

Legal and institutional foundations for universal health coverage, Kenya

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Abstract Kenya's Constitution of 2010 triggered a cascade of reforms across all sectors to align with new constitutional standards, including devolution and a comprehensive bill of rights. The constitution acts as a platform to advance health rights and to restructure policy, legal, institutional and regulatory frameworks towards reversing chronic gaps and improving health outcomes. These constitutionally mandated health reforms are complex. All parts of the health system are transforming concurrently, with several new laws enacted and public health bodies established. Implementing such complex change was hampered by inadequate tools and approaches. To gain a picture of the extent of the health reforms over the first 10 years of the constitution, we developed an adapted health-system framework, guided by World Health Organization concepts and definitions. We applied the framework to document the health laws and public bodies already enacted and currently in progress, and compared the extent of transformation before and after the 2010 Constitution. Our analysis revealed multiple structures (laws and implementing public bodies) formed across the health system, with many new stewardship structures aligned to devolution, but with fragmentation within the regulation sub-function. By deconstructing normative health-system functions, the framework enabled an all-inclusive mapping of various health-system attributes (functions, laws and implementing bodies). We believe our framework is a useful tool for countries who wish to develop and implement a conducive legal foundation for universal health coverage. Constitutional reform is a mobilizing force for large leaps in health institutional change, boosting two aspects of feasibility for change: stakeholder acceptance and authority to proceed.

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Introduction

The constitution of a country is its supreme law, which underpins all other laws as well as citizens' pursuit of peace, justice and human development.¹ Explicit constitutional provisions on the right to health exist in 28 of 47 Member States of the World Health Organization (WHO) African Region.¹ Yet there is limited knowledge about country experiences with constitutionally mandated health reforms, particularly in low- and middle-income countries.

Kenya's 2010 Constitution² replaced the constitution adopted when the country gained independence in 1963, creating new normative, structural, institutional, policy and administrative standards. The 2010 Constitution provides important opportunities for fundamental reform, through key reform agents such as independent commissions and a restructured judiciary and parliament, among other core institutions, agencies and organs in government.³ A key constitutional standard requires the state to take policy, legislative and other measures to fulfil its obligations in respect of health. Consequently, in 2010 the Government of Kenya embarked on a reform of health policies, legislation and institutions. The health reforms are complex, with several multistakeholder processes running concurrently, developing various laws and detailing the formation or restructuring of various bodies. The reforms resonate with the United Nations high-level declaration on universal health coverage (UHC), which includes a commitment to

strengthen legislative and regulatory frameworks for UHC.⁴ In this respect, measuring change in Kenya's health reforms would contribute knowledge to advance UHC.

On the 10th anniversary of the constitution, we describe our efforts to review the status of these health reforms. The Health Systems Governance Collaborative,⁵ in efforts to simplify governance to improve its understanding and applicability, has outlined a three-level approach for assessing the different elements and levels of governance: structural, process and outcome. Our paper focuses on structural measures, specifically the national laws and governance entities – the public implementing organizations and formal groupings across the entire health system. The aim of this article is to demonstrate an approach to measurement of health-system structure, and to apply that approach to analyse gaps and generate evidence for action to strengthen the structural capabilities in the Kenya health system.

In the following sections we first outline our theoretical framework on structural reforms in health systems. We then describe the background to Kenya's health-system reforms and the adapted health-system framework that we developed to analyse the multi-institutional reforms. Finally, we present our analysis and lessons learnt.

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Theoretical framework

There is considerable evidence associating the constitutional right to health with better health outcomes.^{6,7} A significant association has been found between a right to health in a national constitution and reductions in infant and under-five mortality rates.⁶ Other researchers found that institutional environments shaped by a right to health encourage more and better delivery of health services and can partly account for a positive impact on health outcomes.⁷ In this section we highlight some key linkages across health rights, health law, health institutions and health outcomes.

The rule of law is increasingly recognized as a determinant of health, and pivotal to health and development. WHO has observed that most public health challenges have a legal component and that the concept of public health law “includes the legal powers that are necessary for the State to discharge its obligation to realize the right to health for all members of the population.”⁸ Further, it has been argued that the rule of law is a largely unacknowledged prerequisite for a well-functioning health system.⁹ The law can translate vision into action on sustainable development, strengthen the governance of national and global health institutions and implement fair, evidence-based health interventions.¹⁰ The law can be an effective tool to harmonize the mandates of public agencies, clarify functions and promote multiagency cooperation; to designate the responsible agency to resolve a particular issue; and to create new entities to coordinate activities across multiple agencies.¹⁰ WHO notes that countries that have achieved UHC have built it on legal foundations, underscoring that developing and implementing a legal environment conducive to UHC is a critical investment.¹¹ WHO highlights three critical elements to assess country contexts on whether UHC law reform is feasible: (i) whether there is acceptance of (or opposition to) the proposed reform; (ii) whether there is authority to proceed (especially authority from political decision-makers); and (iii) whether the country has the ability to complete the work (the capacity to make, implement and administer laws).¹² Using the context of Kenya, we aim to demonstrate the extent of feasibility of UHC law reform, and to contribute lessons on the systematic assessment of legal and regulatory frameworks for UHC.

Effective health reforms should include reforming and restructuring the institutions through which health policies are implemented.¹³ One author has described institutions as the rules of the game – the formal and informal rules and norms that structure citizens’ rights, entitlements, opportunities and voices.¹⁴ A distinction can be drawn between organizations and institutions. Organizations (public or private) are created to perform defined functions. Organizations are primarily the agent for institutional change with the emphasis on the interaction between the rules of the game (institutions) and the players of the game (organizations).¹⁴ Formal institutions, the focus of this article, include the written constitution, laws, policies, rights and regulations enforced by official authorities (public organizations or agencies).¹⁵ An analysis of institutional change includes considering whether a particular function is necessary or not (for example, the need for an agency or new patterns of service delivery by organizations). Organizational change, however, focuses on internal capacities (for example, automation of business processes or upgrading equipment).¹⁶ Institutional change analysis must be driven by a focus on desired outcomes: in the case of health, multiple outcomes relating to UHC. Appropriate approaches and tools are needed to analyse and diagnose gaps and to predict further institutional change to strengthen the health system for UHC.¹⁶ We describe an approach to analyse concurrent change to multiple health laws and public organizations.

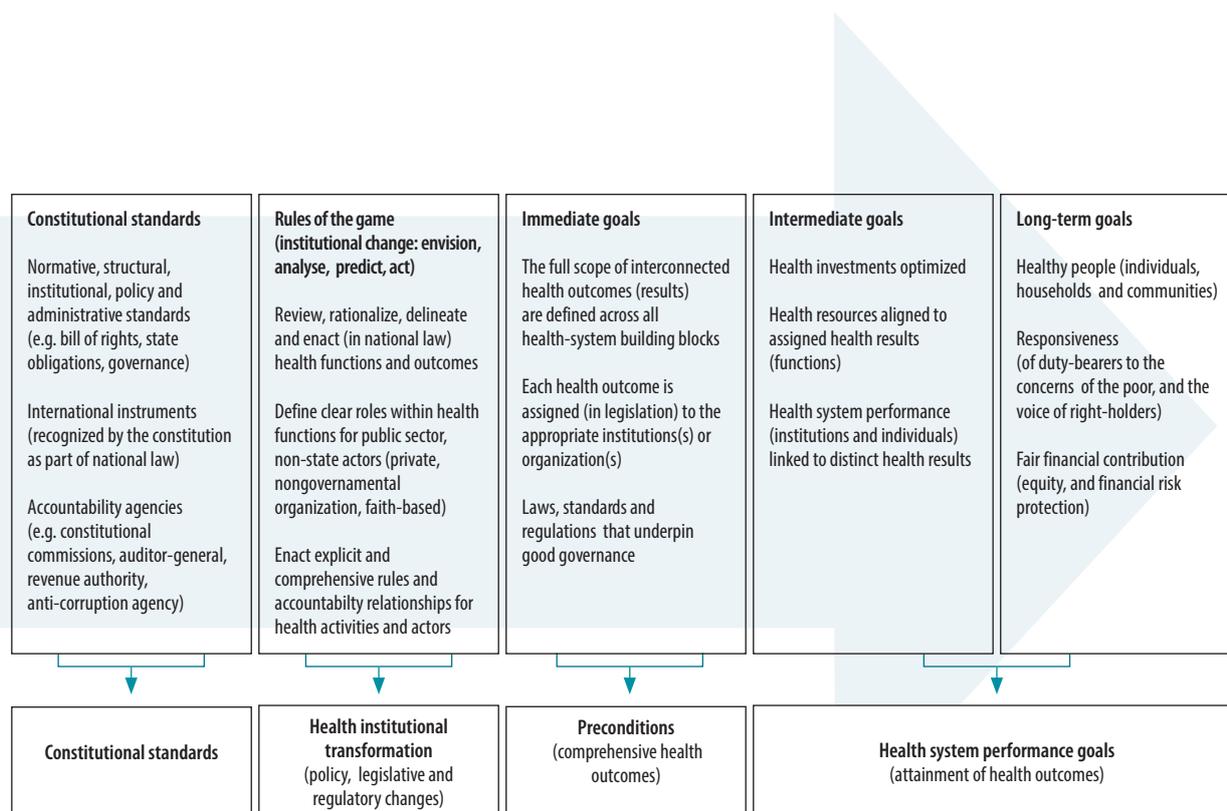
We also consider social science theories related to advocacy and policy change efforts.¹⁷ Among these, the large-leaps theory posits that “when conditions are right, change can happen in sudden, large bursts that represent a significant departure from the past, as opposed to small incremental changes over time that usually do not reflect a radical change from the status quo.”¹⁷ In Kenya, the 2010 Constitution created a major shift in feasibility for health law reforms, which triggered large changes in policies, laws, institutional and regulatory frameworks. In Fig. 1, we illustrate a theoretical connection between constitutional standards and long-term health-system goals, via analysing institutional change, optimizing the interconnected health outcomes, and rationalizing their assignment to health actors (public and private).

Background to reforms

The key aspects of Kenya’s 2010 Constitution in relation to health were twofold: devolution of power to 47 county governments; and explicit provisions on the right to health. The extent of devolution of administrative functions varies across sectors. The health functions are extensively devolved: the national government is assigned health policy, national referral services and capacity-building for counties; county governments are assigned person-based and public health services within their jurisdictions.^{18–20} The constitution prescribed mechanisms and timelines for implementation of the various constitutional changes, including a time-limited independent body to oversee the transition to devolved government. This process entailed the development of enabling legislation and institutions for devolution, including intergovernmental relations, applicable to all sectors. The constitution triggered a large number of public-sector reforms and energized political commitment to reforms, including initiatives to streamline the governance of public agencies in all sectors, and to prioritize government investments and reforms in UHC, agriculture and nutrition, housing and manufacturing.^{21,22}

To guide the transformation in the health sector, the Kenya Health Policy (2012–2030) was formulated²³ with policy priorities structured around WHO’s six key components of a well-functioning health system: (i) leadership and governance; (ii) service delivery; (iii) health system financing; (iv) health workforce; (v) medical products, vaccines and technologies; and (vi) health information systems.^{24–26} This six-component structure was adapted for Kenya by highlighting additional policy issues and areas for investment. The policy proposed to overhaul the health legal framework by installing a new general health law and specific laws to restructure each component. This comprehensive legal framework incorporated health infrastructure as a seventh component (Fig. 2). After the county governments were elected in 2013, the health policy was validated and updated to the Kenya Health Policy (2014–2030),²⁷ and health research was added as an eighth component. At various stages, the health ministry established ad hoc technical working groups and formal advisory panels. These groups act as the primary

Fig. 1. Theory of change on translating constitutional standards to health goals



platforms for elaborating the needed change within the various reform initiatives and for facilitating broad stakeholder engagement and external technical support.^{28,29}

Conceptual and analytical framework

A major challenge in analysing the multi-institutional change in Kenya was the lack of a uniform and coherent approach. The use of simplistic tools to analyse complex health systems often contributes to interventions that upset the equilibrium of the system, which can lead to policy resistance from stakeholders.³⁰ To align the health sector with the 2010 constitutional standards, Kenya's health policy prescribed specific laws to transform multiple parts of the system, but lacked detail on the overall structural design, offering no rationale on the configuration of health functions or the implementing organizations envisioned to optimize health outcomes across the devolved system. Therefore, to analyse what has changed since 2010, we deconstructed the health legal (and institutional) frame-

work, component-by-component and function-by-function, guided by WHO concepts and definitions.

WHO describes a health system as a set of interconnected parts that have to function together to be effective, consisting of all the organizations, institutions, resources and people whose primary purpose is to improve health.^{31,32} The WHO framework for health-systems performance assessment identifies four basic health-system functions through which health investments flow: (i) stewardship; (ii) resource generation; (iii) service provision; and (iv) financing. In this respect, a health system would be considered well performing when all the relevant organizations, institutions, resources and people are functioning together and contributing optimally to attaining three intrinsic goals or outcomes: health; responsiveness; and fair financial contribution.³³ Consequently, health institutional reforms would be expected to optimize institutional capabilities to achieve the intrinsic health outcomes by transforming health functions component-by-component.

We developed an approach – the adapted health-system framework – which enables a structured, all-inclusive framing of health functions, and promotes uniform and coherent analysis to identify structural gaps across the health system. We superimposed the core eight components of the Kenya Health Policy 2014–2030 and the four basic health-system functions described above. In this way, we created a grid with each cell representing a distinct health function. Our framework allows structure and function to converge, giving a perspective of the health system's foundational elements and acting as a tool to visualize change. We used the framework to systematically document the national health laws and public bodies (those already enacted and those in progress) to assess the extent of change, diagnose gaps and identify corrective adjustments. Hence, this article is not concerned with monitoring constitutional implementation,^{34,35} or assessing whether specific health-system functions or accountability mechanisms are achieving desired outcomes (such as access to medicines³⁶ or immunization coverage³⁷).

Other authors have observed that stewardship is usually the most neglected function within health systems, yet it “anchors health to the wider society, comprising three broad tasks: providing vision and direction, collecting and using intelligence, and exerting influence through regulation and other means.”³⁸ The sub-function of regulation has been discussed when describing the complex health-care regulatory system in the United States of America. Seven distinct areas of regulatory focus were identified,³⁹ all addressing three competing health outcomes (access, quality and costs). These seven regulatory spheres are essentially a subset of our adapted framework since they relate to WHO’s concept of health stewardship, and they align with WHO’s six core health-system components. The spheres exclude health leadership (responsible for overall stewardship), and the other five components are subdivided and expanded to distinguish the perspectives relating to health regulation. Thus, health business relationships, public health and health research are distinct regulatory components. Our discussion will therefore highlight two stewardship sub-functions: overall system design and regulation.

Assessment methods

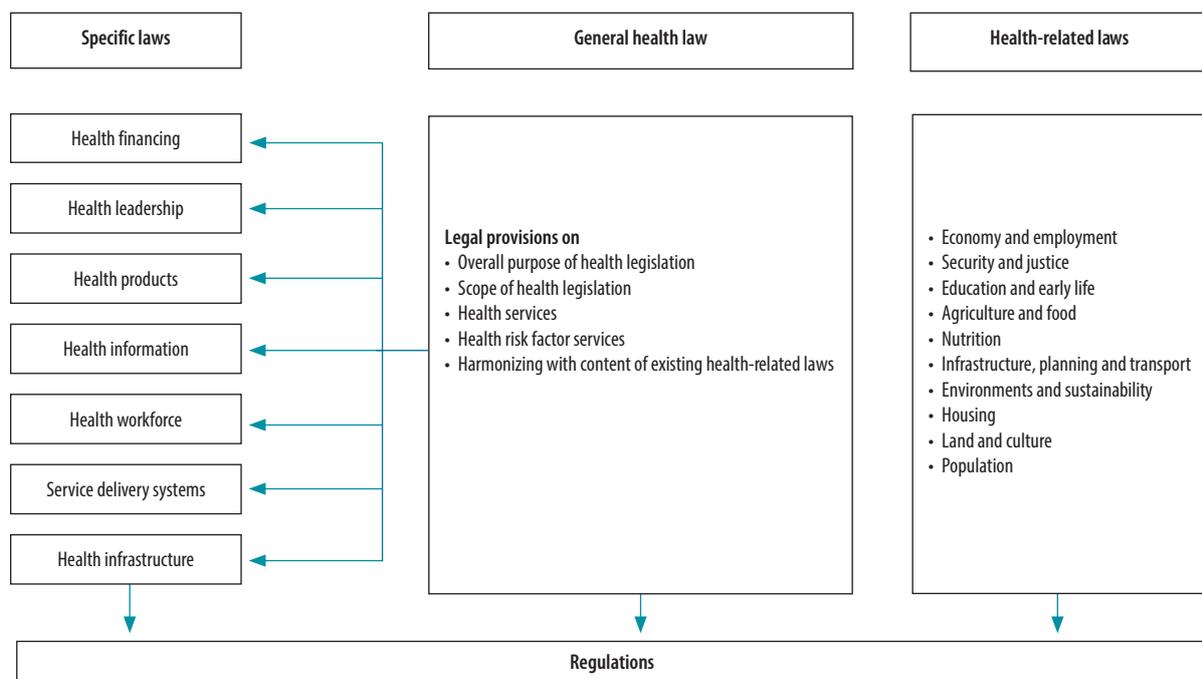
We obtained empirical evidence for this assessment from two primary sources. First, all the authors were closely involved in the health reform processes in various capacities, either as government planning experts or as technical advisors, engaging through the technical working groups and advisory panels. Second, we analysed various documents including national policies, legislative instruments (laws, executive orders, legal notices and legislative bills). We identified all the instruments enacted for purposes relating to health, as published in the official Kenyan Government website.⁴⁰ We then compiled a chronological list of these legislative instruments from 1921 to June 2020. For each instrument listed, we reviewed the legal text and identified two attributes: public body created and health function assigned. We then mapped all the bodies onto the adapted framework according to assigned function to see which governing entities and implementing organizations are in place and functional. We created two profiles: pre-constitution and post-constitution. Similarly, we mapped the initiatives that were in progress by June

2020 (technical working groups, advisory panels or parliamentary bills). To assess the extent of change in the regulatory sub-functions, we also extracted the data on the regulatory bodies formed to date (enacted and in-progress) and mapped these onto the seven regulatory spheres.³⁹

Legal and institutional changes

Before the 2010 Constitution, Kenya’s health system was managed centrally by two health ministries and governed through the Public Health Act of 1921 and other statutes governing specific functions. A total of 28 public bodies existed (in the statutes), although three of these were not currently operating, and we could not ascertain whether they had ever been constituted (Table 1). Shortcomings of the pre-constitution health structures were that institutional change was largely aligned to vertical public health programmes or to health professions. In particular, health professional bodies regulated most aspects of health in a cadre-centric model, creating a disproportionate focus on professional practice, with virtually no balancing

Fig. 2. Comprehensive health legal framework for Kenya



Source: Kenya Health Policy (2012–2030).²³

Notes: The Specific laws column is the same as the World Health Organization *Key components of a well functioning health system*²⁴ with one additional component (Health infrastructure). After the onset of devolution, the health policy was subsequently updated to the Kenya Health Policy 2014–2030, which includes Health research – an eighth building block. For purposes of our analysis, our framework corresponds to the eight building blocks, and also separates Service delivery systems into two parts: person-based and population-based services (Table 1; Table 2).

Table 1. Structure and function of public health bodies existing in Kenya before the 2010 Constitution, 1921–2010

Core components	Functions			Notes	
	Stewardship: oversight	Financing: collecting, pooling and purchasing	Creating resources: investment and training		
Leadership and governance	<ul style="list-style-type: none"> Ministry of Medical Services (2008) Ministry of Public Health and Sanitation (2008) 	None	<ul style="list-style-type: none"> Kenya Institute of Administration (1961) 	None	The two health ministries were created as part of an expanded cabinet of the coalition government established after the signing of the Kenya National Dialogue and Reconciliation Accord (February 2008)
Health-system financing	None	<ul style="list-style-type: none"> National Hospital Insurance Fund (1966) 	None	None	NA
Health workforce	<ul style="list-style-type: none"> 7 professional boards and councils, each established by statute: (i) Pharmacy and Poisons Board (1957); (ii) Medical Practitioners and Dentists Board (1978); (iii) Nursing Council of Kenya (1983); (iv) Radiation Protection Board (1984); (v) Clinical Officers Council (1989); (vi) Kenya Medical Laboratory Technicians and Technologists Board (2000); (vii) Council of the Institute of Nutritionists and Dieticians (2007) 	None	<ul style="list-style-type: none"> 7 university schools (various years); 4 medical schools 2 dentistry schools 1 pharmacy school Kenya Medical Training College (1991) 	None	The Pharmacy and Poisons Board is listed twice because it was established with a dual regulatory mandate from the outset (drugs and poisons; and pharmacy practice) Courses offered in the various medical schools are approved by the respective professional boards and councils: Kenyan Medical Practitioners and Dentists Council, and Pharmacy and Poisons Board
Service delivery (population-based)	<ul style="list-style-type: none"> Central Board of Health (1921; not operational) National Public Health Laboratory Service (1923) Public Health (Standards) Board (1961; not operational) Kenyan Board of Mental Health (1991; not operational) National AIDS Control Council (1999) HIV and AIDS Tribunal (2006) Tobacco Control Board (2007) 	None	None	None	The National Public Health Laboratory Service was created by the Ministry of Health, and is considered as a health ministry entity for administrative purposes
Service delivery (person-based)	<ul style="list-style-type: none"> The regulatory boards and councils oversaw their respective areas of practice within health facilities and undertook joint inspections 	None	<ul style="list-style-type: none"> Various bodies The referral hospitals are teaching facilities. Other public hospitals also act as learning centres for clinical training (pre-service and in-service) 	<ul style="list-style-type: none"> Semi-autonomous referral hospitals: <ul style="list-style-type: none"> Kenyatta National Hospital (1987) Moi Teaching and Referral Hospital (1998) Hospitals, health centres and dispensaries, managed centrally by health ministry 	All public health-care facilities (except the two referral hospitals) were managed centrally by the two ministries of health. The Ministry of Public Health and Sanitation was responsible for rural health centres and dispensaries; and Ministry of Medical Services was responsible for hospitals. The health facilities were not established as distinct legal entities

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Core components	Functions			Notes
	Stewardship: oversight	Financing: collecting, pooling and purchasing	Creating resources: investment and training	
Medical products and technology	<ul style="list-style-type: none"> Pharmacy and Poisons Board (1957) National Quality Control Laboratory (1992) 	<ul style="list-style-type: none"> Kenya Medical Supplies Agency (2000) 	<ul style="list-style-type: none"> Kenya National Blood Transfusion Service (2001) 	<p>Laboratory testing is one of the core functions of a national medicines regulatory authority. This overlap of roles between two bodies (Pharmacy and Poisons Board and National Quality Control Laboratory) contributes to conflicts in carrying out this regulatory function in Kenya</p> <p>The Kenya National Blood Transfusion Service was created by the Ministry of Health, and is considered as a public body for administrative purposes. The health law reforms captured a long-standing advocacy for the Kenya National Blood Transfusion Service to be established by statute</p> <p>NA</p>
Health information systems	None	None	None	None
Health infrastructure	None	None	None	NA
Health research	<ul style="list-style-type: none"> National Council for Science and Technology (1977) 	None	<ul style="list-style-type: none"> Kenya Medical Research Institute (1979) 	NA

NA: not applicable.

Notes: Cells of the adapted health-system framework show public health-sector bodies (and year of enactment) created before the 2010 Constitution of Kenya. Core components are based on World Health Organization's (WHO) *Key components of a well-functioning health system*, 2010.²⁴ Functions are based on WHO's framework for health systems performance assessment, 1999.³³ In some cases we could not ascertain the reasons why a body was non-operational.

laws or independent authorities to safeguard consumer interests (such as safety, pricing and confidentiality).

In the period since the 2010 Constitution was adopted there has been a large increase in the number of health bodies. This transformation has included enactment of eight laws and creation of 65 new bodies (16 national, two intergovernmental and 47 county health departments). Seven additional reforms were in progress by June 2020 (Table 2).

Of the new laws, the Health Act, 2017 was the first major post-independence health legislation, delineating multiple health functions at the national, intergovernmental and county levels, establishing new bodies and mandating others to be enacted. The Act signalled a fundamental shift towards cadre-neutral health stewardship bodies (professions, products and institutions) and a greater focus on consumer aspects within health functions. These multiple reform initiatives demonstrate significant feasibility for health reforms. By prioritizing UHC reforms, political decision-makers have signalled authority to proceed, and broad acceptance by stakeholders. The multiple stakeholder engagement mechanisms led by the health ministry (technical working groups and advisory panels) enable the articulation of specific reforms within functions, facilitate consensus-building and isolate contentious issues to be resolved. Parliament is actively (but independently) engaged, including sponsoring bills in some priority areas (blood services, food and drug regulation), which creates pressure on health stakeholders to fast-track any related reform initiatives. These multiple forces are driving the large-leaps change to a new state of governance arrangements for health, aligned to devolution, and to broader government policies (such as governance of state agencies).

The function of health stewardship has shown the greatest transformation, with the creation of a steward of stewards (the national health ministry) and delineated stewardship sub-functions across the devolved system. Of the 65 new bodies created, 59 have stewardship mandates (the other six are concerned with creating resources). Of the seven reforms in progress, six involve elaborating stewardship sub-functions (the other reform is concerned with a financing function). This considerable change would be expected to enhance system capabilities in providing vision

Table 2. Structure and function of public health bodies created in Kenya after the 2010 Constitution, 2010–2020

Core components	Functions			Notes
	Stewardship: oversight	Financing: collecting, pooling and purchasing	Creating resources: investment and training	
Leadership and governance	<ul style="list-style-type: none"> Ministry of Health (2018) Kenya Health Sector Inter-governmental Consultative Forum (2017) 47 county health departments (2013) Council of Governors Health Committee (2012) 	None	<ul style="list-style-type: none"> Kenya School of Government (2012), created by amalgamating the Kenya Institute of Administration and three other government training institutions 	Three successive Executive Orders on the structure of the National Government (2013, 2016 and 2018) established a single health ministry and its portfolio responsibilities have not changed fundamentally
Health-system financing	<ul style="list-style-type: none"> Independent body for health benefit package design, proposed by the Health Financing Reform Experts Panel, 2019 (in progress) 	<ul style="list-style-type: none"> Social Insurance Scheme to be created by converting the National Hospital Insurance Fund, proposed by the Health Financing Reform Experts Panel, 2019 (in progress) 	None	The recommendations of the Health Financing Reform Experts Panel include the creation of a social insurance scheme, and two independent bodies: (i) health financing and (ii) health-care services accreditation
Health workforce	<ul style="list-style-type: none"> Kenya Health Professions Oversight Authority (2017) Kenya Health Workforce Council (2017) Radiographers Board of Kenya (in progress) 5 professional boards or councils, each established by statute: (i) Public Health Officers and Technicians Council (2013); (ii) Physiotherapy Council of Kenya (2014); (iii) Counsellors, Psychologists and Psychotherapists Board (2014); (iv) Health Records and Information Managers Board (2016); (v) Occupational Therapy Council of Kenya (2017) 	None	<ul style="list-style-type: none"> 4 university schools (various years): 4 medical schools 2 dentistry schools 1 pharmacy school Kenya Medical Training College (1991) 	The courses offered in the medical schools are approved by the respective professional bodies: Kenyan Medical Practitioners and Dentists Council, and Pharmacy and Poisons Board
Service delivery (population-based)	<ul style="list-style-type: none"> National Cancer Institute (2012) National Committee on Infant and Young Child Feeding (2012) Health ministry technical working group on National Public Health Institute (in progress) 	None	None	Population-based services are the focus of many donor-funded vertical programmes in Kenya's health sector. Institutional change relating to public health tends to follow a similar pattern

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Functions			Notes
Financing: collecting, pooling and purchasing	Creating resources: investment and training	Delivering services: provision	
<p>None</p> <p>Various</p> <ul style="list-style-type: none"> The referral hospitals are also teaching facilities Other public hospitals also act as learning centres for clinical training, pre-service and in-service 	<p>Various</p> <ul style="list-style-type: none"> The referral hospitals are also teaching facilities Other public hospitals also act as learning centres for clinical training, pre-service and in-service 	<ul style="list-style-type: none"> Kenyatta National Hospital (1987) Moi Teaching and Referral Hospital (1998) County health services 	<p>The role of the Kenyan Medical Practitioners and Dentists Council was expanded in 2019 to include regulation of health facilities. However, health services regulation (includes accreditation) is expected to transfer to a new independent body, in line with the Health Financing Reform Experts Panel recommendations (see above, under financing)</p>
<p>None</p> <ul style="list-style-type: none"> Kenya Medical Supplies Authority (2013) Two parallel mechanisms in progress – both addressing Part XI of the Health Act, 2017 on Human Organs, Human Blood, Blood Products, Other Tissues and Gametes: (i) Draft Kenya National Blood Transfusion and Transplant Service Bill (2019, health ministry technical working group); (ii) Kenya National Blood Transfusion Service Bill (2020, parliament) 	<p>None</p>	<p>None</p>	<p>A proposed Kenya Food and Drug Authority is the anticipated single regulatory body for health products and technologies. Two parallel processes to create the proposed authority are in progress and need to be harmonized: one led by the health ministry, another led by parliament. Part XI of the Health Act, 2017 covers the full scope of human-derived medicinal products, but only provides for a blood service organization (Section 85). This discrepancy reflects in the scope of the two draft bills in progress, which need harmonizing</p>
<p>None</p>	<p>None</p>	<p>None</p>	<p>A bill on electronic health has been drafted to implement the relevant provisions of the Health Act, 2017</p>
<p>None</p>	<p>None</p>	<p>None</p>	<p>Although the Kenya Health Policy distinguishes health infrastructure as a separate component, the regulation of health infrastructure is part of health services regulation</p>

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