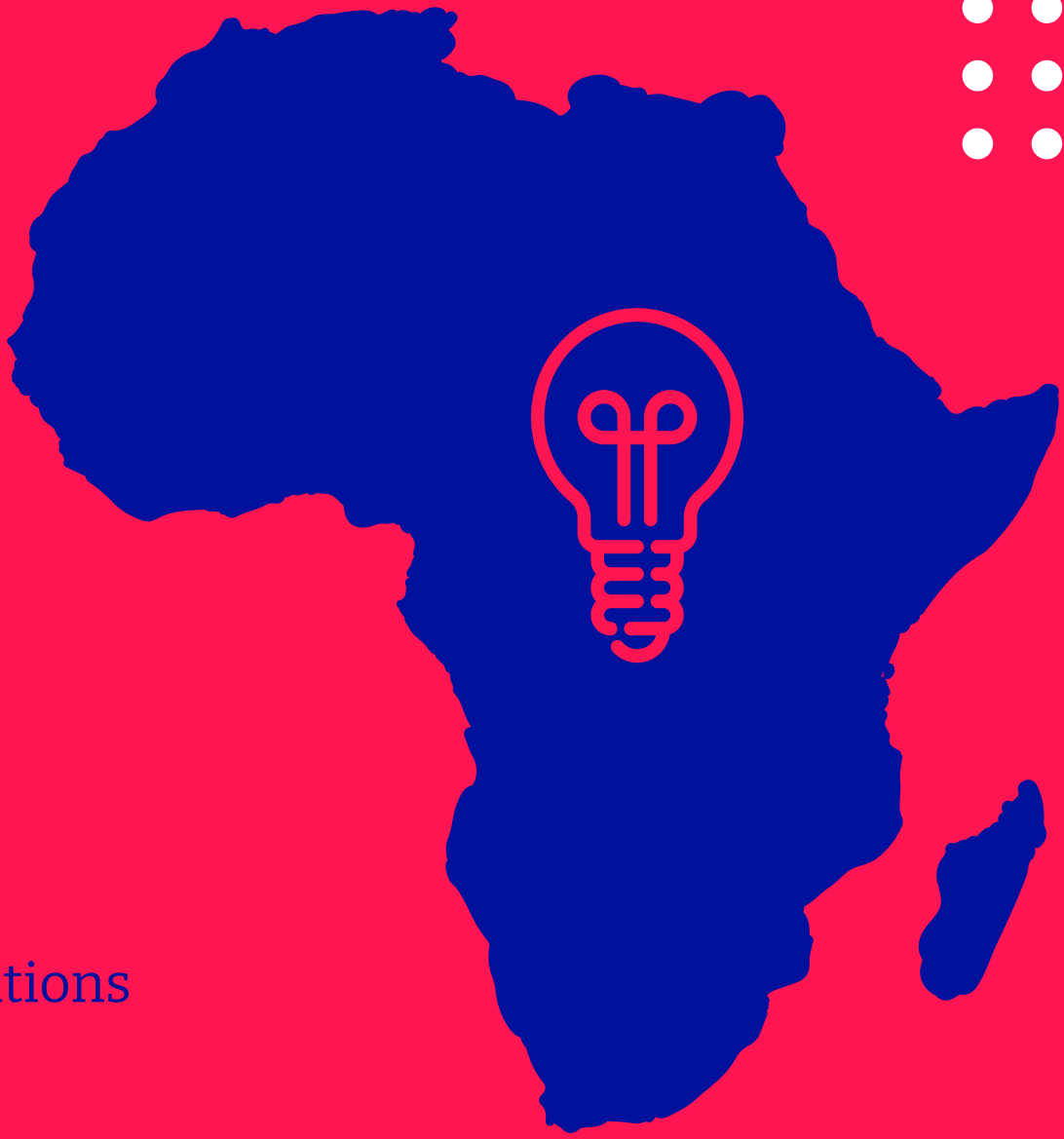
HEALTHTECH HUB



POLICY BLUEPRINT

to Fast-Track Healthtech Innovations in Public Health in Africa

SUMMARY

Interactive PDF clickable links throughout

Acknowledgements

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Blueprint Development Partners

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1. Background

Background

The World Bank and African Development Bank have described healthtech as one of the most powerful tools needed to close the gap in health care delivery globally.[1]

Healthtech holds great potential for patients, health care providers, health systems, communities and for the achievement of Universal Health Coverage and the health-related Sustainable Development Goals. Healthtech can help mitigate challenges in the health system, such as the shortage of health care professionals and poor logistics and supply systems.[2] 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.[3]

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.[4] 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.[1,5,6,7] Acknowledging this broad foundation of existing efforts, the HealthTech Hub Africa (HTHA) set out 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.

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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 landscape 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.

These activities focused on gathering perspectives from key stakeholders in Africa on the common challenges that they face in developing and implementing healthtech innovations and pragmatic solutions to the identified challenges. The Blueprint captures the challenges, opportunities, recommendations, enablers and examples identified during the consultations and analyses.

The Blueprint 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.

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.

The HTHA plans to build upon the initial work of the Blueprint by convening governments and partners to validate and refine the recommendations and supporting the identification and implementation of specific actions to accelerate healthtech innovations that are tailored to each country's specific situation, needs and priorities.

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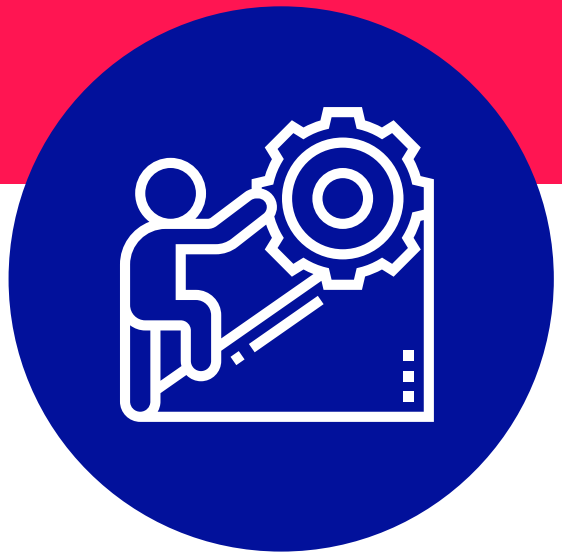
2. Challenges in Accelerating Healthtech in Africa



Challenges in Accelerating Healthtech in Africa

Stakeholder consultations identified a set of key challenges that limit the development, adoption, implementation and scaling of healthtech in Africa:

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

One of the obstacles to implementing and scaling-up healthtech in Africa most frequently cited by stakeholders is the lack of policies or frameworks that comprehensively address all aspects of the subject.[4] This includes policies regarding health data privacy and security, data sharing, data interoperability and licensing procedures for healthtech products. In countries where healthtech policies exist, they are often unclear, incomplete, inconsistent and open to misinterpretation, or are not implemented or enforced accordingly.[2]

B. Complex, lengthy and unclear healthtech licensing processes

Stakeholders identified the cumbersome, unclear and lengthy licensing process as a barrier to the introduction of healthtech in Africa. Most of the innovators interviewed echoed that the licensing processes in their countries are inefficient, lack clear and concise criteria, are poorly communicated and inconsistent, are not coordinated across regulators and hinder innovation.

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C. Poor infrastructure to support healthtech

Poor infrastructure, including unreliable electricity supply and limited internet connectivity, is hindering the introduction, adoption, scaling, and sustainability of healthtech in most African countries.[8] The situation is particularly bad in rural, and some urban, areas where internet services are not available or connection is sub-optimal because of challenges with limited bandwidth, network instability, erratic electricity supply, slow speed and high cost of data.

D. Limited access to health care data

While there has been progress in digitizing health data across low- and middle-income countries, 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.[3] In some cases, policies and processes regarding access to health data from government institutions by innovators are unclear and countries also lack policies which allow innovators to directly collect patient data.[9] Policies and regulations on ownership of health data are inconsistent within and between countries which impacts resource allocation, coordination and accountability. Such situations limit access to healthtech data and information needed for innovations.[10]

E. Data insecurity

Although data sharing has benefits, there is a risk of system security breaches through malware attacks or hacking, and sale to third parties for use outside of the original plan for which healthtech users gave consent.[3] Health data are particularly sensitive and open to misuse or abuse during storage or when shared with third parties.[9] There is therefore a challenge of how to maintain data security while providing access to innovators and other private sector stakeholders.

F. Lack of protection for healthtech intellectual property rights

Regulations and laws regarding healthtech innovations and intellectual property vary from country to country in Africa and the legal proceedings are unclear.[2, 3] Weak protection and enforcement of intellectual property rights and fear of copyright infringement in some countries has discouraged innovators and researchers from investing in healthtech or openly engaging with government regarding their innovations.

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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. Digital systems sometimes vary across departments within the same facility.[8] 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.[2,3] This lack of integration poses a serious challenge to data aggregation, integrity, interoperability, digitization and standardization. It also ngatively impacts the efficient use of health data and the sustainability of healthtech solutions.[2,3]

H. Limited operational capacity for healthtech

Technical capacity in the public sector to manage healthtech is inadequate in most African countries.[3, 5, 11] Respondents noted that health systems, public health authorities and health workers are inadequately empowered to maintain and operate digital technology or to keep up with the latest developments in healthtech.

I. Poor coordination, partnerships and collaborations

The lack of coordination, coupled with limited collaboration and partnerships among multisectoral teams of experts involved in healthtech, is a barrier to developing a common understanding about the goals of healthtech, the development of comprehensive context-specific guidelines and effective development and deployment of innovative health technologies.[12]

J. Insufficient funding for healthtech

Healthtech is among the least prioritized in health systems funding in Africa.[2] Governments rely heavily on donor funding for healthtech solutions and do not provide incentives for healthtech. Therefore, innovators do not see the public health sector as a viable healthtech market and face difficulty securing the much-needed capital to develop, implement and sustain their solutions.

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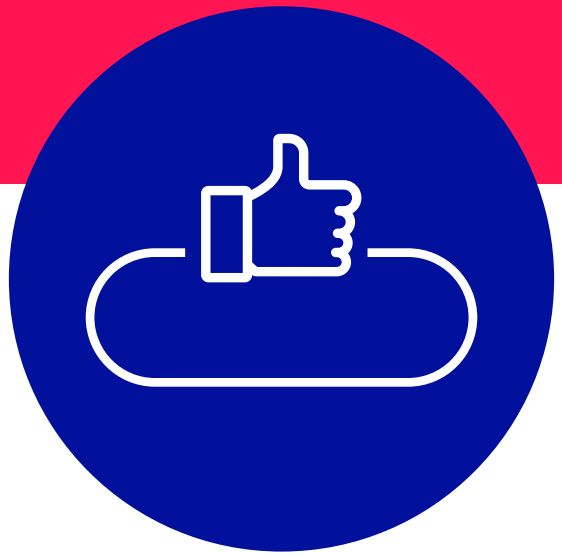
3. Healthtech Policy Recommendations

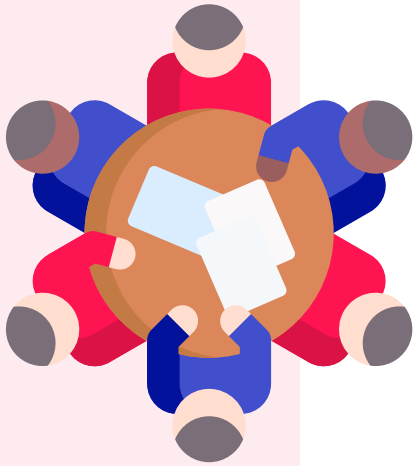


Healthtech Policy Recommendations

Stakeholders identified challenges associated with licensing of healthtech and those related to health data sharing, hosting and interoperability as priority areas for immediate attention. Therefore, the following four Blueprint policy recommendations were made to address these two categories of challenges:

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. 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 them, including representatives of government, health care providers and institutions, patients, civil society, private sector, funders, international and bilateral organizations, and healthtech experts.



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Specific Actions

- Map existing entities and forums in the country that can be leveraged to enhance co-ordination among healthtech stakeholders, 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, or establish new coordination mechanism if necessary.
- If not already existing, establish an intellectual property protection and confidentiality system to enable and encourage open dialogue between innovators and governments.
- 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.

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

Governments should review their healthtech policies, where they exist, to identify gaps. In some cases, policies may need to be updated to account for new realities (e.g. the delivery of services virtually rather than through physical sites or health facilities, changes to health workers' scope of practice and remuneration due to uptake of virtual care or consultations, etc). Where there is no relevant policy, new policies should be developed.

The following emerged as specific areas requiring policy and regulatory attention:

- **Private sector access to health data:** 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), including data shared by health institutions and those collected directly from patients.
- **Use of cloud-based services for data hosting and analysis:** Governments should revisit their policies to optimize the balance between strategic, operational and data security objectives and identify opportunities for storing data on cloud-based services, e.g. aggregated data, and regional data hosting on Africa-based servers.
- **Interoperability of health data:** Governments should accelerate healthtech innovation by refining their interoperability strategies and advancing priority initiatives to define and adopt standards, in collaboration with regional and international partners and interoperability forums.

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Specific Actions

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.

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.

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).
- 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).
- 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.

Interoperability of health data

- 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 and partnering with international agencies such as Africa CDC and WHO, other interoperability forums, and providers of technical assistance and testing platforms such as the Pan-African Health Informatics Association (HELINA).

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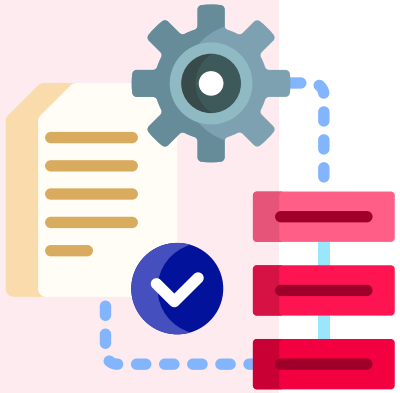
Recommendation 3: Establish a streamlined and transparent healthtech licensing process at country level

To reduce barriers to licensing, there is an urgent need to establish a simplified, streamlined, transparent, documented and digitized one-stop licensing process managed by appropriate regulatory agencies with expertise in health technologies and procedures. Beyond sharing licensing information online, regulators should develop online platforms that will facilitate the entire licensing process. These would serve as the main portal for innovators and regulators to interact regarding submissions.[3,4]



Specific Actions

- 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 and advise on other pertinent issues.
- Consolidate, map and review all existing policies and guidance documents. Address gaps and inefficiencies and publish a unified and streamlined set of policies and guidelines for healthtech licensing.
- Digitize the licensing process to facilitate online submissions by innovators and provide real-time updates on the status of each application.

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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.[2,3,7,11] It will help in streamlining administrative and operational processes, including licensing, and standardization of data collection and assessment tools.

Specific Actions

- Establish a pan-African level healthtech regulatory working group with representation from the regional economic communities, to provide a forum for sharing experiences and best practices in healthtech and identifying opportunities for inter-country collaborations.
- Compare approaches across countries in the region to identify areas of alignment in policy and licensing.
- Develop unified policy frameworks that could be uniformly implemented by countries in the region or sub-region, drawing from existing regional and international standards and harmonization efforts (e.g., the Africa Union/Africa CDC Health Information Exchange Guidelines and Standards).
- 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.

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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 above is a sandbox.

A 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.[2,3,6] For example, a sandbox can be established for a specific type of health technology, enabling the testing and evaluation of solutions from selected participating innovators. Solutions can be evaluated for compliance with existing regulations within the sandbox, and observations can inform adaptation of existing policies and regulations or development of new ones.

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5. Other Programmatic Considerations For Healthtech

Other Programmatic Considerations For Healthtech

Apart from implementing the prioritized policy recommendations, it is important to consider the following interconnected program components for the success of healthtech in Africa:

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

B. Sustainability must be the ultimate vision from the onset

C. Durable infrastructure is a must for healthtech to function effectively

D. Strengthening capacity of stakeholders to operate healthtech innovations at country level

E. Healthtech programs must be inclusive and enhance equity

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

You can access the full version of the Blueprint at:
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References

1. African Development Bank Group. (2021). Strategy for quality health infrastructure in Africa 2021-2030 revised version. https://www.afdb.org/en/documents/strategy-quality-health-infrastructure-africa-2021-2030
2. O'Brien N, Ayisi-Boateng NK, Lounsbury O, Leis M, Ghafur S, Darzi, A, Moosa S, Neves AL. Digital health in primary health care: Current use and future opportunities in the Sub-Saharan African region. London: Imperial College London, 2023. https://spiral.imperial.ac.uk/bitstream/10044/1/104371/2/ImperialReport_DigitalHealthSubSaharanAfrica.pdf
3. The World Bank. Digital-in-Health: Unlocking the value for everyone. Washington DC: World Bank, 2023. https://www.worldbank.org/en/topic/health/publication/digital-in-health-unlocking-the-value-for-everyone
4. Arias A, Wright A, Waszak J. Digital Health Systems in Africa: A convergence of opportunities. USA: IQVIA, 2023. https://www.iqvia.com/-/media/iqvia/pdfs/mea/white-paper/iqvia-digital-health-system-maturity-in-africa.pdf
5. Framework for implementing the global strategy on digital health in the WHO African Region: report of the Secretariat
6. Africa CDC. Africa CDC Digital Transformation Strategy (2023-2030). Addis Ababa: Africa CDC, 2023. https://africacdc.org/download/digital-transformation-strategy/
7. World Health Organization. Global strategy on digital health 2020-2025. Geneva: World Health Organization, 2021. https://www.who.int/docs/default-source/documents/gs4dhdaa2a9f352b0445bafbc79ca799dce4d.pdf
8. Manyazewal, T., Woldeamanuel, Y., Blumberg, H. M., Fekadu, A., & Marconi, V. C. (2021). The potential use of digital health technologies in the African context: A systematic review of evidence from Ethiopia. Npj Digital Medicine, 4(1). https://doi.org/10.1038/s41746-021-00487-4
9. UN Human Rights Council Side Event: Digital Innovation, New Technologies & The Right to Health. (2023, June 23). https://www.youtube.com/watch?v=AzqsTwoTHjk
10. Qhala Limited Kenya. (2023). One Digital Health Landscape in Africa: Assessment Findings in Four African Countries. Deutsche Gesellschaft für Internationale Zusammenarbeit GmbH.
11. World Health Organization. Regional strategy for fostering digital health in the Eastern Mediterranean Region (2023–2027). Cairo: WHO Regional Office for the Eastern Mediterranean, 2022. https://applications.emro.who.int/docs/Digital-Health-EMR-2023-2027-eng.pdf
12. Mugwagwa, J., Edwards, D., & de Haan, S. (2015). Assessing the implementation and influence of policies that support research and Innovation Systems for Health: The Cases of Mozambique, Senegal, and Tanzania. Health Research Policy and Systems, 13(1). https://doi.org/10.1186/s12961-015-0010-2

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