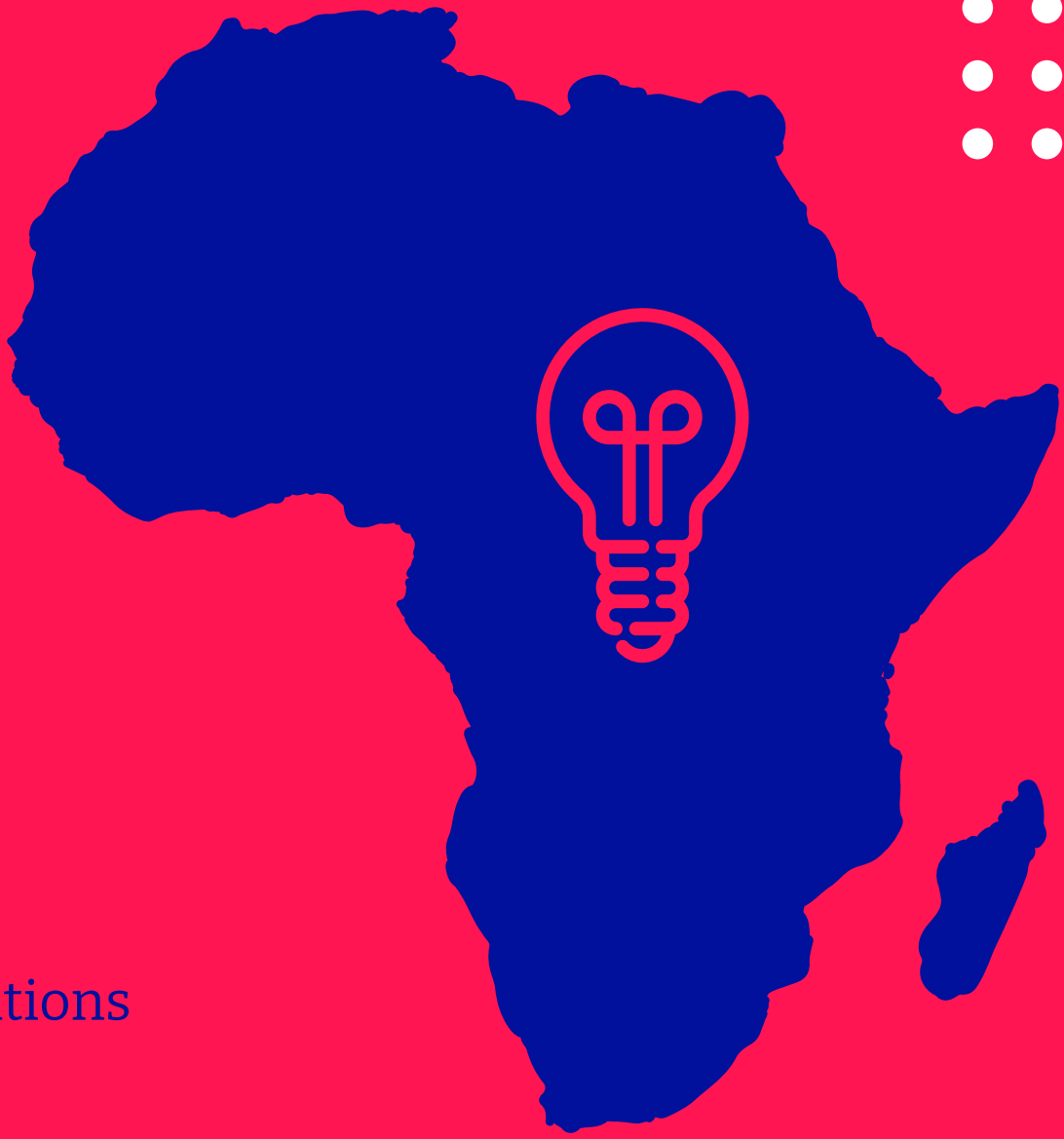
HEALTHTECH HUB



POLICY BLUEPRINT

to Fast-Track Healthtech Innovations in Public Health in Africa

Interactive PDF clickable links throughout

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Acknowledgements

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We acknowledge previous work done on healthtech by the World Health Organization, the World Bank, World Economic Forum, Imperial College London, IQVIA, African Development Bank, and other institutions, from which this work has drawn some inspiration. Above all, we thank the governments of Côte d'Ivoire, Ethiopia, Kenya, Malawi, Nigeria, Rwanda, Senegal, South Africa, Tanzania, Uganda and Cameroon for granting us permission to use learnings and cases from their countries' policy and regulatory frameworks for this Blueprint.

Executive summary

Health technology (or healthtech as used in this document) is a broad term that includes the application of technology to health care to prevent, diagnose or treat medical conditions; promote health and wellbeing; improve the quality of care; provide rehabilitation; organise health care delivery; and improve treatment outcomes.[1]

The World Bank and the African Development Bank have described healthtech as one of the most powerful tools needed to close the gaps in health care delivery globally.[2,3] Healthtech can help mitigate challenges in the health system, such as the shortage of health care professionals and poor logistics and supply systems.[4] An analysis in several African countries found that effective use of electronic medical records and virtual interactions such as telemedicine can generate up to 15 percent efficiency gains and free up resources to address other patient needs.[2]

African governments recognize the value of healthtech and some have made significant advancements toward leveraging innovations to improve their health systems and health care delivery. [5,6,7,8,9] Acknowledging this broad foundation of existing efforts, the HealthTech Hub Africa (HTHA) set out to contribute to efforts to expand the healthtech knowledge base, leveraging the large set of startups participating in its accelerator program and its existing relationships with many African governments and stakeholders.

Between May 2023 and February 2024, VillageReach, on behalf of the HTHA and in collaboration with other partners, conducted various activities to collect data, gain insights and document experiences from innovators, government representatives and other stakeholders on the use of healthtech in selected African countries. Data collection methods included a situation analysis, interviews with 43 key informants and face-to-face consultations with stakeholder groups from Côte d'Ivoire, Ethiopia, Kenya, Malawi, Nigeria, Rwanda, Senegal, South Africa, Tanzania, Uganda and Cameroon. Stakeholders consulted included healthtech innovators or startups, academics, investors, policymakers, civil society representatives and government officials, who identified some of the opportunities, challenges and enablers for accelerating healthtech innovation in Africa.

This Blueprint captures the challenges, opportunities, recommendations and examples identified during the consultations. It aims to support decision-makers by providing overall policy directions, specific actions and practical examples to complement their existing efforts to accelerate healthtech in Africa and enable the development, testing and sustainability of innovations.

Although some African countries already have policies, strategies and/or legislation on healthtech (sometimes referred to as a digital health strategy), those strategies and policies do not focus on the needs of innovators, thus hindering the optimal use of healthtech across the continent.

Section 1 provides a brief introduction to the Blueprint, defining key terms and providing background to the document.

Section 2 highlights the key challenges identified by participants in the interviews and consultations: lack of a unified, comprehensive and updated set of policies governing healthtech at country and regional levels; complex, lengthy and unclear healthtech licensing processes; poor infrastructure to power health technology; limited access to health care data; data insecurity; lack of protection for healthtech intellectual property rights; limited integration of healthtech systems; limited operational capacity for healthtech; poor coordination, partnerships and collaborations; and insufficient funding for healthtech.

During the multistakeholder meeting, two main categories of challenges were identified as priorities requiring urgent attention: (i) challenges associated with licensing of healthtech and (ii) challenges related to health data sharing, hosting and interoperability.

Section 3 therefore highlights four key recommendations for addressing the two priority areas and for enhancing the transformation and optimization of healthtech in Africa: (i) Establish or strengthen existing mechanisms for dialogue and coordination among healthtech stakeholders; (ii) Review and refine policies regarding access to, hosting and interoperability of health data to accelerate innovation while safeguarding data; (iii) Establish streamlined and transparent healthtech licensing systems at country level; and (iv) Make progress towards regional healthtech harmonization and licensing platforms.

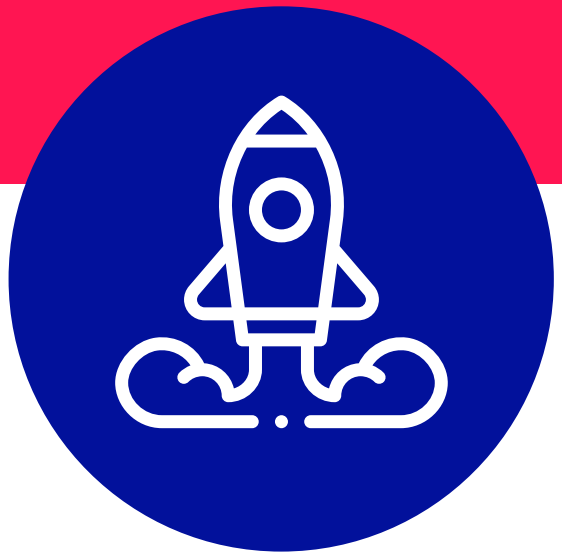
Section 4 describes the concept of a data and regulatory sandbox, which is one tool that can support implementation of some of the policy recommendations if planned with sustainability in mind. This section provides general guidelines that governments and other stakeholders may consider for implementation of healthtech sandboxes, which should be examined and adapted in accordance with the prevailing local context.

Section 5 highlights other key program considerations that are important for the success of healthtech implementation in Africa. These considerations surfaced in stakeholder consultations during development of the Blueprint and go beyond the prioritized areas that are the focus of the policy recommendations. These include considerations for sustainability, infrastructure, funding, operational capacity, inclusiveness and equity, and continuous monitoring, evaluation and learning.

The recommendations in this Blueprint are broadly applicable, but actions would need to be tailored by individual countries to their specific situations and needs. The recommendations are complemented by practice cases from around the globe to provide lessons and examples of how each of the recommendations has been implemented in different contexts.

The Blueprint serves as a starting point for further dialogue and analysis within and across countries. HTHA plans to build upon the initial work of this Blueprint by convening governments and partners to validate and refine the recommendations and support in the identification and implementation of specific actions to accelerate healthtech that are tailored to each country's specific situation, needs and priorities.

1. Introduction



Introduction

a. Concept and definition

Health technology (or healthtech as used in this document) is a broad term that includes the application of technology in health care to prevent, diagnose or treat medical conditions; promote health and wellbeing; improve the quality of care; provide rehabilitation; organise health care delivery; and improve treatment outcomes.[1]

Healthtech includes all digital technologies used for prevention, diagnosis, medical devices, treatment, medicines, vaccines, blood products, procedures, programs or systems involved in the continuum care and wellbeing.[1,5,6]

b. Background information

The World Bank and African Development Bank have described healthtech as one of the most powerful tools needed to close the gaps in health care delivery globally.[2]

Healthtech holds great potential for improving service delivery and bridging the human resource gap in the health sector. Although healthtech was in use long before the emergence of COVID-19, the pandemic triggered an unprecedented surge in its use for emergency and routine health care services, thus offering an opportunity to accelerate and scale-up its implementation.[6] Because of the lockdown and the need to curtail the spread of COVID-19, there was a general shift towards new no-contact ways of doing business, thus making healthtech a necessity for the provision of services.[6] This increased use is one of the positive outcomes of the pandemic.

Before the pandemic, some low- and middle-income countries (LMICs), including African countries, were already making efforts to develop and optimize the use of healthtech, following the exponential increase in the use of mobile technology, internet connection and the development of new web-based applications.[12] This increase in technology entrepreneurship and healthtech innovations became a springboard and created an enabling environment for the use of technology in health care even before the pandemic.[12]

Available data has shown that LMICs that had higher levels of digital technology adoption before the COVID-19 pandemic, had basic capacity to respond more effectively to the pandemic; they were more decisive in their response and better equipped to track and trace cases, thereby reducing casualties.[12] For instance, Senegal's Ministry of Health had begun the process of digitizing the country's health system, developed telemedicine regulations and launched a healthtech strategy.[12] Rwanda had launched a National eHealth Policy in 2016 and adopted drones, mHealth and online learning technologies that helped increased health services and bolstered the health system.[13] These became useful in accelerating response to the pandemic.

African governments recognize the value of healthtech and some have made significant advancements toward leveraging innovations to improve their health systems and health care delivery. A 2023 mapping by IQVIA shows that most African countries have well-established national digital health strategies and have allocated human resources and established dedicated teams to identify, evaluate and implement effective healthtech solutions.[14] Some multilateral partners are also making significant contributions to advance healthtech, including through the development of frameworks and the provision of technical assistance and financial resources. Examples are the World Health Organization, Africa CDC, African Development Bank, World Bank and the World Economic Forum, to highlight just a few.[1,5-8]

Acknowledging this broad foundation of existing efforts, the HealthTech Hub Africa (HTHA) set out to expand the healthtech knowledge base. The HTHA is a hybrid pan-African healthtech accelerator working to drive the development of healthtech in Africa and fast-track public

health system innovation through collaboration with government partners and global health funders. The HTHA accelerator program nurtures healthtech startups and scale-ups through supportive peer and partner systems and connection to government stakeholders and resources. The HTHA sought to leverage the large set of startups participating in its accelerator program and its existing relationships with many African governments and stakeholders to further explore challenges related to healthtech. Documented challenges include differing levels of availability, accessibility and affordability of healthtech across African countries; policies that are unclear, inadequate or unavailable in some countries; challenges with licensing, scaling and financing healthtech and lack of supportive infrastructure; and debate among stakeholders over access to and ownership of health data.[15,16]

Between May 2023 and February 2024, VillageReach, on behalf of the HTHA and in collaboration with partners, conducted various activities to collect data, gain insights and document experiences from innovators, government representatives and other stakeholders on the use of healthtech in selected African countries. Data collection methods included a situation analysis, interviews with 43 key informants and face-to-face consultations with stakeholder groups from Côte d'Ivoire, Ethiopia, Kenya, Malawi, Nigeria, Rwanda, Senegal, South Africa, Tanzania, Uganda and Cameroon. Stakeholders consulted included healthtech innovators or startups, academics, investors, policymakers, civil society representatives and government officials, who identified some of the opportunities, challenges and enablers for accelerating healthtech innovation in Africa.

The consultations focused on gathering perspectives from key stakeholders in Africa on the common challenges they face in developing and implementing healthtech innovations and pragmatic solutions to the identified challenges, particularly issues relating to licensing, regulation, legislation, ownership, interoperability, data security, access to health data, funding, partnership and collaboration on healthtech.

This Blueprint is based on feedback received during these consultations. It captures the challenges, opportunities, recommendations and examples identified during the consultations and analyses.

We anticipate that this Blueprint will catalyze discussions and spur actions towards a positive change to increase the effectiveness and efficiency of healthtech in the target countries and on the African continent more broadly. The long-term goal is to make healthtech development, testing, scaling and sustainability possible and easier across the continent. We hope that adoption and implementation of the policy recommendations will ultimately help increase access to people-centered healthtech that will improve patient safety and health outcomes in Africa.

Policy Blueprint

c. What and who is this Blueprint for?

Several frameworks on healthtech or digital health have been developed and published by different entities, including WHO, Africa CDC, World Bank, the World Economic Forum, etc.5-8,9 Some of these frameworks provide general recommendations for the development of healthtech at different levels of care and were referenced during the development of this Blueprint. The Blueprint complements these already existing documents and provides specific recommendations that will foster an enabling environment to increase and advance the development and use of healthtech in Africa.

A blueprint is a guidance document to provide instructions or describe the process or patterns to follow to achieve a desired goal. This Blueprint serves as a foresight policy guide that provides recommendations on how governments, innovators, startups and other stakeholders can work together in strengthening healthtech in Africa. It aims to support decision-makers by providing overall policy directions, specific actions and practical examples to complement their existing efforts to accelerate healthtech in Africa and enable the development, testing and sustainability of innovations.

This Blueprint has two main objectives:

i. To document key gaps and challenges in implementing healthtech in Africa based on consultations, reviews and learnings from healthtech stakeholders in Côte d'Ivoire, Ethiopia, Kenya, Malawi, Nigeria, Rwanda, Senegal, South Africa, Tanzania, Uganda and Cameroon.
ii. Recommend policy interventions to accelerate healthtech in Africa.

The recommendations address the most pressing and consistent challenges identified during our engagement across the countries and are meant to be broadly applicable across Africa. They serve as a starting point for further dialogue and analyses within and across countries. Enabling policies are critical in the introduction (registration and licensing), development, scaling, transitioning and advancement and sustainability of healthtech innovations.

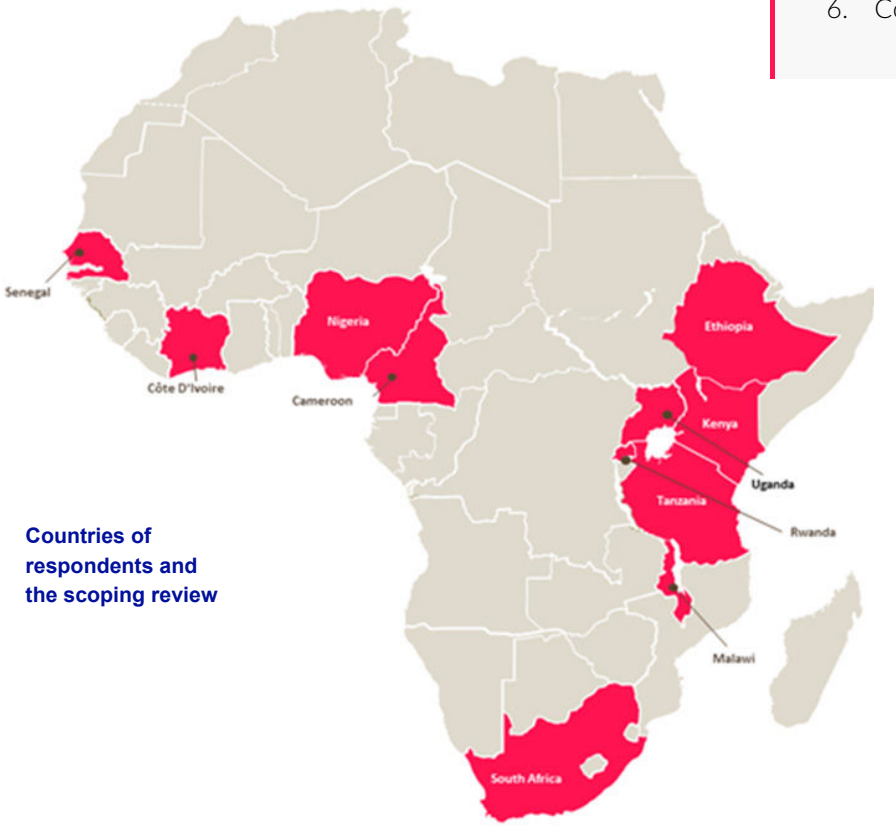
The primary target stakeholder groups for this Blueprint are government ministries, agencies and departments that regulate the healthtech environment and healthtech innovators, including startups and scaleups. We anticipate that other stakeholders will also find it was a useful resource in accelerating healthtech in Africa. The information used for developing the Blueprint were sourced largely from 11 African countries. However, the lessons and recommendations can be applied in other African countries, where additional consultations may be needed to account for the differences in context, culture and the level of advancement of healthtech specific to those countries.

d. Development of this Blueprint

The development of this Blueprint was based on a desk review of literature, key informant interviews and face-to-face consultations with key stakeholder groups.

Key informant interviews were conducted with 43 individuals who were leaders of healthtech startups, non-government and government institutions in Côte d'Ivoire, Ethiopia, Kenya, Malawi, Nigeria, Rwanda, Senegal, South Africa, Tanzania, Uganda, and Cameroon, between May 2023 and February 2024. Findings from the key informant interviews were validated and complemented with face-to-face discussions and consultations during workshops involving representatives of healthtech innovators, academics, investors, policymakers, civil society, and government representatives from the focal countries. Special consultation missions were undertaken in Ethiopia and Rwanda to discuss and document specific experiences of different stakeholders.

A scoping review was conducted on Google Scholar, PubMed and Journal Storage (JSTOR) search databases using the following search terms: barriers to healthtech innovation, health technology framework, barriers to scaling health technology innovation, enabling health technology innovation, health technology innovation, digital health strategy, health technology strategy and healthtech start-ups. The searches were geolocated for Africa, Cameroon, Côte d'Ivoire, Ethiopia, Kenya, Malawi, Nigeria, Rwanda, Senegal, South Africa, Tanzania, and Uganda. We also searched the databases of some organizations for related content, including World Health Organization, Africa CDC, World Bank, World Economic Forum, African Development Bank and Imperial College London Institute of Global Health Innovation.
Findings from the consultations, interviews and reviews were collated, synthesized and summarized to develop this Blueprint. Selection of the focal countries – Cameroon, Côte d'Ivoire, Ethiopia, Kenya, Malawi, Nigeria, Rwanda, Senegal, South Africa, Tanzania, Uganda – for the development of this Blueprint, was based on previous work experience and collaborations on healthtech startups by VillageReach and its partners as well as the availability of existing healthtech initiatives in those countries.



Countries of respondents and the scoping review

e. Socioeconomic value of healthtech

Healthtech holds great potential for patients, health care providers, the health system, the community, as well as for the achievement of Universal Health Coverage and the health-related Sustainable Development Goals.[4-6]

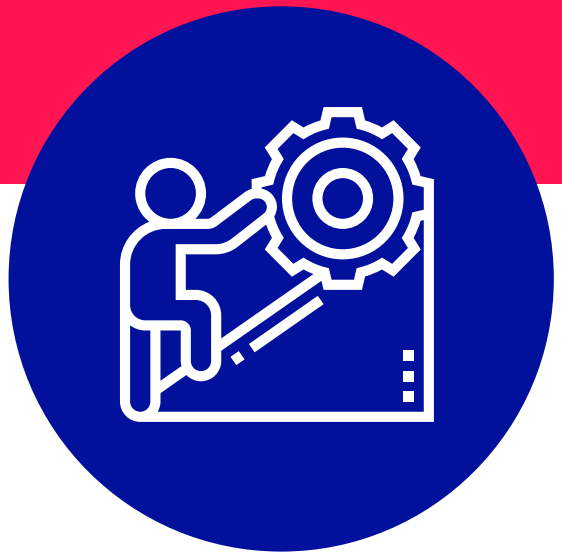
It can help mitigate challenges in the health system, such as the shortage of health care professionals and poor logistics and supply systems.[4] It can help increase access, affordability, efficiency, quality-of-care, workforce capacity, accountability, resource allocation, coordination, management and overall health systems governance, especially where resources are limited. Healthtech offers great opportunities for minimizing inequities in health care by improving access for vulnerable, underserved, underprivileged and geographically hard-to-reach individuals and communities, including adolescents and young adults, migrant populations, the physically challenged, elderly and frail individuals.

Healthtech is data-driven and can be used to generate impact analysis reports and evidence that will provide insights into community health trends, disease prevalence, outbreaks and health-seeking patterns for policy- and decision-making. Economically, availability of digitally analyzed health data can provide credible evidence for improving health financing.

An analysis to quantify the financial impact of digital health tools in Kenya, Nigeria and South Africa showed that these countries could save up to 15 percent of health system costs by scaling up digital solutions such as virtual interactions, paperless health information exchanges, electronic medical records, decision intelligence systems, workflow optimization and simplification and patient-focused interventions such as patient selfcare and patient self-service.[2] Another study found that effective use of electronic medical records and virtual interactions such as telemedicine can generate up to 15 percent efficiency gains and free resources to address other patient needs.[2]

While healthtech innovations alone won't solve health care access for all, they are a powerful tool for extending healthcare's reach to underserved communities.

2. Challenges in accelerating healthtech in Africa



Challenges in accelerating healthtech in Africa

A 2021/2022 WHO report indicates that some African countries have policies, strategies and/or legislation on healthtech (sometimes referred to as a digital health strategy) and this was confirmed by the interviews, reviews and consultations conducted by VillageReach.[2] However, these strategies and policies do not focus on the needs of innovators, thus hindering the development and optimal use of healthtech innovations across the continent.

This section highlights the key challenges identified by participants in the interviews and consultations, which include: lack of a unified, comprehensive and updated set of policies governing healthtech at country and regional levels; complex, lengthy and unclear healthtech licensing processes; poor infrastructure to power health technology; limited access to health care data; data insecurity; lack of protection for healthtech intellectual property rights; limited integration of healthtech systems; limited operational capacity for healthtech; poor coordination, partnerships, and collaborations; and insufficient funding for healthtech. Although the challenges are many, stakeholders prioritized the challenges related to licensing and data as the most urgent in efforts to accelerate the development and use of healthtech in Africa and these form the basis for the policy recommendations in section 3 of this Blueprint.

a. A lack of unified, comprehensive and updated set of policies governing healthtech at country and regional levels

Healthtech is an emerging area of focus in health care programming, therefore, there is a general lack of policies or frameworks that comprehensively address all aspects of the subject.[8] This is one of the most frequently cited obstacles to implementing and scaling-up healthtech in Africa.

For example, some innovators in Nigeria and Rwanda said the lack of a feasible policy on healthtech and patient privacy has made it difficult to scale-up some of their innovations. As a result, the relevant healthtech regulators in a country, which may include the Ministry of Health, the Ministry of Information and Communication Technology (ICT), a data protection authority and other agencies, often discuss healthtech issues on a case-by-case basis, which is time-consuming and does not allow for standardization of the decision-making process.

Where healthtech policies (sometimes called digital health policies) exist, they are often vague, incomplete, inconsistent and open to misinterpretation or are not implemented or enforced accordingly.[4] Healthtech policies vary widely within and between countries, thus making regional application challenging. In some countries data security and privacy policies do not specifically address health care issues. A research report from Rwanda shows how the lack of laws on ethical use of digital technology in health, including the protection of patient privacy, has impacted the way patients interact with health services.[15] Mozambique, Senegal and Tanzania have a range of policies and strategies to support health research and innovation, however, implementation of these policies and strategies is low because of inconsistency and lack of enforcement and accountability.[17]

Technology is rapidly evolving, however, public policy is not keeping pace with technological innovation and expansion. This limits the guidance available for healthtech innovations and makes it difficult for innovators or startups to understand how their products fit within the legal and regulatory framework of a country.[15]

b. Complex, lengthy and unclear healthtech licensing process

Licensing is essential for ensuring the safety and efficacy of healthtech innovations; however, it has been identified as a barrier because the licensing process is often cumbersome, unclear and lengthy.

Licensing includes all the processes required to register and secure government approval for a healthtech innovation and licenses and approvals differ according to the type of product, context or situation.

Healthtech licensing processes are time- and resource-intensive for innovators, they vary from country to country and can be different within the same country.[11] Most of the innovators interviewed for this Blueprint said the licensing processes in their countries are inefficient, lack clear and concise criteria, are poorly communicated and inconsistent, and hinder innovation. The processes are usually impacted by limited government capacity and bureaucracy, with long delays in receiving feedback and approval. The innovators also stated that in most cases the guidelines and requirements for obtaining licenses are not well defined and do not specify timelines for review and approval. The guidelines are not publicly accessible through the internet in most countries and therefore require more effort and time to obtain and understand. The licensing process lacks coordination across regulators and is typically paper-based and requires significant in-person engagement.

One innovator working on a health and well-being app said they spent significant time obtaining documents for a license even when the process was “fast-tracked” by government officials. It took one month to obtain initial approval from the biomedical center and up to four months to obtain approval to process the data outside the country. Another respondent said they had been waiting for almost a year to get their product registered. Such delays slow or limit implementation and scale-up of relevant technologies.

c. Poor infrastructure to support healthtech

Poor infrastructure, including unreliable electricity supply and limited internet connectivity, is a barrier to the adoption and sustainability of healthtech in most African countries.[18]

During the conversations, innovators and healthtech users frequently mentioned inconsistent supply of electricity as a major challenge to healthtech innovations. The situation is particularly bad in rural, and even some urban, areas. Many of the innovators said they experienced delays or were unable to scale their innovations in most rural areas due to a lack, or inconsistent supply, of electricity.

Many of the experts interviewed noted that limited access and unstable electricity supply creates severe limitations for the development and implementation of healthtech. The challenge with electricity supply often makes health workers maintain both paper and electronic systems, reverting to the use of paper systems when there is no electricity. Only half of the primary health care facilities in sub-Saharan Africa have access to basic water and sanitation services and only one-third have access to reliable electricity supply.[3]

Healthtech platforms cannot be operated without electricity, and the cost of procuring, servicing, and maintaining electric power generators is very high. An innovator in Nigeria said the energy policy, including the unstable electricity supply to health facilities, has made it difficult to scale-up their healthtech and to increase its reach.

Apart from the unstable electricity supply, there are challenges with internet connectivity and access. Establishing and maintaining a reliable internet infrastructure, whether fiber optic cables, cellular networks or satellite internet, is capital-intensive and many African governments are finding it difficult to finance it.[2] This is a service provided mostly by the private sector and because of this the cost of internet access is very high in many countries.[2] Where services are available, connection is not always guaranteed; there are challenges with limited bandwidth, network instability, slow speed, and high cost of data. Strong bandwidth is needed for video calls during teaching and teleconsultation.

During the interviews, there were concerns about health care workers who sometimes make personal out-of-pocket payments for internet access to carry out their duties at health facilities because their facilities have no, or limited, internet connection. This poses a serious challenge to the reliability and sustainability of healthtech services in such facilities.

The digital divide between and within countries is a barrier to healthtech innovations. As of 2021, some 96% of the 2.9 billion people who were still offline lived in LMICs.[16] Only 61% of Africans owned a mobile phone and 42% had an active mobile broadband subscription. Up to 15% of the continent's population lived outside internet network coverage and 14% had access only to a 2G network, meaning that 29% could not access the internet. Three hundred million Africans lived more than 50 kilometers from a fiber or cable broadband connection.[19]

The existence of this digital divide means that digital innovations may exacerbate the existing inequity in health care and undermine the economic, social and cultural rights of those affected. Implementing healthtech with limited infrastructure could, therefore, unintentionally further widen the digital divide in Africa especially among rural and hard-to-reach communities. The most vulnerable communities are most likely to be sidelined by healthtech innovations.

d. Limited access to health care data

While there has been progress in digitizing health data across LMICs, in many settings health data collection tools are not yet fully digitized, patient data are still stored on paper registers and patient cards and data collection and handling systems are fragmented.[2]

For example, most African countries that use the DHIS2 system still collect data on paper and enter them manually into the system every month.[20]

The government is responsible and accountable for protecting confidential and personal health data. However, in most cases, they are of the opinion that sharing data with innovators and the private sector increases the risk of breaching digital security systems and exposing personal data. Yet, if innovators cannot access health data, they are not able to develop appropriate and tailored solutions that are well-integrated into the health system.

Further, in some cases, policies and processes regarding access to health data from government health institutions by innovators are unclear and lack policies which allow innovators to directly collect patient data.[16] One innovator described how their inability to access telemedicine and telehealth data due to a restrictive policy hindered them from collecting and using patient data and information the way they should. Another innovator described how the use of paper-based data collection tools made it difficult for them to access and use health data for healthtech innovations.

Policies and regulations on data protection are inconsistent within and between countries which impacts resource allocation, coordination and accountability. A report showed that the ministries of health of Ethiopia, Kenya, Malawi and Rwanda have established policies to guide data governance, collection, storage and dissemination but have no system to routinely share data with other government entities or the private sector. Such situations limit access to health data, health system information such as health registries and other relevant information for healthtech innovations.[20]

e. Data insecurity

There have been concerns about the safety, security and accountability for health data and this has affected the willingness of health data custodians to share their data with third parties and to store their data, for example, in cloud-based servers outside their country.

Although data sharing has its benefits, there is a risk of system security breaches through malware attacks or hacking, which can expose private and confidential health information.[2] Data security can be breached through sale to third parties for use outside of the original plan for which healthtech users gave consent. There is a belief that government ownership of health data increases security, accountability and transparency which may not be a guarantee with private sector ownership.

Health data are particularly sensitive and open to misuse or abuse during storage or when shared with third parties.[15] Respondents questioned the practice of extracting and transferring health data from low-income countries or minority communities to more affluent countries often without the consent of those who provided the data. They said this may lead to ethnic profiling or other forms of data misuse, such as data breaches, misuse of personal information, or discriminatory practices; for instance, the risk associated with the exposure of sexual and reproductive health data in communities where certain health services like abortion are illegal or exposing the identities of LGBTQ+ community members in places where members of this group face persecution/stigma.[16]

f. Lack of protection for healthtech intellectual property rights

Regulations and laws regarding healthtech innovations and intellectual property rights vary from country to country and the legal proceedings are unclear because most countries do not have laws that specifically address healthtech issues.[4,5]

This raises concerns among innovators that their innovations can be copied and distributed without permission or compensation. Weak intellectual property right protection and enforcement and fear of copyright infringement in some countries has discouraged innovators and researchers from investing in healthtech or sharing their innovations with the government. Several interviewees said they had pitched their healthtech ideas to government officials, only to learn later that the concept had been shared with third parties, or that a government entity was taking forward the concept without their knowledge or permission. This has created tension and a lack of trust between the public and private sectors.

g. Limited integration of healthtech into health systems

The majority of healthtech innovations are created to provide solutions for specific disease programs, organizations, or health facilities. Also, within the same facility, digital systems sometimes vary across departments, e.g. outpatient, inpatient, laboratory or pharmacy departments.[2]

The data collection and storage tools and systems are mostly fragmented, thus making data management difficult. African countries that have invested in health data collection and storage have not invested commensurately in functioning interoperability frameworks that support integration into health information systems.[2,4] This lack of integration poses a serious challenge to data aggregation and data integrity and can be frustrating for health workers, policymakers, researchers and patients because of the additional time required to enter data into the different systems. It makes medical records and other patient data inaccessible to facilities other than the primary source or to different service points within the same facility. In some cases, there may be barriers to integration of health data collected by private sector actors into government data systems.

Limited integration constitutes a barrier to data interoperability among health system actors and the efficient use of data for healthtech solutions.[2,4] The inability to integrate data at the national level and across different disease programs has a negative impact on national health planning, programming, operations and budgeting and can be a barrier to the effectiveness of response efforts during health emergencies.[1] Without integration, innovators find it difficult to develop impactful solutions that provide optimal health systems benefits and governments are not able to sustainably implement healthtech solutions.

There is a greater challenge in digitizing and standardizing health data across countries because of the lack of integration at country level. This limits data interoperability and data exchange across health systems for learning, support and research purposes at the regional and global levels.

h. Limited operational capacity for healthtech

Limited operational capacity is one of the reasons for the slow adoption of healthtech in Africa. Technical capacity in the public sector to manage healthtech is inadequate in most African countries.[2,6] Our respondents noted that health systems, public health authorities and health workers are inadequately empowered to maintain and operate digital technology and to keep up with the latest developments in healthtech.

Therefore, support for healthtech operations is mostly outsourced to third parties. Such outsourcing limits the oversight of health systems and places major limitations on the digital operations of health facilities. It also places limitations on ownership of healthtech by health facilities, which in turn has serious implications for the safe and appropriate use of technology.

Further, many African countries lack data storage and hosting capacity, which impacts directly on their ability to implement healthtech policies effectively.[2] Some of the technologies used for healthtech in Africa are outdated and this has serious implications for quality-of-care and data security.[4]

Finding local service providers with the operational capacity to store and process health data in Africa is a great challenge, yet there are data hosting policies in some countries that require data to be maintained on local servers.[6] Some innovators said such policies and capacity limitations hamper their efforts to enhance innovation within and across countries.

i. Poor coordination, partnerships and collaborations

The multisectoral teams of experts involved in healthtech development and use at country level in Africa are often poorly coordinated. Often overlaps exist in the functions and activities of the multiple government agencies and partners that make regulation, licensing and other processes confusing and time-consuming.[17]

This poor coordination, coupled with limited collaboration and partnership, is a barrier to common understanding about the goals of healthtech and development of comprehensive context-specific guidelines and to effective development and deployment of innovative health technologies.

Some interview respondents noted that the public, private, nongovernment and research sectors frequently do not sufficiently collaborate to create an enabling environment for positive impact, which sometimes leads to conflicts. For example, when innovators are not engaged during policy development, their perspectives will be missed, which can limit the sustainability of any proposed solution. It would be difficult for healthtech to deliver improved health outcomes when the much-needed coordination, collaboration and partnership are absent. The stakeholders will not be able to understand each other's perspectives and challenges enough to be able to engage productively.

j. Insufficient funding for healthtech

Healthtech is among the least prioritized in health systems funding in Africa.[4] Healthtech can have high operational costs and is often perceived as a luxury compared to the provision of essential medicines, physical infrastructure, basic medical equipment, diagnostics and staff salaries.

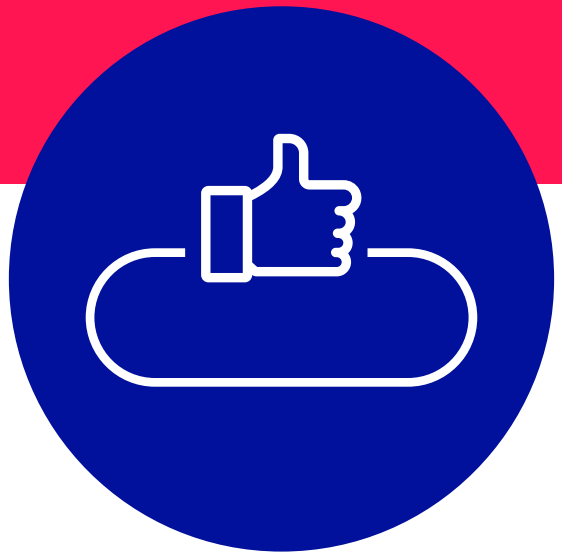
The lack of financial incentives for healthtech by the respective African governments makes it difficult for innovators to secure the capital needed to develop, implement and sustain their solutions.[4] It also makes it difficult for innovators to incorporate government priorities into their designs. The literature also confirms that lack of financial incentives makes it difficult for innovators to scale-up and that out-of-pocket fees impact poor households, further perpetuating the vicious cycle of poverty and inequity.[21] One report describes the extreme competition for funding among healthtech innovators and how governments can help.[22]

Participants interviewed for this Blueprint noted that the development and marketing of healthtech is a serious challenge for innovators who often have limited financial resources and cannot self-fund. Several innovators said it was difficult to acquire initial investment to fund a new idea. Some of them said the lack of funding delayed the creation and implementation of their healthtech innovation and slowed the process of getting their technology into the market. In addition, governments have limited experience in the procurement of digital health solutions and do not have the capacity to assess the quality of healthtech solutions. Similarly, innovators often have limited experience with government procurement processes.

One innovator said the health financing models in their country, such as health insurance and payment models, have a negative impact on public-private partnership. The home care system, which they said is essential to patients who cannot travel, is not included in the national insurance plan. Because of this, patients make out-of-pocket payments, which is unsustainable. Another innovator described how they charge clients to sustain their healthtech services.[21]

Many healthtech projects in Africa and other LMICs are donor-driven, which is not sustainable. Donor-funded solutions undermine the market for local healthtech innovations and sometimes limit the expansion of contextualized local solutions.

3. Healthtech Policy Recommendations



Healthtech Policy Recommendations

Healthtech holds the key to transforming health care and achieving Universal Health Coverage and the health-related Sustainable Development Goals in Africa and globally.[2,4,9]

It has a pivotal role to play in increasing access to health care to the rapidly increasing African population, including those in rural and hard-to-reach communities and vulnerable populations. However, to increase access using healthtech, African countries need to adopt a transformative approach to mitigate the challenges facing healthtech.[16]

Although the challenges outlined in section 2 of this Blueprint are numerous, during a multistakeholder meeting, two main categories of challenges were identified as priorities: (i) challenges associated with licensing of healthtech and (ii) challenges related to health data sharing, hosting and interoperability. This section highlights four key recommendations for addressing these two priority areas and for enhancing the transformation and optimization of healthtech in Africa.

The four recommendations are:

1. Establish or strengthen existing mechanisms for dialogue and coordination among healthtech stakeholders
2. Review and refine policies regarding access to, hosting and interoperability of health data to accelerate innovation while safeguarding data
3. Establish streamlined and transparent healthtech licensing systems at country level
4. Make progress towards regional healthtech harmonization and licensing platforms

The recommendations highlight key actions to be taken by stakeholders and some expected outcomes. These recommendations are broadly applicable, but would need to be tailored by individual countries to their specific situation and needs. Each recommendation has some practice cases from around the globe to provide lessons and examples of how each of the recommendations has been implemented in different contexts.

Before describing each of these recommendations, the following subsection highlights the roles and responsibilities of the different healthtech stakeholders, as critical prerequisites to understanding the interlinkages between them and how to involve them optimally.

a. Healthtech stakeholders and their roles

Healthtech stakeholders are diverse and play complementary roles in technological innovations, licensing and access. The government, as the custodian of healthtech policies, represented by the ministries, agencies and parastatals; the legislature; and health authorities play a lead role and need to work closely with the other stakeholder groups. The following highlights the key roles and responsibilities of different stakeholder groups and the support they require from one another to function effectively. This stakeholder analysis aims to facilitate targeted advocacy and consultations at all levels of regulation and implementation.

Stakeholder group	Roles/responsibilities	Type of support needed from other healthtech stakeholders
Government – represented by the ministries, agencies, parastatals mandated to tackle healthtech issues	• Ensure availability of basic infrastructure to support healthtech. • Develop/review/update policies relevant to healthtech. • Develop a framework for monitoring and evaluating healthtech implementation. • Facilitate integration and alignment of healthtech across health programs. • Provide incentives to healthtech innovators. • Develop a framework for data sharing with healthtech startups and innovators. • Issue public procurements for relevant healthtech	• Research evidence on progress and gaps in healthtech implementation • Policy/advocacy briefs to help them understand the healthtech situation • Feedback from innovators and technology users • Supplemental funding from donor and development organizations • Feedback on policy implementation to support improvements
Regulatory authorities	• Establish policy framework to regulate healthtech, including data access and protection ethics. • Assess and assure the quality of healthtech solutions.	• Healthtech policy documents • Training on healthtech regulatory practices • Updated information on international best practices, guidelines and recommendations • Research evidence on progress and gaps in healthtech implementation • Feedback from innovators and technology users

Stakeholder group	Roles/responsibilities	Type of support needed from other healthtech stakeholders
Health managers and specialized institutions that have the mandate for health care provision	• Provide guidance on the use of healthtech. • Ensure appropriate implementation of healthtech policies. • Ensure that providers have the capacity to implement and correctly use healthtech. • Facilitate integration of healthtech across health programs. • Secure adequate funding for implementation of healthtech. • Advise government on the procurement and commissioning of healthtech.	• Government financing as well as partnership financing by the private sector and the donor community • Support with community engagement • Feedback from other healthtech stakeholders • Access to policies • Enabling environment to operate healthtech
Legislators/lawmakers	• Deliberate and approve laws and policies to regulate the provision and use of healthtech. • Support mechanisms for ensuring accountability in healthtech implementation.	• Research evidence on progress and gaps in healthtech implementation • Policy/advocacy briefs to help them understand the situation of healthtech • Support in drafting healthtech legislation and bills
Civil society	• Facilitate partnerships and collaborations among all healthtech stakeholders. • Foster accountability by government, platform providers, platform users and innovators. • Support policy advocacy and fundraising for healthtech implementation. • Support demand creation for healthtech. • Ensure the involvement of communities in healthtech policymaking. • Engage communities to document their input into healthtech policies. • Monitor ethical use of healthtech by all stakeholders. • Monitor healthtech implementation to ensure accountability.	• Funding by donor and development organizations • Research evidence on progress and gaps in healthtech implementation • Compliance by innovators, regulators and end-users • Access to policies • Updates on healthtech implementation

Stakeholder group	Roles/responsibilities	Type of support needed from other healthtech stakeholders
Innovators and healthtech service providers, including health information professionals	• Develop patient-centered healthtech innovations. • Ensure regular and reliable provision of healthtech services. • Conduct research to improve healthtech innovations and services. • Continuous improvements of health technologies. • Facilitate capacity-building for optimum use of healthtech. • Understand country-level priorities and ensure alignment to relevant regional and global strategies. • Provide input and feedback to the government and regulators. • Ensure privacy and security of data collected/ provided.	• Research evidence on progress and gaps in healthtech implementation • Feedback from technology users • Enabling environment that will allow them to operate creatively, consistently and sustainably • Government priorities in terms of health system challenges and needed innovations • Guidance on compliance with relevant laws, regulations and policies • Incentives for the development and scale-up of innovations • Access to policies
Health care providers	• Provide feedback to innovators, government and civil society on the effectiveness and efficiency of adopted healthtech. • Support monitoring, evaluation and operational research for the improvement of healthtech • Publish findings on their healthtech experiences. • Share data with healthtech startups and innovators.	• Enabling environment to provide candid and objective feedback • Funding for clinical trials where necessary • Access to policies
Patients and everyone accessing health care services	• Provide feedback to innovators, government and civil society on the effectiveness and efficiency of adopted healthtech. • Support monitoring and evaluation of healthtech. • Participate in research activities as respondents. • Allow data use by healthtech innovators.	• Enabling environment to provide candid and objective feedback • Access to policies

Stakeholder group	Roles/responsibilities	Type of support needed from other healthtech stakeholders
Researchers and research institutions	• Conduct research on various aspects of healthtech. • Publish and disseminate research findings to provide evidence for policymaking. • Provide data for improving the quality of care with the use of healthtech. • Facilitate knowledge- and experience-sharing among stakeholders.	• Funding for different types of research on healthtech, including clinical trials • Access to policies • Updates on healthtech implementation
The media	• Support demand creation for healthtech. • Set the stage for productive debates and discussions on healthtech.	• Research evidence on progress and gaps in healthtech implementation. • Access to policies • Updates on healthtech implementation
Donor and development agencies	• Provide funding for healthtech research, including testing of innovations and healthtech sandboxes. • Provide technical support, including training and planning, for healthtech implementation.	• Research evidence on progress and gaps in healthtech implementation • Access to policies • Updates and progress reports on healthtech implementation

b. Policy recommendations

Recommendation 1: Establish or strengthen existing mechanisms for dialogue and coordination among healthtech stakeholders

A clear pathway for building effective partnerships that foster mutual understanding, co-creation and alignment of healthtech processes should be established under the coordination of respective national governments. Such partnerships will enhance dialogue and collaboration among stakeholders for the development of innovative solutions while safeguarding patient data.[2,4-6,14] The coordination mechanisms should be inclusive of a broad set of stakeholders involved in different aspects of developing and implementing healthtech and those impacted by healthtech solutions, including representatives of government, health care providers and institutions, patients, civil society, private sector, funders, international and bilateral organizations and healthtech experts.

Establishing or strengthening mechanisms for regular dialogue will create avenues for government officials to provide timely information to stakeholders about their healthtech strategies and priorities as well as updates on policies and processes.[4,5] Innovators will have an opportunity to share information about solutions they are developing or planning and provide feedback on their experiences. Such mechanisms may include steering committees or technical working groups that can monitor and ensure sustainability of healthtech. It is essential that users and beneficiaries of healthtech, e.g. health workers, health care service providers, civil society representatives, patients and the community, are a central part of the dialogue because they are directly impacted by government policies and innovators' solutions.

A multistakeholder partnership that includes patients, health care providers, families, caregivers, and communities will enable the development of programs and innovations that are targeted to meet patient needs and pave the way for greater efficiency, effectiveness, equity, patient-centeredness, safety and timeliness.[2,4-6,14] Strong partnerships will ensure that healthtech interventions are properly integrated into the health system. They will provide opportunities for regulators, innovators or startups and technology users to interact, discuss challenges together and identify ways to improve processes and technologies. This will enhance sustainability and scalability of innovations. Through partnerships, innovators can receive information about available funding mechanisms and governments can provide dedicated funding for solutions that align with national priorities, thus accelerating progress towards the achievement of healthtech indicators. Although the structure of partnerships may vary by country, the principle should be the same.

One specific opportunity for enhanced coordination is data governance, which encompasses issues related to health data, such as patient data privacy and protection, private sector access to health data, data hosting and use of cloud-based systems.[2,4-6,14] The establishment of an effective data governance entity would help in identifying issues and discussing potential solutions; identifying opportunities to review and update health data-related strategies, policies, regulations and processes; and provide a suitable mechanism for stakeholders to make input to any healthtech policy and framework reviews conducted.

Specific actions to establish or strengthen dialogue and coordination

- Map existing entities and forums in the country that can be leveraged to enhance coordination among stakeholders on healthtech, e.g. technology accelerators or incubators, healthtech technical working groups, science and technology forums, etc.
- Within these existing forums, establish regular points of dialogue between government, innovators, regulators and other stakeholders.
- Where necessary, establish new coordination mechanisms to supplement existing forums.
- If not already existing, establish an intellectual property protection and confidentiality system to enable and encourage open dialogue between innovators and governments.
- Ensure that beneficiaries and users of healthtech are well represented in coordination mechanisms.
- Establish a country-level multistakeholder, multisectoral data governance coordination entity to engage on health data issues, as part of broader efforts to enhance stakeholder coordination and collaboration. This entity should be convened by the Ministry of Health and should include representatives of other relevant government agencies, health care providers and institutions, patient advocacy groups, private sector, NGOs, international organizations and technology and data experts.

Expected outcomes and impact of establishing or strengthening dialogue and coordination

- Increased awareness, clarity and understanding among stakeholders of the different perspectives, considerations and challenges related to data access, storage, and use; innovation licensing; and the development and use of healthtech.
- Direct connections between government, innovators, funders and healthtech users, enabling them to engage and agree on actions, including healthtech policy and framework reviews, clarifications and improvements.
- More opportunities to capture lessons, best practices and identify optimal regulatory frameworks.
- Shared understanding and more collaborative engagement among all stakeholders, leading to more efficient processes, user-friendly products and better patient outcomes.

Case Studies

Coordination practice case 1: South Africa National Science and Technology Forum

The National Science and Technology Forum (NSTF) is an example of a large, multi-stakeholder, multisectoral, collaborative forum that promotes technological innovations and engages with government on related policy issues. It is a non-profit initiative that seeks to influence policy through dialogue and support for technological innovations. NSTF serves as a watchdog for influencing the formulation and delivery of science, engineering, technology and innovations primarily in South Africa and other countries. It provides information, raises awareness, and hosts networking platforms, discussion forums, youth engagement and awards on current technological innovations.

Since its establishment in 1995, NSTF has grown to become the largest and most formidable stakeholder network of its kind. Its 124 members, made up of organizations, councils and national institutions, have used their professional expertise and experience to provide groundbreaking solutions to challenging human and developmental issues through technological research and innovation. This is an example of best practice for coordination, collaboration and partnership that African governments can establish or plug into for the advancement of healthtech.

Resource: https://nstf.org.za/

Case Studies

Coordination practice case 2: Government–innovator dialogue in Rwanda facilitated by HealthTech Hub Africa (HTHA)

HTHA supports healthtech innovators across Africa and has a physical co-working and community space in Kigali, Rwanda. It has been at the forefront of enhancing collaboration between government stakeholders and healthtech innovators in Rwanda. For example, in March 2023, HTHA convened a healthtech policy summit in Kigali attended by 65 startup healthtech innovators, private sector investors and high-level government officials from Rwanda and Senegal. The participants discussed in plenary and small groups alongside healthtech innovators (founders and chief executive officers) on a range of healthtech policy topics.

Deep dive breakout group discussions at this summit focused on two topics: (1) data protection and sharing and (2) licensing and procurement. The government and innovators shared experiences and perspectives on the state of healthtech and key challenges. Based on the discussions they made recommendations on how the public and private sectors could further their engagement. For example, regarding data protection and sharing, they identified the need to co-develop a technical checklist that would enable government to evaluate the data policy and protective measures of healthtech startups and provide innovators with guidance on how to be accountable.

HTHA has held other in-person dialogues between healthtech innovators and minister-level government stakeholders in Rwanda to share information, perspectives and feedback. HTHA serves as an example of how governments can leverage existing forums to enhance dialogue and collaboration with healthtech stakeholders, including innovators.

Resources: https://thehealthtech.org/; https://thehealthtech.org/summits/blueprint-summit-2023/

Coordination practice case 3: VillageReach-supported introduction of drones in Democratic Republic of Congo through a multisectoral coordinated approach

Building on its initial work in Malawi on introducing drones for health care delivery, in 2018, VillageReach began supporting the Democratic Republic of Congo (DRC) to integrate the use of medical drones into the health system to improve transportation and distribution of vaccines, laboratory samples and other medical supplies to low-resource and hard-to-reach communities.

This led to the development of the Drones for Health project a partnership between the DRC Government and VillageReach. Using the government procurement system, a private sector drone provider was selected to operationalize medical drones transport service in the country.

The use of drones requires strict coordination among multiple government entities responsible for civil aviation, defense, import taxation, health, information and technology, communication, medical regulation, among others. Due to this, careful coordination was critical to the establishment of the Drones for Health operations. The project is being implemented in partnership with the Ministry of Health, Ministry of Interior, Ministry of Defense, Ministry of ICT, CAA, Gavi, Swoop Aero, among others. This broad multisectoral partnership and coordination is critical for successful integration into the public sector and development of clear regulations and processes. It makes alignment with government priorities possible and enhances sustainability of the initiative.

Coordination practice case 3 (cont.)

Phase 1 of the project integrated drones into the healthcare supply chain of Equateur Province. VillageReach collaborated with partners to establish a National Drones for Health Commission and a Provincial Working Group, providing governance and oversight for all drone-related healthcare activities. To ensure safe operations, VillageReach supported the Civil Aviation Authority in developing regulatory guidelines and standard procedures.

Building on this success, VillageReach partnered with the Ministries of Higher Education and Labor to establish Central Africa's first drone academy, addressing the need for a skilled workforce to support the growing drone industry in the DRC. Furthermore, at the recommendation of VillageReach, the Minister of Industry dedicated a section of the Special Economic Zone for drone manufacturing and assembly.

This example underscores the potential of healthtech innovations to deliver greater returns when developed, introduced, and managed effectively through multisectoral collaboration. While this case focused on a single innovation, ideally, governments should partner with healthtech stakeholders to create broader collaboration mechanisms and platforms adaptable to emerging innovations.

Resources:
https://www.villagereach.org/wp-content/uploads/2020/12/DRC-Webinar-2019.pdf
https://www.villagereach.org/wp-content/uploads/2020/12/DRC-Poster-2019.pdf

b. Policy recommendations

Recommendation 2: Review and refine policies regarding access to, hosting and interoperability of health data to accelerate innovation while safeguarding data

A policy framework is the starting point for effective regulation of healthtech systems and specific technologies.[2,4-6,14] Governments should review their healthtech policies, where they exist, to identify gaps and shortcomings. Existing policies may require updates to accommodate the evolving landscape of health technology, such as virtual service delivery, digital tools for expanding healthcare worker roles and compensation, and remote consultations. In instances where relevant policies are absent, new frameworks should be established.

Policy makers should draw lessons from best practices and standards set by regional, global and expert bodies such as the Africa Union/Africa CDC, WHO, the World Bank, etc. and should tailor their policies to local context and priorities. For example, the Health Data Governance Principles developed by Transform Health (see policies and regulatory framework practice case 2) and the Health Information Exchange Guidelines and Standards developed by Africa CDC.

During consultations at the healthtech policy summit in Kigali, the following emerged as specific areas requiring policy and regulatory attention for expanding the use of healthtech.

Private sector access to health data: Difficult trade-offs must be managed with regards to the sharing of health data with the private sector. Governments are accountable for the protection of individual private health data, but without access to data, innovators cannot develop impactful solutions and integrate them into the health system. Governments should review and clarify policies and processes governing private sector access to and use of health data and health systems data (e.g. health facility registries), encompassing both data shared by health institutions and those collected directly from patients. Updated policies should reflect best practices in data governance, including establishing security measures to minimize the risk of data breaches.

Use of cloud-based services for data hosting and analysis: In some countries, existing policies require that health data be hosted on local servers. This can hamper innovation by restricting the sharing and pooling of data across countries and the additional insights this could provide. It can also create operational challenges when in-country data hosting capacity is insufficient. Cloud-based services can offer advantages in terms of cost, functionality and cybersecurity. Governments should revisit their policies to optimize the balance between strategic, operational and data security objectives and identify opportunities where data can be stored and analyzed on cloud-based services, e.g. aggregated and regional data hosting on Africa-based servers.

Interoperability of health data: Progress remains slow in digitizing health data and adopting interoperability standards and frameworks within and across countries, thus creating a bottleneck for the advancement of healthtech and limiting data exchange and integration of systems.[2-6] Some standards development organizations, for example, Health Level Seven International and Integrating the Health Enterprise, have developed standards that have been adopted or adapted in many countries. Governments should accelerate efforts to refine their interoperability strategies and advance priority initiatives in defining and adopting standards, in collaboration with regional and international partners and interoperability forums. To make healthtech interoperable, healthtech strategies should be an integral part of the overall national health strategy.

A multi-stakeholder approach involving healthtech innovators, health workers, patients, professional associations, civil society, etc. should be adopted during the review and development of healthtech policies and regulatory frameworks to ensure they are comprehensive, address the needs of all the stakeholders and are implementable.[2, 4-6,14]

Specific actions to streamline health data policies

General policy review and principles

- Healthtech continues to evolve rapidly; therefore, regulators should familiarize themselves with emerging best practices and standards in healthtech and participate in peer exchange forums to update their policies and frameworks regularly to align with latest technological advancements.
- Ensure effective translation of policies to implementation by involving stakeholders responsible for implementation in the policy design process and developing clear operational guidelines to clarify their implementation.
- To facilitate the development of policies for new healthtech areas with undefined regulatory approaches, countries can implement a 'regulatory sandbox', whereby innovators and regulators jointly convene to define specific requirements and parameters for pilot-testing, with regular progress review. One of the outputs of this process can be lessons to inform the development of a long-term regulatory approach (See section 4 for more information about sandboxes).

Specific actions to streamline health data policies (cont.)

Private sector access to health data

- Review and refine policies and processes for private sector access to health and health systems data, differentiating between accessing government-held data and directly collecting patient data.
- Define the types of health data and personal information that can be accessed and collected by the private sector and apply best practices in data governance, including developing a framework for fair use of such data, making provision for obtaining informed consent from individuals, as well as for purpose limitation, anonymization and security.
- Simplify, streamline and communicate the process for requesting access to health data and create centralized digital platforms for innovators to submit their requests.
- Define the criteria for evaluating the security measures of private sector institutions accessing health data to mitigate the risk of data breaches.

Specific actions to streamline health data policies (cont.)

Use of cloud-based services for data hosting and analysis

- Reassess data hosting policies, including the use of cloud-based services for data hosting and analysis, in comparison with global and regional best practices. Consider strategic implications (e.g. impact of policies on the ability to meet healthtech priorities and use technologies) and revisit data security implications (e.g. relative strength of in-country versus cloud-based security measures).
- Assess in-country operational capacity to host data and investments required to expand existing capacity to meet future needs versus use of cloud-based services.
- Identify opportunities to refine policies, including clarifying principles and regulations on when cloud-based services can be used (e.g. translating recurring exceptions that allow cloud-based storage into formal policy) and differentiating data hosting requirements by type of data (e.g. aggregate versus individual).
- Explore opportunities to test and evaluate cloud-based services, e.g. regional data hosting.
- Invest in infrastructure that will enhance local data hosting capacities at all levels of the health care delivery system, while identifying near-term solutions that will not limit the advancement of innovation while that infrastructure is being developed.
- The private sector and other partners should provide technical assistance and capacity-building support to governments for the establishment and maintenance of robust data hosting infrastructure.

Specific actions to streamline health data policies (cont.)

Interoperability of health data

- Building on existing mapping, review the status of information systems, interoperability layers and associated standards and regulations to identify gaps and opportunities.
- Develop or refine the interoperability strategy and define overall objectives for data exchange and integration. Identify specific use cases where interoperability is critical and prioritize specific systems and types of data and stakeholders that need to be interoperable.
- In prioritized areas, determine the interoperability standards and specifications, leveraging internationally accepted interoperability standards and frameworks, e.g. from international standards development organizations such as Health Level Seven International, IHE International. Create guidelines for the adaptation of international standards to local needs and their implementation.
- Partner with regional and international agencies such as Africa CDC, WHO and participate in interoperability forums such as the Pan-African Health Informatics Association (HELINA) to access technical assistance, testing platforms, knowledge exchange and other resources.
- Working closely with the private sector, make direct investments in health information systems, digitization of health data, establishment and implementation of standards and testing and certification of interoperability.

Expected outcomes and impact of streamlined health data policies

- Clearer, more appropriate and more effective policies and regulations that draw from global, regional and national best practices and are tailored to the local context.
- Policies that holistically reflect the perspectives of regulators, developers, users and beneficiaries and are thus implementable, enforceable and responsive to needs.
- Refined policies that appropriately balance trade-offs between fostering health technology innovation, protecting patient data and operational implications.
- Sufficient and standardized frameworks that allow for continuous monitoring and evaluation of compliance to quality and ethical standards regarding data and innovations, including evaluation of security systems of innovators and management of the risks associated with personal data exposure.
- Enhanced capacity to securely store health data, thus allowing data hosting policies to be effectively implemented.

Case Studies

Policies and regulatory framework practice case 1: Data security and privacy policy in Kenya

In Kenya, the Health Act, 2017, under section 104, mandated the enactment of e-health legislation for providing guidelines for the administration of health information banks, including interoperability, data interchange, and security, the collection and use of personal health information, and health service delivery through m-health, e-learning, and telemedicine. This set the foundation for the development of the Digital Health Act.

In October 2023, building on the Health Act 2017, the president of Kenya signed into law the Digital Health Act 2023, to promote privacy, confidentiality and security while facilitating health data sharing and use for informed decision-making. The Act proposes the establishment of a Digital Health Agency to provide oversight for health information systems and associated data governance concerns.

The Digital Health Act 2023 is one of four bills proposed to operationalize the Health Act 2017 and healthtech policy in Kenya, bridge existing legal and regulatory gaps in healthtech and facilitate the realization of Universal Health Coverage in the country. It aims to help increase access to health care and improve health outcomes, especially in remote and hard-to-reach communities. The Act sets a precedent for other African countries on the regulation of healthtech.

Resources:
https://www.ecolex.org/details/legislation/public-health-act-cap-242-lex-faoc129231/#:~:text=This%20Act%20concerns%20the%20protection,of%20nuisances%20including%20nuisances%20arising

http://www.parliament.go.ke/sites/default/files/2024-02/THE%20DIGITAL%20HEALTH%20BILL%2C%20NATIONAL%20ASSEMBLY%20BILLS%20NO.%2057%20OF%202023.pdf

https://www.president.go.ke/president-ruto-new-healthcare-plan-will-leave-no-one-behind/

https://www.kelinkenya.org/patient-empowerment-innovation-interoperability-and-privacy-the-core-of-the-digital-health-bill-2023/

Case Studies

Policies and regulatory framework practice case 2: Health data governance principles

The Health Data Governance Principles were developed by Transform Health in 2021 to address the challenges with health data governance, including the complex data collection, processing, storage, analysis, use, sharing and disposal processes. It is intended as a comprehensive set of principles to guide health data governance globally and across health systems. The principles are in three categories and a small subset of the specific principles in each category is provided to illustrate the overall framework:

1. **Protect people:** collect personal or sensitive data only when necessary and with informed consent; use de-identification and anonymization; define inappropriate use of health data; require strong technical security measures for data processing; ensure transparency around data breaches.
2. **Promote health value:** establish data sharing rules and guidelines; define common data structures across health systems; apply health data governance to emerging technologies; use data to enhance health services for individuals and communities.
3. **Prioritize equity:** consider the unique needs of marginalized groups and populations; mitigate data bias; define clear governance roles and responsibilities; develop health data trust and cooperatives; employ participatory data governance mechanisms.

The principles are applicable and can be used by a wide range of stakeholders, including governments, the private sector, international organizations, civil society, innovators, etc. They are unique and different from other existing principles because they were developed and driven by civil society through engagements with governments, international organizations, civil society, research institutions and private sector actors. They provide guidance for the development and adaptation of health data policies.

The governments of Cameroon, Philippines, Sri Lanka, as well as the World Bank, PATH, Jhpiego and other organizations have already endorsed these principles as best practice on health data governance that governments can adapt.

Resource: https://healthdataprinciples.org/principles

Policies and regulatory framework practice case 3: Data interoperability in India – the Ayushman Bharat Digital Mission

The Ayushman Bharat Digital Mission (ABDM) was launched by the Government of India in 2021 to promote digitization of health care and create an open interoperable healthtech system for the country. It allows various health care providers who may be using different healthtech systems to share data with one another. The basis for ABDM is the National Digital Health Blueprint, which was developed in 2019 and provides the overall vision and framework for the creation of India's integrated healthtech infrastructure.

To achieve interoperability, ABDM recommends common standards that are based on internationally recognized standards and frameworks for different types of health data, including Fast Healthcare Interoperability Resources (FHIR), Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT), International Classification of Diseases 10th Revision (ICD-10) codes, Digital Imaging and Communications in Medicine (DICOM) and Logical Observation Identifiers Names and Codes (LOINC).

ABDM is based on a set of core modules: patient registry (using a unique 14-digit identification number for each individual and an electronic record of health-related information); health care professionals registry; health care facilities registry; drug registry; etc. The Health Information Exchange and Consent Manager facilitates exchange of health information between a health information provider (e.g. a health care provider or a diagnostic center generating laboratory reports) and a health information user (e.g. another health care provider or patient). A key feature of ABDM is its use of federated health data structure whereby data is stored at the source (e.g. a server or device currently being used by a health facility or provider) rather than in a single, central system.

Policies and regulatory framework practice case 3 (cont.)

Participation in ABDM is voluntary for all stakeholders, however, it has been encouraged through the provision of financial and non-financial incentives. To facilitate integration into the health system, a sandbox platform was created, which offers a testing environment for stakeholders to pilot interoperability solutions, validate standards compliance and evaluate interoperability capabilities. A suite of resources such as guidelines, documentation of integration mechanisms, tutorials and webinars are available to support health care professionals, integrators and developers.

ABMD can serve as a potential model for other countries aiming to achieve health data interoperability and to create a platform for health data exchange.

Resources:
https://abdm.gov.in/
https://sandbox.abdm.gov.in/
https://www.dpi.global/globaldpi/abdm
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10064942/

b. Policy recommendations

Recommendation 3: Establish a streamlined and transparent healthtech licensing process at country level

To reduce barriers to licensing, there is an urgent need to establish a simplified, transparent, documented and digitized one-stop licensing process managed by appropriate regulatory agencies with expertise in health technologies and procedures. Licensing guidelines should clearly state the licensing requirements, timelines for review and government contact points. In the short-term, information on the licensing process should be made accessible online so that all innovators can access and incorporate it into their planning without the need for in-person engagement with regulators.

Beyond sharing licensing information online, regulators should develop a digital platform to facilitate the entire licensing process, which would serve as the main portal for innovators and regulators to interact on submissions.[2,14] A technical committee on licensing may be needed to enhance dialogue and collaboration among key stakeholders involved in licensing of health technologies, facilitate coordinated development and refinement of licensing requirements and regulations and facilitate decision-making on unique and challenging issues. Government should create forums to engage with innovators and provide orientation on the licensing process during the early stages of their projects.

Specific actions to establish streamlined and transparent healthtech licensing process

- Convene a cross-regulator technical committee at country level, with representatives of all relevant agencies and partners responsible for regulating licensing of healthtech, e.g. ministries of health and ICT; data protection authorities; innovators; etc. to deliberate on and resolve licensing issues, and advise on other pertinent issues.
- Create terms of reference for membership; roles and responsibilities; procedures for identification and initiation of topics for adjudication; decision-making approach; and cadence for the technical committee.
- Consolidate, map and review all existing policies and guidance documents. Address gaps and inefficiencies and publish a unified and streamlined set policies and guidelines for healthtech licensing. As license types will vary by the type of technology, it is critical to first categorize the technologies and identify the licenses and processes relevant for each technology type.
- Digitize the licensing process to facilitate online submissions by innovators and provide real-time updates on the status of each application.
- Develop and disseminate, on the digital platform, information relating to the licensing pathway, which specifies roles and responsibilities, processes and procedures, timelines, specific requirements and points of contact for healthtech licensing.

Expected outcomes and impact of a streamlined and transparent healthtech licensing process

- Gaps and inefficiencies in the licensing process identified and actions taken to address them.
- Standardized, efficient, timely and timesaving licensing process, including the resolution of unique licensing issues for emerging technologies, which reduces the time and resource requirements for government and innovators.
- Licensing requirements that are well understood by innovators, consistently and fairly applied to all innovators and facilitate the development and introduction of appropriate products that fit well within the regulatory framework.
- Licensing issues and questions addressed holistically across regulators, rather than in silos.
- Increased transparency in the licensing process.

Case Studies

Health technology licensing practice case 1: The Singapore healthtech platform

Singapore has been recognized as a leader in the use of healthtech. To ensure coordination among the country's several providers and standardize devices being used across the country, in 2017, the Singapore Health Sciences Authority (HSA) developed its first set of guidelines for all healthtech devices. Other guidelines were subsequently developed to provide comprehensive guidance on registration, licensing, consultations, regulation and safe use of artificial intelligence. These guidance documents are available on a user-friendly, one-stop-shop platform for manufacturers, developers, providers and users of healthtech.

Availability of these guidance documents has helped simplify registration, approval and licensing of healthtech products in the country, guiding users efficiently and quickly through the regulatory process. Through the platform, users have access to all relevant guidance documents, including those specific to telehealth products, software medical devices and Artificial Intelligence in Health care alongside relevant application forms.

This streamlined approach has allowed innovative health solutions to reach the market quicker, benefiting businesses and patients. It has enhanced transparency and accessibility, as stakeholders find it easy to understand and fulfill local regulatory requirements. This is an example best practice for a digital information platform for healthtech.

Resource: https://www.hsa.gov.sg/medical-devices/digital-health

Case Studies

Health technology licensing practice case 2: Indian medical devices online registration

India's Central Drugs Standard Control Organization (CDSCO) is an example of a digital licensing platform by a LMIC. CDSCO, the national regulatory authority for medical devices in India, operates a portal for the online submission of applications by innovators and businesses seeking approval for the manufacturing of a new medical device, importation of a medical device or conducting a clinical trial for a device. All processes are managed online, including preparation of relevant documentation, submission, review, approval, as well as post-approval surveillance, quality management, reporting of adverse events, renewal of registration and product updates. Processing time typically takes 6–9 months (or longer for innovative devices) and applicants can track the status of their applications online. The CDSCO portal can be used as an example for governments interested in developing a one-stop online licensing portal to manage submission and approval of healthtech.

Resource:
https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/MDFAQ1324.pdf
https://cdscomdonline.gov.in/NewMedDev/Homepage

b. Policy recommendations

Recommendation 4: Make progress towards regional healthtech harmonization and licensing platforms

While countries make efforts to strengthen their individual healthtech systems, they should also begin discussing regional harmonization as a longer-term goal within the framework of existing regional structures. Regional harmonization will facilitate the integration of healthtech platforms and programs within and across countries in a particular region and facilitate interconnectivity and interoperability among the different actors.[2,4-6] It will help in streamlining administrative and operational processes, including licensing and standardization of data collection and assessment tools. With regional harmonization, data exchange and licensing will become more simplified and integrated within and across countries, thus increasing access physically and virtually to data from government health institutions and the private sector. Harmonization will help reduce variations in licensing processes across countries and enhance scale-up of effective technologies regionally. For example, countries can agree on a regional or subregional healthtech license "passport" that will help expedite licensing across a group of countries or in a region and eliminate the need for innovators to obtain new licenses in each country within the region. Harmonization will enhance peer-to-peer engagement and learning across countries. Even if harmonization is not possible in the short-term for all aspects or types of healthtech, establishing harmonization in selected areas can still be of significant value for regulators and innovators.

Specific actions to progress towards regional healthtech harmonization and platforms

- Establish a pan-African level health technology regulatory working group with representation from the regional economic communities, to provide a forum for sharing experiences and best practices and identifying opportunities for inter-country collaborations.
- Review and compare approaches across countries in the region to identify and facilitate alignment in policy and licensing.
- Develop unified policy frameworks that could be uniformly implemented by countries in the region or sub-region. Draw from and build on existing regional and international standards and harmonization efforts (e.g. the Africa Union/Africa CDC Health Information Exchange Guidelines and Standards) and leverage international experts to assist with specification, adaptation and adoption.
- Identify and pursue opportunities to coordinate health technology licensing across the countries, such as establishing a 'regional passport' that will allow licenses granted in one country to be recognized in the other countries within the region.
- Establish a unified digital platform for licensing health technologies by countries in the region.

Expected outcomes and impact of regional healthtech harmonization and platforms

- Greater consistency in regulatory and licensing processes across countries in a region and enhanced alignment with established standards and regional and international best practices.
- Reduction in the amount of time and resources required to develop, introduce and facilitate adoption and scale-up of effective technologies by countries in the region.

Case Studies

Regional harmonization practice case 1: IGAD regional cross-border health data sharing and protection policy framework

The Intergovernmental Authority on Development (IGAD) countries – Djibouti, Eritrea, Ethiopia, Kenya, Somalia, South Sudan, Sudan and Uganda – identified a critical gap in health data sharing and protection among them despite the regular movement of populations across their borders. This gap posed a significant challenge to the provision of health care to the mobile populations. In March 2022, IGAD Member States endorsed the IGAD Regional Health Data Sharing and Protection Policy Framework to facilitate ethical health data sharing within and across the eight countries.

The framework aims to strengthen disease surveillance and enhance the capacity of countries in the sub-region for preparedness and response to health emergencies. While prioritizing the rights of individuals to privacy and significant control over the use and sharing of their personal health data, the policy provides clear guidelines on consistent, coherent and standardized health data sharing among the countries. It clarifies the roles of different actors involved in the collection, use and sharing of relevant health data to ensure transparency and accountability. IGAD also developed an implementation guide to assist countries in adopting and implementing the framework.

IGAD continues to conduct advocacy and training to enable its Member States adopt and domesticate the framework. This is an example of regional harmonization of policy on data sharing and protection.

Resource:
https://igad.int/download/igad-regional-health-data-sharing-and-protection-policy-framework/

Regional harmonization practice case 2: Comparison of online pharmacy regulations across African countries

Pharmacies and consumers across Africa are increasingly adopting online services for the sale and purchase of health-related goods and services, making it essential to establish regulations and guidelines for online pharmacies. During the first half of 2023, Salient Advisory conducted a rapid assessment of the regulatory frameworks for the operation of online pharmacies in selected African (Benin, Burkina Faso, Cote d'Ivoire, Ethiopia, Ghana, Guinea, Kenya, Mali, Mauritania, Niger, Nigeria, Rwanda, Senegal, South Africa, Togo) and non-African (India, Indonesia, Pakistan, Singapore) countries.

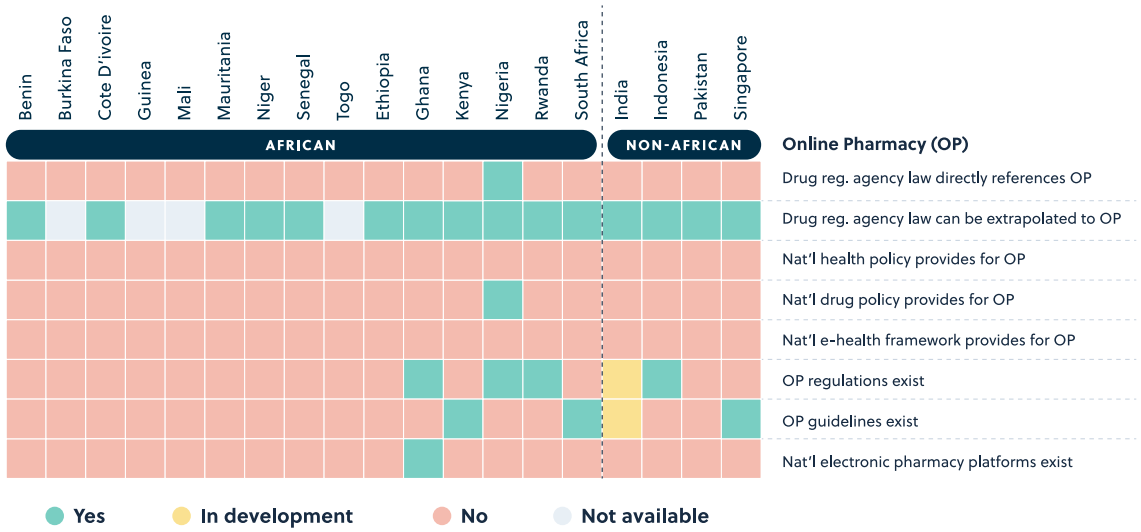
The process that Salient Advisory followed provides a potential template for how a pan-African group can conduct a comparison of regulatory approaches across its member countries toward identifying opportunities for harmonization. Their assessment followed a three-step process:

1. **Framework development:** identification of the key elements and questions to assess the status of online pharmacy regulations.
2. **Data collection:** desk review of online pharmacy laws, policies and guidelines across the countries; review of drug or medicine policies, e-health or cyberhealth strategies and national essential medicines lists; and key informant interviews with regulators from the African countries.
3. **Analysis:** development of country summaries, crosscutting insights on state of online pharmacy regulation and opportunities to advance regulations in the African countries.

Overleaf is one of the high-level graphical summaries of the cross-country regulatory review, which examines specific components of what is/is not captured in the online pharmacy regulatory approach in each country.

Regional harmonization practice case 2 (cont.)

Figure 3. Online pharmacy regulations exist in most Anglophone African countries, while existing laws can be extended to regulate online pharmacies in Francophone Africa.



Resource:
https://www.salientadvisory.com/report-media/online-pharmacy-in-africa-landscape-of-regulations-and-opportunities-for-action/

Case Studies

Regional harmonization practice case 3: The African Medicines Agency

The African Medicines Agency (AMA) is an example of a regional collaborative approach to harmonizing health technology regulation, legislation and licensing. It represents a significant advancement in ensuring access to high-quality medicines across Africa. AMA was ratified by African Union Member States in October 2021 and will soon be operational, with headquarters in Kigali, Rwanda. The vision of AMA is to ensure equitable access by all Africans to quality-assured, safe, efficacious, and affordable medical products that adhere to internationally recognized standards, especially for priority diseases and conditions. AMA will facilitate coordination of medicines regulatory systems at the national and sub-regional levels; conduct regulatory oversight of selected medical products, including traditional medicines; and promote cooperation, harmonization and the mutual recognition of regulatory decisions.

As a central reference and coordinating body, AMA will support growth and catalyze trade in support of local African pharmaceutical production; support evaluation of medical products for the treatment of priority diseases as determined by the African Union; and regularly inspect, coordinate and share information about products that are authorized for marketing. It will coordinate joint reviews of clinical trial applications for vaccines and assessment of “highly complex” product dossiers such as bio-similars, as well as joint inspections of sites which manufacture active pharmaceutical ingredients. AMA will collaborate with Regional Economic Communities and National Medicines Regulatory Authorities in the identification of substandard and falsified medical products and facilitate information sharing across countries. AMA will be responsible for harmonizing legislation across the continent by developing common standards and regulations.

Resource:
https://www.nepad.org/publication/african-medicines-agency-ama-brochure
https://joppp.biomedcentral.com/articles/10.1186/s40545-020-00281-9

4. Healthtech Data And Regulatory Sandboxes

Healthtech Data And Regulatory Sandboxes

One potential tool that governments may consider using to implement some of the policy recommendations mentioned is a sandbox.

A healthtech sandbox is a controlled environment that allows innovators to develop, test and refine their solutions under the supervision of a regulator or other convening entities.[2,4,7] Sandboxes have a defined and limited scope, focusing on specific technologies or use cases and with selective participation. However, they can contribute to longer-term and sustainable solutions if they are planned with considerations for sustainability, where their ability to serve as testing grounds and learning opportunities is explicitly part of the broader processes for sustainable and comprehensive policy development or refinement. This section has been included in the Blueprint to provide guidance to countries and other stakeholders wishing to implement healthtech sandboxes at the regional, subregional or country level. The recommendations should be examined and adapted in accordance with the prevailing local context.

Common objectives of data and regulatory sandboxes

- Provide innovators access to health data while ensuring secure handling and compliance with data privacy policies. (supports Policy Recommendation 2)
- Support interoperability and integration of digital solutions with existing health data systems. (supports Policy Recommendation 2)
- Enhance collaboration among stakeholders engaging in the healthtech process, e.g. innovators, regulators, health care workers, service providers, etc. (supports Policy Recommendation 1)
- Enable evaluation of healthtech solutions for compliance with existing regulations and provide learnings for regulators so they can adapt regulations or develop new ones. (supports Policy Recommendation 3)

Guidance for entities seeking to develop and launch a sandbox

- Seek technical assistance during the setup phase.
- Convene a diverse set of stakeholders to ensure sandbox design and implementation considers holistic perspectives. This should include government, policymakers, innovators, end users, amongst others.
- Begin by identifying and prioritizing specific areas that are relevant for the application of a sandbox. For example, an emerging technology area for which a regulatory framework is not well defined, such as AI-enabled technologies or virtual care solutions.
- Define the scope and objectives of the sandbox, operating procedures and the regulatory guidelines.
- Establish an application process with eligibility criteria for innovators.
- Establish infrastructure and platforms that can support sandbox operations.
- While implementing the sandbox, stakeholders should engage innovators regularly to review progress and outcomes based on a defined monitoring and evaluation framework.
- Monitor lessons from implementation of the sandbox and continually refine and improve sandbox procedures.
- Utilize learnings from the sandbox to inform the broader development or refinement of policies and regulations.

Sandbox deep dive:
The Datasphere Initiative and lessons from the use of sandboxes

Datasphere Initiative is a non-profit organization dedicated to addressing urgent, multidimensional, and cross-border challenges of data governance. Their mission is to build agile frameworks that responsibly unlock the value of data for all. The Initiative connects stakeholders from various sectors, conducts research on data challenges, and experiments with policy and technical data-sharing solutions.

Datasphere Initiative champions sandboxes as an innovative governance mechanism for addressing new and complex challenges around data. They explore the use of sandboxes for cross-border data sharing and have developed a roadmap for the design and implementation of such sandboxes.

In a recent report titled “Sandboxes for data: creating spaces for agile solutions across borders”, Datasphere summarized lessons from the use of sandboxes over the last 10 years, most prominently in the financial technology sector. With regards to benefits, the report notes that sandboxes can be an effective way of reducing legal and regulatory uncertainty, giving innovators access to a controlled testing environment, subsequently facilitating market entry, which will enhance overall competition and access to innovation.

For regulators, sandboxes can provide firsthand contact with the latest technological developments and solutions that will build regulator capacity and help them anticipate developments driven by technological change and future business models. Where regulatory requirements are unclear or missing, or where they create barriers to entry, sandboxes can help with clarity and certainty and in communicating with market actors.

Sandbox deep dive (cont.)

The Datasphere report also highlights risks and challenges with using sandboxes. It notes that regulators often work with information asymmetrically and may not have the knowledge or skill to design sandboxes that anticipate and control risk, as initiatives in the sandbox become more innovative. While sandboxes can provide enormous value, they require focused, collaborative work grounded in careful preparation to ensure concentration on bounded questions, and a close fit between the activity to be sandboxed and the public interest served by dedicating resources to doing so.

While the report focuses on the use of sandboxes for cross-border data sharing, it can be a helpful resource for governments considering implementing sandboxes for healthtech because it contains general takeaways on how best to use regulatory sandboxes and specific case studies.

Resource: https://www.thedatasphere.org/wp-content/uploads/2022/05/Sandboxes-for-data-2022-Datasphere-Initiative.pdf

5. Other Programmatic Considerations For Healthtech

Other Programmatic Considerations For Healthtech

This Blueprint has focused on addressing a set of prioritized, interconnected issues relating to healthtech policies, regulations and licensing, including regarding health data, in Africa. However, these priority issues are interlinked with a broader set of challenges that also have important implications for the ability to sustainably accelerate the development and use of healthtech across Africa.

This section highlights some of the key program considerations that are important for the success of healthtech implementation in Africa. While not prioritized as challenges requiring policy recommendations in this Blueprint, these areas also surfaced in stakeholder consultations. These include considerations for sustainability, infrastructure, funding, operational capacity, inclusiveness and equity and continuous monitoring and evaluation.

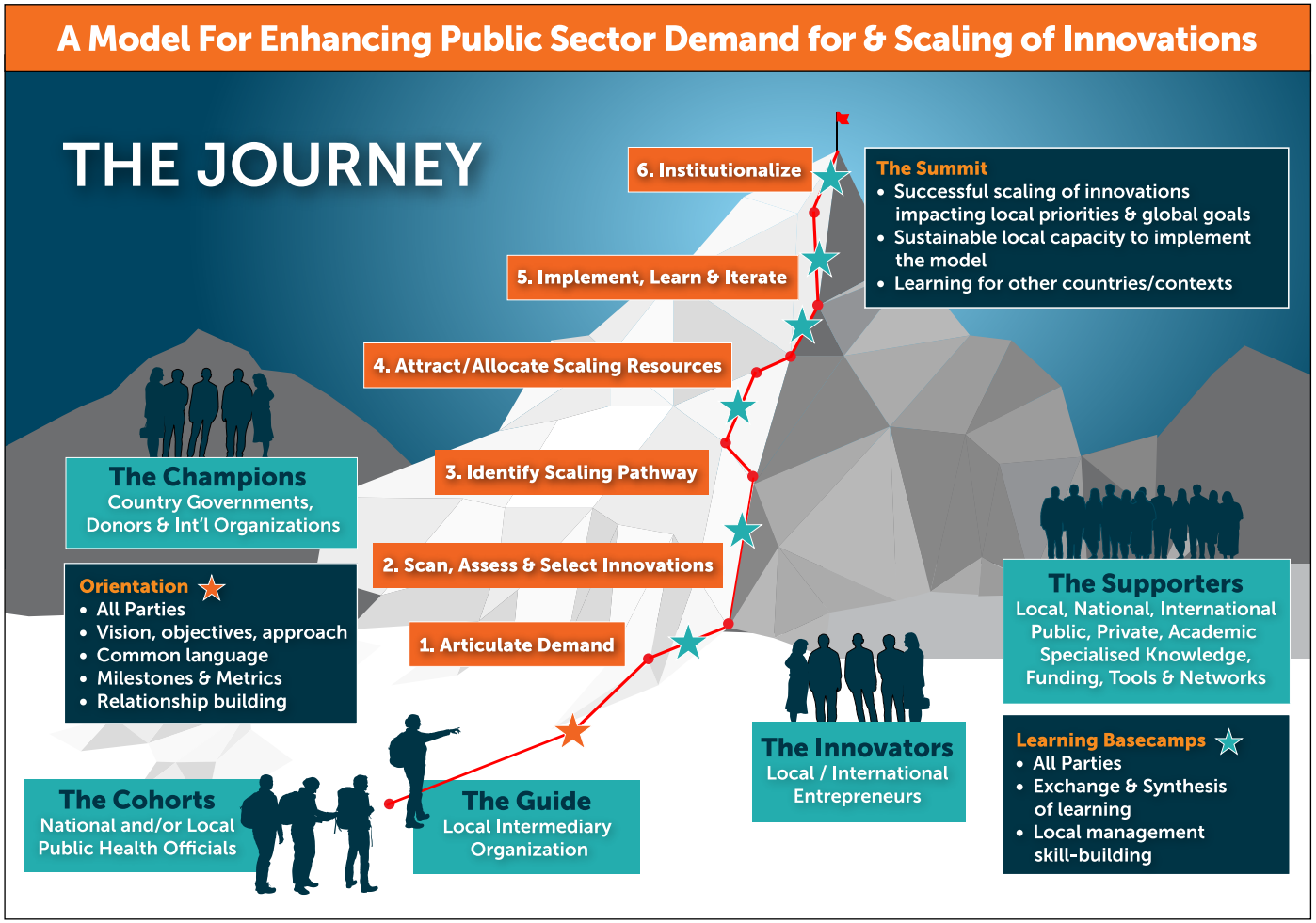
a. Sustainability must be the ultimate vision from the onset

All healthtech policy and regulatory frameworks must be developed with considerations for scale-up and sustainability from the onset.

Governments should be the drivers of the process and innovators and implementing partners should make provision for co-creation and co-testing; alignment with government strategies, priorities, budget cycle and end-user needs; evaluating for impact; costing; carefully phased transitions; consistent coordination across stakeholders; and sustainability planning. The government can help set the expected policies and standards for what they expect of innovators and key attributes and milestones required to absorb innovations. Governments can also help emphasize to innovators that when they develop an innovation, it should not just be something that can work in a small and controlled setting, but should be adaptable and scalable and eventually integrated into the system.

The VillageReach Transitioning Well approach and the Journey to Scale with Government Tool and Stakeholder Alignment Workshop are important interactive tools that can help governments, innovators, donors, funders and loan providers navigate towards government-owned solutions with sustained impact at scale.[23,24] The Journey to Scale with Government Tool provides a foundation for governments, social impact organizations and funders to foster stronger collaboration for the development of sustainable and scalable solutions. It highlights five stages for the development of government-owned solutions that will sustainably address a problem: mobilize, co-create, execute, re-align, and embed.

Another iteration of the journey to sustainability is the Mountain Model, developed by the International Development Innovation Alliance (IDIA).[25] The model is an example of how governments and partners can build a strong foundation for sustainable healthtech strategies. It articulates six stages that stakeholders in LMICs should implement to ensure sustainable progress in sourcing and scaling innovations to meet their needs: articulate demand; scan, assess and select innovations; identify the scaling pathway; attract or reallocate scaling resources; implement, learn, and iterate; and institutionalize.



The Cohort Journey through the Mountain Model
Source: Enhancing Public Sector Demand for & Scaling of Health Innovation

Like Transitioning Well, the Mountain Model can help governments identify what they want and expect from innovators. Both models can be used to develop policy and required checklists from governments to innovators on the minimum sustainability milestones and attributes required if the government is to consider purchasing or embedding their solution.

This policy Blueprint is a foundation from which innovations can begin and it is the first of many steps towards achieving sustainability.

b. Sustainable and durable infrastructure is a must for healthtech to function effectively

Infrastructure is the backbone of healthtech; it drives the development and use of digital applications for the delivery of a range of health services.[2, 4-6,14]

The success of healthtech depends largely on the availability of supporting infrastructure, including electricity, internet connection and data storage servers. Efforts must be made to invest in the development of infrastructure needed to support healthtech such as regular and reliable electricity supply, fast and reliable data connectivity with high bandwidth and technological hardware.

Healthtech policies should include clear guidelines on how to bridge the digital divide and ensure that vulnerable and disadvantaged populations have access to healthtech services. Digital technology innovators should also consider the interplay between infrastructure and geographical locations when developing and scaling up their innovations to make healthtech functional even in low-resource settings.

c. Domestic funding and local market shaping for healthtech is critical

Healthtech gains can only be realized when there is adequate funding for relevant technologies.[2,4,14]

Every stage of healthtech, from inception to technology creation, experimentation, implementation, adoption and scaleup requires money. It is therefore important to include healthtech in the country's health investment priorities, provide sufficient funding that will assure sustainability of adopted technologies and create appropriate market-shaping opportunities to allow government to procure services from startups.

Essentially, governments should develop sustainable funding models for their healthtech programs to make them sustainable. They may offer financial incentives to emerging innovators, for example, through loan schemes for healthtech innovators, while the civil society helps mobilize funds and technical support from donors, development partners and the private sector. The Government of Ethiopia, for example, is providing this opportunity by screening and evaluating healthtech innovations before bringing them to the market where government departments can be matched with startups. While this is a critical step, startups are often not equipped to compete with other players for market share and government processes may lead to delayed payments which startups cannot afford in their operations. However, establishing systems and creating an enabling environment for local market-shaping are critical first steps.

d. Operational capacity is needed for healthtech at country level

In addition to infrastructure, finance and other provisions, the capacity of health care workers and health care system operators to use healthtech platforms has a critical role to play in increasing access to healthtech.

Human and material capacity are needed to operate healthtech.[2,6] Governments should invest in systematic capacity-building to improve the skills of health care workers, health managers and everyone providing and operating healthtech services. Capacity should be built for in-country data entry, storage, monitoring and interoperability as necessary. It is important to build capacity for local development of healthtech at all levels within the country and capacity to provide technical support for imported technologies. This will help institutionalize the use of digital technology for health care and facilitate sustainability of services. Building capacity at all levels can also help create demand for healthtech services.

e. Healthtech programs must be inclusive and enhance equity

When implemented effectively, healthtech has the potential to minimize the inequity in health care currently being experienced in Africa and other LMICs. Healthtech should be inclusive, accessible and affordable to minimize the increasing digital divide and the challenges with access.[2,4,5]

Healthtech innovators and other stakeholders should pay attention to gender-related inequities, variations in geography, disparities in education and development levels, availability of social amenities, degrees of exposure to technology and access to digitization to make their technology inclusive. Lower literacy levels or illiteracy and high costs may pose a challenge to accessibility and increase the risks for excluding certain populations.

While it is easier for people in higher echelons to support healthtech advancement, those in the lower socio-economic and/or less literate groups may struggle with its adoption. This can further widen the technological gap if not taken into consideration in policies and innovations. Digital technologies that use speech-to-text functionality and video tutorials, for example, can empower disadvantaged patients to engage with their health care, just as the facilitation of remote care can enable previously under-reached or vulnerable populations to access services.[4]

Gender and ethical issues should always be part of discussions and considerations in the design of healthtech innovations, strategies and frameworks.[5,6] The ageing and elderly and the physically challenged populations constitute a vulnerable population in Africa and healthtech should be tailored to address their health care needs.

f. Continuous monitoring, evaluation and learning are essential for constant improvement

Regular monitoring and evaluation should be incorporated into healthtech policies and programs to ensure that technologies are safe, effective, ethical and efficient.[2,4-6,14]

Monitoring and evaluation will help in identifying system inadequacies and possible adjustments to improve them. Monitoring and evaluation should focus on quality-of-care; cost-effectiveness; equity and accessibility; compliance, regulation, and patient safety; data security, privacy, and ethics; technology performance; and user acceptance and satisfaction.

Performance indicators and targets along with the relevant data collection tools should be included in healthtech operational plans. This is particularly important when services are to be expanded or scaled up to new areas. There should be a feedback process between innovators and users of the technologies and countries should track their investment and expenditure on healthtech.

Finally, as the four policy recommendations in this Blueprint are taken forward and adapted by each government for their specific situation and needs, a monitoring, evaluation and learning framework should be developed to support implementation. This framework should include recommendations for the definition of a theory of change for each initiative, with intended outcomes and impact and for the development of relevant key performance indicators.

6. Conclusion

Healthtech has the potential to transform and strengthen health care and health systems globally and in Africa. However, Africa faces unique challenges that have hindered healthtech innovations as highlighted in this Blueprint. This Blueprint offers a set of recommendations that can transform healthtech in Africa if implemented systematically and strategically through dialogue and regular coordination between government and healthtech stakeholders. The practice cases in this Blueprint provide key learnings from different parts of the world that can be leveraged and adapted in specific contexts to facilitate healthtech implementation at national, regional and global levels.

Although there are numerous challenges facing healthtech innovation and application in Africa, this Blueprint has focused on only two main aspects – challenges associated with licensing of healthtech and challenges related to health data sharing, hosting and interoperability – and the recommendations are tailored to these two aspects. This limited focus was intentional to ensure that the Blueprint captures and represents the views of the innovators, government officials and other stakeholders who were consulted during its development. Their views and suggestions have been carefully collated and summarized in the Blueprint.

Following the release of this Blueprint, HTHA encourages governments of the focal countries – Côte d'Ivoire, Ethiopia, Kenya, Malawi, Nigeria, Rwanda, Senegal, South Africa, Tanzania, Uganda and Cameroon – as key contributors to this Blueprint to begin the process of adopting and implementing it at country level. To ensure smooth implementation, some of the recommendations may need to be adapted and contextualized.

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Annexes

Annex 1: Acronyms and abbreviations

ABDM	Ayushman Bharat Digital Mission
Africa CDC	Africa Centre for Disease Control and Prevention
AMA	African Medicines Agency
CAA	Civil Aviation Authority
CDSCO	Central Drugs Standard Control Organization
CSOs	Civil society organizations
DICOM	Digital Imaging and Communications in Medicine
DRC	Democratic Republic of Congo
FHIR	Fast Health care Interoperability Resources
Healthtech	Health technology
HELINA	Pan-African Health Informatics Association
HSA	Health Sciences Authority
ICD-10	International Classification of Diseases 10th Revision
ICT	Information communication technology
IDIA	International Development Innovation Alliance
IGAD	Intergovernmental Authority on Development
JSTOR	Journal Storage
LGBTQ	Lesbian, gay, bisexual, transgender, queer
LMICs	Low- and middle-income countries
LOINC	Logical Observation Identifiers Names and Codes
NGOs	Non-government organizations
NSTF	National Science and Technology Forum
SNOMED-CT	Systematized Nomenclature of Medicine-Clinical Terms
WHO	World Health Organization

Annexes

Annex 2: Blueprint key informants

Name	Organization	Designation
Jelle Schuitemaker	GOAL 3	Chief Marketing & Co-Founder
Babajide Oke	Render Health Technology	CEO/Founder
Iréné Mizero	Mizero Care Ltd	Chairman & Executive Director
Mayoro Diagne	Baamtu Technologies	Director of Operations
Bethel/Asteraye Belay	WeCare Digital Health	(Deputy Manager)/General Manager
Arnaud Michel Nibaruta	Dotpharma Ltd	Co-founder and Partnership Lead
Conrad Tankou	GIC Space	CEO
Theophila Huriro Uwacu	TIP Global Health	Director, E-Heza Data Solutions
Ayodeji Alaran	PBR Life Sciences	CEO
David Chen	Kapsule	Co-CEO
Tom Kinyanjui Njoroge	Neural Labs Africa	Co-founder & CEO
Winston Osuchukwu	Trans-Sahara Investments	Managing Partner
Bethel Dereje	WeCare Digital Health	General Manager

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Annex 2: Blueprint key informants (cont.)

Name	Organization	Designation
Jerome Nshimiyimana	Jo Group Ltd/JoCare	Founder/CEO
Moses Enokela	SonoCare Healthcare, Inc.	Founder/CEO
Ekundayo Ajayi-Obe	Subsaharan Health Solutions, Nigeria Limited	Founder/CEO
Naom Monari	Bena Care	Founder
William Mapham	Vula	CEO
Alexis Tazinya	Waspito	Chief Health Officer
Eva Ntaganda	Rwanda Biomedical Centre	Director of Cardiovascular Disease Program
Dr Shibu Vijayan	Qure.ai	Medical Director Global Health
Peta-Anne Browne	Wardworx	Founder
Kiran Dellimore	Goal 3	Head of Innovation & International Business Development
Bigirimana Jean-Damascene	HealthEdu Ltd	CEO & Founder
Puni Mamdoo	SPHER3	Director public health medicine specialist physician

Annexes

Annex 2: Blueprint key informants (cont.)

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Philippe Gerwill	Docthus Healthtech	Board Member
Che Mfombong Howard	NASLA	Student
Simon Njoya Mounshingam	CNTS/NBTS (National blood transfusion service)	Regional representative for the national blood transfusion team for the northwest region of Cameroon
Anne Stake	Medtronic LABS	Chief Strategy and Product Officer
Nembot Raoul	EPI	Data Manager
William Mapham	Vula	CEO
Bahati Sambayuka	Clinton Health Access Initiative	Program Officer
Stephen M Mutiso	Ministry of Health, Kenya	Lead, Renal Health, NCD Division Digital Health
Andrew Ddembe	Mobiklinic	CEO
Eyob Esatu	Organization for Innovation and Sustainable Development Africa	Executive Director

Annexes

Annex 2: Blueprint key informants (cont.)

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Dawit Birhan	Ministry of Health, Ethiopia	Senior Digital health governance specialist
Stephen Ogweno	Lifesten Health	CEO
Neville Newey	Viebeg	Chief Technology Officer
Jean Baptiste Byiringiro	Ministry of Health, Rwanda	Chief Digital Officer
Esther Kunda	Ministry of ICT and Innovation, Rwanda	Director General, Innovation and Emerging Technologies
Eraste Rurangwa	National Cyber Security Authority, Rwanda	Data Protection Officer

Annexes

Annex 3: Participants in the consultative forums

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16. Amadou S Camara
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20. Araya Kassaye
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43. Deguene Cisse
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45. Doreen Abanyana
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49. Elena Dia
50. Elijah Oyeyinka
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Annex 3: Participants in the consultative forums (cont.)

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136. Pauline Barra
137. Peta-Anne Browne
138. Philippe Gerwill
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