment for digital health and in resolving some of the above-cited challenges. They can help in preventing duplication of effort, in harmonizing standards to promote interoperability and in coordinating stakeholders across both the public and the private sectors. Governments also have a role in developing appropriate legislation to ensure, among other needs, data protection and privacy, medical device regulation, reimbursement policies and security for the exchange of sensitive health data.

WHO reports that 73 of 116 (63%) of its member states have defined national digital health strategies and corresponding plans to implement them.[8] Many governments are now coming to grips with the task of

implementing these strategies, but as the WHO data imply, close to 40% of countries have yet to develop a digital health strategy.

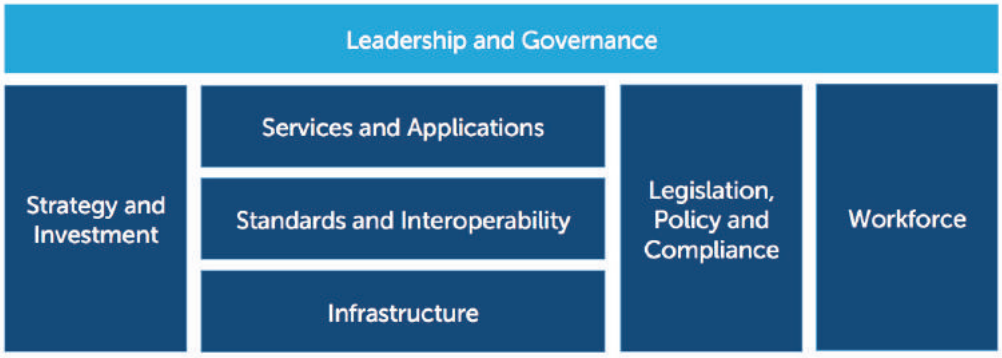
The WHO-ITU National eHealth Strategy Toolkit[9] provides a comprehensive roadmap for governments to develop a digital health strategy. The WHO-ITU Toolkit identifies seven essential components that are needed to build a strategy. This report focuses on the first component, namely leadership and governance (Figure 3). Many stakeholders see this component as the first brick needed to build a robust digital strategy, however challenging the task might be.

As a first step toward national digital health implementation, a national vision for digital health should align with the country's health priorities, as well as with the existing capacity of the country's ICT infrastructure and systems. A detailed action plan and a monitoring and evaluation framework can then address fundamental issues such as regulation, governance, standards and interoperability, workforce and financing. Bringing together multiple stakeholders from both the ICT and health sectors is a complex and time-consuming undertaking and yet essential if the national digital health strategy is to be effective. Stakeholders can be academics, donors, health professionals, patients, professional associations, multilateral organizations, NGOs,partner countries and private-sector organizations.

The case studies demonstrate that a national ICT framework or plan, if built in coordination between health and ICT authorities (e.g., Ministry of Health, Ministry of Communication, eGovernment agency), enables common policies and ICT standards and thereby supports data interoperability across systems and programs. Cooperation between ICT and health ministries also rationalizes investments and allows for shared responsibility in their respective domains and areas of expertise. Clearly defined governance mechanisms not only help anchor cooperation between the ministries but also organize and guide the complex stakeholder management aspect of a strategy. Figure 4 summarizes three critical elements needed to realize implementation of a national digital health strategy.

The report identifies three potential governance mechanisms that can guide the implementation of a national digital health strategy (Figure 5), each presenting advantages and drawbacks. These governance mechanisms may change over time and are not intended to be prescriptive. The country case

Figure 3: WHO-ITU National eHealth Strategy Toolkit Components



Source: World Health Organization. (2012). National eHealth Strategy Toolkit. February 29, 2016, from https://www.itu.int/pub/D-STR-E_HEALTH.05-2012

Figure 4: A Recipe for Success

studies give examples of governance mechanisms and describe the elements needed to implement national digital health strategies across a variety of geographical and resource settings. Each case study tries to answer questions such as: What elements trigger the political leadership and commitment to digital health? How do governance mechanisms develop frameworks that facilitate stakeholder management and ensure that the health and ICT government entities work in close collaboration? How do governments address financing and funding? What are the lessons and insights that can be shared with other countries?

The following points exemplify how the eight countries analyzed for this report have used leadership and governance to develop and implement digital health strategies.

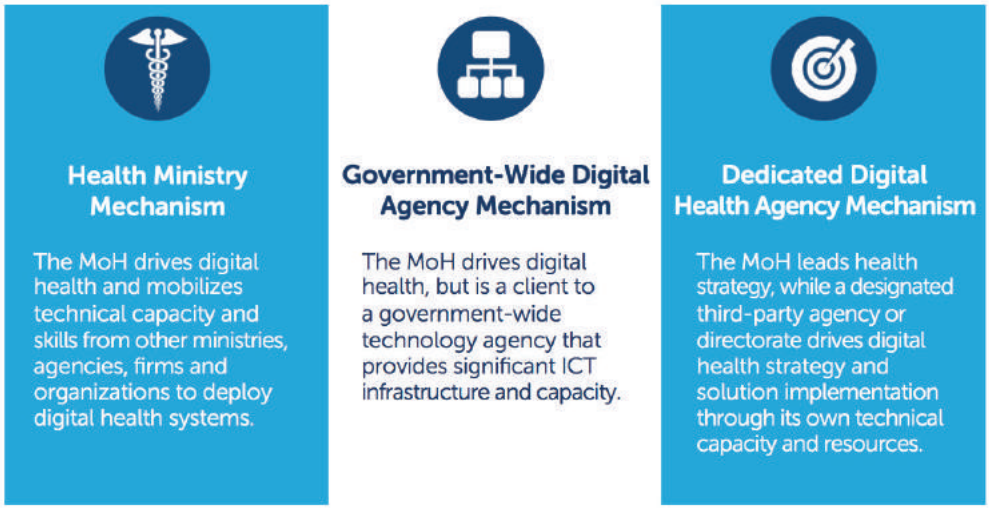
- **Rwanda** provides an example of how the long-term commitment of national political leaders to a broad societal vision for using broadband and ICTs translates into catalyzing digital health progress at the national level, based on accountability at all levels of the health system.
- **Nigeria's** national digital health strategy development process, which unfolded over several years, exemplifies successful stakeholder involvement and management in a highly complex cultural and political context.
- **The Philippines'** experience demonstrates how close cooperation between health and ICT ministries, materialized in a joint memorandum of understanding and governance mechanisms with clear roles and responsibilities, provides a solid basis for effective cooperation in implementing a digital health strategy.
- **Malaysia** illustrates how the development of project management capacity in the Ministry of Health, aligned with the country's comprehensive ICT and eGovernment framework, can deliver steady progress in the deployment and institutionalization of digital health solutions.
- **Estonia** highlights the benefits of a digital health approach based on a comprehensive eGovernment framework with basic structural elements, such as a national electronic ID and a system architecture, designed for interoperability.
- **Norway's** experience exemplifies how a country's digital health governance structure can evolve as the result of an ambitious national-

scale electronic medical record design and deployment process. The complexity of stakeholder management is reflected in the many boards and coordination bodies involved in digital health and the active involvement of healthcare providers, professional associations, regional health authorities and municipalities.

- **Canada** provides an objective lesson in how pathways to national digital health implementation can be used in politically decentralized countries by creating a separate agency for digital health. The Infoway agency works with the country's provinces and territories to implement solutions in line with its national digital health architecture.

- **Mali** illustrates both the advantages and disadvantages of an independent agency model and how more effective donor coordination could play a role in addressing the fragmentation and interoperability issues common to so many donor-dependent LMICs.

Figure 5: Three Governance Mechanisms



Moving Ahead

These countries show that success in implementing a national digital health strategy depends on the presence of committed senior government leaders, on effective governance mechanisms to facilitate coordination among stake-holders, and on a national ICT framework promoting alignment between stakeholders in both the health sector and the ICT sector. The findings and insights contained in the report provide leaders with an understanding of the steps and elements needed to achieve these three conditions, illustrated by real-world experiences and lessons learned. Progress is happening in digital health, and with that progress comes the real prospect of realizing the potential of ICTs to achieve global health goals through the SDGs and beyond.

Introduction

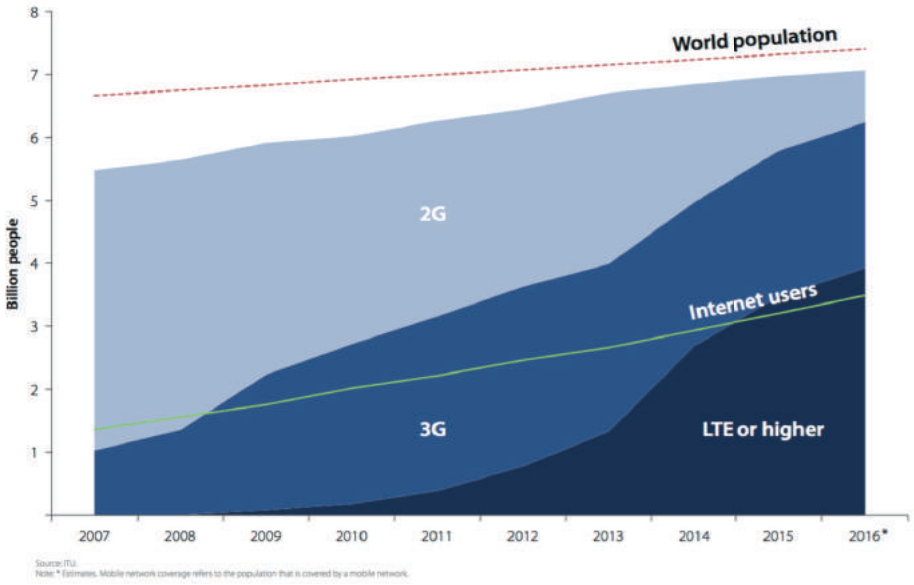
"The use of eHealth to improve the delivery of health care continues to increase around the world. In line with the principles of universal health coverage, eHealth can potentially make health systems more efficient and more responsive to the needs and expectations of the people they serve."

Dr. Margaret Chan, Director General, World Health Organization (WHO)

Background: Over the past decade, great progress has been made in reducing maternal and child mortality and infectious diseases such as HIV/AIDS. Yet low- and middle-income countries (LMICs) now not only face the threat of new diseases and epidemics, but also the rising tide of noncommunicable diseases which are wreaking a heavy toll on countries with health systems ill-prepared to face these threats. In 2013, the WHO estimated a global shortage of over 17 million healthcare workers, mostly in Africa and Southeast Asia.[1] Pressures on global health systems are compounded by the escalating costs of delivering healthcare and the lack of sufficient financial resources to meet these. As national leaders strive to reach the ambitious health-related targets of the Sustainable Development Goals, they are realizing how information and communication technologies (ICTs) can support health systems to cope with their growing disease and cost burdens.

The number of mobile connections (7.6 billion in 2016) is now nearly equal to the world's population[2] and smartphone penetration is already at 48%. The GSMA projects that there will be 5.6 billion smartphones in the world by 2020 and that around 90% of users will be in LMICs.[3] Moreover, the Broadband Commission for Sustainable Development, in its 2016 annual report, states that fixed broadband prices have dropped by 65% over the past five years and that the majority of countries have reached the Broadband Commission's target of offering fixed broadband services to their inhabitants at a cost of less than 5% of gross national income per capita.[4] Countries are clearly making progress in lowering the cost of connectivity, with the ultimate aim of providing all inhabitants with access to ICT services.[5]

Figure 6: Growth in Access to Broadband internet



Source: ITU

"Despite the promise and potential of global connectivity, we cannot lose sight of the fact that nearly four billion people have yet to be brought online. Connecting the unconnected and bridging the digital divide must be addressed as an urgent policy priority requiring more innovative public-private partnerships and finance and investment models."

Houlin Zhao, Secretary-General of the International Telecommunication Union (ITU)

Meanwhile, access to ICT remains problematic for many of the world's poor. Mobile broadband costs the equivalent of 1% to 2% of average monthly income in high-income countries versus 11% to 25% in LMICs.[6] Some 3.9 billion people remain unconnected to the Internet, implying the need for greater efforts to bridge this digital divide. In the least developed countries, only 15% of the population has access to the Internet. In 2016, Internet usage rates were about twice as high in developed countries as in developing countries and more than twice as high as in the least developed countries.[7] The digital divide also disproportionally affects women and people living in remote rural areas, even though these populations could benefit most from digital access.

One constraint in attempting to bridge the digital divide is the need for infrastructure to develop and deploy more advanced digital health (eHealth), mobile health (mHealth) and telehealth applications. This constraint applies to broadband coverage and also to reliable sources of electricity.

Another constraint looms large on the digital health landscape. Although the 2015 survey of the WHO Global Observatory for eHealth found that the number of mHealth pilots was falling and that more established, larger-scale projects were being consolidated, digital health solutions in LMICs are often still being designed as stand-alone efforts to solve specific health problems rather than as part of an integrated approach to strengthening health systems.[8] Countries continue to face a proliferation of uncoordinated digital health projects resulting in a fragmented ecosystem which inhibits scaling and long-term sustainability.

Exploring the Digital Health Landscape

The Broadband Commission Working Group on Digital Health, chaired by the Novartis Foundation and Nokia, convened leading digital health experts from governments, international and non-governmental organizations, academic institutions and the private sector for the purpose of producing this report. The Chairs commissioned Vital Wave to conduct primary and secondary research and interviews in consultation with the Working Group. The primary research involved interviews with forty-six digital health experts from over twenty countries and international organizations. They represented government, implementing partners, donors and transnational regulatory bodies. Secondary research included a

"Fragmentation in digital health is driven by perverse incentives in the ecosystem. Until donors collaborate on shared funding to support interoperability and countries set and publish e-governance standards to guide implementations, we will not solve the problem of fragmentation. However, multiple point-of-service applications should be continued—they just need something to plug into."

Kate Wilson, CEO, Digital Impact Alliance at United Nations Foundation

literature review of peer-review white papers, websites and other sources of public information.

The literature review identified twenty one countries with unique attributes of digital health: **Bangladesh**, **Brazil**, **Canada**, **Chile**, **Estonia**, **Gabon**, **Ghana**, **India**, **Kenya**, **Malawi**, **Malaysia**, **Mali**, **Mexico**, **Nigeria**, **Norway**, **Pakistan**, **the Philippines**, **Rwanda**, **Singapore**, **South Africa** and **Uruguay**. These countries represent a range of demographic, geographic and economic contexts with varying levels of maturity in digital health systems.

In addition, case studies from eight countries at different stages on the path to institutionalizing digital health were reviewed in depth: **Canada**, **Estonia**, **Malaysia**, **Mali**, **Nigeria**, **Norway**, **the Philippines** and **Rwanda**. Countries researched for this report are depicted in Figure 7.

This report aims to provide insights into leadership, governance and intragovernmental cooperation. Other topics are explored only if related to the main focus of the report. Research outputs and conclusions are based on the secondary research and on interviewees' responses.

There are three main parts to this report: the first touches on the development of a national digital health strategy and the second on implementation of such strategies and potential governance mechanisms. The third part describes selected challenges that countries face when embarking on the development and implementation of a digital health strategy related to stakeholder engagement, financing and workforce capacity building, along with potential approaches to addressing them that are drawn from country experiences and international best practices.

Digital Health Strategies and the Role of Government

A change in mindset across sectors and disciplines and throughout the entire healthcare value chain is needed to translate digital health applications into scalable, evidence-based and integrated health solutions that yield long-term public health benefits. Government leaders can play a fundamental role in fostering an enabling environment for digital health by bringing together stakeholders from the public and private sectors, academia, civil society and international organizations.

Strong leadership and governance can prevent duplication of effort and harmonize standards for digital technology. By developing supportive policies and national-level legislation

Figure 7: Countries Surveyed for this Report

Source: Vital Wave

"The Government of India has launched the Digital India Programme in order to transform the entire ecosystem of public services through the use of information technology. We need to transform healthcare by empowering people to become active healthcare citizens with choice but most powerfully with information and to take more responsibility over their own health and life choices."

Shri J.P. Nadda, Union Minister of Health and Family Welfare, India

and regulations, public health services can incorporate ICT and protect privacy, security and confidentiality of health data, as well as promote the exchange of information. A recent survey found that the majority of healthcare professionals (61% in **China**, 63% in **South Africa**, and 78% in the **United Arab Emirates**) believe that governments should provide citizens with connected technology to help them manage their own health.[9]

As a first step toward national digital health implementation, leaders can develop a national digital health vision and strategy. The annual WHO eHealth survey for 2015 found that 73 of 116 responding countries (63%) had developed eHealth strategies, while 76 (66%) had developed electronic health information systems and 66 (57%) had developed a national telehealth policy or strategy (Figure 8).[10] The ITU report for 2016 found that 151 of 196 Member State countries (77%) had developed national broadband plans,[11] illustrating how countries are developing strategies in both digital health and broadband connectivity.

Despite these advances, another 2015 digital health survey by the Pan American Health Organization reports (PAHO) called for greater institutional support for the development of national digital health policies and strategies.[12] Only 61% of the surveyed countries in the PAHO region had a national digital health policy or strategy, while 78% of countries had a national policy or strategy for universal health. In Africa, WHO statistics show that 24 out of 47 (51%) respondent countries had developed an eHealth strategy in 2015.[13] Housseynou BA, who supports coordination of eHealth for WHO in the Africa region, notes, "Although there is progress, the large majority of countries in Africa still need to move from strategy to implementation."

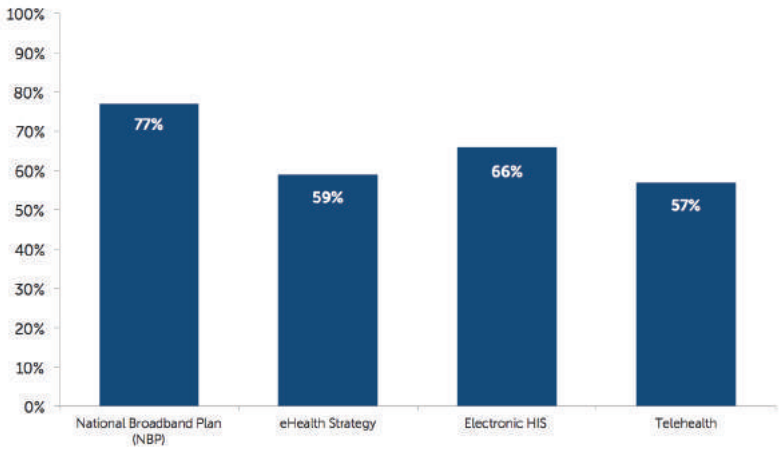
The WHO-ITU National eHealth Strategy Toolkit (WHO-ITU Toolkit) provides a roadmap for leaders seeking to build a national eHealth strategy.[14] The WHO-ITU Toolkit identifies seven essential components to build such a strategy: 1) leadership and governance, 2) strategy and investment, 3) legislation, policy and compliance, 4) workforce, 5) standards and interoperability, 6) infrastructure, and 7) services and applications (Figure 9). Although all seven of these are required, the focus of the report is on the first component of leadership and governance, as it is fundamental for the others to be deployed effectively.

Also, the literature reviews and interviews and discussions with experts constantly highlighted leadership and governance as the main challenge faced by stakeholders developing and implementing national digital health strategies.

"The world is changing, and we cannot afford to lag behind. Let us take a giant step forward to transform our health sector and use ICT to advance medicine. We have the will and all it takes to achieve this."

Hon. Isaac F. Adewole, Minister of Health, Federal Republic of Nigeria

Figure 8: Prevalance of National Digital Health and Broadband Plans



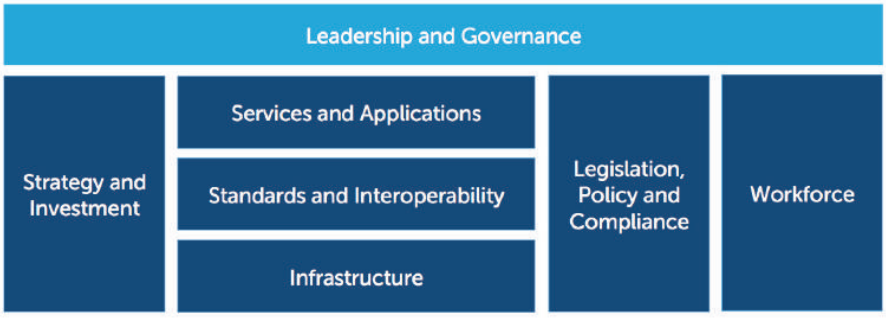
Source: Global survey on eHealth 2015, WHO Global Observatory for eHealth http://www.who.int/goe/en/. http://www.broadbandcommission.org/Documents/reports/bb-annualreport2016.pdf. Responses are the subject of rigorous attempts at standardization, but nevertheless, countries respond according to their own criteria and view of the policy situation. This means that survey responses should be similar, but may not be fully consistent at the international scale.

The case studies in this report illustrate how different countries go about developing and implementing national digital health strategies. They do so in ways that are consistent with their specific needs, their priorities and their ability to muster the necessary investments and resources. The case studies also outline the catalysts and key performance indicators (KPIs) which countries can use to facilitate the development of a national digital health strategy and to monitor its implementation. Three possible governance mechanisms have been identified as guidelines or frameworks for countries seeking to adopt a digital health strategy: a health ministry mechanism, a government-wide digital agency mechanism, and a dedicated digital health agency mechanism. This report gives a high-level overview of these mechanisms, of which the components should be viewed as a dynamic spectrum rather than as a static model.

The Promise of Digital Health

Recognizing the transformational potential of digital technology is important. The digital revolution is spurring an increased demand among individuals and healthcare providers to

Figure 9: WHO-ITU National eHealth Strategy Tookit Components



Source: World Health Organization. (2012). National eHealth Strategy Toolkit. Retrieved February 29, 2016, from https://www.itu.int/pub/D-STR-E_HEALTH.05-2012

What is Governance?

Governance, in the sphere of digital health, is the means by which intragovernmental and cross-sectoral collaboration is organized by entities that advise, coordinate, support, regulate, monitor, and implement digital health services and applications, and ensure the security of the health information exchange (HIE).

A governance mechanism facilitates the commitment of stakeholders, which is a critical prerequisite for buy-in, ownership, expertise and outreach through communication. Stakeholders in a governance mechanism include, but are not limited to, the public or private sector, academia and professional associations.

access health data and information. For individuals, there is a desire to manage their own health, a desire partly fueled by technology and the ease with which information can be obtained. With chronic diseases requiring lifetime management and compliance with treatment, digital health can faciitate personalized care and empower patients to manage their health.

The number of mHealth products and services has doubled in the past five years in LMICs,[15] and there are now over 165,000 mobile applications for health services.[16] Fifty-nine percent of patients in the LMICs are using mHealth applications and services versus 35% in high-income countries.[17] Globally, 44% of mobile users have seen a medical professional using a mobile device during diagnosis or treatment,[18] and 86% of clinicians believe that health applications can facilitate diagnosis.[19] Although robust evidence of the merits of many of these applications is still lacking, the demand from patients and providers is expanding. Research2Guidance, for example, showed that mHealth application downloads rose from 1.7 billion in 2013 to 3 billion in 2015.[20] There is clearly a need to meet the demand through evidence-based digital health solutions.

More recent advances in technology, such as connectivity and the cloud domain, can accelerate the potential benefits of digital health. Several trends in digital health include mHealth, connected sensors and devices and the growing ease with which to capture information and data.

Connectivity and the cloud domain: As of November 2015, 89% of the world's urban population had access to 3G coverage versus only 29% of the world's rural population.[21] Progress still needs to be achieved on 3G and 4G network coverage but the future holds great promise—with 5G to be deployed around 2020, future networks are likely to benefit from high reliability and security, very high speeds and increased reach and mobility.

With continuing fiber deployments that enable gigabyte connectivity, 5G is poised to enhance digital health. Its high bandwidth and low latency will, for example, make high-resolution video conferencing possible at an affordable price and will enable patients in rural or underserved areas to access specialist care remotely. The reliability of the 5G network will facilitate the connectivity of all types of sensors and devices that will electronically transmit medical data, generate alerts, and give advice on medication intake or on other issues. Future technology will also facilitate point-of-care testing where diagnostic tests and results can be produced on site. In addition, low-cost medical devices

and applications that use smartphones have the potential to radically transform healthcare diagnosis and treatment in emerging markets by being easier to use and significantly cheaper than traditional alternative medical devices. Advances in cloud computing and the new ways of dynamic network management, such as software-defined networking, will bring considerable gains in agility and cost. Private cloud architectures will provide the needed high security and high availability.

mHealth by SMS and applications: The mobile revolution is a key development of the past two decades. The adoption of mobile technology occurred faster than almost any other technology in world history. In 1991, mobile phone penetration stood at only one 1% of the world's inhabitants, while 25 years later, it stands at 99% with 4.7 billion unique subscribers.[22] In Africa, where fixed Internet penetration stands at less than 1% but mobile penetration at 80%, the potential to leverage mobile technology is evident.

Although there is a proliferation of mHealth applications, digital health solutions do not always have to be complex. Phones connecting providers and individuals via voice, video or messaging services (including SMS and platforms such as WhatsApp and Facebook) can have a substantial impact. The **Ghana** Health Service telemedicine program, supported by the Novartis Foundation and other partners, uses a mobile phone to connect remote primary healthcare facilities and community health workers to a teleconsultation center at a referral facility. In 2013, approximately 54% of the medical calls received at the center could be resolved by telephone consultation.

In **Malawi**, cStock, an mHealth reporting and resupply system, improved the rate of availability of medicines from 27% to 62%, according to results from the 2011 pilot across six districts, mainly due to an improvement in stock reporting rates from 43% to over 80%. Users also reported that the system took less time and saved significant effort to resupply products. The program has now been scaled up to all of Malawi with reporting rates continuing to be over 80%.[23]

A nationwide program called MomConnect in **South Africa** sends health information on pregnancy via SMS, and an associated help desk is accessible by phone. Over one million women have registered with MomConnect since its launch two-and-a-half years ago and the help desk has processed over 500,000 messages. Early results show that HIV-positive mothers subscribing to the service have higher rates of antenatal visits and better birth outcomes than mothers not subscribing.[24]

Mobile phones can also be used to educate health providers. The Government of **India** has launched a nationwide mHealth program that aims to train one million community health workers to reach ten million pregnant women. To date, 150,000 health providers in four states have received the training.[25]

These mHealth approaches, especially in LMICs, have the potential to strengthen the capacity of health providers working in remote areas, improve quality of care at the frontline and strengthen referral systems, thereby also alleviating the workload at often overburdened secondary and tertiary facilities.

Connected devices and sensors: Connected devices, such as wearables and sensors, can facilitate remote monitoring, consultation and real-time analysis. Already one in ten mHealth applications have the capacity to link to a sensor or device.[26] These devices, sensors and applications, along with

"Technological advances bring opportunities to enhance patients' lives. At Novartis, we want to harness the power of digital health to create innovative solutions that complement our medicines."

Joe Jimenez, Chief Executive Officer, Novartis

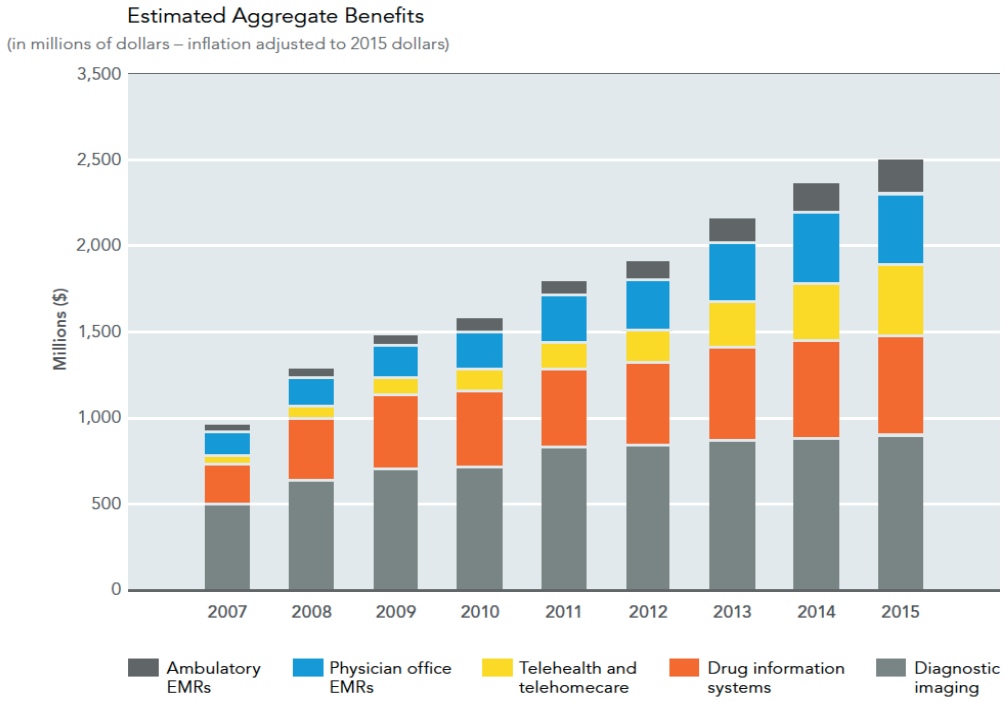
rapid testing technologies, strengthen the potential of person-centered care to facilitate diagnosis and treatment closer to a person's home. Many of these technologies are still in the early stages of research and development, but point-of-care devices already show promise of providing rapid diagnosis by leveraging mobile phones. A smartphone accessory connected to a phone has the potential to detect HIV within fifteen minutes in a drop of blood from a finger[27] The WellDoc's BlueStar FDA-approved mHealth monitoring medical device and application generates tips and education materials in response to information entered by Type 2 diabetes patient about their diet, exercise, medications and blood glucose readings. It was able to lower hospitalization rates by 58%, reduce blood glucose levels and contribute to a 1.9 point drop in HbA1C from 10% to 5% in 90 days, a result that is not typically achieved with traditional methods of diabetes management.[28]

The power of information and data: Mobile data collection applications, such as the electronic Tool to Improve Quality Healthcare (eTIQH) [29] and CommCare, have enabled organizations and health managers to collect data on dashboards, providing real-time evidence for decision-making. The sources and quantity of health data from mobile devices, Internet searches and wearables are growing. Growth in computing power and predictive analytics is enabling the study and use of vast amounts of information that reveal patterns, trends and associations thanks to Big Data.[30] After the Haiti earthquake in 2010, for example, research teams used data from two million mobile phones to track population movements during the cholera outbreak which helped aid organizations know where relief services and supplies were needed.[31] Big Data will create a vital repository of information for scientists and can accelerate research and new treatment protocols.

Another promising benefit from digital health is the long-term saving of costs that it can offer. A recent report from GeSI, the Global e-Sustainability Initiative, and Accenture estimates that 1.6 billion people could benefit from quality medical services through digital health solutions, which could generate over US$200 billion in additional annual revenue for the health sector by 2030.[32] A report commissioned by GSMA in 2013 found that the increased use of mobile interventions could reduce healthcare costs in high-income countries by US$400 billion by 2017.[33] A PricewaterhouseCoopers report calculated that between 2013 and 2017 mHealth could enable an additional 15.5 million people in **Mexico** to access health services and reduce public and private healthcare spending by US$3.8 billion. The same report estimated that mHealth would increase health access to 28.4 million people in **Brazil** and reduce public and private healthcare spending by US$14 billion.[34] **Canada** calculated the return on investment (ROI) for the implementation of electronic medical records (EMR), telehealth and district information systems at an estimated aggregate cost savings of CAN$16 billion since 2007 [35] (Figure 10).

In addition to generating cost savings, digital innovations such as mobile money have the potential to advance

Figure 10: Canada's Estimated Aggregate Digital Health Savings



Source: Canada Health Infoway Annual Report 2015-2016

central goals such as universal health care by enabling new mobile-based products in health insurance and remittances, which can expand coverage while reducing waste and inefficiencies in health system financing.

Despite these promising results, more evidence is needed on the cost implications of digital health and the degree to which it can improve health outcomes over the short and long term.[36] While there is anecdotal evidence that digital health can bring health benefits, the lack of sufficient rigorous clinical evidence and large-scale studies to confirm this claim is a barrier to investment.

These promises of digital health can be more rapidly attained with a national digital health strategy founded on committed government leadership, effective governance mechanisms, and coordination among the health and ICT sectors. As highlighted in the following sections of this report, countries meeting these conditions can prevent duplication, harmonize standards, promote interoperability and ensure the coordination of stakeholders across the public and private sectors.

"The big challenge is to ensure the sustainability and continuity of digital health initiatives, whose benefits can sometimes only become apparent after ten to fifteen years. And to accomplish this, it is fundamental to promote the production of scientific evidence to raise awareness among decision-makers about the importance of investing in eHealth."

David Novillo-Ortiz, Coordinator of PAHO/WHO's Regional eHealth Program

1 Developing a National Digital Health Strategy

Part 1: Developing a National Digital Health Strategy

Developing and implementing a national digital health strategy is not a simple task. It calls for knowledge about issues that span the health and ICT domains and for sustained collaboration between a diverse set of stakeholders. The process can take anywhere from three to ten years, starting with a development stage then moving to implementation. Countries do not develop national digital health strategies in a vacuum. They undertake many digital activities and work with components that are likely to be already in place, such as legacy health management information systems (HMIS), telemedicine initiatives, mHealth projects, electronic health records (EHRs) or electronic insurance reimbursement claims.

Clear governance, with elements including a steering committee and a dedicated management team, is essential when developing a national digital health strategy.

Nigeria provides a case study for this component of strategy development. It clearly describes how the country's leadership and intragovernmental cooperation were essential in developing a comprehensive digital health strategy. A long-term commitment, a clear vision of the benefits of digital health and the support of committed government leaders made the building of the national digital health strategy possible.

A national digital health vision and strategy sets the stage for a common framework comprising the required policies and standards, the plans for financial resources and for strengthening the health and ICT workforce, and the coordination with stakeholders throughout the entire process. The common architecture frames the process for establishing standards to support interoperability across differing systems and programs. For example, establishing government databases or portals for different systems makes it easier for programs and solutions to communicate with each other and for accountability and monitoring of population health to be more effective. In addition, a national digital health strategy facilitates the drafting of roadmaps to prioritize approaches, enables initiatives to move beyond the pilot phase and reduces the fragmentation of the digital health landscape.

Laws and legislation, including those for data privacy and security, are crucial to the digital health sphere, as the exchange of health data is particularly sensitive. A lack of appropriate legislation can seriously hinder the scaling of digital health solutions and deter further innovation and investment. There is also a fine line between protecting privacy and fostering innovation. If regulation is too stringent and not built in consultation with the health ICT sector and experts, it may hamper the benefits of digital health.

Finally, a digital health strategy can mobilize additional resources, prioritize needs and build capacity through external support, such as from regional networks or partners through targeted technical training for program management or technical expertise.

Through all of these efforts, a government can foster an enabling environment for digital health.

Policy and regulation

Governments play a key role in enabling and accelerating the digital health opportunity by implementing the appropriate policies. Clear, consistent regulatory frameworks that ensure safety and build trust will support adoption of digital health solutions and encourage investments.

The healthcare and ICT sectors are regulated industries in their own right. Digital health brings together these two worlds, which calls for a rethinking of how policy and regulatory frameworks should evolve in order to take into account the fast-paced technological developments that both worlds are undergoing. Based on close collaboration across the different government departments involved, good practices can be adopted from both sectors and used as a set of digital health policy and regulatory principles that help to drive deployment and take-up.

In order to move toward the large-scale adoption and integration into clinical practice of digital health solutions, governments worldwide are recommended to develop and implement holistic policy and regulatory frameworks in the following key areas:

Data protection and privacy

- Build trust and confidence through the consistent application of data protection and privacy principles across the digital health ecosystem. It will be essential for the success of digital health to gain the trust of patients and consumers that the privacy of their data will be protected. Privacy is about the ability of individuals to know and express choice and control over the way information about them is collected, shared and used.

  The term privacy is sometimes used interchangeably with that of security, although they are two distinct, albeit closely related, concepts. Privacy is about the appropriate use of information related to an individual, while security is about the integrity and access to platforms and networks.

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

  Digital health does not necessarily require completely new approaches, but it will be important to remove any unnecessary regulatory barriers and ensure legal certainty. There are over one hundred data protection and privacy laws around the world. Governments can facilitate the sharing of data across borders in a way that is consistent with these laws by supporting industry best practices and frameworks for the movement of data and working to make these frameworks interoperable.

Governments should also ensure that data protection and privacy legislation is technology-neutral and that rules are applied consistently to all players in the ecosystem. Inconsistent rules, or inconsistently applied and interpreted rules, lead to uncertainty for businesses, in turn negatively impacting investment and innovation. As a result, consistency in the application of well-established privacy and data protection principles across the ecosystem and value chains is critical. In addition, regulatory measures should be balanced and should facilitate the use of data in creating patient-centered and sustainable healthcare systems.

Medical device regulation:

- Ensure quality and safety of digital health solutions through clear, proportionate and risk-based medical device regulation. Whether something is considered a medical device is by and large determined by its intended use. Generically speaking, if a device is intended for diagnosis, intervention, monitoring and treatment of a medical condition, it will be considered a medical device. Based on the level of risk or potential to do harm, medical device regulations specify different classes for these device types, together with their corresponding regulatory requirements.

  When thinking about this in a digital health context, a connected blood glucose monitor would be considered a medical device. A mobile handset used by a doctor or nurse, or a fitness tracker, would fall outside this definition. However, not all cases are necessarily so clear cut. It is therefore important for companies operating in the digital health space to understand clearly whether or not their product would be considered a medical device and subject to the relevant regulatory requirements. Regulation should provide this level of clarity, sometimes including additional guidance.

  The European Union (EU) and the US Food and Drug Administration (FDA) have made great progress in clarifying this boundary between what constitutes a medical device versus a wellness or generic device. They also recognize that regulatory instruments should be proportionate and risk-based in order to ensure that innovative and transformative solutions that are safe and effective can indeed reach and benefit consumers. Governments from other regions of the world can leverage this work and reference EU and FDA approvals when defining their regulatory frameworks in order to enable global deployment and ensure global harmonization of regulatory approaches.

  As recognized by the European Commission (EC) and the FDA, expertise from the private sector that needs to apply the regulation is very important. This is to ensure that regulatory frameworks are "fit for purpose" and adapted to technological and scientific developments. This is particularly important in the digital space where services and solutions are constantly evolving. Consultation with digital health experts is therefore recommended. The EC has put this into practice by establishing expert working groups that support the implementation of medical device regulation.

Reimbursement policies:

- These policies enable equal access and inclusion through reimbursement regimes that reward health outcomes. Digital health solutions have the ability to support increased access to prevention, diagnosis and care and reduce health inequalities. They are able to follow and support an individual throughout his or her lifetime, for example, aiding in the prevention of conditions arising or reducing the likelihood of readmission. Some of these effects can occur years later, such as the benefit of diabetes management solutions. Others are measurable only at population level, such as the benefit of smoking cessation campaigns.

  The challenge with current predominant principles of healthcare payment models, however, is that they are based on reimbursing medical interventions rather than on achieved outcomes. To facilitate widespread access to digital health, policies need to evolve in order to move from intervention-based reimbursement to regimes that reward health outcomes and support the adoption of innovative, value-based approaches.

Interoperability

- Governments should promote the adoption of common standards and interoperable platforms in the healthcare sector. The use of common standards ensures that digital health applications are secure, robust and easy to use. It further reduces the cost and complexity of developing applications for healthcare. Interoperability is required to enable digital health to reach scale and ensure that solutions can be used across systems, networks and borders.

  Governments can support the adoption of common standards by, for example, incorporating requirements for the use of interoperable approaches in public health tenders or promoting the development of digital skills within the healthcare sector. This includes the implementation of interoperable electronic health record platforms as a fundamental building block to realize digital health solutions at scale.

  Overall, in order to enable global deployments and realize economies of scale, it will be important to achieve harmonization of these policy and regulatory approaches around the world. Dialogue and collaboration between governments across regions will help facilitate a global market to develop. Further resources can be found in Annex 3.

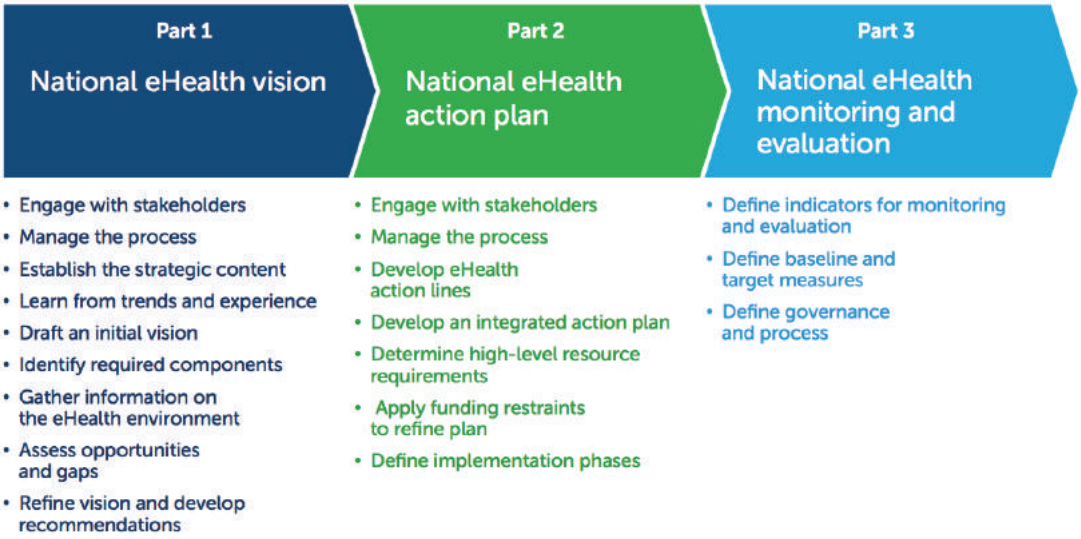
Source: GMSA

Three steps are required to develop a national digital health strategy, as described in the WHO-ITU Toolkit: 1) establishing a national eHealth vision, 2) developing a high-level action plan, and 3) establishing a national eHealth monitoring and evaluation framework.

As shown in Figure 11, engagement with stakeholders is an overarching activity when developing a national digital health strategy. Early mapping of stakeholders and of existing digital health initiatives is part of the initial development process. The involvement of stakeholders such as donors, states, provinces and private-sector sources should be based on this mapping process, as well as on the needs identified as the strategy is developed.

Committed government leadership and the creation of effective governance mechanisms for intragovernmental cooperation between health and ICT stakeholders, all of whom have well-defined roles and responsibilities, will facilitate engagement with stakeholders. Leaders stressing the importance of integrated digital health solutions and systems, rather than disease or technology-specific solutions, can drive coordination and efficiency of digital solutions in health. A program management unit and working groups can incorporate stakeholder feedback and advance the strategy development process.

Figure 11: Developing a National Digital Health Strategy



Source: World Health Organization, National eHealth Strategy Toolkit, 2012
https://www.itu.int/pub/D-STR-E_HEALTH.05-2012

A strategy that is realistic, practical and achievable guides digital health stakeholders and activities during implementation. Although most of the case studies in this report are from countries that are already implementing a national digital health strategy, the research and interviews conducted for the report raised some consistent issues that also correspond to the recommendations of the WHO-ITU Toolkit:

- **Aligning with national health priorities:** Although ICT agencies or ministries support the health agencies with technical expertise, the Ministry of Health (MoH) leads the digital health strategy and aligns the strategy with the country's health priorities. The digital health strategy thus serves the health needs of the population, and thereby facilitates its adoption and integration. As a result, healthcare practitioners, including clinicians, pharmacists, nurses and community health workers as well as professional associations and patients, should be consulted in the strategy development process.

- **Assessing the health and ICT context:** Identifying the existing resources in the ICT and health environments will mark the starting point for developing a digital health strategy. Mapping the inventory of existing ICT systems, hardware and software helps leaders to understand the assets that can be leveraged for digital health and the additional capacity that is needed, while at the same time avoiding further fragmentation. The WHO-ITU Toolkit defines the stages of a country's digital health environment as Experimentation and Early Adoption, Developing and Building Up, and Scale-up and Mainstreaming.

- **Measuring effectiveness:** A thorough monitoring and evaluation strategy embedded within the digital health strategy is essential to assess the effectiveness and impact of the strategy. KPIs allow leaders to better allocate resources and undertake adjustments where needed. Generating evidence on the benefits of digital health solutions is crucial to allocating further resources and justifying continued investments.

- **Adapting to a flexible and iterative process:** Countries have different needs, resources, infrastructures and political constraints. As the environment progresses with new technology, increased connectivity or a growing number of community health providers, the national digital health strategy needs to evolve and grow accordingly.

What is interoperability?

Interoperability is critical to achieving a mature national digital strategy and refers to "the ability of different information technology systems and software applications to communicate, exchange data, and use the information that has been exchanged." [1] Interoperability makes it possible for data to be shared across health providers, laboratories, hospitals, pharmacies, and patients regardless of the device, application, software platform or application vendor.

Based on common standards at foundational, structural and semantic levels, interoperability enables the secure, reliable and consistent exchange of data between devices, applications and platforms. Semantic interoperability is an essential requirement in a digital health context, making sure that any data exchanged across devices and systems is understood, interpreted, and can be acted upon in the correct manner.

Benefits arising from semantic interoperability,[2] which allows computer systems to exchange and share data, include easier and faster access to patients' information, opportunities for better diagnosis, quality of treatment and patient safety, and improved cost effectiveness, as well as increased consumer choice and enhanced competition.

While no single standard can deliver semantic interoperability, existing standards can be combined to ensure information is seamlessly exchanged. The following example organizations provide interoperability guidelines: the Personal Connected Health Alliance with its Continua Design Guidelines and the Integrating the Healthcare Enterprise, Health Level Seven International (HL7) with its Fast Healthcare Interoperability Resources (FHIR) standard for representing data, and Open Health Information Exchange (OpenHIE) with its offering of standards-based approaches, reference technologies and peer technical assistance.

Despite these mechanisms, there are still challenges to implement interoperable approaches. Awareness of standards and how they can be applied remains generally low, in part because digital health is a new area for many organizations and governments with advances in ICT moving at a rapid pace. Healthcare providers and the clinical community are often not aware of the importance and use of standards and so fail to bring these requirements to the attention of those developing digital health solutions before systems are finalized and integrated into their work. The complexity involved in implementation is another factor requiring significant expertise in the definition, design and delivery of systems.

Furthermore, market demand has historically been low for interoperable systems, meaning vendors have not yet considered a direct need to deliver solutions based on common standards. However, the benefits of open standards-based interoperable approaches outweigh the extra effort required, due to the inherent potential of systems being able to exchange information, and the potential to swap out and upgrade solutions that are standards based.

Governments can play the following roles in addressing the above challenges:

- Engage with digital health stakeholder groups, including healthcare providers and clinical communities, medical device vendors, and the pharmaceutical and mobile industries.
- Identify best practices and learn from effective leadership provided by pioneering countries moving forward with implementations of interoperable solutions, e.g., the **Norway** case study in Part III of this report.
- Consider adopting frameworks for open, interoperable digital health architecture and standards.
- Help drive adoption by encouraging procurers to specify open standards in their medical device and healthcare ICT system acquisitions.

A more comprehensive report expanding on the above can be found at gsma.com/digitalhealth/

Source: GMSA

1. HIMSS Dictionary of Healthcare Information Technology Terms, Acronyms and Organisations, 2nd Edition, 2010, Appendix B, p190, original source: Wikipedia
2. eHealth Stakeholder Group report, *Perspectives and Recommendations on Interoperability*, March 2014

Nigeria recently completed the development of a national digital health strategy. The process took three years and involved over two hundred stakeholders, not surprising in a country with a population of 174 million and a federal structure of thirty-six states. Although not all countries will require as many stakeholders and so long a time as **Nigeria** did to complete the process, the leadership, the coordination of stakeholders, and the solid cooperation between ICT and health authorities were essential to the development and implementation of the national digital health strategy in this country.

NIGERIA:

Creating inclusive strategy development in a complex ecosystem

Digital Health Snapshot

- Population: 174 million
- Strategy Development Timeline:

  2013 – 2015: Strategy Developed

  March 2016: Strategy Approved
- Implementation Status: Ongoing (2016–2020)

  National Health ICT Vision: "By 2020, health ICT will help to enable and deliver universal health coverage"

From development to operationalization: The implementation and operationalization of the strategy commenced with the approval of the National Council of Health, the signing by the Honorable Minister, and the inauguration of the eHealth Governance Structure. The Program Management Office is housed in the ICT department of the Federal Ministry of Health (FMoH) and includes representatives from the Federal Ministry of Communication Technology (FMCT). The Program Management Office team sustains the collaborative approach used during the strategy development. Other stakeholders will be brought in as needed.

Digital health context and catalyst

- In 2012, the FMoH, under the guidance of then-Minister Pate, recognized the lack of harmonization between the ICT and health sectors. The Saving One Million Lives (SOML) initiative was created to achieve the Millennium Development Goals 4 and 5 that aim to reduce child and maternal mortality, respectively. The SOML Office, the Norwegian Agency for Development Cooperation (Norad), the United Nations Foundation (UNF), represented at the time by the mHealth Alliance, GSMA and Intel formed a partnership to support the ICT and health ministries in their strategic planning and systematic scaling of ICTs to reach the SOML goals.

- Thanks to the ICTs for Saving One Million Lives (ICT4SOML), which is now called the ICT4HEALTH Project, the UNF supported both the FMoH and FMCT in strengthening the enabling environment for health ICTs. It did so by conducting a baseline assessment of digital health needs, by supporting the establishment of a national coordinating mechanism for digital health, by developing a strategic framework for health ICT, and by outlining critical gaps in capacity, policy, standards and interoperability.

- As a result, the FMoH and FMCT jointly developed a unified vision and strategy, Nigeria's National Health Information and Communication Technology (Health ICT) Vision and Framework. The development of the strategy was carried out in 2014 and 2015 and engaged over fifty government agencies, as well as all federated units (states) and more than two hundred stakeholders from government, private-sector and development organizations.

Roles, responsibilities, governance and cooperation mechanisms

- **In-country governance:** Government leadership involving agencies in both health and technology were instrumental in developing a successful digital health strategy. "*The importance and critical necessity of a strong, effectual and country-led governance structure cannot be over-emphasized,*" says Olasupo Oyedepo, Project Director for the Health Strategy and Delivery Foundation's ICT4HEALTH Project. The strategy development and implementation process involved capacity building, knowledge sharing, and mentoring to ensure that digital health investments were appropriately aligned with the health sector priorities and goals of the country.

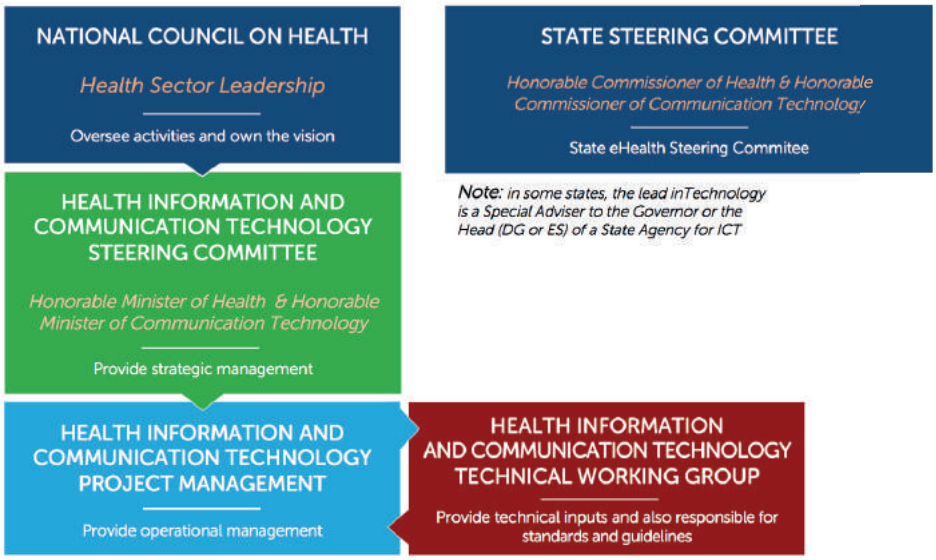
- **Creation of a local implementation team:** The ICT4SOML team member in each ministry was able to strengthen the capabilities of fellow government representatives, provide technical assistance for health and ICT-related issues, and create personal relationships within the different agencies. The FMCT and the FMoH assigned contact points who reported directly to the Director of the Department of Health Planning, Research and Statistics of the FMoH and the Director of the FMCT eGovernment department.

  ICT4SOML was responsible for aligning the different government representatives and stakeholders and for facilitating the collaboration needed to finalize the strategy. As a neutral entity with technical expertise and an understanding of the Nigerian digital health ecosystem, ICT4SOML ensured equal representation and ownership between the FMCT and the FMoH. Stakeholders across public and private sectors and technology and health disciplines developed the strategy using two processes: 1) National-level socialization for both strategy development and approval by national authorities, and 2) State-level socialization for feedback and approval by state governments. Representatives from government agencies, most importantly the FMoH and FMCT, formed a community of ownership so that when Norad and UNF were no longer involved, the Nigerian government owned the strategy and its implementation.

- **State-level socialization:** As a result of Nigeria's population size and federal structure, input and participation from Nigeria's thirty-six states

and its federal capital territory were critical. The state engagement meeting in Abuja brought two representatives from the state MoH and one technology representative from each state government. This meeting ensured that the state teams were appropriately involved in the strategy development process and that they supported the presentation of the strategy to the National Council on Health. The National Council of Health approved the strategy in March 2016, about five months after the extensive stakeholder consultations.

Figure 12: Nigeria Health ICT Strategic Framework 2015-2020[36]



Source: United Nations Foundation. (2015, October). "National Health ICT Strategic Framework 2015–2020 // October 2015 Draft for Review". Available at: http://www.unfoundation.org/features/mhealth/national-health-ict-strategic.pdf

- **Continuity during the election cycle:** The strategy development process took three years to complete and as a result was confronted with changes brought about by the political election cycle. The permanent secretary-level officials remained unchanged throughout the different administrations. As the new administration appointed new leaders, they were informed about the digital health strategy. Having an entity such as ICT4SOML also provided continuity across these changes.

Funding

- Initial funding support came from Norad, which invested US$2.5 million to develop the strategy. UNF provided additional operational support.
- Nigeria's national digital health strategy includes a recommendation to establish a trust fund for health ICT to pool the resources of the government and development partners in order to simplify, coordinate and oversee the management and investment of funds in a spirit of transparency and accountability.

Lessons and insights

- **Importance of peer-to-peer learning from global experts and other countries:** The Asia eHealth Informatics Network (AeHIN) provided technical assistance and valuable peer learning to representatives from the FMCT and the FMoH during a workshop in Accra, Ghana, in early 2015. AeHIN shared lessons learned from the Philippines' experience, in particular on leadership and governance, and PATH, a non-governmental organization, shared lessons from the development of the African Network for Digital Health.

- **Creation of a national health information system (HIS) architecture:** Regenstrief Institute facilitated the initial development of a national HIS architecture. The architecture was aligned with the ongoing national health ICT framework development which was built on existing information systems using best practices from other LMICs. This technical assistance underscored the importance of better coordination of investments that were already in place, such as the National Health Insurance Scheme, the National Identity Management Commission and Human Resources for Health.

Training for the implementation of the National Health ICT strategic framework

Technical training: The FMoH staff were trained in Project Management Professional certification and COBIT 5, the leading framework for the government and management of enterprise IT, which helps address the needs of all stakeholders across the enterprise. Finally, FMCT staff received training in the policy development and review process.

Capacity building and mentoring: Several training sessions were also held to build understanding of the WHO-ITU Toolkit.

2 Implementing the National Digital Health Strategy and the Role of Governance

Part 2: Implementing the National Digital Health Strategy and the Role of Governance

Implementation refers to the operationalizing of the national digital health strategy described in Part I. Implementation is highly complex, involving many actors, components and stages. It requires a strong governance mechanism that defines roles and clarifies decision-making.

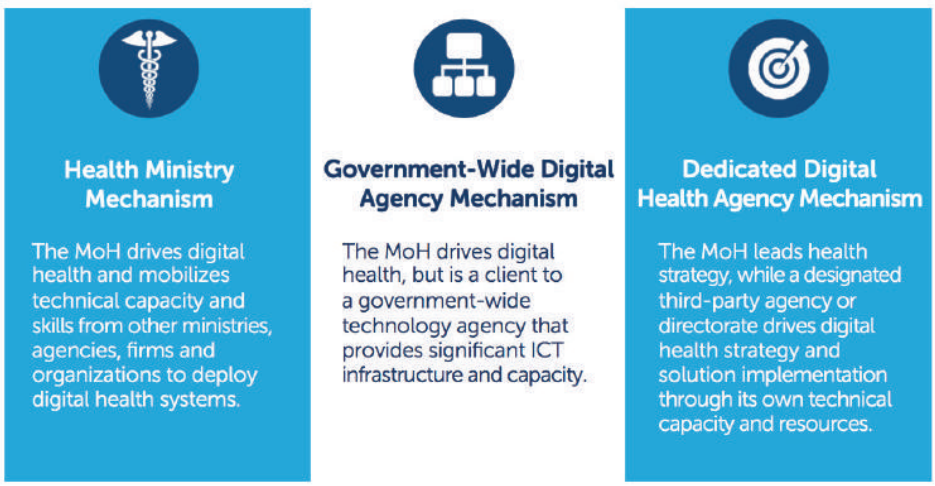
Throughout the case studies and interviews for the report, three main governance mechanisms were identified that can be of guidance for countries seeking to implement a digital health strategy: a *health ministry* mechanism, a *government-wide digital agency* mechanism and a *dedicated digital health agency* mechanism. They reflect the different approaches that countries represented in this report have adopted in establishing their digital health strategies. The development and implementation of these governance mechanisms are complex, however, and may take many years to mature. The report gives a high-level overview of each of the three types of governance, which should be viewed as components of a spectrum rather than as rigid models. Over time, countries can modify their choice of mechanism depending on who drives the process of developing and implementing the national strategy for digital health. Depending on its needs and specific circumstances, a country may choose to stay with a single mechanism, combine elements of the different governance mechanisms or adopt a hybrid approach.

Each of the governance mechanisms has advantages and drawbacks:

A. **Health ministry mechanism:** The MoH is responsible for driving the national digital health strategy, typically by a unit or department responsible for digital health, while providing considerable technical and financial capacity. The ICT ministry or agencies play a supportive role in implementing digital health systems and solutions.

B. **Government-wide digital agency mechanism:** An intragovernmental technology agency provides ICT services to all ministries. The MoH drives the digital health strategy and programs, but acts as a client of the government-wide technology agency. In some countries, this agency can be the department in charge of implementing eGovernment.

Figure 13: Three Governance Mechanisms



C. **Dedicated digital health agency mechanism:** A designated agency or directorate with substantial financial and technical capacity is responsible for enabling and delivering digital health services and programs. Health and ICT policy and strategy is often led by the MoH and a cross-sector ICT ministry or agency. Although the agency may or may not reside under the purview of the MoH, it has substantial dedicated capacity and resources.

Countries can choose which of these, or perhaps other, governance mechanisms would best align with their context, resources, political system and health objectives.

Country case studies corresponding to each governance mechanism illustrate in this report how leaders have tailored digital health governance to their specific country contexts. The case studies are presented for illustration and best-practice sharing; the implementation of a national digital health strategy is obviously more complex than presented.

In this report, each case study identifies:

- the factors that catalyzed the decision to develop a digital health strategy:
- the roles, responsibilities and decision-making processes within the governance mechanism, giving specific emphasis to those of the key health and ICT government ministries and agencies;
- some KPIs for monitoring and evaluating the implementation of the national strategy, as well as elements of financing; and
- specific key lessons and insights from each country.

A) Health ministry mechanism

Case studies: Rwanda and the Philippines

The defining characteristic of the health ministry mechanism is that the MoH is responsible for defining, coordinating and implementing the digital health strategy while other agencies are playing a supporting role. For example, the ICT ministry or eGovernment agency may provide inputs on data security standards, privacy protocols and digital infrastructure requirements and may share resources in building ICT-related capabilities, while other ministries play a role in their domains. The Ministry of Education, for example, may give advice or share investments for health worker training and capacity building. Although these ministries can have an important and active role, the MoH ultimately leads and executes the digital health strategy. **Brazil, Chile, Ghana, Kenya, Malawi**, the **Philippines, Rwanda**, and **South Africa** are among the countries that have adopted this governance mechanism.

One advantage of this model is that the MoH has a comprehensive view of national health priorities and can ensure close alignment of the digital health strategy with the national health strategy. This type of governance also creates clarity for both domestic and international stakeholders. In addition, it can reduce the potential for confusion or competition between sectors in countries where responsibilities in the digital health arena are diffuse.

Challenges and examples of solutions

Ensuring intragovernmental cooperation: With the MoH responsible for digital health, intragovernmental cooperation, especially with the lead ICT ministry or eGovernment agency, is important. The MoH defines a plan for leveraging external technical capacity for such implementations or for financing the development of internal capacity.

- *Successful solution:* The examples of **Rwanda** and the **Philippines**

illustrate the approaches that can be used to ensure cooperation between ministries. In both countries, cooperation was fostered by the presence of steering committees, technical working groups (TWGs) and strong program management with representatives from each ministry. In the **Philippines**, a joint momerandum of understanding codified the role and authority of each ministry in advancing the country's digital health agenda.

Building and sustaining technical capacity: Capacity for digital health implementation may reside outside the government. The MoH can engage resources, skills and knowledge from the private sector, civil society, academia, expert bodies or other government entities (e.g., data privacy agencies, telecommunication regulators) to execute the national digital health strategy and solutions.

- *Successful solution:* **Malawi** collaborated with academia to strengthen its technology capabilities and expertise for implementing the national HIS. In 2004, the country used the first version of the District Health Information System (DHIS) for reporting, analyzing and disseminating health data. DHIS 2, the following version, provided a more robust, web-based, integrated system. The Central Monitoring and Evaluation Division within the MoH, responsible for coordinating digital health programs, had limited ICT capabilities to achieve the rollout of DHIS 2. As a result, the Ministry of Health collaborated with the University of Malawi which provided free hosting for data servers, computers and network access as well as professional staff to build the digital health system. **Malawi** completed the national rollout of DHIS 2 by 2013.

Surviving changes in leadership: The health ministry mechanism is particularly vulnerable to changes in government leadership, especially when the country is in the process of building a digital health strategy. Leadership changes can shift priorities accorded to the digital health strategy.

- *Successful solution:* In **Nigeria**, an independent, supportive and dedicated entity outside the MoH provided continuity when changes occurred with election cycles. ICT-4SOML was able to demonstrate the value of digital health to the new leadership and to continue engaging with stakeholders throughout the process.

RWANDA:

Achieving country leadership and effective financing

Digital Health Snapshot

- Population: 12 million
- Strategy Development Timeline:

  2000: Vision 2020 launched with ICTs identified as a tool for socioeconomic transformation

  2006: First eHealth Strategy launched

  2009: Revised eHealth Strategy released for 2009–2013; launch of Rwanda Health Enterprise Architecture to improve health systems interoperability

  New 2016–2020 eHealth strategic plan in final stages of development
- Implementation Status: Significant implementation progress in several major solutions including OpenMRS, an open source medical records system; TRAC for HIV/AIDS drug distribution and patient information; Electronic Integrated Disease Surveillance and Response for monitoring and responding to disease outbreaks; RapidSMS to track pregnant women and newborns; e-LMIS, a drug and health commodity supply monitoring system; HMIS for data reporting and management; and eLearning and telemedicine tools to reach the most remote healthcare workers and patients.

Digital health context and catalyst

Sweeping ICT-based government reform in the early 2000s: As part of an effort to rebuild Rwanda after the upheavals of the mid-1990s, the government under President Paul Kagame's leadership initiated changes to government and social services in the late 1990s and early 2000s, using ICTs as a central component to the reform effort. This government overhaul included the adoption, in 2000, of a National Information Communications Infrastructure strategy, which aimed to fully digitize the nation and its public services in four five-year stages.

The first stage included the adoption of extensive regulatory and legal frameworks to open the country's telecom markets, followed by laws aimed at establishing standards in line with ITU standards in areas such as data security and data protection. The subsequent stages focused on the development of a national ICT infrastructure, including a nationwide broadband network and data center. Government ministries, including the Ministry of Health, were mandated to adopt accountability measures aimed at ensuring their alignment with the new, broader ICT effort.

Improvements in ICT indicators reflect the government's focus. Mobile subscriptions have more than tripled since 2009, with over 99.9% mobile penetration, and the number of Internet users has increased from less than

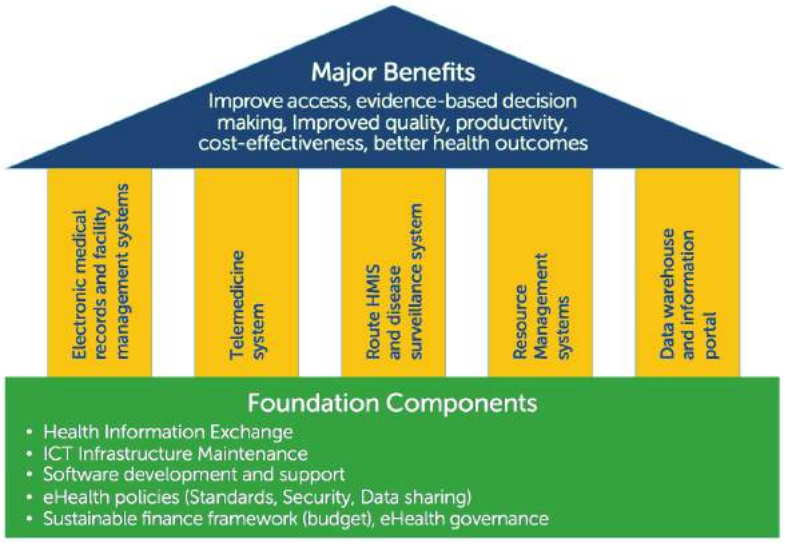
150,000 to over 3.6 million over the same period. Rwanda is currently in the fourth phase— implementing the Smart Rwanda 2020 Master Plan—which focuses on digital innovation, entrepreneurship, and research and development in areas such as the Internet of things, drones, Big Data, cybersecurity and creative industries.

Strategic vision including health, with a clear role for ICTs: Vision 2020, instituted in 2000 as a roadmap for social and economic transformation, seeks to elevate Rwanda to middle-income status by 2020 and sets forth strategic goals to move the country in that direction. The vision encompasses six components, one of which includes ambitious efforts for achieving health-related development goals, including the achievement of universal health coverage (UHC) through community-based health insurance. A key component of the country's broadband strategy has been to link public health facilities to the Internet, including hospitals and health clinics, with the government projecting that 100% of facilities will have Internet access by late 2016. As part of the framework for the new 2016–2020 eHealth strategic plan the key pillars include (Figure 14):

- EMRs and facility management systems
- Telemedicine
- Routine HMIS and disease surveillance systems
- Resource management systems
- Data warehouse and information portal

The Government of Rwanda recently accredited the first digital healthcare service provider in the country, Babylon Health, signaling a shift in focus to digital consumer health technologies and related opportunities.

Figure 14: Rwanda National Digital Health Framework



Source: Rwanda Ministry of Health

Roles, responsibilities and decision-making

Government and donor entities and roles: The eHealth unit in the MoH assumes all responsibilities for policies and strategies related to eHealth, and for follow-up, evaluation and promotion. In collaboration with Rwanda Biomedical Center, the implementing agency of the Ministry, and other government and donor partners, the MoH implements a number of digital health initiatives.

The Ministry of Youth and ICT (MYICT), which launched a comprehensive eGovernment initiative in 2013, is the key ICT partner of the MoH and provides leadership and technical guidance in areas such as national ICT policies, standards for ICT infrastructure and technology to be procured.

The ICT department of the Rwanda Development Board, soon to be changed to the Rwanda Information Society Agency, is the designated coordinating and implementing agency of all Governmentof Rwanda (GoR) ICT initiatives, in partnership with service providers and the private sector. The Agency has led the implementation of national ICT-related projects such as the national fiber-optic backbone, the national data center, the national Computer Security and Incidents Response Team, the national public key infrastructure, and a national telepresence network connecting all central government institutions and the country's thirty districts.

International donors and intergovernmental organizations provide a large percentage of the financing for Rwanda's health sector, including significant health budget support. In addition to providing technical assistance, they fund many of its digital health projects that are in their initial stages.

Governance, cooperation mechanisms and decision-making: Key governing bodies managing eHealth implementation within the MoH include an eHealth Steering Committee and a Technical Working Group (TWG). The eHealth Steering Committee is responsible for making strategic decisions regarding digital health programs and funding priorities and is chaired by the MoH and the Minister of MYICT along with directors from MYICT and the ICT department of the Rwanda Development Board.

The TWG, a much broader stakeholder group, is a subset of the committee and includes the eHealth Director of the MoH (chair), the digital program technical leads, and international implementing partners who provide technical assistance for digital programs and donor partners such as USAID, US Centers for Disease Control and Prevention (CDC) and UNICEF. The TWG meets on a biweekly basis and schedules separate meetings around ICT such as preparing the eHealth strategic plan, providing technical input on specific eHealth initiatives and helping to address issues such as data standards, privacy and security.

With control of strategy and implementation concentrated within the leadership, lines of accountability and decision-making processes are clear. MYICT, as the leading ICT government agency, must advise and approve all MoH hardware and hosting requests necessary for implementing digital health services and solutions.

KPIs

- Percentage of health facilities connected to the Internet: 96% in 2015
- Number of health facilities reporting into HMIS: 1,161 in 2015
- Number of patients/clients at community level tracked using RapidSMS: 186,719 in 2015
- Percentage of hospitals using telemedicine: 27% in 2015
- Number of registered private clinics/dispensaries routinely using HMIS: 301 in 2015

Funding

Overall funding structure: Through the Ministry of Finance and Economic Planning both the MoH and the GoR contribute funding to the national eHealth system implementation efforts. Additionally, the GoR receives funding for digital health implementation projects through partnerships with The Rockefeller Foundation, The Global Fund, the Bill & Melinda Gates Foundation, the World Bank, UNICEF, bilateral programs with US government sources (USAID and CDC), KOICA and Belgian Technical Cooperation.

In 2009, the GoR committed US$32 million to eHealth for its five-year eHealth plan—US$7 million to ICT infrastructure development, US$6.3 million to hospital HMIS, US$5 million to surveillance, US$4.5 million to Internet-enabled eHealth services and US$4 million to community-level systems. The new 2016–2020 eHealth strategic plan will cost US$21 million, a decrease due in part to the shift from solution building to maintenance, as well as from infrastructure investment to services. (These figures do not represent all digital health spending, as much spending is included in program budgets and is not disaggregated). In 2014, the GoR partnered with Africa Development Bank to fund its university system with US$14 million to build out its in-country capacity in biomedical engineering and eHealth. This program was uniquely designed to provide the country with a workforce equipped with skills in hard sciences as well as engineering and ICT.

Lessons and insights

Bold vision along with clear goals and accountability: As with other countries that have made great strides in advancing digital health, Rwanda's top political leadership set ambitious goals and a clear plan for societal transformation, including the health sector, with ICTs identified as a central component in achieving these goals. This focus on technology led to the development of ICT-related KPIs in health sector strategic plans, with an emphasis on strong standards of accountability for meeting these targets.

"Setting indicators and clearly defining what you are trying to achieve makes it easier to create a climate of transparency and accountability all the way down to the village level. In Rwanda, there are meetings where people are required

to report back on how they did, and [they] can be held accountable," says Richard Gakuba, former Head of the Rwandan eHealth unit.

"Another shift in the new strategic plan is a focus on systems, such as the EMRs, that can produce a strong return on investment and are largely funded from the domestic resources of the health facilities that use them," says Erick Gaju, Head of the Rwandan eHealth Unit.

Strategic budgeting: During the development of Rwanda's first digital health strategy, officials debated whether to budget most digital health expenditures through a separate funding category in the Health Sector Strategic Plan or to budget them under the programs they were developed to serve (including the TRACnet solution development as part of the HIV division's budget). The latter option was chosen because eHealth initiatives were crosscutting and this approach created a sense of ownership on the part of the program's leads who might have otherwise seen digital health funding as competitive. The development of a strong strategic plan and budget also served as powerful tools to convince both domestic government and international donors to commit funds, as The Rockefeller Foundation is doing to support the dedicated digital health leadership staff within the GoR. *"The Foundation was able to look at the plan and select a few critical items that aligned with their goals for the country. Having a well-defined plan and budget was a major tool for us in getting that support,"* says Gakuba.

Proactive donor relations with government leadership: As Rwanda is highly donor dependent for its digital health activities, strong donor relations are of paramount importance. The GoR recognized this at the inception of digital health programming and built in regular touchpoints and coordination mechanisms with key donors. The GoR even invited donor organization representatives to sit on the TWG that oversees eHealth system implementation. This level of transparency and agency allows donors to have structured involvement in the GoR's programs while maintaining the government's overall leadership position.

Digital health regulation and standards: Rwanda's development of national broadband and data infrastructure and its creation of an eGovernment framework demonstrate a cross-sector, systems-based mindset that improves the environment for interoperability. The country's creation of the Rwanda Health Enterprise Architecture reflected such an approach and is helping the country to scale digital health solutions in a way that will reduce the proliferation of stand-alone solutions with little chance of scaling. It also promotes standards that facilitate data exchange—such as facility, provider and client registries, providing unique identifiers for each of these entities across all types of information systems—and standardized coding for drugs and medical diagnoses by a terminology server.

THE PHILIPPINES:

Clarifying roles and leveraging best practices

Digital Health Snapshot

- Population: 98 million
- Strategy Development Timeline:

  2010: National eHealth Strategy launched

  2013: National eHealth Governance Committee and TWG created by Department of Health, Philippine Health Insurance and Department of Science and Technology

  2014: Release of eHealth Strategic Framework and Plan for 2014–2020
- Implementation Status: Implementation of Philippines Health Information Exchange launched in 2016 to facilitate interoperability of new and existing facility-and community-based digital health solutions, including PhilHealth electronic claims reimbursement system, iClinicSys EMR system, RxBox telehealth devices and various mHealth applications.

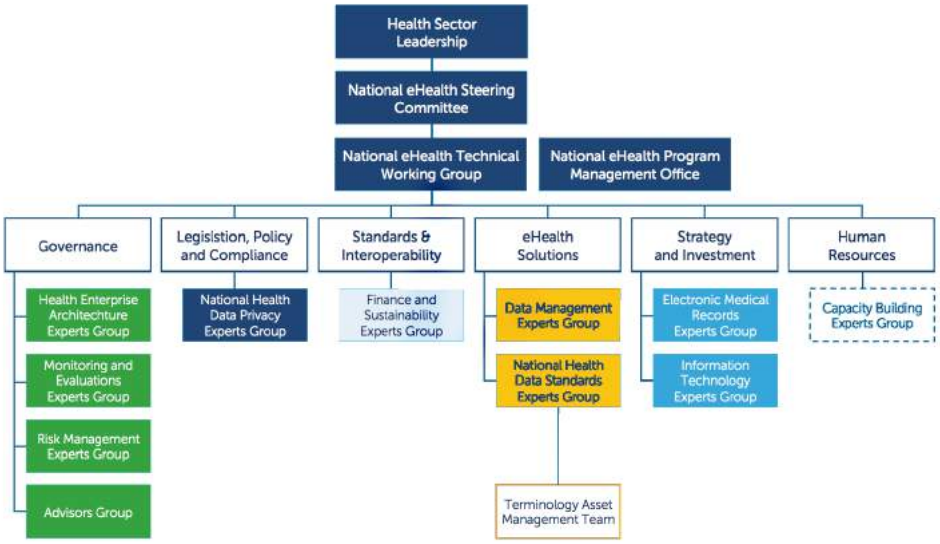
Digital health context and catalyst

Achieving UHC: The establishment in 1995 of National Health Insurance, which is provided by the national insurer PhilHealth, and the launch in 2010 of a plan for UHC, which is to provide access to affordable health services for all Filipinos, provided a powerful driver for the development of the National eHealth Strategy in 2010 and the eHealth Strategic Framework and Plan in 2014.

Lack of interoperability: A workshop on health information systems, held in 2011 for Asian government digital health leaders and funded by USAID and WHO, concluded that digital health systems in the Philippines and across the region lacked interoperability. This conclusion also concerned the digital health systems managed by the Philippines Department of Health (DoH). As a result, the Philippine Health Information Exchange was developed and launched, and it now provides a comprehensive eHealth architecture and facilitates interoperability between systems and solutions.

Regional peer networks and international agencies: As the Philippines embarked on efforts to create a shared architecture and governance, the creation of AeHIN, a regional peer-learning network, allowed Filipino digital health leaders to learn from countries such as Thailand about health data standards and from Malaysia about eHealth architecture approaches. *"We thought, rather than making the same mistakes, why don't we form a regional network so that we can learn from what others have done?"* says Dr. Alvin Marcelo, Executive Director of AeHIN and former CIO of PhilHealth.

Figure 15: Philippines Digital Health Governance Structure



Source: The Philippines Department of Health

Government departments and domain areas: Division of responsibilities between the DoH, the Department of Science and Technology (DoST) and PhilHealth, among other departments, is codified in a joint memorandum created in 2013 and included in the eHealth Strategic Framework and Plan. Each organization has responsibility for specific domains that fall within its area of expertise. The DoH oversees health-related subjects such as the selection of health indicators for various solutions and clinical treatment guidelines. The DoST oversees areas such as data standards and technical interoperability, and PhilHealth leads efforts related to payments and reimbursement solutions.

Governance, cooperation mechanisms and decision-making: In order to manage the needs of many stakeholders and obtain assurance amidst the complexity of information systems in the public and private sectors, a strong governance structure mandated the adoption of an IT governance framework, COBIT 5. Cooperation between the entities responsible for digital health is facilitated by two committees, the National eHealth Steering Committee and a TWG. The Steering Committee is chaired by the Secretary of Health, co-chaired by the Secretary of Science and Technology, and includes the President/CEO of PhilHealth and the Chancellor of the University of the Philippines Manila. The Steering Committee evaluates, directs and monitors projects recommended by the TWG. The TWG is, in turn, composed of senior representatives from all three organizations responsible for advancing the country's eHealth Action Plan. Advisory groups on health data standards and health data security and privacy, as well as groups that advise on areas such as EMR and monitoring and evaluation, include experts from academia and the private sector and provide subject-matter inputs to eHealth Action Plan components. After six months of slow starts, the TWG created an eHealth Project Management Office to ensure that eHealth activities across agencies were managed and controlled. Dr. Marcelo notes, "*The Project Management unit resides in the DoH, but is partially funded by the DoST, which helps the*

DoST have a stake in the process." The governance structure for digital health in the Philippines is represented in figure 15.

KPIs

Examples of objectives laid out in the 2014 eHealth Strategic Framework and Plan:

- 70 hospitals and 2,500 rural health units to use DoH/PhilHealth eClaims system by late 2015
- 1,000 RxBox telehealth devices to be deployed by late 2016
- 85 million Filipinos to be covered under the eClaims system (part of the UHC goal) by late 2016
- Government data warehouse established by 2015
- Implementation, by 2015, of 8 eHealth projects, including establishment of health data standards and training initiatives

Funding

Overall funding structure: Implementation of individual digital health solutions is funded from the departmental budgets of the DoH, DoST and PhilHealth, which are requested and approved by Congress through the Department of Budget and Management (DBM). For some projects, such as the deployment of the PhilHealth eClaims system, funds are provided jointly by two entities (the DoH and PhilHealth), while other projects, such as the RxBox telehealth solution, are funded solely through the budget of one department (DoST). In addition, international agencies and donors provide funding for specific projects.

Interoperability and infrastructure funding: The Medium Term Information and Communication Initiative (MITHI) is within the DBM and funded at the national level. The initiative aims to have a national ICT harmonization plan with an eHealth architecture to promote interoperability and shared ICT infrastructure across departments. MITHI funded the National Health Data Warehouse and the Philippines Health Information Exchange and encourages departments to work together independently to maximize limited resources.

Lessons and insights

Early codification of roles and responsibilities: At the start of the eHealth strategy development a joint memorandum between the DoH and the DoST created the basis for a shared understanding of roles and responsibilities and mechanisms for cooperation and decision-making. Each agency has its own IT teams which makes it hard to know which team is responsible for what. Dr. Marcelo notes that there was early recognition regarding the leadership issue: "*In our country, the DoST was keen to start working on eHealth but realized that it needed to be led by the health sector as per the WHO-ITU Toolkit. Fortunately, our DoH also shared the same view. From this common ground, the seeds for the multisectoral approach emerged. The key is to get those two*

persons engaged, one from the DoH and one from the DoST, and involved in the development of the national eHealth strategy."

Need for effective governance framework: The Philippines is a notable example of learning from the insights and experiences of other countries. As digital health leaders worked to build a comprehensive digital health architecture, the adoption of The Open Group Architecture Framework (TOGAF) and COBIT 5, an internationally recognized governance framework, allowed the country to benefit from best practices developed elsewhere. Over fifteen people were trained in both TOGAF and COBIT 5 in the DoH and DoST, which allowed for shared understanding of processes and mechanisms and fostered greater cooperation between departments. In addition, the creation of advisory groups allowed universities and private-sector representatives to share their expertise and views.

Dr. Marcelo explains how this governance framework helped to mitigate tensions: "*Each agency has a different set of priorities and dependencies with each other. For example, DoST needs to provide network infrastructure before the health applications can work over the Internet. They also had their own funding streams and flagship projects that had to have their own 'brand'. [...] But this is why the governance structure was important. It provided space for the agencies to be transparent to each other and have visibility on the other and how they can work more effectively together while delivering on their specific mandates. Business as usual would mean the agencies will have to operate in silos. But the new governance structure allowed them to meet regularly, to collaborate and to create space for resolving conflicts and overlaps and address gaps.*"

B) Government-wide digital agency mechanism

Case studies: Malaysia and Estonia (Hybrid)

Although the MoH drives digital health strategy and program management, the defining characteristic of a government-wide digital health mechanism is a digital agency that provides shared ICT infrastructure and implementation expertise for all government entities. This mechanism provides a common set of standards, policies and guidelines, such as:

- interoperability standards
- data security and confidentiality standards
- service, software and hardware components such as digital platforms, data centers and data management capabilities
- cloud services
- technical capacity

Apart from the health ministry, other ministries act as clients to this digital agency. In many countries, this role is played by the designated eGovernment agency.

A shared digital agency provides opportunities for collaboration and shared investments across ministries. The shared investments of an eGovernment agency can include ICT infrastructure, such as Internet connectivity or enterprise transaction systems, as well as technical expertise and capacity, which are often limited in the health ministry mechanism. As a result, the MoH can leverage the shared ICT services to implement its digital health strategy and access a broad network of ICT resources, including cross-governmental initiatives such as national unique identifiers which are particularly useful in healthcare. The Estonia case study, which displays characteristics of the government-wide digital agency mechanism and the dedicated digital health agency mechanism, highlights the strength of creating a unique national identification system.

The advantages of this governance mechanism include:

- a common digital architecture that different ministries can use to develop their digital strategies;
- the presence of a separately funded one-stop shop for ICT expertise and resources, and;
- established processes for interaction and communication between ministries and the digital agency.

A national digital architecture can also help to unify legacy information systems and ICT programs built at different times and for different priorities and can advance progress toward interoperability across systems and sectors. Finally, the shared digital infrastructure enables economies of scale resulting in cost savings.

What is eGovernment?

While public health systems around the world face sector-specific challenges in areas such as privacy and data security, they can benefit from a multisector approach to providing ICT-enabled services to citizens, otherwise known as eGovernment. The ITU defines eGovernment as the use of information and communication technologies in government to provide public services, to improve managerial effectiveness, and to promote democratic values and mechanisms; as well as a regulatory framework that facilitates information-intensive initiatives and fosters the knowledge society. There has been an increase in the number of countries that are using eGovernment to provide public services online through a one-stop platform. From 2003 to 2016, countries that had a one-stop platform increased from 45 to 90 countries, and countries that had online transactions increased from 33 to 148. [38]

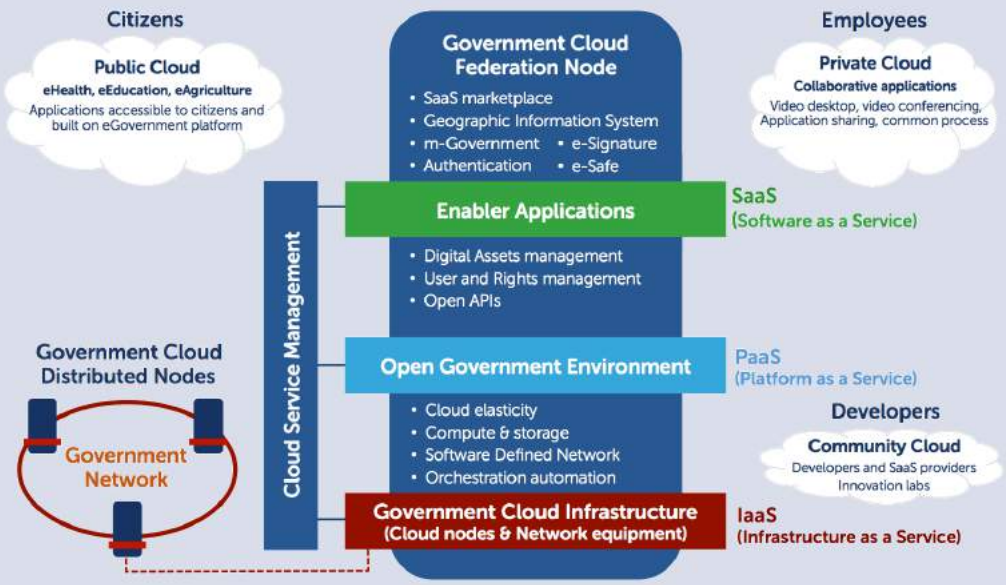
eGovernment strategies typically aim to improve the speed and quality of ICT, while increasing efficiency, reducing costs, and promoting transparency and accountability. Today, rather than the original top down eGovernment strategies which focused on the needs of each ministry or agency in each sector, integrated eGovernment strategies are being implemented. These integrated approaches are designed for the population and leverage shared assets such as a common ICT architecture and universal national identification.

eGovernment agencies are often closely related to the government-wide ICT agency mechanisms cited in this report, but this user-centric approach to designing services for citizens and providing access to them moves beyond the provision of shared infrastructure and resources. eGovernment approaches also give stakeholders outside the government, including application developers, healthcare providers and non-governmental organizations, the ability to safely leverage government data and design interoperable solutions, reducing the burden of solution development on the government and leveraging the talents and resources of the private sector.

The progress in technology and cloud computing has enabled open and distributed cloud solutions for eGovernment, where operational resources such as network, servers, storage and applications can be deployed in agencies, hospitals, care centers and administrations throughout a territory, and where users can take the initiative, while still enabling the eGovernment agency to control all of these digital resources as a single infrastructure. These end-to-end inclusive approaches allow governments to capture, channel and streamline bottom-up initiatives by providing a collaborative and shared environment to application developers for various public services (health, education, social services, agriculture, etc.). Thus, each stand-alone resource of an application becomes a building block in the creation of other applications, fostering innovation and enhancing

the digital economy in the country. Of specific interest to digital health is the trend and move to separate the application development process from the health data which is stored in a trusted environment controlled by policy makers on a government cloud. This is where components and systems are open in terms of data, models and application program interfaces and where standards will ensure interoperability. It is a shift away from large all-in-one hospital information systems for example, which are expensive and not flexible. The future lies in a health computing platform approach which opens up health data for use by multiple applications; this leads to a platform-based health ICT economy, in which various suppliers can produce back- or front-end systems that integrate across a defined interface, rather than the current situation of numerous silos.[39]

Figure 16: Sample eGovernment Cloud Architecture



Source: Nokia

ESTONIA:

Advancing digital health in a comprehensive eGovernment framework

Early and ambitious strategy for eGovernment and eHealth: From the outset, Estonia's overall eGovernment initiative envisioned digitizing health services in the country. The government set a goal in 1999 that all public services would be digitally available to citizens by 2013. In 2000, the Estonian National Health Information System was launched, followed by a comprehensive eHealth strategy in 2004–2005. In 2005, the Ministry of Social Affairs, which is responsible for health and social policy, established the Estonia eHealth Foundation (EeHF) to oversee digital health projects in line with the country's wider eGovernment goals. Private-sector companies built and maintained the overall ICT infrastructure and services under regulations developed by EeHF.

Strong leadership, governance structures and cross-sector cooperation: The Prime Minister's Office prioritized both the eGovernment and digital health initiatives, giving these initiatives credibility, and helped to create a governance structure with the appropriate representation across the government. The project management board of the EHR initiative, which is run by the EeHF, comprises the Ministry of Social Affairs, the Estonian Information System Agency, and the Ministry of Economic Affairs and Communication. The Secretary General of the Ministry of Social Affairs chairs the board, providing high-level leadership and representation. The board meets monthly, ensuring robust cooperation and alignment.

A coordinator from the Ministry of Social Affairs works with the EeHF's project team, which works with external partners and providers. The Estonian Informatics Centre manages the X-Road, and their participation ensures that the initiative complies with the X-Road's technical standards and architecture. The X-Road is the architecture that creates common standards through which disparate systems can communicate with each other via the electronic identification (eID) system.

Finally, an EHR Council established by the Ministry of Social Affairs comprises experts from professional medical associations and patient groups, academics and private-sector representatives and provides these stakeholders with input into areas related to system design and implementation

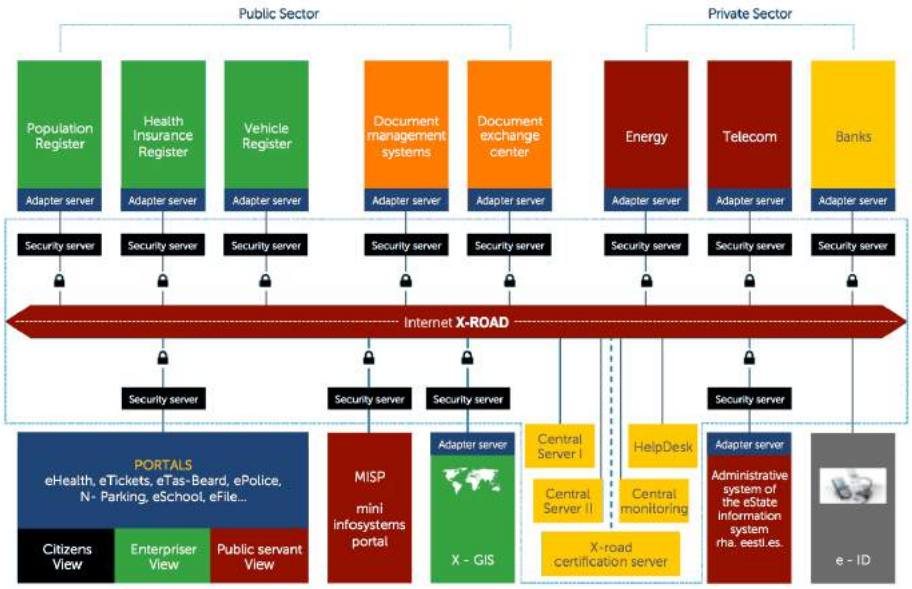
Interoperability based on shared infrastructure: The EHR, which allows both citizens and health providers to view a patient's medical history and share data for patient care, is central to Estonia's digital health system. The EHR pulls information from disparate IT systems into a common record through a health information exchange (HIE), which was developed using the same key infrastructure assets as are used for the larger eGovernment architecture (the X-Road). eID authenticates every individual's identity so that the individual can securely access online government services while data are linked on that

individual from various systems. Using this common infrastructure reduced the costs associated with developing the HIE and clarified the health and ICT standards with which private-sector IT firms and health providers need to comply as they develop digital health solutions.

Clear and robust regulation: In 2008, as the EHR was being launched, Estonia developed regulations for its eHealth information. Providers are legislatively required to share their records with EeHF. Electronic clinical documents must use an internationally recognized standard called HL7, while rigorous regulation defines the security requirements for accessing patient records. The use of common standards was crucial. eID was developed to create secure access for citizens to their data, and legislation was enacted early on to protect their privacy with the use of audits ensuring that these rights were being respected. Additionally, in response to large-scale cyber-attacks directed at the country, Estonia has developed strong cybersecurity mechanisms across the X-Road for protection against data theft. These measures are crucial to ensuring that the population, including healthcare providers, trust and use the system.

A focus on KPIs and cost savings: Estonia's eGovernment initiatives aim to demonstrate that they improve uptake and reduce costs. As of 2015, the HIE is used by over 98% of the Estonian population, while 99.5% of prescriptions are currently renewed online through ePrescription. With 70% of the population having access to the Internet, making health and medical information available online has reduced costs. Patients can use information to manage their own care, thereby reducing the burden on the healthcare system overall (e.g., facility visits and healthcare providers' time). The HIE cost €10 million or €7.5 per citizen.

Figure 17: Estonia X-Road eGovernment Architecture



Source: Estonia Information System Authority

Malaysia and **Singapore** have shared government-wide digital agencies: the Malaysian Administrative Modernization and Management Planning Unit (MAMPU), and the Singapore Government Technology Agency. Both agencies were created with the vision of social transformation through ICTs. These agencies have a high-level mandate, authority from political and governmental leaders and stable funding. The two agencies assist ministries in implementing ICT-based initiatives and ensure alignment with national ICT objectives, policy and standards.

Another example is **Bangladesh**, where the Access to Information (a2i) program aims to create harmonized eGovernment services for the country's citizens. a2i is located in the Prime Minister's Office and supports the building of a digital nation. The MoH data and programs were previously fragmented, but thanks to a2i, seven thousand health facilities now report routine data, and there are linkages to the National Data Warehouse. These efforts have enabled health workers to track patients through individual records, to consolidate administrative needs into an integrated system and to make routine information available to health policy makers.

Uruguay has also adopted this governance mechanism. Agencia de Gobierno Electrónico y Sociedad de la Información y del Conocimiento (AGESIC) is the national eGovernment agency for Uruguay, and it considers health a priority area in its Digital Agenda Uruguay 2011–2015 plan. To implement the eHealth strategy, AGESIC signed an agreement with the Presidency, the Ministry of Public Health, and the Ministry of Economy and Finance that resulted in the creation of an executive implementing body called Programa Salud.uy. Programa Salud.uy aims to strengthen the Integrated National Health System through the use of ICT and to create tools that facilitate access to quality health services. A Steering Committee was established as the highest-level decision-making authority in a governance framework that is aligned with national ICT policies and conducive to interinstitutional and intersectoral coordination. Within the framework of the Ministry of Public Health's leadership and in conjunction with health stakeholders, national standards and informatics applications are defined. The executive body and its strategy are enabling a favorable technical and regulatory context for digital health, as well as developing the necessary infrastructure.[40]

Challenges and examples of solutions

Centralization of responsibility. Alignment across all ministries toward a common framework and architecture and shared resources can create resistance. For example, it may include the phasing out of legacy systems that are not compatible with this shared architecture. The development of common ICT strategies, policies and standards by the Ministry of ICT or eGovernment agency may reduce the influence or control of other ministries, including the MoH.

- *Successful solution:* The creation of a common architecture and set of standards may be less challenging for health ministries if the MoH manages the health-specific requirements of ICT systems. In **Malaysia**, where MAMPU sets standards for data security, the Health Informatics Centre in the MoH controls health data standards such as disease classification codes, which ensures that appropriate subject-matter knowledge is factored into ICT system development.

Alignment and coordination between the MoH and ICT agency. While digital agencies provide implementation capacity in technical areas, such as software development and hardware deployment, the MoH manages the programmatic aspects of digital health solutions. The shared responsibilities

mean that the agency must ensure that digital health solutions align with the functional needs of health workers. This requires an understanding of health systems workflows and the data-use needs of clinicians.

- *Successful solution:* The use of embedded teams can strengthen communication and cooperation between the MoH and the ICT agency. In **India**, the National Informatics Centre (NIC) facilitates the development of ICT solutions across the national, state and district governments in conjunction with the Ministry of Communications and IT. The NIC has an embedded team within the Ministry of Health and Family Welfare (MoHFW) to support the launch and scale-up of several digital health programs as part of the country's Digital India Programme. The NIC team works to facilitate the use of government ICT infrastructure, such as data centers, call centers, software platforms and cloud services, in these programs. The NIC's involvement in these programs is particularly important because the solutions interact with the government's Maternal-Child Tracking System (MCTS). MCTS is a nationwide data collection system used to track pregnant women so that community health workers can provide them with information and encourage them to seek antenatal care. Interoperability of the digital health solutions with MCTS provided both the MoHFW and the NIC with powerful incentives to work closely together.

Sustained and significant resources. A government-wide digital agency mechanism will require significant upfront investment in resources and technical capacity to meet the needs of the various ministries. In LMICs, which are more dependent on external funding, there may not be sufficient resources, long-term financing and capacity to develop a government-wide digital agency mechanism. Moreover, the MoH may also need to develop program management capacity and digital technical expertise, as in the health ministry mechanism.

- *Successful solution:* Short- and long-term approaches should be adopted to meet immediate needs while promoting a sustainable ICT workforce. Short-term approaches may include program management training and certification programs, which are highlighted in the **Malaysia** case study. Long-term strategies focus on incorporating digital health into core curricula for health professionals and ICT-degree programs.

MALAYSIA:

Developing digital health under a national ICT vision

Digital Health Snapshot

- Population: 30 million
- Strategy Development Timeline:

  eHealth strategic plans largely align with national five-year Malaysia Plans (MP) for social and economic transformation

  1997: First telemedicine blueprint (7th MP)

  2005: First Health Information Management System blueprint (9th MP)

  2010–2015: Health Information System Strategic Plan (10th MP)

  2016–2020: Health Information System Strategic Plan (11th MP)
- Implementation Status: Rollout of the Malaysia Health Information Exchange, which was launched in 2009 and creates a patient records-based interoperability platform for data sharing, moving to version 2.0 in 2017. Key solution implementations launched and slated for scaling include a hospital information system currently deployed in 25% of hospitals, an integrated primary care and oral health clinical information system is being piloted in twelve clinics and future nationwide roll-out, and a pharmacy information system in the process of a nationwide rollout. A Malaysia Health Data Warehouse project is currently underway.

Digital health context and catalyst

Impact of a broad ICT vision: Beginning in the 1990s, government initiatives such as the Multimedia Super Corridor and Digital Malaysia rallied government leaders and workers in all sectors around the idea that ICT was central to the economic and social development of the country, which aims to become a high-income nation by 2020. Healthcare and communications content and infrastructure are two of the National Key Economic Areas identified within the country's Economic Transformation Plan, with specific goals set for sectoral transformation. This commitment was manifested in the creation of an empowered intragovernmental agency (MAMPU) that develops national ICT strategy and infrastructure and ensures that ministries are aligned with them. *"We really dove into ICT in 1996 when the Prime Minister had this information corridor idea, and so we were very lucky to have a leader that had the vision,"* says Dr. Fazilah Shaik Allaudin, Director of Telehealth Division at the Malaysian Ministry of Health.

Early experimentation and learning with ICTs: Malaysia began using digital health in the late 1990s, when the Malaysian MoH unveiled the first telemedicine blueprint and created the first paperless hospital in the world. The "big bang" approach of going all-digital was disruptive and difficult. Consequently, a progressive approach was adopted starting from front-

end systems in hospitals such as patient management and advanced digital technology, and then moving to record-based solutions such as EMRs.

Roles, responsibilities and decision-making

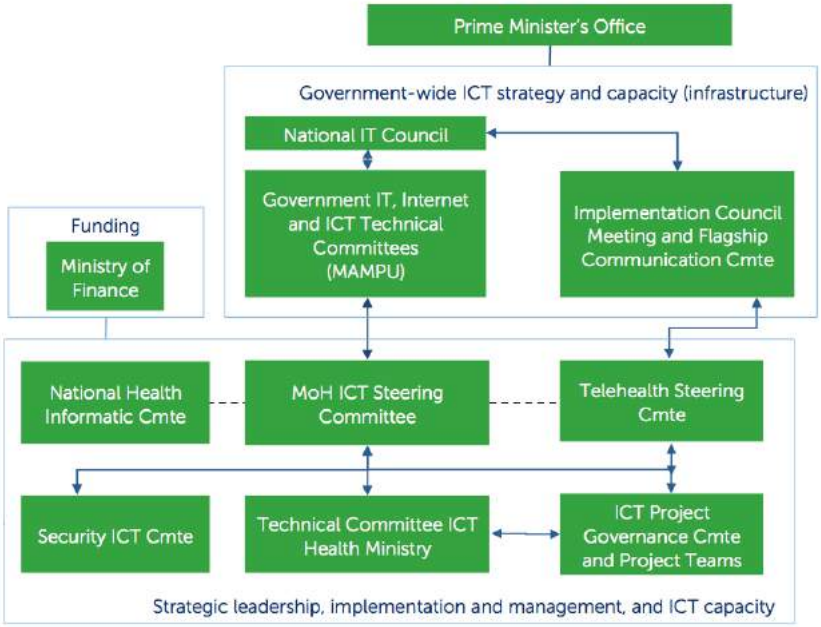
Government entities and roles: The MoH provides digital health leadership, strategy and program implementation in the form of three divisions: ICT, Planning and Telehealth. Through the National Informatics Centre, the Planning Division develops health assets such as health informatics standards (e.g., health data dictionaries) and the Malaysia Health Data Warehouse. The Telehealth Division leads the deployment and program management of digital solutions in the health system, mainly enterprise-wide solutions and the health information exchange (HIE), while the ICT Division provides technical capacity and support and oversees internal MoH information systems. MAMPU, an intragovernmental ICT authority that reports to the Prime Minister's Office, provides overarching ICT guidance, capacity and infrastructure. MAMPU's mandate is to modernize the public sector, establish national ICT policies, standards and protocols, and assist ministries in the operationalization of ICT implementation. The MoH also works with MIMOS, the Malaysian ICT research and development agency housed under the Ministry for Science, Technology and Innovation, for a few development and implementation solutions. MIMOS uses domestically developed ICT solutions, which reduce cost, promote local innovation and reduce reliance on foreign vendors.

Governance, cooperation mechanisms and decision-making: An ICT Steering Committee that includes leaders from the MoH reports to MAMPU on technology implementation. The ICT Steering Committee also coordinates the efforts of the other MoH divisions, each of which has its own Steering Committee. A dedicated ICT division supports the MoH and is in regular communication with MAMPU on ICT guidelines and infrastructure. Technical committees in areas such as security and privacy advise the ICT Steering Committee, while individual digital health solutions have governance committees with representation from both health and ICT domain areas. Dedicated project teams carry out day-to-day implementation activities within the programs. The MoH and MAMPU each have a voice in policies and guidelines related to digital health. For example, MAMPU defines standards for secure data sharing, but the MoH ensures that the sharing of patient data between health workers meets MoH privacy guidelines. MAMPU approves the MoH's ICT strategic plan and ensures alignment with the national ICT strategic plan. The governance structure for digital health in Malaysia is depicted in Figure 18.

KPIs

- 85% of facilities connected to 1Gov*Net
- Target of 100% connectivity by 2015 (except rural clinics)

Figure 18: Malaysia Digital Health Governance Structure



Source: Malaysia Ministry of Health

Funding

Overall funding structure: MAMPU funds shared ICT infrastructure across ministries, including connectivity infrastructure used to provide secure Internet access to health facilities and government offices. MAMPU is also responsible for guidance in technology procurement with increasing input from MoH program managers. The MoH is responsible for funding digital health program implementation and initiatives. Digital health projects typically consume approximately 5% of the MoH capital budget, while approximately 15% to 20% of project budgets are directed to operating costs, maintenance and support. Overall funding is determined by five-year plans approved by the Ministry of Finance. These plans include the MoH's ICT strategic plan and funding requests for specific initiatives. MAMPU must approve these plans. Requesting funds for additional ad hoc programs is not encouraged.

Lessons and insights

The need for project management capacity building: MoHs often lack project management capacity in implementing ICT solutions and initiatives. To address this problem, Malaysia developed a six-month project management program for MoH personnel involved in ICT implementation. The program includes multiple modules on a range of disciplines, including vendor contract negotiation, procurement, Microsoft Project, monitoring and impact evaluation. The MoH-led program regularly invites experts from other government ministries, thereby promoting inter-ministry collaboration and capacity building. *"We've seen our project management improve so much through this. We bring in other ministries and agencies, as well,"* says Dr. Fazilah.

Engaging clinicians and bringing resisters on board: *"Our biggest challenges are still the user, change management and training. And clinical leadership is so important! If you don't get buy-in from the clinicians, the system won't work. We learned from experience,"* notes Dr. Fazilah. When projects shift to implementation, the introduction of new technologies can be seen by users as frightening or challenging. Malaysian leaders developed a two-pronged approach: firstly, by creating project committees to advise and provide feedback on the design of solutions (members of these committees became "super users", who then trained others), and secondly, by engaging healthcare providers resistant to change as leaders in solution deployment efforts. *"People talk about the 80/20 rule, where you try to get around the 20% of users who are likely to resist. But it's the 20% that are going to bring down the project. We're identifying the 20% early on and making them the leaders,"* says Dr. Fazilah.

Monitoring and evaluation and private-sector engagement are still challenges: Despite Malaysia's long-standing commitment to digital health, certain areas remain challenging. For example, in monitoring and evaluation (M&E), Dr. Fazilah notes, *"We're still struggling with M&E and how to do it effectively. We haven't really come up with a mechanism for this yet. We've seen hospitals give up on digital systems and go back to paper or situations where the core team involved in an implementation leaves and the project dies or loses momentum. How do you keep this when the leader leaves? How to keep the fire burning?"* Another challenging area is private-sector engagement. Involvement of the private sector in developing solutions for the public sector is difficult because of the emphasis on the use of low-cost, domestically developed technology. The MoH is exploring the use of public-private partnerships to increase private-sector contributions and activity in digital health. Health ICT collaborative platforms have already been planned and will be launched in 2017. Likewise, two national-level Steering Committees have been established, bringing together a number of key stakeholders in a coordinated manner. These early initiatives will build momentum for further collaboration.

C) Dedicated digital health agency mechanism

Case studies: Canada, Mali and Norway (Hybrid)

In contrast to the government-wide digital agency mechanism, the defining characteristic of the dedicated digital health agency mechanism is that it operates as an independent unit, with dedicated capacity and resources and an explicit role in coordinating digital health efforts under the purview of government representatives. These representatives may be on the board of the organization or may act as shareholders. The dedicated agency develops the digital health strategy with input and guidance from the MoH and drives implementation in concert with other digital health actors. The agency can be structured as a not-for-profit third-party agency (as Infoway in **Canada**), as a foundation that operates autonomously (as the eHealth Foundation in **Estonia**), as a directorate under the MoH (as in **Norway**) or as an independent agency with the MoH participating in its executive committee (as in **Mali**).

Advantages in executing a dedicated digital health agency mechanism include:

Interoperability and a common architectural design: An enterprise view of the digital health blueprint developed by a dedicated agency serves as a common reference for implementation across multiple government units and diverse solutions or applications. It guarantees and enables interoperability, a clear architectural framework, and clear protocols for vendors and technology partners.

Continuity through changes in government leadership: Given that the digital health strategy and its implementation are independent, this mechanism can navigate changes in government and ministry leadership. The impact of leadership changes is usually less disruptive than in other governance mechanisms.

Market creation and long-term focus: Designing and implementing digital health systems takes time, a long-term vision and sustained investment. The long-term view is often at odds with the reality of short-term election cycles and ministry appointments. The dedicated agency can, however, cultivate a long-term vision and investment strategy that encourages long-term participation and investment by the private sector while ensuring greater continuity in the health system.

Capacity and technical knowledge: The dedicated agency is responsible for the strategy and implementation of digital health and has the necessary in-house human capacity and technical knowledge. This arrangement simplifies the coordination aspect of digital health governance and promotes clarity of ownership for stakeholders in the private and development sectors.

Challenges and examples of solutions:

Establishing credibility and accountability: separating the dedicated agency from the MoH or the government can lead to perceptions that the agency lacks credibility or accountability. Outsider status can cause problems in the areas of change management or funding. The agency needs to establish itself as a credible and legitimate partner for executing the national digital health strategy and implementing digital health solutions and initiatives.

- *Successful solution:* Credibility can be reinforced through clear and frequent support from government and funding partners. The agency also needs to have clear transparency and accountability mechanisms in place to avoid conflicts of interest. The **Canadian** example with Infoway showcases how these conflicts of interest can be addressed by the involvement of provincial and territorial authorities in the governance mechanism of the country's dedicated agency.

Distance from health program requirements and the MoH: Separation from the MoH can keep the agency at a distance

from changes in the national health strategy and delay understanding of the functional requirements for digital health solutions. To address this challenge, the dedicated agency leadership must ensure that mechanisms are in place to keep the agency up to date with health program requirements and to enable it to coordinate required strategy changes accordingly. With digital health expertise being built in a separate agency, awareness and skills are not embedded within the MoH. This can delay the adoption of the digital health strategy within national health priorities. **Mali,** for example, is faced with this challenge.

CANADA:
Advancing interoperability

Digital Health Snapshot

- Population: 35.1 million
- Strategy Development Timeline:

  1999: Report issued by Advisory Council on Health Infostructure outlining vision for transforming Canada's health information system; Office of Health and the Information Highway created as ICT lead

  2001: Establishment of and CAN$500 million investment by federal government in Canada Health Infoway (Infoway) to accelerate development of digital health solutions

  2006: Electronic Health Record Solution (EHRS) Blueprint released by Infoway, a framework for the development and scaling of interoperable record-based solutions

  2016: Update to Infoway's EHRS Blueprint released, covering broader digital health landscape and incorporating solutions into health delivery processes
- Implementation Status: Major digital projects have been funded, launched and scaled since Infoway inception in 2001. Key solutions implemented nationally and within provinces and territories include laboratory information systems, drug information systems, a national public health surveillance system, telehealth solutions and electronic medical records (EMRs). Availability and use of EMRs has increased steadily since 2007, with approximately 75% of family physicians now using EMRs, while the number of public employees using the country's public health surveillance system increased from 1,000 in 2013 to over 12,000 in 2016.

Digital health context and catalyst

Formation of a broad government-led information highway initiative: In the mid-1990s, the Canadian federal government established the Information Highway Advisory Council to examine the use of information technology for social and economic transformation across the country. The Advisory Council recommended that the federal, provincial and territorial governments focus on four key sectors, of which health was one. An Advisory Council on Health Infostructure was formed, followed by an authorization and a CAN$500 million investment in Canada Health Infoway, an independent non-profit organization formed to accelerate development of interoperable health solutions that would improve the quality of health service delivery.

Formation of a cross-sector dedicated digital health agency: Canada is a federation with multiple jurisdictions, which include a federal Crown, ten provinces and three territorial governments. Each jurisdiction and territory is responsible for delivering health services. Consequently, Health Canada (the federal MoH) may not have been able to promote shared standards across the country, and sub-national governments could have pursued independent

digital health strategies. The creation of Infoway as an independent entity leading digital health created a mechanism and incentive for all the jurisdictions and the private sector. Infoway also facilitated the development of a national digital health architecture which could strengthen interoperability.

Roles, responsibilities and decision-making

Government entities and roles: In its first decade, Infoway operated as a strategic investor to foster and accelerate development and adoption of digital health systems and solutions in twelve investment programs. Jurisdictional systems and solutions have compatible standards and technologies aligned with Canada's digital health architecture as defined by Infoway.

Health Canada is responsible for setting national public health policy and standards, while provincial and territorial ministries of health lead the provision of health services and provide public health insurance. Digital solutions are developed or acquired based on provincial and territorial priorities.

Governance, cooperation mechanisms and decision-making: Canada's federal government and its ten provinces and three territories are shareholders in Infoway. The Deputy Ministers of Health of each jurisdiction are Members of the Corporation, giving them a direct role in key strategic and operational decisions. A few of these deputy ministers also sit on Infoway's Board of Directors. The Infoway board of directors includes representatives from the private sector and academia, as well as three of the fourteen deputy ministers. Infoway's Portfolio Management Office provides project management guidance for, and review of, digital health implementations in coordination with the provinces, territories and federal government.

Infoway engages with jurisdictional partners and stakeholders through both regional- and national-level approaches. Regional teams are led by Executive Regional Directors responsible for Infoway's investment portfolio. The teams are composed of investment project managers and experts in enterprise architecture, telehealth, change management, privacy and security. As a condition of funding approval, these teams assist in: the identification of investment opportunities, the qualification and vetting of proposed projects, and the review of project deliverables. This regional representation and collaboration with Infoway's stakeholders is seen as a critical factor in the success of their investments.

At a national level, Infoway partners with a broad range of stakeholders, including IT professionals, vendors, healthcare organizations, clinicians and researchers. Meetings are also held regularly with jurisdictional representatives accountable for enterprise architecture, health analytics and privacy. Infoway also has a clinical engagement team that has established working groups comprising physicians, nurses and pharmacists to review and guide Infoway's proposed approaches to digital health. Additionally, to support the adoption and effective use of digital health solutions, the engagement team has established professional peer leadership networks of clinicians across the country. In the area of standards, Infoway funds and manages national licensing for several health ICT standards, such as SNOMED CT, LOINC and

HL7. Infoway ensures that these standards are current and oversees Canadian adaptions or subsets.

KPIs

- 139,000 clinicians are active users of electronic health records
- 600,000 teleconsultations were held between physicians and patients in 2015
- In 2016, 11,000 patients, families and caregivers were enrolled in projects enabling them to view health information, book appointments or consult with providers online
- CAN$200 million identified in measured benefits, such as improved quality of care, safety, access, and productivity, from outpatient EMRs in 2015
- 12,000 public employees used national public health surveillance systems in 2015
- An estimated CAN$16 billion identified in cost savings and efficiencies from use of EHRs and EMRs since 2007 (see chart on page 19)

Funding

Overall funding structure: Infoway does not receive annualized funding. It receives periodic budget allocations based on general budget availability. It has received six federal grants totaling CAN$2.15 billion since 2001. Traditionally Infoway has co-invested in digital health projects with the provincial and territorial health authorities using a gated funding approach that provides payments when agreed milestones are met.

Infoway often works with provincial and territorial health authorities to identify potential projects. The authorities then develop formal proposals to submit to Infoway for consideration. Infoway then determines the eligibility of these proposals and manages project funds which are invested jointly by Infoway and these jurisdictions. Given that Infoway's investments cover 80% of eligible costs and that not all costs are eligible for reimbursement, Infoway's public sector partners have also invested approximately half of fully loaded project costs bringing the total investment in digital health to CAN$4.2 billion. Unspent funds are returned to Infoway and reinvested in other projects. Infoway's use of funds is subject to federal audit oversight.

Infoway generally does not fund network infrastructure or acquisition of hardware or operating systems. These infrastructure capital investments require the jurisdictions to self-fund or work with other Canadian federal ICT investment programs. Infoway also does not fund related projects within federal ministries or departments. It does, however, support implementation of digital health solutions with indigenous populations by approving funding for jurisdictionally led projects through collaboration with the federal First Nations Inuit Health Branch of Health Canada and the Assembly of First Nations.

Infoway's foundational investments have laid the groundwork for a new wave of innovation in digital health. Infoway and its partners are now focusing on transforming health care in Canada through digital health innovation. This includes: promoting medication safety through e-prescribing; scaling and spreading innovative solutions that have demonstrated the greatest potential; connecting Canadians with their health information so they can actively manage their health and wellness; and continuing to provide thought leadership in things like solution architecture, clinical interoperability, standards, and privacy and security.

Lessons and insights

Building credibility by demonstrating impact: Infoway measures the impact of its investments in digital health. Infoway estimates cost savings of CAN$16 billion and greater efficiency of the Canadian healthcare services delivered since 2007. A study by the Conference Board of Canada found benefits beyond health. The CAN$500 million in Infoway funds allocated in 2010 created CAN$1.48 in added GDP for every dollar invested in increased job creation and tax revenue.

The evidence generated by Infoway provides a case for continued investment in digital health. This focus on results and impact has also helped to demonstrate Infoway's value to provincial and territorial governments who now see it as a valued partner. The evidence of cost savings continues to encourage the federal government to provide funding for Infoway to accelerate purpose-specific health IT and innovation projects. As a result, Infoway has continued to fulfill its mandate well beyond its originally planned lifespan of five to seven years.

Leveraging informal mechanisms for ICT harmonization: The involvement of federal, provincial and territorial ICT agencies in Infoway's projects and activities is limited, largely due to Canada's federal political structure. While eGovernment portals for the federal and provincial governments exist, they are limited in scope and mandate compared to eGovernment agencies in countries such as Estonia. Provinces and territories, as the entities responsible for delivering health services, maintain and enforce their own ICT standards in digital health projects, thereby limiting interoperability between these jurisdictions and the federal government. Infoway has instead relied on informal mechanisms to promote the use of appropriate ICT standards and guidelines among its partners in governments at all levels. It participates in the Information Technology Association of Canada, an industry association that comprises leading Canadian health ICT providers and thereby promotes consensus on standards for the private and public health sectors. It also advises its government partners on issues related to standards, security and privacy.

Creating a common technical architecture while allowing customized solutions: Infoway started with a focus on EHRs. Its objective was to enable an integrated view of patient/client data across healthcare services and providers. It has taken an enterprise architecture approach. It is responsible for creating and promoting a common business and technical architecture that is accepted across jurisdictions and by vendors. Infoway has also established clear privacy

and security protocols that all vendors must follow. The common architecture enables each jurisdiction to create a network of interoperable EHRs or other digital health solutions that link multiple points of healthcare. The architecture also allows design and implementation of digital solutions that are context specific and tailored to meet the needs and priorities of specific regions or provinces.

MALI:

Dedicated digital health agency cooperating with government-wide digital agency

Digital Health Snapshot

- Population: 16 million
- Strategy Development Timeline:

  2008: Creation of National eHealth Agency (ANTIM)

  2012: National Country eHealth Survey and Assessment

  2013: eHealth Policy and Strategic Plan for 2014–2020 drafted

  2014: Adoption of National eHealth Agency Roadmap 2014-2018

  2014: Adoption of the National Health Policy 2014–2023
- Implementation Status: Implementation of national HIS repository database on DHIS2, implementation of real time mobile phone information system for Integrated Disease Surveillance and Response (IDSR), and various eHealth applications.

Digital health context and catalyst

Experience with individual solutions: Mali initially recognized the need for a comprehensive digital health strategy through its experience with implementing individual initiatives in digital health. These initiatives included consultations with the Toulouse-based European Institute of Telemedicine in neurosurgery and remote training in epidemiology for Malian doctors using telemedicine in 1996. The eHealth and telemedicine agency of Mali, Agence Nationale de Télésanté et d'Informatique Médicale (ANTIM), was created in 2008. Much has been accomplished since then, such as the wider use of informatics with one thousand computers used by healthcare providers. Interoperability, however, remains a challenge. Ousmane Ly, Executive Director of ANTIM, notes, *"Harmonization is necessary at the early stage of equipment and software acquisitions and installment to ensure cohesion in standards. We need data and information to be easily accessible and efficiently exchanged."*

Creation of ANTIM: ANTIM is a publicly owned institution with a scientific ICT focus and is a sub-agency reporting to the MoH. It is responsible for promoting and developing digital health initiatives and medical informatics, which includes research, training and technical support of digital health solutions. ANTIM is also responsible for harmonizing and standardizing processes, procedures and software. Its staff of thirty-one includes IT professionals, engineers, physicians and support staff.

ANTIM implements telemedicine solutions, reinforces information systems for hospitals, provides continuing education via ICTs and promotes use of ICTs for healthcare professionals. In addition, ANTIM designs ICT solutions for the

MoH in areas such as intranet and online data services for the MoH Datacenter. The secured data management information system developed for the MoH by ANTIM will centralize all the national health system data. ANTIM also coordinates and promotes mHealth solutions by convening stakeholders once a month to an mHealth working group.

Governance, cooperation mechanisms and decision-making

ANTIM's Executive Board, presided by the Minister of Health, defines the strategic direction and makes the executive decisions that the ANTIM staff and management team propose in order to advance digital health solutions. Members of the ANTIM Executive Board include representatives from the Ministry of Communication, Mali's eGovernment agency (AGETIC-Agence des Technologies de l'Information et de la Communication), the Ministry of Finance, the ministry in charge of social security and health insurance, hospitals, ICTs in the private sector, patient associations and civil society.

ANTIM's Executive Director is also a board member of AGETIC. AGETIC is responsible for all eGovernment initiatives and manages and coordinates government e-services provided to the population. ANTIM participates in the AGETIC working group on digitization of the public administration and eGovernment activities and was the main contributor to the health solutions of the Mali Digital Plan for 2020.

ANTIM convenes scientific and technical committees in which the relevant organizations participate (with similar organizational representation in the executive board of ANTIM but at an operational level); expert groups develop standards and regulation in digital health.

The Health Information System Working Group holds a quarterly meeting attended by all government officials involved in digital health (Ministry of Health, AGETIC, ANTIM), as well as by representatives of private and civil society sectors.

Software and infrastructure sharing: AGETIC acts as an ICT government-wide digital agency and is responsible for developing the fiber-optic infrastructure and for storing and centralizing the health data generated by ANTIM's eGovernment data center projects. ANTIM uses software provided by AGETIC, such as the internal public administration sharing tools to manage archives and electronic correspondence. There are currently two physically connected data centers: one at AGETIC and the other at ANTIM. All government data storage is centralized in the AGETIC data center but ANTIM's digital health applications run on ANTIM's servers where health data is also stored. Mali operates a distributed infrastructure whereby data from hospital servers are saved on a daily basis in ANTIM's data centers, partly in order to deal with connectivity and electricity power outages.

KPIs

Select indicators from the 2014–2018 ANTIM Roadmap:

- Six university hospitals, six regional hospitals, sixty-five district hospitals and 1,350 rural health units to use eHealth tools by late 2018
- Health data warehouse established in 2014
- Will have implemented six additional eHealth initiatives and training initiatives by 2018
- Will have established comprehensive health data standards by 2018

Funding

ANTIM requests budgets and funds from the budget department. These funds are used also to implement specific digital health solutions. For certain projects, such as the deployment of DHIS2, external support from international agencies is provided.

ANTIM's budget increased from €100K in 2009, to €400K in 2010 and to €1 million in 2016 (in addition to a €1.5 million investment in real estate).

Lessons and insights

Comprehensive adoption of digital health: Although having an independent agency has many advantages, such as independent resources, technical expertise and continuity across election cycles, the MoH has not fully integrated digital health into the overall health strategy and priorities. Since digital health expertise resides outside the MoH, the committees with MoH representation and coordination are important.

Continued donor fragmentation and lack of interoperability: Mali receives a significant degree of development assistance for health and, as a result, there are a number of digital health solutions and initiatives focused on specific diseases. The funding institutions generally come with their own set of tools and systems and are not integrating with the standards and architecture that are in place. The result is that when the funding cycle ends, the country is unable to sustain and support the required projects. There are, for example, eleven different mHealth initiatives for maternal and child health that are funded by different institutions in Mali. Most of these institutions use their own tools and systems which are not interoperable with the current systems used by ANTIM. Although there is an existing digital health agency and an eGovernment office, much progress still needs to be achieved with regard to coordination and harmonization.

Peer networks and international bodies: The support of international bodies and networks has been instrumental at all stages. Mali used the WHO-ITU Toolkit to develop its digital health strategy and participates actively in all meetings and workshops related to digital health organized by WHO and

ITU. Mali is also an active participant in all eHealth meetings organized by Organisation Ouest Africaine de la Santé-OOAS (West African Health Organization-WAHO), and is participating in the creation and development of a peer-network organization for digital health, African Network for Digital Health, which is supported by PATH. Mali is also a member of the African Center for eHealth Excellence, where collaboration is currently focused on developing a training curriculum for digital health operations management together with eight African universities.

3 Crosscutting Challenges and Considerations

Part 3: Crosscutting Challenges and Considerations

The case studies in this report illustrate the importance of committed government leadership and the way in which governance mechanisms and intragovernmental cooperation can be achieved between ICT and health sectors when developing and executing a national digital health strategy. Challenges identified across the different governance mechanisms include: engaging and managing stakeholders, financing the implementation of the digital health strategy and solutions, and building the required technical capabilities and human resources. One way of addressing these challenges is to leverage the experience of other countries and regional peer networks in digital health. These considerations are not exhaustive but hold crucial lessons for countries that are operationalizing digital health strategies.

Stakeholder Management

Bringing together multiple stakeholders from overlapping domains is a complex and time-consuming undertaking. For example, domains to be considered when developing and executing a national digital health strategy include clinical health guidelines, ICT infrastructure, standards, monitoring and evaluation, health workforce training, and data privacy and security. Stakeholders can be academics, donors, health professionals, patients, professional associations, multilateral organizations, NGOs, partner countries, private-sector organizations and patient representatives.

A country's context will dictate which stakeholders are brought in and at what stage. However, engaging with multiple stakeholders from both the ICT and health fields throughout the process is critical. Coordination with stakeholders helps to ensure that the deployment and testing of digital innovations designed by organizations outside the government align with and support the national digital health framework and help to avoid fragmentation. Providing a forum for discussion and decision-making with stakeholders is needed at both leadership and management levels. Leadership in the health and ICT sectors, as well as a well-defined governance framework, can help to align external stakeholders and sectors.

Stakeholder management is especially important, since digital health solutions often change the way care is being delivered and received. Engaging healthcare providers, professional associations, and stakeholders in charge of delivering health services will increase the chances of adoption for long-term success and the adoption of the necessary changes. For example, the **Malaysia** case highlights how one of their biggest challenges was change management and training of users.

Malaysian leaders created project committees of healthcare professionals to advise and provide feedback on the design of solutions. The committee members then helped to train other healthcare professionals. Subsequently, they chose to focus on engaging and convincing healthcare professionals who were particularly resistant to change but who then became leaders in deployment of digital health solutions.

"The complexity and number of eHealth stakeholders can be overwhelming and is yet fundamental in bringing coherence in the ecosystem. It has been a pleasure to see different sectors of society, often with competing agendas, coming together to make eHealth work for the people."

Dr. Alvin Marcelo, Executive Director, Asian eHealth Information Network (AeHIN)

In **Norway,** a Health Professional and Architectural Advisory Board created a forum where healthcare providers could interact with technology experts to ensure that digital health solutions adhered to best practices and established standards. The complexity of stakeholder management is reflected in the multiple boards and coordination bodies, as well as by the active participation of healthcare providers, professional associations, regional health authorities and municipalities. The development and periodic maintenance of a ministry-led national inventory of investments in digital systems can provide a coordination and management mechanism that ensures efficiency.

Stakeholder engagement can also foster innovation and leverage expertise and implementation capabilities. **Bangladesh,** for example, has a strong NGO sector with long-standing organizations, such as BRAC, dedicated to large-scale projects which aim to combat poverty, and the Grameen Foundation. The government engaged with BRAC to scale a large health program using behavior-change SMS messaging. Community health workers administered the WHO-recommended DOTS (directly observed treatment, short course) to 87,000 TB patients. The treatment was effective in 95% of the patients.

In **Chile,** the creation of a participatory and inclusive forum for discussion with stakeholders, along with a clearly defined governance framework, stimulated the political will to build an integrated national telemedicine framework and network, as well as a national digital health policy. The participatory process resulted in the creation of a working group and a board made up of representatives from various governmental divisions and health services. The working group and board validated a work plan in 2016.

NORWAY:
Coordinating an ambitious EMR plan

Digital Health Snapshot

- Population: 5.2 million
- Strategy Development Timeline:

  2012–2013: Parliament White Paper for the vision of One Citizen – One Record

  2014–2015: Study and analysis of the vision

  January 2016: Norwegian Directorate of eHealth established

  June 2016: Ministry of Health and Care services announces support for the direction of development in One Citizen – One Record
- Funding: Approximately €750 Million in 2016 for the Directorate of eHealth, the Directorate of Health and the Regional Health Authorities. Currently, each stakeholder has independent funding although sharing of resources is expected for harmonization.

Digital health context and catalyst

Recognition of continuing interoperability challenges: Although digital health has been relatively well adopted in Norway, challenges remain in interoperability and harmonization. The IT solution landscape is very fragmented and many solution areas need reinvestment. The government of Norway estimates that most of the seventeen thousand EMR installations for different health providers lack interoperability. A political consensus arose to address this fragmentation. The goal of the government is to create effective and robust healthcare services. The government will use digitization to achieve a more user-oriented public service and the adoption of digital health solutions proposed by stakeholders across primary, secondary and tertiary levels of the healthcare system. Stronger governance and coordination are needed to ensure that more than one stakeholder covers different levels (central, regional etc.) within the health administration. Strong support from the central government is needed to work across agencies and municipalities to develop and implement digital health solutions that can be used across the systems. Health ICT has enjoyed strong support from all areas of the political spectrum and particularly from government leadership. Convinced of the value of digital health, leaders have sustained their efforts despite changes in the political landscape. Norway's national digital health strategy aims to develop a common national solution for managing clinical documentation, workflow support and patient administration. This aim prompted the creation in January 2016 of the Norwegian Directorate of eHealth.

Vision and approach for EMRs

The new EMR strategy will involve many independent projects to be implemented at different levels of government. The Norwegian Directorate of eHealth is responsible for national coordination.

The objective of the new strategy is:

- to give healthcare personnel access to patient and user information encapsulating the patient's complete trajectory, wherever the patient becomes ill or receives treatment;
- to ensure that support of decision-making is part of the EMR user experience;
- to give citizens ready access to secure digital services; and
- to make data available to improve health monitoring, governance and research. Reporting should be automatic and an integral part of the work process.

The ultimate objective is to have a common national solution for clinical documentation, workflow support and patient administration. To achieve this objective, the active participation of stakeholders, such as healthcare providers, professional associations, regional health authorities and municipalities, will be required.

Governance, responsibilities and decision-making

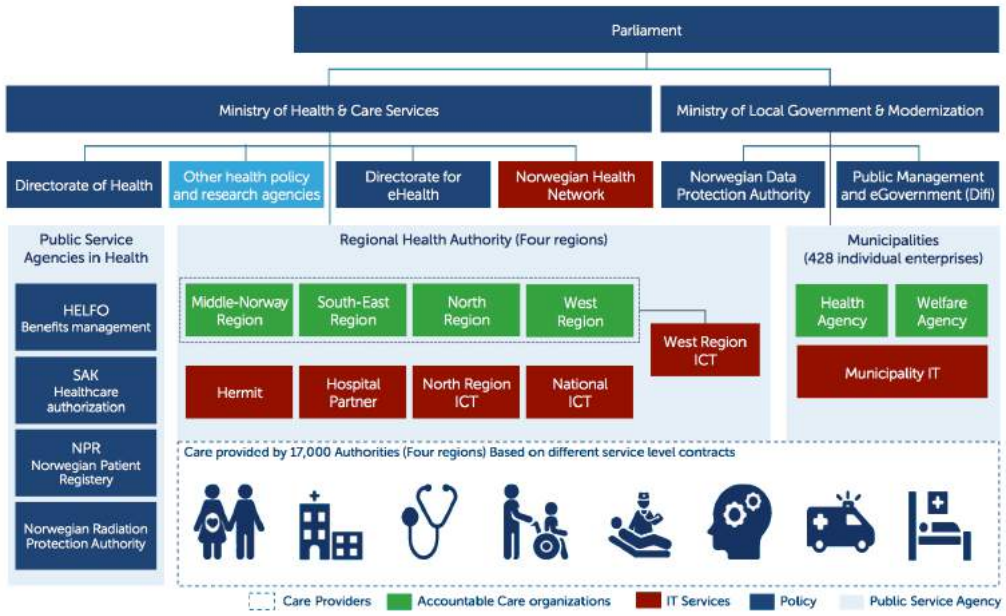
The Norwegian Directorate of eHealth provides coordination and digital health advocacy at the national level. The Directorate reports to the Ministry of Health and Care Services and is responsible for ICT standardization to ensure interoperability. The Directorate also develops and manages national digital health solutions, such as EMR, ePrescription, Patient Summary Records and the National Health Portal, and serves as the main advocacy vehicle for eHealth in Norway.

To coordinate digital health stakeholders, the Norwegian government established three national governance bodies:

- National Advisory Board for eHealth, which encompasses health specialists, primary- and public-care general practitioners and other stakeholders and advises on all digital health matters.
- National Forum for Portfolio Management, which defines the national digital health priorities, aligns participation of stakeholders and provides resources for coordinated actions.
- Health Professional and Architectural Advisory Board (NUFA), which works with healthcare providers and technology specialists to ensure that digital health projects fulfill the tenets of best practices and established standards.

In addition, the Norwegian Data Protection Authority provides input to the Directorate of eHealth on embedding security and privacy in digital health programs and architectural blueprints.

Figure 19: Norway Digital Health Governance Structure



Source: Norway Directorate for eHealth

ICT and health coordination: Norway has seven common national ICT/digital components managed by four different government agencies and the Digital Health Directorate sits on the board of each of these seven components. Four of these seven components are managed by the Agency for Public Management and eGovernment (DIFI), which reports to the Ministry of Local Government and Modernization.

Intragovernmental cooperation between DIFI and the Norwegian Directorate of eHealth includes:

- representatives from the Directorate of eHealth participate in the governance board of all seven common ICT components, which includes the electronic identification platform (eID-a central element of the national health portal) as well as SKATE, the coordinating council for eGovernment services provided by DIFI.

- representatives from the Directorate of eHealth who participate in the governance board for the electronic identification platform, one of the seven components of ICT and a central element of the national health portal, as well as SKATE, the coordinating council for eGovernment services provided by DIFI.

Lesson and insight

The drive to develop a comprehensive EHR, the One Citizen – One Record vision, revealed ongoing challenges in solution interoperability and prompted a thorough effort to remake Norway's digital health governance.

Financing

Establishing sustainable sources of funding to support digital health is a challenge, even in high-income countries. Digital health may not immediately have a return on investment (ROI) or health impact and there are significant capital expenditures required to develop the necessary infrastructure and systems.[41] Common funding challenges include fluctuations in health ministry budgets, competing priorities and initiatives across agencies, short-term budget cycles that are not aligned with long-term health system goals and investments and, in some countries, over-reliance on external donor support. The lack of solid clinical-outcome evidence as well as proof of ROI for digital health previously cited in this report can deter governments from justifying significant initial capital investment or ongoing operating costs. That is one reason why KPIs and impact measurement of health outcomes, which can demonstrate ROI, are so important.

Committed government leaders can strengthen sustainable financial support and resources for a digital health strategy and can establish dedicated, credible and resourced governance structures, which will in turn help to build strong management teams and competence.

Some pertinent findings from the research and expert interviews undertaken for this report include:

- **Total cost of ownership (TCO) modeling to determine capital and human resource expenditures:** Digital health systems and solutions have often failed because costs of building and maintaining them were underestimated. Financial sustainability can only be achieved when stakeholders are aware of the true cost of building, deploying and maintaining these systems and can carry out TCO modeling. These efforts often reveal that the costs of hardware and software, which are often assumed to be the costliest elements of digital health deployment, are dwarfed by the costs of other elements such as human resources, training and technical support.

- **Sustainable business models:** Government leaders can form partnerships with the private sector and social entrepreneurs to develop financially sustainable business models. Digitizing reimbursement of insurance claims is another way of working with insurance partners. In the **Philippines**, the eClaims health reimbursement system developed and deployed by the national insurer (PhilHealth) has been critical to bolstering efforts to include private-sector health providers in the quest to achieve UHC. In **Brazil**, the Siga Saude system in the state of Sao Paulo has integrated provider payments into its comprehensive digital health resource management system.

- **Creating long-term sustainable funding mechanisms:** Some LMICs face severe constraints in both funding and capacity for digital health implementation and must rely largely on external funding. Donors often fund projects that do not take into account a country's priorities, a situation that contributes to fragmentation. **Mali** shows how donor funding has exacerbated its interoperability problems.

  Alternative national funding sources can be developed with public-private partnerships, innovative financing mechanisms and cooperation mechanisms that strengthen local capacity. An innovative funding mechanism was recently implemented in **Pakistan** using the country's Universal Service Fund (USF). USF is a fund that pools taxes collected from telecom operators in order to increase access to connectivity and mobile services for remote and disadvantaged segments of the population. **Pakistan** used the funds to develop telemedicine networks throughout the country.

The **Philippines** is currently piloting a tobacco cessation program (mCessation) using mobile technology in partnership with Be He@lthy Be Mobile, an initiative led by the WHO and the ITU. The Department of Health plans to use revenues from a sin tax on tobacco as a source of funding to support the program if nationally scaled. **Mexico** is exploring a similar approach on sugary drinks to fund an mHealth initiative to prevent diabetes and obesity (mSalud).

- **Leveraging donor support productively:** External funding resources for digital health programs can also support long-term financing needs if they are configured in a way that strengthens workforce capacity and transition. In **Malawi**, the Bill & Melinda Gates Foundation provided the initial financial needs of the Kuunika Initiative which aims to integrate HIV data systems with a view to improving the use of data in clinical care and service delivery. The initiative provided financial resources to strengthen the overall capacity of a management team with digital expertise to operate in the MoH and also to develop governance mechanisms, such as steering committees and TWGs, which would build digital health expertise within the MoH. **Rwanda** offers an example where donors have aligned with the country's standards and priorities and where the government includes donor organization participants in TWGs and regular coordination meetings.
- **Aligning digital health funding with program funding:** While digital health programs require some level of shared resources and infrastructure to be effective, the creation of digital health units or agencies may be seen as potential competitors of other programs. In **Rwanda**, requests for funding for digital solutions are dealt with under the existing relevant programmatic area such as HIV or maternal health, thereby allowing the leaders of these programs to advocate for digital health solutions without being seen as competitors of other programs.

Workforce and Capacity Building

Governance mechanisms are only as strong as the availability of human and technical resources to implement the digital health strategy. Capacity building is needed not only to strengthen healthcare providers' technical literacy and management capabilities, but also to boost the capacity of ICT professionals to manage, maintain and improve the system through a dedicated digital health program management team or unit. In many countries, experienced project managers are in high demand and short supply, particularly those working in digital health such as health IT specialists, medical informatics experts and IT experts who also possess a deep understanding of the healthcare system and the end-users needs.

As a result, the development of long-term capacity-building programs by government and non-government leaders is required to ensure that necessary skills are in place. As implementations progress, leaders need to support managers, analysts and clinicians with continuing education, financial resources, and clear and consistent oversight and expectations. Strategies include assessments of core competencies before the digital solutions are integrated into the health system. They also include ICT training programs for healthcare workers and ICT professionals, the development of incentive mechanisms to encourage workforce development of health ICT skills and competencies, and the accreditation of health ICT training curricula.

The case studies included in this report demonstrate how different governance mechanisms supported the development of program management capacity, specifically by creating a dedicated program management team or unit uniquely mandated to develop and implement

"Our biggest challenge is still the user change management and training. If you don't get buy-in from the clinicians, the system won't work."

Dr. Fazilah Shaik Allaudin, Director of Telehealth Division, Ministry of Health, Malaysia

the digital health strategy. **Malaysia,** for example, recognized the dearth of skills in this area and developed within the MoH a specific course on program management dealing particularly with ICT domains, such as software applications and vendor negotiation and procurement. **Nigeria** and the **Philippines** both had their digital health teams trained in COBIT 5, a leading framework for managing enterprise IT.

Leveraging private-sector expertise is another potential strategy. When **Estonia's** eHealth Foundation, housed within the Ministry of Social Affairs, began work on HIE, a private-sector firm further developed and maintained the system. Similarly, **Belize** deployed a comprehensive EMR-based resource management system which it had procured from a Canadian company and which complied with the country's health system and privacy requirements.

Global Benchmarks for Comparisons and Lessons

Irrespective of the governance mechanism and country context, the case studies and research presented here have pointed out the complexity of developing and implementing a digital health strategy. Understanding the successes and failures, applying best practices, and gleaning trends from other countries as well as from global institutions and expert bodies should provide an opportunity for countries to replicate the successes and avoid the pitfalls.

ITU and WHO are important facilitators. Both organizations develop and share best practices and standards on digital health and work directly with government agencies in the health and ICT sectors. The WHO-ITU Toolkit is an important resource as countries develop and refine their digital health strategy, their action plans and their monitoring and evaluation frameworks. In 2005, WHO launched the Global Observatory for eHealth[42] which provides useful information for governments on eHealth evolution and global trends. WHO is currently in the process of developing guidelines on evidence-based recommendations for the use of digital interventions for strengthening health systems. These guidelines will facilitate country–level prioritization of digital investments. Additionally, within the Health Data Collaborative global mechanism, WHO supports countries developing an inventory of digital health investments for use in government planning through the Digital Health Atlas.

Regional platforms for peer-to-peer learning are also critical. AeHIN was established in 2011 to strengthen peer-to-peer learning and knowledge sharing in the South, East and Southeast Asia regions with significant support from the WHO South-East Asia Region. AeHIN provides guidance on leadership, supports policy and standards, expands the exchange of knowledge and implements capacity building practices. In Latin America and the Caribbean, PAHO, through their Regional Program on Digital Health, coordinates a network of high-level officials in charge of digital health issues, thereby facilitating an assessment of country level needs and the exchange of knowledge and experiences between countries. In sub-Saharan Africa, there are multiple digital health learning networks through which participants learn from each other, document best practices and develop digital health plans to be implemented in their home countries.[43] As part of the new USAID-catalyzed digital health

initiative, PATH and its partners, drawing on the successes of AeHIN, will advocate for and support additional investments to strengthen regional capacity building in sub-Saharan Africa. A strong African digital network has the potential to play a key role in the development and implementation of digital health strategies and in promoting a digital health community of practice and peer-to-peer learning across the continent.

4 Key Observations and Conclusions

Part 4: Key Observations and Conclusions

As evidenced by the case studies in this report, the catalyst for developing a national digital health strategy may be different in each country. In **Rwanda, Malaysia** and **Canada** the impetus for digital health efforts came from ambitious national ICT or broadband plans. In some cases, these broadband plans came from even wider economic development plans, such as **Rwanda's** Vision 2020 or **Malaysia's** Plan for Social and Economic Transformation. In **Nigeria** and the **Philippines**, leaders committed to the notion that ICT could accelerate their UHC goal.

The three key observations and best practices that were identified across all case studies were

1. **Sustained senior government leadership and committed financing for digital health are prerequisites for a successful national digital health strategy**

Initiating and operationalizing a national digital health strategy can take several years, implying a long-term commitment. A strong vision supported by senior government leadership that can articulate the value and potential impact of digital health and ensure the buy-in and alignment of stakeholders is required. Endorsement and leadership across sectors are needed, both from health leaders who recognize the transformative potential of ICTs in healthcare and from ICT leaders who understand the potential of digital technology to address health challenges. Commitment from those leaders can consolidate sustainable financial support and the resources for a digital health strategy. It will also prompt the establishment of dedicated, credible and resourced governance structures which can help to build strong and competent managerial teams.

For example, integrating ministers of health and ICT within digital health steering committees, as **Rwanda, Nigeria** and the **Philippines** have done, provides strong leadership. Ensuring that senior level leaders enable effective and timely decisions when digital health initiatives face problems is also essential. **Estonia** and **Bangladesh** strongly support digital health, as evidenced by the fact that their digital health proponents sit in the Prime Minister's Office.

2. **Effective governance mechanisms that engage stakeholders, who have clearly defined roles, can help to ensure efficient decision-making for a national digital health strategy.**

Governance mechanisms formalize decision-making and provide a forum for discussion. They bring together leaders and stakeholders from overlapping domains. They clarify how and when external stakeholders, from the private sector or the development community, can provide input, and they promote the drafting of a digital health strategy by creating management units. In developing the strategy, clarifying and codifying organizational roles can be used as a basis for governance structures and domain ownership.

Nigeria's example shows the value of defining such governance mechanisms early on and creating a dedicated program management team to engage with multiple stakeholders in adopting the digital health strategy. Clearly defined governance bodies helped

"The single greatest success factor is having a strong regional or country champion. Leadership is one element that can make or break electronic health information systems."

Dykki Settle, Director of the Digital Health Solutions Program at PATH

"Our plan is to operationalize the eHealth strategy with leadership from the Federal Ministry of Health, and with a specific focus on governance. We have come to the conclusion that the lack of appropriate governance is possibly the greatest challenge to the application of technology in health."

Olasupo Oyedepo, Project Director ICT4HEALTH Project
(Health Strategy and Delivery Foundation), Nigeria

to engage both the ICT and health government entities in formalizing their respective roles. A digital health ICT steering committee, chaired by the Minister of Health and the Minister of Communication, provides strategic direction for digital health. Because of the country's federal structure, specific attention was also paid to defining governance mechanisms at state levels via state eHealth committees.

The **Philippines, Rwanda** and **Malaysia** case studies all demonstrate how different steering committees and Technical Working Groups (TWGs) provide well-defined governance mechanisms. The steering committee, which often includes the health and ICT ministries, sets overall direction. The committees are supported by TWGs that have specific mandates in different domain areas, such as data standards, privacy and security.

3. **A national ICT framework that facilitates alignment between health and ICT sectors can promote connectivity and interoperability, establish common standards, and enable appropriate policies and regulations in digital health.**

Digital health lies at the intersection of health and ICT. A strong government-wide ICT framework will enable shared capital investments, rationalized resource allocations, and leveraged workforce capabilities between government entities, while at the same time avoiding duplication of solutions. Coupling digital health efforts to national ICT frameworks, such as national broadband plans or national digital plans, can enhance cooperation.

While the MoH leads the digital health strategy, ICT agencies need to support the health sector's prioritizing efforts. Dual expertise is needed in technology and health, and there is also little doubt that greater dialogue and cooperation between the health and ICT sectors will result in more effective use of investments and funding. For example, for digital regulation to be effective, health experts familiar with patients' rights should work with ICT regulation experts who are experienced in data protection and security.

In **Rwanda,** the national broadband plan was linked to the digital health strategy and thereby enabled the establishment of an ICT regulatory and legal framework. The leading ICT government agency, the Ministry of Youth and ICT, provides guidance to the health authority, the MoH, on technology procurements, and the Ministry of Youth and ICT is responsible for approving all MoH hardware and hosting requests for digital health solutions.

Digital health initiatives can greatly benefit from an overarching eGovernment architecture which defines the common sets of data security and privacy standards or facilitates interoperability. The eGovernment architecture can help, for example, to link data managed by different ministries to a unique identifier number. Such a system can make sure that government welfare funds are provided to people complying with eligibility criteria or that EMRs are linked to birth and civil registration records using unique national identifiers. In **Estonia,** the ambitious eGovernment strategy launched in 2000 enabled a health information exchange (HIE) that facilitates solution interoperability through an

"The development of a comprehensive national digital health strategy and its implementation has to be co-created and co-owned by the ICT and health ministries. Digital health is at the intersection of the two sectors and as a result requires leadership, expertise and investments from both."

Hon. Jean Philbert Nsengimana, Minister of Youth and ICT, Government of Rwanda

integrated electronic health record (EHR) system. These initiatives rely on a government-wide ICT architecture and a national universal identification system.

In **Norway,** cooperation between the ICT and health authorities is established in all boards and working groups, including the MoH, the DIFI, and the Ministry of Local Government and Modernization, which oversees the country's ICT policy. Another example is **Mali's** eHealth agency (ANTIM) which works in close cooperation with AGETIC, the country's ICT agency, and stores health data on the national server at AGETIC.

A national broadband plan, typically led by the Ministry of Communication or ICT, can support the eGovernment strategy as well as the eHealth strategy. Experience shows that when broadband plans and eGovernment initiatives are developed and include the health sector, the result is greater coherence and synergy and more effective national eHealth strategies. **Rwanda** exemplifies how a national digital health strategy can be effectively integrated into the overall broadband and digitization plan of the country. In some countries, broadband plans define the frameworks with which a country will connect hospitals, clinics and care centers. It is clear that more effective use of investments and funding can be achieved by stronger cooperation and dialogue between the two sectors of health and ICT.

In some cases, digital health can act as a catalyst to the overall broadband strategy of a country. In the **Philippines,** the digital health strategy launched in 2010 triggered a need for common standards and interoperability beyond health and catalyzed efforts on broadband expansion in the country. This prompted the creation in early 2016 of the Department of ICT. The Department of Science and Technology, a member of the eHealth Steering Committee and TWG, was influential in the establishment of a fund specifically allocated to the connectivity of primary health centers. The country recently announced the establishment of a new national broadband plan to accelerate the deployment of fiber-optic cables and wireless technologies.[44]

The testimony in this report of countries that have experienced the satisfaction of adopting a national digital health strategy shows that the task, however challenging, can be achieved and is clearly worth achieving. As these countries have found, though, a successful digital health strategy must include an unwavering vision supported by sustained senior government leadership, committed financing, and sound governance that supports intragovernmental cooperation between ICT and health ministries.

On an overarching level, it is only when digital health becomes institutionalized that it can realize its full transformational potential to accelerate progress in reaching the development goals of universal health coverage, healthy lives and well-being for all.

5 Annexes

Annex 1: Case Study Sources

Nigeria

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Annex 2: Research Methodology and Interviews Conducted

To create this report, The Broadband Commission Working Group on Digital Health, chaired by the Novartis Foundation and Nokia, convened leading digital health experts from governments, international and non-governmental organizations, academic institutions, and the private sector. The Chairs commissioned Vital Wave, to conduct primary and secondary research and interviews, consulting with the Working Group on Digital Health on a quarterly basis. Secondary research included literature review of peer reviewed, white papers, websites and other public information. Primary research involved interviews with 46 digital health experts from over twenty countries and international organizations. They represented government, implementing partners, donors, as well as transnational regulatory bodies.

The literature review identified twenty countries with unique attributes of digital health: Bangladesh, Brazil, Canada, Chile, Estonia, Gabon, Ghana, India, Kenya, Malawi, Malaysia, Mali, Mexico, Nigeria, Norway, Pakistan, the Philippines, Rwanda, Singapore, and South Africa. These countries represent a range of demographic, geographic, and economic contexts, with varying levels of maturity in digital health systems.

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Annex 4: Abbreviations

3G Third Generation Mobile Communication Technology

4G Fourth Generation Mobile Communication Technology

AeHIN Asia eHealth Information Network

DoH Department of Health

DoICT Department of ICT

eHIS Electronic Health Information Systems

EHR Electronic Health Record

eIDSR Electronic Integrated Disease Surveillance and Response

EMR Electronic Medical Record

FDA Food and Drug Administration

GNI Gross National Income

GOe WHO Global Observatory for eHealth

GSMA GSM Association

HIE Health Information Exchange

HIS Health Information System

HL7 Health Level Seven International

HMIS Health Management Information System

ICT/ICTs Information and Communication Technology

IHE Integrating the Healthcare Enterprise

ITU International Telecommunication Union

KPI Key Performance Indicator

LDCs Least Developed Countries

LMICs Low and Middle-Income Countries

MCH Maternal and Child Health

mHealth Mobile Health

MoH Ministry of Health

MoICT Ministry of ICT

NBPs National Broadband Plans

OpenHIE Open Health Information Exchange

PAHO Pan American Health Organization reports

PCHA Personal Connected Health Alliance

POCT Point of Care Testing

ROI Return on Investment

SDG Sustainable Development Goals

SDN Software Defined Networking

SMS Short Message Service

TCO Total Cost of Ownership

TOGAF The Open Group Architecture Framework

TWG Technical Working Group

UHC Universal Health Coverage

WHO World Health Organization

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