POLICY ANALYSIS BRIEF

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Diagnosis for all

A NATIONAL DIAGNOSTICS POLICY AND PLAN TO STRENGTHEN HEALTH SYSTEMS IS CRITICAL TO IMPROVE HEALTH CARE IN KENYA: A POLICY ANALYSIS BRIEF

Introduction

Universal health coverage (UHC) ensures that people have access to quality health care without financial hardship. Quality of care cannot be achieved without access to affordable and quality diagnostic services that involve correct detection, identification, and monitoring of diseases or conditions. Diagnostics have proven crucial to quick response and management of disease outbreaks. For example, during the COVID-19 pandemic, testing immediately emerged as a critical medical countermeasure alongside vaccines, treatments, and strategies, including isolation and contact tracing[1]. Post-pandemic, some of the greatest improvements in the availability and utilisation of diagnostic services at health facility and community levels in sub-Saharan Africa have been seen for HIV, tuberculosis (TB), and malaria[2]. Still, diagnostic service availability and utilisation gaps remain large.

In low- and middle-income countries (LMICs), diagnostic tests and services are often unavailable, inaccessible, or expensive[3]. Consequently, diagnostic gaps affect the accurate assessment of disease progression and the development of appropriate treatment plans, and referral systems, negatively impacting the quality of care available. In Kenya, a study conducted in 2021 recorded a test availability of 55.5% across health facilities as listed in the WHO's Essential Diagnostics List[4]. An assessment by Foundation for Innovative New Diagnostics (FIND) and Jomo Kenyatta University of Agriculture and Technology (JKUAT), also in 2021, on diagnostic services for children under five years of age and women in Nyeri and Kisumu counties in Kenya, found that distance is a key barrier to accessing diagnostic services. This study found that individuals had to travel an average of 24 km to access diagnostic services. Notably, for respiratory diseases such as pneumonia, critical diagnostic tests that can help clinical decisions were sparsely distributed across all levels of care (primary to tertiary); in both counties, only 9% and 17% of facilities offered chest X-rays and full blood counts, respectively.

Gaps and barriers that limit individuals and the community at large from accessing essential diagnostics – and jeopardize the achievement of UHC – include a scarcity of trained staff, insufficient resources, inaccurate procedures, inadequate quality assurance protocols, and a lack of national diagnostic policy or strategic plan to deliver comprehensive and integrated quality diagnostic services[5]. To contribute to efforts to address this problem, a review of existing policies was conducted to understand the provisions, gaps, and policy opportunities for strengthening access to quality diagnostic services in Kenya.

Study objective

To synthesise policies, guidelines, and strategies for strengthening access to quality diagnostic services in Kenya.

Key Messages

- Diagnostics are essential to sustainable, resilient health systems, enabling disease surveillance, disease detection, guiding treatment prognosis, and informing referrals.

- In Kenya, major gaps in diagnostic service availability and utilisation have been documented, including availability, accessibility, and cost of tests and diagnostic services.

- The lack of access to diagnostics is compounded by a lack of trained staff, insufficient resources, and a lack of a national diagnostic policy or strategic plan to deliver comprehensive and integrated quality health care.

- This policy review and analysis conducted by AFIDEP, JKUAT, and FIND revealed no overall policies to guide the availability and utilisation of diagnostic services in Kenya.

- There is a need to develop a comprehensive policy on diagnostic services at national and county levels. In Kenya, the 'to be developed' diagnostic policy needs to be guided by the Kenya health system structures and functions at the national and county levels.

- The 'to be developed' diagnostic policy also needs to be accompanied by a comprehensive implementation plan and monitoring system to ensure that diagnostic services are not only accessible but also utilised to enhance clinical decisions leading to quality care.

Methods

From November 2022 to January 2023, the African Institute for Development Policy (AFIDEP), in partnership with JKUAT and FIND, conducted a policy review and analysis using Google Scholar, PubMed, and Web of Science databases, reviewing publications from the inception of the databases to January 2023. Additionally, the organisations received country-level grey resources from various government entities that lead diagnostic services, including the National Ministry of Health (MoH). The team reviewed the documents and extracted the information using a predefined piloted extraction framework.

The analysis involved the synthesis of policies, guidelines, strategies, and legislation on health and development within the following diagnostic service spaces:

- Infrastructure, biosafety, and waste management
- Laboratory management
- Capacity building
- Commodity management and inventory control
- Selection, specification, and quantification of equipment and diagnostic commodities
- Diagnostic referral systems
- Disease-specific technical procedures
- Quality assurance
- Data management

[1]P1Peeling, R.W. et al. (2022). Diagnostics for covid-19: moving from pandemic response to control. *The Lancet, 399*(10326), 757–768. https://doi.org/10.1016/s0140-6736(21)02346-1
[2]Chanda-Kapata, P. et al. (2022). Tuberculosis, HIV/AIDS and malaria health services in sub-Saharan Africa – a situation analysis of the disruptions and impact of the COVID-19 pandemic. *International Journal of Infectious Diseases, 124* (Suppl 1), 41–46. https://doi.org/10.1016/j.ijid.2022.03.033.
[3]Nichols, K. et al. (2021). Bringing data analytics to the design of optimized diagnostic networks in low- and middle-income countries: process, terms and definitions. *Diagnostics, 11*(1), 22. https://doi.org/10.3390/diagnostics11010022
[4]Bahati, F. et al. (2022). Reporting of diagnostic and laboratory tests by general hospitals as an indication of access to diagnostic laboratory services in Kenya. *PLoS ONE, 17*(4), e0266667. https://doi.org/10.1371/journal.pone.0266667
[5]Fleming, K.A. et al. (2021). The Lancet Commission on diagnostics: transforming access to diagnostics. *The Lancet, 398*(10315), 1997–2050. https://doi.org/10.1016/S0140-6736(21)00673-5

Results

The policy analysis resulted in 15 policies/strategies on health-related topics as summarized in **Table 1.**

Table 1: *List of health policies/strategies in Kenya with diagnostic components*

Policies/ strategy	Year
Suicide Prevention Strategy	2016–2021
National Reproductive Health Policy	2022–2032
Rehabilitative Services and Assistive Technology Strategy	2022–2026
Kenya National Oral Health Strategic Plan	2022–2026
Kenya National Oral Health Policy	2022–2030
Universal Health Coverage Policy	2022–2030
Kenya Non-Communicable Disease (NCD) Strategic Plan	2021–2025
Kenya Strategic Plan for Control of Leishmaniasis Strategy	2021–2025
Kenya Health Sector Strategic Plan (KHSSP)	2018–2023
Kenya Health Policy (KHP)	2014–2030
Kenya Health Sector Strategic and Investment plan (KHSSP)	2014–2018
Kenya Cancer Policy	2019–2030
Kenya AIDS Strategic Framework II	2020/21–2024/25
National Strategic Plan for Tuberculosis, Leprosy and Lung Health	2019–2023
Kenya Malaria Strategy	2019–2023

Disease-specific policies/strategies on diagnostic services

Among the policies reviewed, only four policies had a clear strategy to boost diagnostic availability and utilisation in primary or mobile health facilities to ensure access to services by the community. These four were specific to certain diseases, i.e., TB, malaria, HIV and cancer (Table 2). The HIV policy includes detailed implementation plans on various aspects of diagnostic services, including capacity building of healthcare workers, the procurement of diagnostic supplies, and how it should be integrated into other services offered at the hospitals. Similarly, TB, malaria and cancer have specific implementation plans in relation to diagnostic services to achieve quality health care. As a result, there has been better diagnostic service availability and utilisation in the management of TB and HIV than in other diseases[6], including wide use of molecular tests to identify TB disease and drug resistance profiles for over a decade following the publication of World Health Organization (WHO) recommendations[7]. However, with policies available for just a few selected diseases, there is a need for national strategies to strengthen diagnostic services across the country, for all diseases, in line with WHO recommendations[8]. Most importantly, such national policies should be able to be cascaded and applied at county level with minimum standards for diagnostic services at different tiers within the health facilities in Kenya.

Photo: Ranelle Sykes/USAID

Table 2: *Policies/strategies that elaborate the availability and utilisation of diagnostic services*

Strategy/policy	Period	Strategic focus area
Kenya AIDS Strategic Framework II	2020/21–2024/25	Scale up targeted prevention and management of sexually transmitted infections and viral hepatitis among high-risk populations
		Expand equitable and quality testing, prevention and treatment services for HIV and syphilis to all pregnant women and children
		Promote integration of HIV testing with sexual and reproductive health services and the diagnosis of other co-infections, including TB and viral hepatitis
		Enhance HIV infrastructure and equipment management systems and services, including laboratory systems
National Strategic Plan for Tuberculosis, Leprosy and Lung Health	2019–2023	Accelerate development and implementation of three new national policies in support of appropriate and timely diagnosis in 1) expanded use of x-ray screening for TB; 2) Xpert as the preferred confirmatory test; and 3) all confirmed TB patients to receive drug sensitivity testing
Kenya Malaria Strategy	2019–2023	Ensure quality of malaria parasitological diagnosis
		Procure diagnostics and treatment commodities
Kenya Cancer Policy	2019–2030	Advance access to cancer screening and early detection

[6]Kenya Ministry of Health. (2018). *Kenya harmonized health facility assessment.* https://www.health.go.ke/wp-content/uploads/2020/01/KHFA-2018-19-Community-Systems-Report-Final.pdf
[7]Ntinginya, N.E. et al. (2021). Unlocking the health system barriers to maximise the uptake and utilisation of molecular diagnostics in low-income and middle-income country settings. *BMJ Global Health, 6*(8), e005357. https://doi.org/10.1136/bmjgh-2021-005357
[8]World Health Organization. (2011). Development of national health laboratory policy and plan. https://www.who.int/publications/i/item/9789290223962

Discussion

Availability and utilisation of diagnostic services in Kenya remain a challenge[9]. WHO advocates for diagnostic testing across all tiers of healthcare systems worldwide[10]. However, evidence shows a crucial gap, especially in public health facilities, on the availability of essential diagnostic tests and their utilisation[11]. Beside low test availability, studies have shown great variation in the scope of essential tests offered, with the greatest range of services offered for TB, HIV, malaria and cancer, as a result of strategic policies and implementation plans being in place that include availability and utilisation of diagnostic services at various tiers of health facility and community levels. This could be partly explained by the higher health budget allocated to TB, HIV and malaria, both from the overall government health budget, as well as from donors including the Global Fund, which is a major financier in Kenya for AIDS, TB and malaria (Figure 1).

The disease specific policy i.e. malaria, HIV, TB and cancer can be a learning platform for the 'to be developed' national diagnostic policy and strategic plan that could provide a framework for all-round delivery of quality and accessible diagnostic services for all diseases. Such services can be guided by the WHO essential diagnostics list (EDL), which consists of 122 clinical diagnostic tests considered to be essential to satisfy most of a population's health care needs[12]. EDLs should be customised according to county-specific priorities[13].

Importantly, there is a need for a coordinated framework that will ensure the integration of existing disease-specific policies into 'the to be developed' overall national diagnostic policy and implementation plan. The new policy should systematically outline the key structure and system to implement diagnostic services to ensure their availability and utilisation by the community. It should outline key areas such as diagnostic infrastructure; biosafety and waste management at the health facility; capacity building; commodity management and inventory control; selection, specification, and quantification of equipment and diagnostic commodities in the health facility; diagnostic referral systems; disease-specific technical procedures; quality assurance; and timely data management. Most importantly, there is a need for a monitoring system at both the individual and community levels to ensure that diagnostic services are available and utilised by all in all healthcare systems.
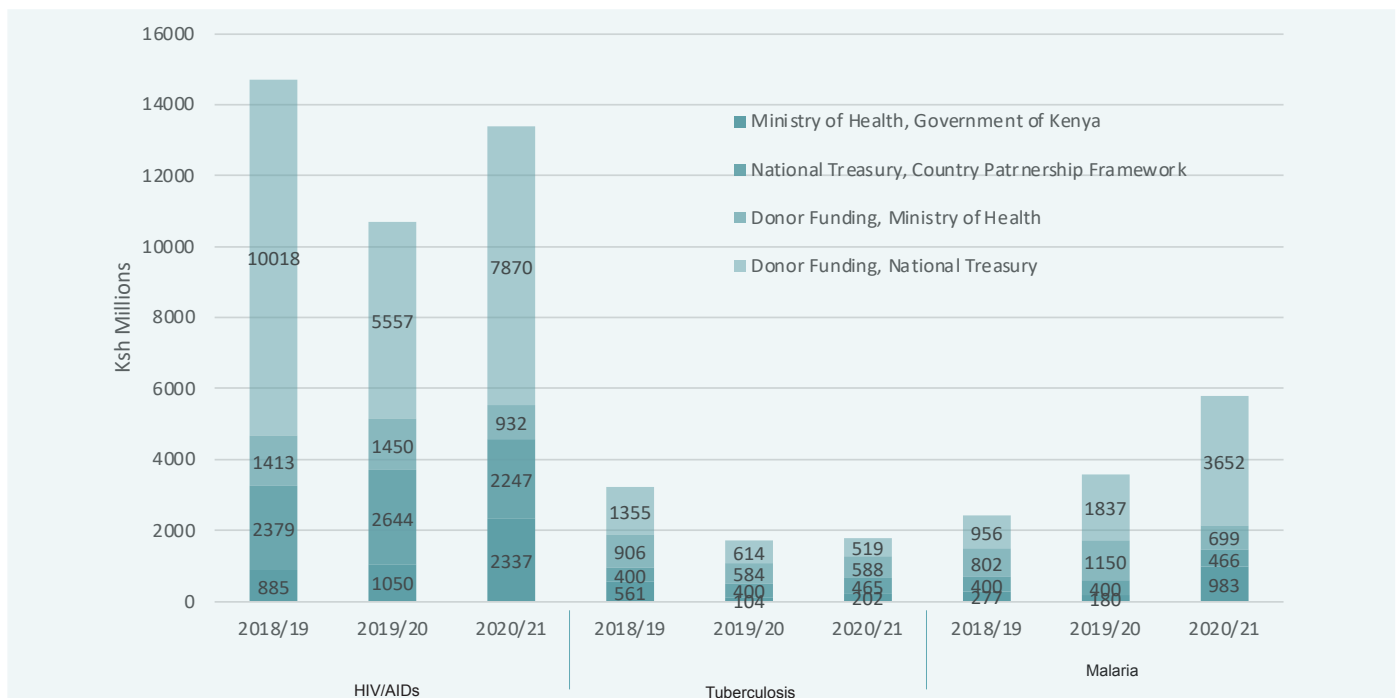

Figure 1: Funding for MoH strategic services, FY 2018/19–FY 2020/21

Photo: Eric Onyiego/ USAID Kenya

Photo: USAID/Mwangi Kirubi

[9] Yadav, H. et al. (2019). Availability of essential diagnostics in ten low-income and middle-income countries: results from national health facility surveys. *Lancet Glob Health, 9*(11), e1553–e1560. https://doi.org/10.1016/S2214-109X(21)00442-3
[10] World Health Organization. (2019). *Second WHO model list of essential in vitro diagnostics*. https://www.who.int/publications/i/item/WHO-MVP-EMP-2019.05
[11] Bahati, F., Reporting of diagnostic and laboratory tests
[12] World Health Organization, Second WHO model list
[13] Government of Kenya. (n.d.). *About Kenya Vision 2030*. https://vision2030.go.ke/about-vision-2030

Conclusion

There is no overall diagnostic service policy in Kenya that guides various aspects of diagnostics services, from supply to demand at the community and health facility levels. For selected diseases like TB, malaria, cancer and HIV it has been shown how structured disease specific policies combined with dedicated funding can positively enhance diagnostic services availability and uptake compared with other diseases. There is a need for a national diagnostic policy encompassing all diseases to enhance diagnostic services and improve the quality of health care in Kenya.

Recommendations

- There is a need for a comprehensive situational analysis to understand the facility context and its diagnostic capability at various facility tiers.
- There is a need for a national and county-specific diagnostic service policy for all diseases at the health facility and community levels. However, there is a need to adapt the policy to suit specific diseases based on changing epidemiological contexts.
- The established policy needs to integrate with existing disease-specific policies, with a focus on the diagnostic services components within those policies.
- The policy needs to be accompanied by an implementation plan with clear timelines, a budget and stakeholders involved, and a monitoring system.
- The national and county-specific diagnostic services policy needs to follow a consultative stakeholder engagement process to benefit from inputs and feedback from various actors. There is a need to work with existing national diagnostic focal points within the government.

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